NICE National Institute for Health and Care Excellence

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HealthTech Programme

Diagnostics Advisory Committee (DAC)

DG10118 Artificial intelligence software to help detect and characterise colorectal polyps – 1st meeting

Thursday 15 October 2025

Technical analyst:	Iain Willits
Technical adviser:	Judith Shore
Committee lead: **Clinical lead (SCM):**	Alex Novak Baljit Singh
EAG leads:	Nicole Downes - Senior Clinical Evidence Analyst Sophie IP - Senior Health Economist
Link to SCM register for topic:	specialist-committee-members.pdf
People and Community partner Experts:	Nigel Westwood Malcolm Oswald

The following documents are made available to the Committee:

1. Cover sheet

2. Final Scope

3. External assessment report overview (ARO) [noACIC]

4. Patient group, professional group and NHS organisation submission:
   Joint Accreditation Group, Royal college of Physicians (JAG) organisational submission [no ACIC]

5. Updated External assessment report (EAR) dated 2025/10/07 - prepared by [EAG] Note, this report is an updated version to the one issued to stakeholders on [date]. The updates are listed on page 5 of the report [noACIC]
   5a. EAR Supplement [noACIC]

6. Collated stakeholder comments on the External Assessment Report (EAR) and draft External Assessment Group (EAG) responses [noACIC]

7. Addendum to External Assessment Report (EAR) 2025/10/07 [noACIC]

NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technologies Programme

Artificial intelligence software to help detect and characterise colorectal polyps

Final scope

August 2024

1 Introduction

The topic selection oversight panel identified artificial intelligence (AI) software to help detect and characterise colorectal polyps during colonoscopy as suitable for evaluation by the Health Technologies Programme based on a topic intelligence briefing.

The final scope was informed by discussions at the scoping workshop on 15 August 2024. A glossary of terms is provided in appendix A.

2 Description of the technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts and on information available in the public domain. NICE has not carried out an independent evaluation of these descriptions.

2.1 Purpose of the medical technologies

AI-assisted colonoscopy supports the detection of colorectal polyps during the colonoscopy procedure by detecting and flagging lesions of concern for the endoscopist to review. This function of AI technologies is known as Computer Aided Detection (CADe). CADe aims to help endoscopists detect polyps that may otherwise have been missed by endoscopist review alone. AI software technologies use machine learning and deep learning to analyse images and videos taken during a colonoscopy.

Some technologies also provide AI-based Computer Aided Diagnosis (CADx) in addition to the CADe function. CADx assists in the characterisation of the detected polyps based on features such as polyp size and histology (see section 3.1.1). The aim of CADx is to improve the optical diagnosis performed by endoscopists to help decisions about whether to remove a polyp or not. This could reduce unnecessary polypectomies (with a resulting reduction in complications such as bleeding and perforation of the bowel) and also improve recognition of polyps for resection. Using CADx to support optical diagnosis may also reduce variability due to different levels of endoscopist experience (see section 6.1).

2.2 Product properties

The level of detail in the following descriptions depends on the extent of information provided by manufacturers during topic scoping. Technologies will only be included in guidance if they are available to the NHS and have appropriate regulatory approval.

AI technologies are intended to be incorporated into usual colonoscopy procedure. An endoscopist makes a final decision on whether to remove any identified polyps. Technologies with CADe function are described below:

Technology (manufacturer)	**Regulatory status**	**Intended use**
Argus (Endosoft)	Regulatory approval is in process	A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device has hardware components to support interfacing with an endoscope.
Discovery (Pentax Medical UK)	CE class I	The product is intended to assist endoscopists in finding potential polyps during a colonoscopy examination. The system is not intended to make or recommend any patient management, diagnosis or therapeutic decisions.
ENDO-AID (Olympus	CE class I	The Endoscopy CAD system processes the electronic signals received from the endoscopy video system center and overlays additional information on the observation monitor. The device directs the user's attention to areas of interest for further clinical assessment.

Medical Systems Corp.)		The device is intended to assist physicians in the detection of mucosal abnormalities such as potential colorectal polyps during colonoscopy. The device is an adjunctive tool, and the user should not rely solely on the device for detection of abnormalities.
ENDOANGEL Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan EndoAngel Medical Technology Co., Ltd.)	Pending clarification from company	Intended use statement not available at the time of finalising the scope. The company's website (accessed 28 August 2024) indicates that ENDOANGEL is computer-aided polyp detection system powered by AI. It is used for polyp identification of lower digestive tract during endoscopic operation. The identification results are only used as a reference for diagnosis and it is not intended to replace clinical decision making.
Endoscopic Multimedia Information System (EMIS; EndoMetric Corporation)	Regulatory approval is in process	Intended use statement not available at the time of finalising the scope. Company have indicated that the technology provides AI-based polyp detection.

Endoscreener (Wision AI)	CE class II	Intended use statement not available at the time of finalising the scope. The company's website (accessed 23 August 2024) indicates that EndoScreener is a computer-assisted detection device for colorectal polyps. EndoScreener takes as input colonoscopy video stream from an endoscopy device, which is analyzed in real-time. The device output consists of blue boxes overlaid onto the colonoscopy images to highlight regions of potential polyp.

Technologies that perform CADe and CADx functions are described below:

Technology (manufacturer)	**Regulatory status**	**Intended use**
CAD EYE (Fujifilm Healthcare UK Ltd)	CE class IIa	This software detects and characterises an area suspected to be a colonic polyp in an endoscopic video image outputted from an endoscopic video processor. The software superimposes the result of Detection Mode or Characterisation Mode onto the endoscopic video image and displays on the monitor in real-time. This software is intended to be used to support diagnosis during colonoscopy under the supervision of medical professionals. Characterisation mode displays a suggestion about whether a suspected colonic polyp is neoplastic or hyperplastic.

CADDIE (Odin Vision)	Company website indicates CE /UKCA marked product (accessed 23 August 2024)	Intended use statement not available at the time of finalising the scope. The product brochure, available on the company's website (accessed 23 August 2024), indicates that the product supports endoscopists to detect and characterise colorectal polyps in real-time during colonoscopy procedures.
GI Genius (Medtronic)	GI Genius Software: CE class IIb	The GI Genius software is an artificial intelligence-based medical device that has been trained to process colonoscopy images containing regions consistent with colorectal lesions like polyps, including those with flat (non-polypoid) morphology. The GI Genius software is intended to be used by trained clinicians as an adjunct to white-light colonoscopy for the purpose of highlighting regions suspected to have visual characteristics consistent with different types of mucosal abnormalities (e.g., colorectal polyps). The target population is represented by persons undergoing colonoscopy procedures. If characterisation support is enabled, a polyp detected and highlighted by the GI Genius software is consistently framed in white-light video colonoscopy, based on the visual characteristics of the detected polyp, the GI Genius software provides an estimation of the possible polyp histology. The following tags are shown: adenoma (when the system predicts a possible adenoma histology), non-adenoma (when the system predicts a possible non-adenoma histology) or no prediction (when the system is not confident enough to provide a possible histology prediction).

		The GI Genius software is intended to be used as an adjunct to colonoscopy procedures and is not intended to replace endoscopist assessment or histopathological sampling.
MAGNETIQ-COLO (MAGNETIQ-EYE)	CE class I	The ME-APDS (Magentiq Eye Automatic Polyp Detection System) is intended to be used by endoscopists as an adjunct to the common video colonoscopy procedure, aiming to assist the endoscopist in identifying lesions during colonoscopy procedure by highlighting regions with visual characteristics consistent with different types of mucosal abnormalities that appear in the colonoscopy video during the procedure. Highlighted regions can be independently assessed by the endoscopist and appropriate action taken according to standard clinical practice. The ME-APDS is trained to process video images which may contain regions consistent with polyps. The ME-APDS is intended to be used as an adjunct to endoscopy procedures and is not intended to replace histopathological sampling as means of diagnosis. The company's website (accessed 28 August 2024) indicates that the technology aides the gastroenterologist detect polyps with additional information (size category and type), on the consistency of the detected lesion.
WISE VISION (NEC Corporation)	CE class IIa, and UKCA class IIa	Polyp Detection (Ce3.0): This product analyses video signals from endoscopic equipment and provides endoscopists with the location of potential colorectal polyps. It aims to invite endoscopists' attention to colorectal polyps and support their diagnosis during colonoscopy.

		Polyp Characterization (Cx3.0): This product analyses video signals from endoscopic equipment to categorize the colorectal polyps detected by the endoscopists as neoplastic or non-neoplastic polyps. It aims to support the endoscopists to make an optical diagnosis during colonoscopy. Polyp Sizing (Cs3.0): This product analyses video signals from endoscopic equipment to categorize the colorectal polyps detected by the endoscopists as diminutive ("5 mm or less") or non-diminutive ("6 mm or more"). It aims to support the endoscopists in sizing of polyps during colonoscopy. The intended population is people who have been determined to be eligible for colonoscopy. All ages, weights, and health conditions are acceptable, however patients with following conditions are excluded: bowel inflammation (Ulcerative colitis or GVHD–related bowel inflammation); familial adenomatous polyposis; or have a history of chemotherapy or radiation therapy for targeted colorectal cancer.

3 Target conditions

3.1 Colorectal polyps

Colorectal polyps are small growths on the lining of the colon. Most colorectal polyps do not cause any symptoms, so people are unaware that they have them. However, some can cause rectal bleeding, mucus in stool, diarrhoea or constipation, and abdominal pain.

Risk factors for colorectal polyps include older age, genetics and family history of bowel polyps or bowel cancer, dietary and lifestyle factors and conditions that affect the gut such as inflammatory bowel disease (IBD).

3.1.1 Classification of colorectal polyps

Polyps can be described in terms of their shape, size, location and histology.

The Association of Coloproctology of Great Britain and Ireland (ACPGBI) recommends the Paris endoscopic classification to describe polyps on the basis of their shape:

- Type 0-Ip: protruded, pedunculated (on a stalk)
- Type 0-Is: protruded, sessile (flat against the surface, slightly raised)
- Type 0-IIa: superficial, elevated
- Type 0-IIb: flat
- Type 0-IIc: superficial shallow, depressed
- Type 0-III: excavated (depressed)

The European Society of Gastrointestinal Endoscopy (ESGE) (2024) guideline on colorectal polypectomy and endoscopic mucosal resection (EMR) defines colorectal polyps by size:

- Diminutive size: 5 mm or less
- Small size: 6 to 9 mm
- Intermediate size: 10 to 19 mm
- Large size: 20 mm or more

A premalignant polyp, as defined by British Society of Gastroenterology (BSG)/ ACPGBI guideline, includes both serrated polyps (excluding diminutive [1–5 mm] rectal hyperplastic polyps) and adenomatous polyps, but not other polyps such as post-inflammatory polyps.

3.1.2 High risk colorectal polyps

The BSG / Public Health England (PHE) / ACPGBI post-polypectomy and post-colorectal cancer resection surveillance guidelines (2020) defines criteria for high-risk polyps as either:

- 2 or more pre-malignant polyps including at least 1 advanced colorectal polyp; or
- or 5 or more pre-malignant polyps

The guideline defines advanced colorectal polyps as either:

- A serrated polyp of at least 10 mm in size or containing any grade of dysplasia, or
- An adenoma of at least 10 mm in size or containing high-grade dysplasia.

3.2 Diagnostic and care pathway

Colonoscopy is often used for people without major comorbidities. It can visualise the entire colon and tissue samples can be taken and examined histologically to confirm a diagnosis, unless this is contraindicated. Colonoscopy is most frequently performed as an outpatient procedure with the person having sedation or painkillers.

Standard colonoscopy uses conventional high-definition white-light endoscopy (WLE) to detect colorectal polyps and may be used in combination with dyes (chromoendoscopy). Virtual chromoendoscopy (VCE) technologies provide colour-enhanced visualisation of blood vessels and surface pattern compared with conventional endoscopy, but without the use of dyes. This helps endoscopists to assess colorectal polyps in real-time during colonoscopy, instead of through later histopathology (known as optical diagnosis). NICE guideline DG28 (2017) recommends that endoscopists assess diminutive polyps (polyps 5 mm or less in size) during colonoscopy by performing optical diagnosis using VCE technologies, instead of histopathology. Clinical experts commented that VCE is used in the NHS,

but the extent of use is not known. They also stated that VCE has a greater role in the characterisation, rather than detection, of polyps.

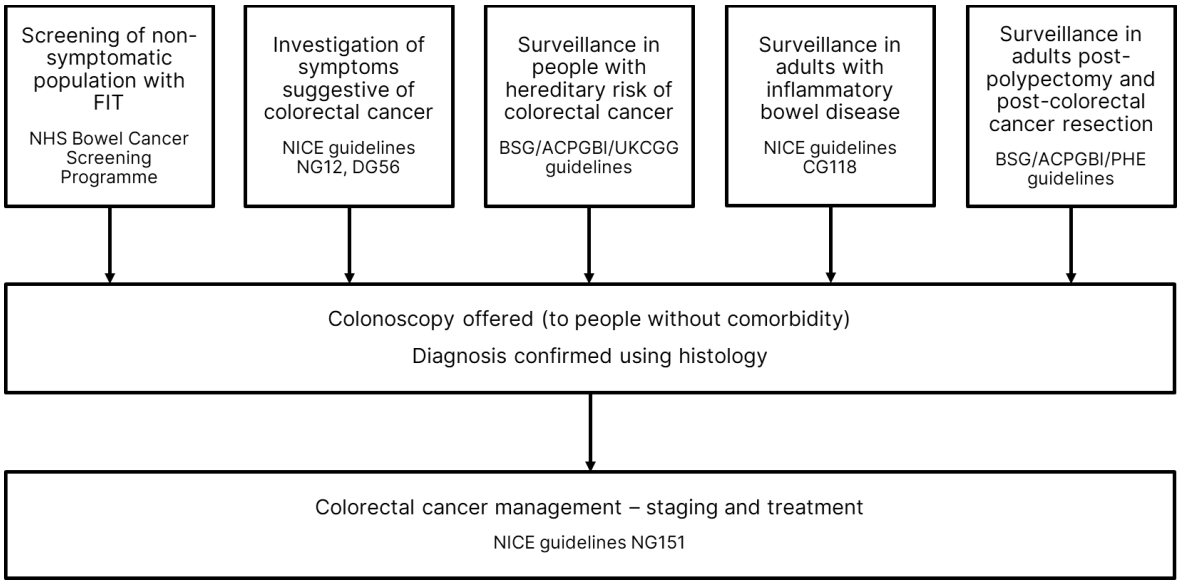
The ESGE (2019) guideline on advanced imaging for detection and differentiation of colorectal neoplasia recommends the use of high-definition white-light endoscopy in combination with VCE to predict the presence and depth of any submucosal invasion in non-pedunculated colorectal polyps prior to any treatment.

Experts also highlighted that Endocuff Vision is used in the NHS. This is a disposable sleeve that fits over the end of most colonoscopes and may be used to improve visualisation of the bowel during colonoscopy. The NICE guideline MTG45 (2019) recommends use of Endocuff Vision to improve adenoma detection for people having a colonoscopy as part of bowel cancer screening following a positive stool test.

The Gastroenterology Get It Right First Time (GIRFT) Programme national specialty report highlights the need to support earlier diagnoses of colorectal cancer and identify areas for improvement in the quality of colonoscopy services.

An overview of the care pathway is presented in figure 1 and described in sections 3.2.1 to 3.2.4.

Figure 1: Overview of the care pathway (adapted from NICE DG28 scope)



3.2.1 Screening of non-symptomatic population with FIT

The NHS bowel cancer screening programme (BCSP) invites people in the UK to return a faecal immunochemical test (FIT) kit every 2 years to detect the presence of blood in the stool. The age groups invited for bowel cancer screening, and the detection threshold for an abnormal test (above or at the FIT threshold) result differs for each UK country. The BCSP for each UK country is described further in the NICE CKS for Bowel screening (2024). Colonoscopy is offered to people if they have an abnormal test result.

3.2.2 Investigation of symptoms suggestive of colorectal cancer

A person referred on the suspected colorectal cancer pathway should receive a diagnosis or ruling out of cancer within 28 days of being referred. For further details, see NHS England's webpage on faster diagnosis of cancer. Section 1.3 of the NG12 NICE guideline on suspected cancer describes the criteria to make a referral through this pathway for colorectal cancer. These recommendations are adapted from sections 1.1 to 1.4 of NICE guideline DG56 for the use of quantitative FIT. The ACPGBI/BSG (2022) guideline on FIT in patients with signs or symptoms of suspected CRC recommends that a FIT threshold of at least 10 micrograms of haemoglobin per gram of faeces should be used in primary care to select patients to the suspected cancer pathway for colorectal cancer investigation. It also recommends that people should not be excluded from referral from primary care on

the basis of FIT alone. Section 1.3 of NG12 states that people with a rectal mass, an unexplained anal mass or unexplained anal ulceration do not need to be offered FIT before referral is considered.

3.2.3 Surveillance colonoscopy

3.2.3.1 Surveillance colonoscopy for people with hereditary risk of colorectal cancer

Some people have genetic factors which increase their risk of getting colorectal cancer. The BSG/ACPBGI/UKCGG (2019) guideline for the management of hereditary colorectal cancer provides recommendations on colonoscopic surveillance for people with increased hereditary risk of colorectal cancer. This includes people with:

- Lynch syndrome
- polyposis syndromes (conditions where there are more than 10 polyps in the colon)
- significant family history of colorectal cancer
- a diagnosis of bowel cancer under the 50 years of age.

3.2.3.2 Surveillance colonoscopy for adults with IBD

NICE guideline CG118 (sections 1.1.1 to 1.1.5) recommends using colonoscopic surveillance to check for signs of colorectal cancer in people aged 18 and over with IBD.

BSG (2019) guidelines on the management of IBD in adults recommends stratifying IBD patients' colorectal cancer risk to determine the frequency of surveillance colonoscopy. Experts noted that there is also a guideline currently in development by the BSG which will update this recommendation.

3.2.3.3 Surveillance colonoscopy post polypectomy and post colorectal cancer resection

The BSG/ACPBGI/PHE (2019) guideline on post-polypectomy and post-colorectal cancer resection surveillance recommends colonoscopic surveillance for people who have undergone removal of either adenomatous polyps, serrated polyps, or colorectal cancer.

3.2.4 Management of colorectal polyps and cancer

The ESGE (2024) guideline on colorectal polypectomy and endoscopic mucosal resection (EMR) recommends resection of all polyps with the exception of diminutive rectosigmoid polyps that are predicted to be non-adenomatous with high confidence. Hyperplastic polyps located in the rectosigmoid have an even lower risk of advanced histology and a negligible risk of progression, therefore the guideline states that a diagnose-and-leave-behind strategy is appropriate to reduce polypectomy risks, pathology workload, and costs.

The ESGE guidance further recommends retrieval and histopathologic analysis of resected polyps. A resect-and-discard strategy using real-time optical diagnosis with virtual or dye-based chromoendoscopy for diminutive colorectal polyps should be reserved for experts only.

Clinical experts advised that typically in current practice resected polyps have histopathologic analysis. However, they highlighted that a resect-and-discard strategy is starting to be used within the BCSP. An accreditation process is in place to ensure that endoscopists are fully trained to use the resect-and-discard strategy effectively.

Clinical experts stated that the BSG/ACPBGI/PHE (2019) guideline is used in current clinical practice in the NHS for the surveillance in people who have had colorectal polyps removed. This guideline highlights the need for a careful polypectomy to be performed for a high-quality index colonoscopy (initial colonoscopy), to ensure complete and safe excision of the polyp. The need for subsequent surveillance colonoscopy is determined based on the individual's age and whether they meet high-risk surveillance criteria (see table 1 in BSG/ACPBGI/PHE (2019) guideline).

NICE guideline IPG503 on combined endoscopic and laparoscopic removal of colonic polyps has recommendations on the use of combined endoscopic and laparoscopic removal of colonic polyps to excise polyps that are unsuitable or high-risk for endoscopic removal.

If colorectal cancer is confirmed, NICE guideline NG151 on colorectal cancer recommends further imaging tests, such as CT and/or MRI, to stage the cancer and determine what treatment is needed. A PET-CT may also be indicated in some cases.

Management of malignant polyps

Experts highlighted that the Management of the malignant colorectal polyp: ACPGBI position statement is a key piece of guidance for practice.

They also noted that there is a guideline currently in development by the European Society of Coloproctology (ESCP) on T1 cancer.

3.3 Patient issues and preferences

Patient understanding of AI and their experiences of encountering AI in healthcare can be varied. They may come with concerns particularly when it is involved as part of their care.

Potential advantages for patients if AI technology improves colorectal polyp detection may be fewer pre-malignant polyps missed during colonoscopy. This could mean reduced risk of colorectal cancer and may also reduce anxiety in some people, particularly those from a high-risk group, if the use of the technology alongside healthcare professional review gives greater reassurance that polyps are not being missed.

Preparation for a colonoscopy involves completely emptying the bowel by following dietary restrictions and taking a strong laxative the day before the colonoscopy. This causes diarrhoea and so a need to stay close to the toilet and this process can be very unpleasant. A person undergoing the procedure would also need to avoid travelling or going to work. Before the colonoscopy the person is given a sedative, which may make them feel drowsy and will mean that they cannot drive themselves home after the procedure. Some people may experience difficulties with requiring time off from work or other activities, both before and after the procedure, and this may have financial implications. Any impact of the tests on the need for further colonoscopy will impact patients.

If polyps are removed during a colonoscopy, there may be a wait for the samples to be examined before receiving the results, which can take 3 weeks and may cause anxiety.

Colonoscopy with polypectomy has an increased risk of bleeding and risk of perforation compared with colonoscopy without polypectomy. If the tests are able to result in fewer unnecessary polypectomies being done, this will have benefits for patients and reduce risk of adverse effects related to polypectomy.

Clinical experts noted that AI technologies that improve optical diagnosis may also reduce the need for histopathology and associated wait times for results from this. AI technologies that improve polyp detection may increase the number of people going for surveillance colonoscopy.

4 Comparator

The comparator is colonoscopy done without use of the AI-supported technologies. This can be with use of other technologies used in the NHS such as virtual chromoendoscopy, dye-based chromoendoscopy, or Endocuff Vision (see section 3.2).

5 Scope of the assessment

Table 1: Scope of the assessment

Decision question	Does the addition of AI-supported colonoscopy technologies to colonoscopy represent a clinically- and cost-effective use of NHS resources?
Populations	People having a colonoscopy because they have been: • Referred for colonoscopy through the NHS bowel cancer screening programme • Referred for colonoscopy for investigation of symptoms suggestive of colorectal cancer • Referred for surveillance colonoscopy because of a hereditary risk of colorectal cancer • Referred for surveillance colonoscopy because of IBD • Referred for surveillance colonoscopy post polypectomy or post colorectal cancer resection.

	Where data permits, subgroups based on these sub-populations should be considered (see section 6.2).
Intervention	Colonoscopy done with AI-supported colonoscopy technologies incorporated to support decision making: • Argus • CAD EYE • CADDIE • Discovery • ENDO-AID • ENDOANGEL • EMIS • Endoscreener • GI Genius • MAGNETIQ-COLO • WISE VISION Not all interventions are indicated for use across all populations listed in the populations above (see section 2.2).
Comparator	Colonoscopy done without AI supported colonoscopy technologies.
Healthcare setting	Secondary care
Outcomes: intermediate measures	Intermediate measures for consideration may include: • Measures of ability or accuracy to detect polyps or cancer • Measures of ability to characterise identified polyps • Measures related to healthcare resource use (such as time to do colonoscopy, need for repeat colonoscopy to be done, need for a second observer) • Time to colonoscopy and impact on waiting lists • Number of polyp removal procedures • Incidences that the technology does not function • Impact on decision making • Ease of use/acceptability of the technologies to healthcare professionals
Outcomes: clinical	Clinical outcomes for consideration may include: • Morbidity (including outcomes related to colonoscopy procedure and cancer, including incidence of post-colonoscopy colorectal cancer) • Mortality
Outcomes: patient-reported	Patient-reported outcomes for consideration may include: • Health-related quality of life (including anxiety)

	• Acceptability of tests to patients
Outcomes: costs	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs of AI systems (including any software, hardware, consumables, maintenance, and service costs) • Cost of training • Costs related to colonoscopy and polyp removal • Costs of histopathology • Cost of treatment for colorectal cancer • Costs of adverse events from the procedure or further diagnostic work up
Measuring cost-effectiveness	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

6 Other issues for consideration

6.1 Impact of endoscopist skill and experience

Clinical experts noted that endoscopist training is standardised across the UK but Bowel Cancer Screener Accreditation (BSCA) differs between the UK nations. England and Wales have national BCSP accreditation and quality standards, but in Scotland screening colonoscopists are approved locally. Health Education England and Health Education and Improvement Wales (HEE and HEIW) have also introduced an accelerated programme to train suitably qualified registered health professionals to perform colonoscopies. Experts commented that this means that there may be variations in the experience levels of endoscopists trained through different programmes.

Clinical experts also noted that there are differences in the surveillance programmes offered to different populations. For example, the BCSP in England includes a surveillance programme for Lynch syndrome, but people with Lynch syndrome in other UK nations may not always have screening accredited colonoscopists performing their procedures. Further, not all hereditary high-risk (such as polyposis) conditions are handled by screening-accredited colonoscopists in England.

Experts noted that AI technologies may offer greater benefit for less experienced endoscopists. The extent that the AI technologies improve endoscopist performance when added to current colonoscopy procedures may depend on the skill and experience of the endoscopist. Analysis of data showing technology performance should take into account the skill and experience of the health care professional performing the colonoscopy.

6.2 Performance variation by reason for colonoscopy

Clinical experts commented that the AI algorithms may not be developed, trained, or validated on data from people with IBD or hereditary risk factors. They raised concern about the performance of the technologies when used for these populations. Evidence levels on performance may also differ between groups. For example, people with IBD have been excluded from studies. The availability of evidence for the difference subpopulations having colonoscopy, and how appropriate it is to generalise data between these subpopulations, should be considered in the assessment. The requirements for the healthcare professional doing the colonoscopy can also vary by reason for colonoscopy (see section 6.1).

6.3 Workforce and capacity issues

Increase in polyp detection could increase the need for polypectomies, increasing workload of gastroenterologists and histopathologists. These changes could exacerbate capacity challenges further and increase existing wait times for colonoscopies. The assessment should consider potential implications of increases in the need for colonoscopy resulting from use of the technologies. Outputs of modelling should include an indication of the estimated change in numbers of colonoscopies, as well as other healthcare procedures such as polypectomies and those related to histopathology.

6.4 Existing guidance on the use of computer-assisted detection and diagnosis in colonoscopy

The Health Technology Wales (HTW) (2024) guidance on AI-assisted endoscopy in the detection of gastrointestinal cancer and pre-cancerous lesions recommends routine adoption of computer aided detection (CADe) colonoscopy for the detection of lower gastrointestinal cancer and pre-cancerous lesions.

The ESGE (2022) position statement on the expected value of AI in gastrointestinal endoscopy has recommendations on the use of CADe and CADx.

6.5 Impact of CADx function of tests

For technologies with CADx functionality, the impact of this on decisions about identified polyps may depend on how resect-and-discard and diagnose-and-leave strategies are used in the NHS, and on how much health care professionals use CADx results in their assessment of identified polyps. The ESGE (2022) position statement on the expected value of AI in gastrointestinal endoscopy recommends that for acceptance of AI optical diagnosis (computer-aided diagnosis [CADx]) of diminutive polyps (≤5 mm), AI-assisted characterization should match performance standards for implementing resect-and-discard and diagnose-and-leave strategies. As described in the section 3.2.4, experts have advised that in current NHS practice use of a resect-and-discard strategy may be limited, but this has recently begun to be used by bowel cancer screening colonoscopists within the BCSP.

If data allows, exploratory analysis investigating the use of the AI-based software to enable greater use of a resect-and-discard strategy should also be considered. This may help to identify the potential impacts of this and help identify areas of uncertainty that would benefit from further data collection.

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Risk of lower gastrointestinal cancer increases with the number and size of polyps and this is related to older age, people who are overweight, people who smoke, and people with significant family history of colorectal polyps or colorectal cancer, conditions such as IBD, acromegaly and with certain genetic conditions such as Lynch syndrome or familial adenomatous polyposis (Cancer Research UK, 2022).

Age and race are protected characteristics. Older people, people from Black African or Caribbean family backgrounds and Jewish people of central and eastern European family origin are thought to be at an increased risk of colorectal cancer,

whereas east Asian populations have a lower prevalence of colorectal cancer. People with cancer are protected under the Equality Act 2010 from the point of diagnosis.

8 Potential implementation issues

Training novice endoscopists

HTW guidance states that the learning curve in using CADe is thought to be minimal with experienced endoscopists and training may be provided free of charge. However, there is potential for CADe to impact the training pathway for novice endoscopists and achievement of key performance indicators.

Integration of the technologies into existing colonoscopy systems

Manufacturers commented there is extensive variability in NHS IT infrastructure specification, performance and reliability which can potentially inhibit or limit AI software adoption. This may be because of installation connectivity and IT compatibility requirements for specific AI technologies. The different AI-based systems vary in which colonoscopy systems they can be used with. So, the colonoscopy system a centre currently uses may impact which of the AI-based technologies it can implement.

Authors

Anam Khan

Topic Lead

Thomas Walker

Technical Adviser

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Appendix A Glossary of terms

Familial adenomatous polyposis (FAP)

FAP is a genetic condition where a large number of polyps develop in the lining of the colon and rectum.

Inflammatory bowel disease (IBD)

IBD is a chronic condition which causes inflammation of the digestive system. It can cause severe stomach pain and diarrhoea. The main types of IBD are Crohn's disease and ulcerative colitis.

Lynch syndrome

Lynch syndrome is an inherited condition that causes an increased risk of bowel cancer. People with Lynch syndrome are more likely to develop cancer at younger ages and may get cancer more than once.

Serrated polyps

Serrated polyps are a class of colorectal polyps that have a 'saw-toothed' appearance under a microscope. These are mostly hyperplastic polyps.

Sessile serrated polyps (SSL)

About 20% of serrated polyps are sessile serrated polyps. These are a sub-type of serrated polyps which are more likely to develop into cancer if not removed.

Appendix B References

Advanced imaging for detection and differentiation of colorectal neoplasia (2019 update) ESGE guideline

Artificial Intelligence (AI)-assisted endoscopy in the detection of gastrointestinal cancer and pre-cancerous lesions (2024) Health Technology Wales guideline

Cancer Research UK Risks and causes of bowel cancer 2021 [online; accessed 7 August 2024]

Bowel screening (2024) NICE Clinical Knowledge Summaries

Colorectal Cancer (2021) NICE guideline NG151

Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas (2022) NICE guideline CG118

Colorectal polypectomy and endoscopic mucosal resection (2024 update) ESGE guideline

Consensus guidelines on the management of inflammatory bowel disease in adults (2019) British Society of Gastroenterology

Endocuff Vision for assisting visualisation during colonoscopy (2019) NICE guideline MTG45

FIT in patients with signs or symptoms of suspected CRC (2022) British Society of Gastroenterology/Association of Coloproctology of Great Britain

Guidelines for the management of hereditary colorectal cancer (2019) British Society of Gastroenterology/Association of Coloproctology of Great Britain/ United Kingdom Cancer Genetics Group

Position statement on serrated polyps in the colon and rectum (2017) British Society of Gastroenterology

Post-polypectomy and post-colorectal cancer resection surveillance (2020) British Society of Gastroenterology/Association of Coloproctology of Great Britain and Ireland/Public Health England guideline

Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care (2023) NICE guideline DG56

Suspected cancer: recognition and referral (2023) NICE guideline NG12

T1 cancer guideline (in development) (2024) European Society of Coloproctology

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy (2017) NICE guideline DG28

NICE Diagnostic Guidance

DG10118 Artificial intelligence software to help detect and characterise colorectal polyps

Assessment report overview

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the final scope and the diagnostic assessment report. A list of abbreviations used in this overview is in appendix A.

1. The technologies

The technologies being assessed have two functions. Firstly, all AI-assisted colonoscopy technologies support the **detection** of colorectal polyps during the colonoscopy procedure by detecting and flagging lesions of concern for the endoscopist to review. This function of AI technologies is known as Computer Aided Detection (**CADe**). CADe aims to help endoscopists detect polyps that may otherwise have been missed by endoscopist review alone.

Secondly, some technologies also provide AI-based Computer Aided Diagnosis (CADx) in addition to the CADe function. **CADx** assists in the **characterisation** of the detected polyps based on features such as polyp size, surface appearance and colour, and morphology. The aim of CADx is to improve the optical diagnosis performed by endoscopists to help decisions about whether to remove a polyp or not. This could reduce unnecessary polypectomies (with a resulting reduction in complications such as bleeding and perforation of the bowel) and improve recognition of polyps for resection.

In total, 10 technologies were identified as being in scope, all of which feature CADe functionality, with 4 also having CADx functionality. The technologies are summarised in Table 1.

Table 1. List of technologies included in the scope.

	MDR class	Cost	CADx available?
Argus® (Endosoft);	In process	Upfront cost of £10,000.00 (excluding VAT) £2,000.00/year maintenance cost.	No
CADDIE™ (Odin Vision)	Class IIa	Not provided*	Yes
CAD EYE® (Fujifilm Healthcare UK Ltd.)	CE class IIa	Upfront cost of [redacted] (excluding VAT), including [redacted] of maintenance.	Yes
Discovery™ (Pentax Medical UK)	CE class IIa	Upfront cost of £34,999.99 (excluding VAT). First year maintenance is included in upfront cost; thereafter, £2,265.00/year maintenance cost.	No
Endoscopic Multimedia Information System™ (EMIS™) (EndoPerv LLC.)	In process	[redacted]	No
ENDO-AID™ (Olympus Medical Systems Corp.)	CE class IIa	£29,916.00 (including VAT) First year maintenance is included in upfront cost; thereafter, £3,189.00/year maintenance cost.	No
ENDOANGEL® Lower (Wuhan ENDOANGEL Medical Technology Co. Ltd.)	CE class II	Not provided*	No
EndoScreener® (Wision AI)	CE class IIa	Subscription: £9,750/year (excluding VAT), waived after four years	No
GI Genius™ (Medtronic)	CE class IIa	Upfront purchase: £42,000 including three years of maintenance. Subscription: £1,750/month including maintenance (including VAT).	Yes
MAGENTIQ-COLO™ (MAGENTIQ-EYE)	Class IIa	Upfront purchase: €30,000 including one year of maintenance. Subscription: €1,000/month including maintenance (excluding VAT)	Yes

* Technologies in which the cost was not provided were ineligible for economic assessment.

2. The condition

Colorectal polyps are small growths on the lining of the colon. Most colorectal polyps do not cause any symptoms, so people are unaware that they have them. However, some can cause rectal bleeding, mucus in stool, diarrhoea or constipation, and abdominal pain. Risk factors for colorectal polyps include older age, genetics and family history of bowel polyps or bowel cancer, dietary and lifestyle factors and conditions that affect the gut such as inflammatory bowel disease (IBD).

It is important to identify and accurately classify colorectal polyps early in their development as most cases of colorectal cancer (CRC) develop from these lesions. Early detection during colonoscopy allows for removal before malignant transformation occurs, with removal of polyps (polypectomy) potentially reducing the incidence of CRC by up to 90%, making it a cornerstone of prevention.

The risk of a polyp becoming malignant can be assessed by categorising them in terms of their shape, size, location and histology. There are two types of polyps that are of particular concern. Adenomatous polyps are precancerous growths and are a key indicator of CRC risk. Sessile serrated lesions (SSLs) are flat or subtly elevated polyps often located in the proximal colon that can progress to CRC, making their detection critical despite their more challenging visual appearance. For more information on the condition, see the final scope.

3. Current diagnostic practice

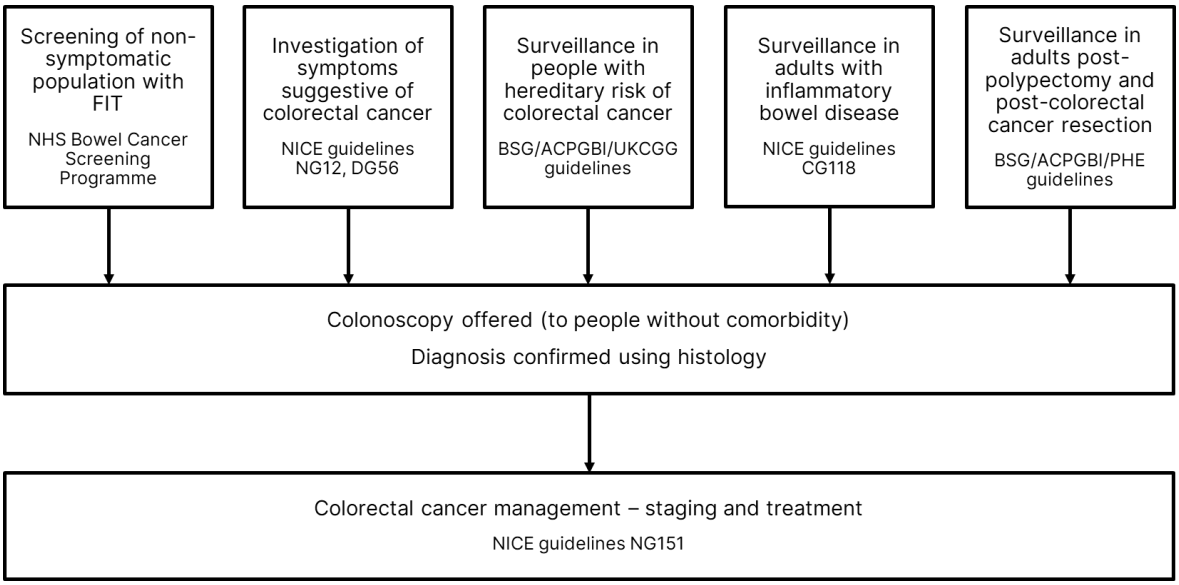
In England, colonoscopy is used for CRC screening in average risk adults from the age of 50 years. Colonoscopy is also used for surveillance following polyp or cancer removal, for people with hereditary cancer risk, and for people with diagnosed IBD. Colonoscopy is also used for investigating symptoms or findings such as rectal bleeding, iron deficiency anaemia, abnormal imaging, or suspected IBD. It can visualise the entire colon and tissue samples can be taken and examined histologically to confirm a diagnosis, unless this is contraindicated. Colonoscopy is most frequently performed as an outpatient

procedure with the person having the option of receiving sedation or painkillers.

Standard colonoscopy uses conventional high-definition white-light endoscopy (WLE) to detect colorectal polyps and may be used in combination with dyes (chromoendoscopy). However, virtual chromoendoscopy (VCE) technologies have also been developed and are used in the NHS (see NICE guideline DG28 (2017)). The AI technologies can be used with adjunctive devices such as ENDOCUFF VISION™ (NICE MTG45).

An overview of the care pathway is presented in figure 1.

Figure 1: Overview of the care pathway (adapted from NICE DG28 scope)



When a polyp is found during colonoscopy, it is usually removed immediately using a polypectomy procedure. The removed tissue is then sent for histological analysis to determine its type and assess any cancer risk. The ESGE (2024) guideline on colorectal polypectomy and endoscopic mucosal resection (EMR) recommends that diminutive rectosigmoid polyps that are predicted to be non-adenomatous with high confidence can be left in place ('diagnose-and-leave strategy').

Clinical experts agreed that typically in current practice resected polyps have histopathologic analysis. However, they highlighted that a 'resect-and-discard' strategy is starting to be used within the BCSP. An accreditation process is in

place to ensure that endoscopists are fully trained to use the resect-and-discard strategy effectively.

The ESGE guideline recommends that a resect-and-discard strategy using real-time optical diagnosis for diminutive colorectal polyps should be reserved for experts only.

4. Unmet need

The NHS faces several unmet needs in colonoscopy, primarily driven by the high demand for procedures from multiple referral pathways (figure 1). A significant challenge is the potential for endoscopists to miss polyps, particularly smaller or flatter ones, which can lead to delayed diagnosis or missed opportunities for early cancer prevention. This variability in detection rates among practitioners can impact patient outcomes. AI for colorectal polyp detection, acting as a 'second observer' during the procedure, could help address these issues.

AI tools could potentially increase the Adenoma Detection Rate (ADR), which is the proportion of colonoscopy procedures in which at least one adenomatous polyp is identified, expressed as a percentage of all examined cases. Improved ADR directly relates to enhanced quality of examinations and a reduction in the risk of missed lesions and consequently negative clinical outcomes. For technologies that support CADx functionality, these could potentially support resect-and-discard or diagnose-and-leave strategies for diminutive polyps, which could reduce unnecessary pathology costs while maintaining safety.

Further details, including descriptions of the decision problem, interventions, comparator, care pathway and outcomes, are in the final scope.

5. Diagnostic accuracy

The External Assessment Group (EAG) did a comprehensive literature search to identify relevant published diagnostic and clinical evidence on the AI technologies identified in the scope. Studies were only included if they applied

the AI technologies to colonoscopies in real time as this reflects the way in which they will be used in clinical practice.

In colonoscopy, standard practice led by experienced endoscopists is already considered the benchmark (reference standard), and CADe is designed to support and not replace their judgement. Therefore, CADe studies rarely reported diagnostic accuracy data (such as sensitivity and specificity) and where these were reported, they were based on autonomous use of the technology rather than as an adjunct to endoscopist judgement. Therefore, these measurements were considered to be of limited use because this is not how the technologies would be used in practice. CADe studies instead generally focused on detection outcomes such as adenoma detection rate (ADR). Randomised controlled trials (RCTs) which compared standard colonoscopy with colonoscopy with adjunctive AI were prioritised for review, but other study types were included where necessary, following a hierarchal approach. The primary outcome of interest was the ADR because of its link to reduced post-colonoscopy CRC risk. ADR is widely regarded as an important key performance indicator (KPI) for colonoscopy, routinely used to benchmark individual endoscopists and centres, and forms part of accreditation standards in the UK (Rees, 2016). ADR was the most widely reported metric in the studies, and for these reasons it was selected by the EAG as the key efficacy input of the economic model.

For CADx, diagnostic accuracy studies where AI supported rather than replaced endoscopist judgement (i.e. adjunctive use, rather than autonomous use) were prioritised. The primary outcome of interest was the diagnostic accuracy in polyp characterisation compared with histology.

The search and selection methods are reported in section 3.1 of the EAG diagnostic assessment report (DAR) with further information given in section 9.2 of the Appendices and in the DAR Supplement.

5.1 Overview of key studies

In total, the EAG identified 70 independent studies reported in 72 publications which were included in the clinical review (see figure 2 of the DAR). Most of

the studies reported data solely for the CADe function of technologies, with a smaller number reporting CADx or combined data. At least one study was identified for all the technologies, and all of the technologies reported data on ADR. The EAG also identified the NIHR-funded NAIAD study, which included 34 hospitals in England, Wales, and Scotland as an informative real-world evidence study.

Risk of bias assessment

The EAG assessed the included studies for risk of bias using appropriate critical appraisal tools. Most CADe studies had 'some concerns' for bias, often due to the unblinded nature of the intervention. High-risk studies were excluded from primary analyses where lower-risk evidence (higher quality) existed, with sensitivity analyses exploring the impact of this. Additional methodological concerns included the potential impact of the Hawthorne effect, where trial participation might inflate ADRs in both arms, and the limited ability to formally assess publication bias due to small numbers of studies in most meta-analyses.

For CADx, only one study was judged free of bias concerns, with others limited by factors such as autonomous AI use or selective inclusion of high-confidence diagnoses. While exclusion of most conference abstracts could increase publication bias risk, the inclusion of unpublished manufacturer data may have mitigated this. The EAG also noted that at least 16 completed trials (by 2022) appeared unpublished as of January 2025, suggesting possible publication bias in this field.

A summary of the characteristics of the identified CADe and CADx studies is provided in Table 4 of the DAR. The risk of bias analysis is reported in section 3 of the DAR supplement.

CADe studies

Most of the CADe studies included were parallel RCTs, with a smaller number being tandem RCTs (trials where the participant receives both colonoscopy with and without AI sequentially, with the order randomised). The trials were set across multiple real-world colonoscopy settings, including average-risk

screening (with and without positive faecal immunochemical test [FIT]), post-polypectomy and high-risk surveillance (e.g. Lynch syndrome), and symptomatic diagnostic procedures. In the studies, CADe was used adjunctively by both expert and trainee endoscopists.

Two technologies had a notably greater volume of evidence reporting ADR suitable for meta-analyses compared with the other technologies. These were GI Genius™, which had 9 studies on CADe (n=10,913 participants), and CAD EYE®, which had 12 studies on CADe (n=7,708). Other technologies had fewer overall studies and participants informing their evidence base, and were Argus® (1 study, n=686); CADDIE™ (2 studies, n=1,549); Discovery™ (1 study, n=497); ENDO-AID™ (4 studies, n=3,046); ENDOANGEL (2 studies, n=995); EMIS™ (1 Study=2,847); EndoScreener® (6 studies, n=4,663); and MAGENTIQ-COLO (1 study, n=916).

CADx studies

The CADx studies enrolled adults with detected colorectal lesions during screening, surveillance (including IBD and post-polypectomy follow-up) or diagnostic colonoscopy across single- and multi-centre sites in Europe, Asia, North America and Australia. Studies reported diagnostic accuracy data for autonomous or adjunctive AI optical characterisation (using histology as the reference standard). Some compared this to optical characterisation performed by the endoscopist alone, but this comparison was not always reported. Study designs varied and included parallel RCTs as well as prospective non-randomised and observational studies.

Data from 7 studies reporting CADx outcomes for CAD EYE® were included, with 5 CADx studies included for GI Genius. The CADDIE™ and DISCOVERY™ technologies were featured in 1 study each, with none of the other technologies having evidence on CADx.

5.2 Meta-analyses and narrative synthesis

The EAG did a series of meta-analyses on each of the key outcomes for each individual technology. Pooling of results across multiple technologies (i.e. technology agnostic) were not done, in line with the study protocol. For some

outcomes, quantitative synthesis was not possible; in these instances, a qualitative synthesis was done.

Methods

The meta-analyses were conducted in Review Manager (RevMan) using random-effects models due to the anticipated clinical and methodological differences between studies (including heterogeneity in patient populations, adjunct tools, and endoscopist expertise). The main outcome of interest was the ADR (section 3.2.2.1.1.1 of the DAR). However, where data allowed, a range of analyses relating to other outcomes relevant to polyp detection were also done.

The risk of bias was addressed by excluding trials deemed high-risk from the main analyses unless they covered unique populations (such as patients with IBD) or no alternative lower-risk data existed; sensitivity analyses then re-incorporated these studies to test robustness.

Dichotomous outcomes were expressed as risk ratios (RR), with Peto odds ratios used for very rare events (<1%) and risk differences for adverse events when both arms report zero events. Continuous outcomes used mean differences, and the outcome of adenoma per colonoscopy (APC) additionally underwent an incidence rate ratio (IRR) analysis, to calculate rate ratios from total or estimated adenoma counts, to support economic modelling (scenario analysis).

The meta-analyses were mainly restricted to RCTs on CADe. However, the large UK-based NAIAD trial (reporting on GI Genius™) was reported alongside RCT meta-analyses rather than pooled with them, recognising its scale and NHS context but preserving RCT evidence for the economic model.

Results of CADe

Adenoma detection rate (ADR)

The results of the meta-analyses for ADR in each intervention are reported in Table 2. All the technologies reported point estimates of the RR were over 1, indicating that CADe was associated with increased rates of adenoma

detection, ranging from an RR of 1.02 (95% CI 0.81 to 1.28) for Discovery™ to RR 1.36 (95% 1.04 to 1.78) for ENDOANGEL®. This was statistically significant for most of the technologies. Where results were not statistically significant, this may have been due to the smaller sample size used in the analyses and the resulting lack of precision. Additional limitations included that the study on Argus® was an abstract only, and Discovery™ was informed by a single, relatively small RCT. 'Of note, the trial covering EMIS™ was described as [redacted] This means it differs considerably to the other technologies included in this review. For a full description of study limitations for each technology, see the DAR report (section 3.2.1).

Table 2. Summary of analyses performed for ADR across interventions

Intervention	Study number (number of participants)	Absolute effect CADe	Absolute effect standard colonoscopy	Relative risk (95% CI)
Argus® (Endosoft)	1 RCT (n= 686)	144/344 (41.86%)	130/342 (38.01%)	RR 1.10 (0.92 to 1.32)
CAD EYE®	12 RCTs (n=7,708)	1,939/3,844 (50.44%)	1,662/3,864 (43.01%)	RR 1.17 (1.11 to 1.24)
[redacted]	2 RCTs [redacted]	[redacted]	[redacted]	[redacted]
Discovery™	1 RCT (n=497)	96/250 (38.40%)	93/247 (37.65%)	RR 1.02 (0.81 to 1.28)
[redacted]	1 RCT [redacted]	[redacted]	[redacted]	[redacted]
ENDO-AID™	4 RCTs (n=3,046)	889/1,650 (53.88%)	595/1,396 (42.62%)	RR 1.25 (1.16 to 1.35)
ENDOANGEL®	2 RCTs (n=995)	104/495 (21.01%)	77/500 (15.40%)	RR 1.36 (1.04 to 1.78)
EndoScreener®	6 RCTs (n=4,663)	716/2,332 (30.70%)	573/2,331 (24.58%)	RR 1.24 (1.13 to 1.37)
GI Genius™	9 RCTs (n=10,913)	2,923/5,452 (53.61%)	2,566/5,461 (46.99%)	RR 1.18 (1.07 to 1.30)

MAGENTIQ-COLO™	1 RCT (n=916 participants)	167/449 (37.19%)	138/467 (29.55%)	RR 1.26 (1.05 to 1.51)

ADR by adenoma size and appearance

Where possible, the EAG also reported on the ADR depending on if the adenomas were advanced (table 3) or non-advanced (table 4). Advanced adenomas were usually defined as those ≥10 mm in size, or with a villous component, high-grade dysplasia or intramucosal cancer (although this may vary very slightly between studies). These data were used in the economic analysis where reported, to reflect differences in the impact of AI on the detection of low and high-risk adenomas.

The available evidence indicates that AI systems may improve detection of advanced as well as non-advanced adenomas (across size categories) although the impact of AI may be lower for larger adenomas. The results for advanced adenomas are also less certain than overall ADR but this may be due to the lower event rates.

Table 3. Summary of analyses performed for advanced ADR across interventions

Intervention	Study number (number of participants)	Absolute effect CADe	Absolute effect standard colonoscopy	Risk ratio (95% CI)
CAD EYE®	8 RCTs (n=6,481)	321/3232 (9.93%)	275/3249 (8.46%)	RR 1.18 (0.98 to 1.44)
[redacted]	1 RCT [redacted])	[redacted]	[redacted]	[redacted]
ENDO-AID™	4 RCTs (n=2,988)	176/1620 (10.86%)	120/1368 (8.77%)	RR 1.12 (0.86 to 1.45)
ENDOANGEL®	2 RCTs (n=995)	16/495 (3.23%)	12/500 (2.40%)	RR 1.35 (0.64 to 2.82)
GI Genius™	6 RCTs (n=9,683)	866/4835 (17.91%)	863/4848 (17.80%)	RR 1.00 (0.92 to 1.08)

Table 4. Summary of analyses performed for non-advanced ADR across interventions.

Intervention	Study number (number of participants)	Absolute effect CADe	Absolute effect standard colonoscopy	Risk ratio (95% CI)
ENDO-AID™	1 RCT (n=312)	85/155 (54.84%)	64/157 (40.76%)	RR 1.35 (1.06 to 1.70)
ENDOANGEL®	1 RCT (n=539)	53/268 (19.78%)	37/271 (13.65%)	RR 1.45 (0.99 to 2.13)
GI Genius™	3 RCTs (n=2,445)	499/1221 (40.87%)	383/1224 (31.29%)	RR 1.31 (1.17 to 1.45)

Sessile lesion detection rate

Although sessile serrated lesions (SSLs) are relatively rare, comprising approximately 3% of total polyps, the detection rate is important, as SSLs are involved in different pathological pathways to malignancy, and SSLs can be challenging to detect, requiring both careful endoscopic technique and experienced histopathologic review. Not all the technologies reported data on SSL detection, with data being absent for Argus® and EMIS™. The results of the meta-analyses for SSL in each intervention, expressed as RR or Peto scores, are reported in table 5. All the technologies reported point estimates suggesting that AI could improve SSL detection. However, none of the results were statistically significant but the EAG noted this is likely due to the lower number of events.

Table 5. Summary of analyses performed for SSL detection across interventions

Intervention	Study number (number of participants)	Absolute effect CADe	Absolute effect standard colonoscopy	Relative risk (95% CI)
CAD EYE®	7 RCTs (n=6,066)	198/3,025 (6.55%)	172/3,041 (5.66%)	RR 1.20 (0.91 to 1.59)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Discovery™	1 RCT (n=497)	46/250 (18.40%)	30/247 (12.15%)	RR 1.51 (0.99 to 2.32)
ENDO-AID™	3 RCTs (n=2,676)	261/1,465 (17.82%)	119/1,211 (9.83%)	RR 1.39 (0.95 to 2.03)
ENDOANGEL®	1 RCT (n=539)	1/268 (0.37%)	1/271 (0.37%)	Peto OR 1.01 (0.06 to 16.21)
EndoScreener®	1 RCT (n=790)	3/393 (0.76%)	1/397 (0.25%)	Peto OR 2.76 (0.39 to 19.64)
GI Genius™	5 RCTs (n=5,069)	246/2,530 (9.72%)	192/2,539 (7.56%)	RR 1.27 (0.97 to 1.66)
MAGENTIQ-COLO™	1 RCT (n=916)	27/449 (6.01%)	18/467 (3.85%)	RR 1.56 (0.87 to 2.79)

Diagnostic accuracy data

Although rarely, some studies reported diagnostic accuracy metrics like sensitivity and specificity for AI-assisted polyp detection The EAG considered these data were limited and not suitable for use in the economic modelling. This was because the reporting of these data for the CADe function was based on autonomous use of the technology, rather than use alongside endoscopist judgement, which does not reflect how the technologies would be used in clinical practice. Most studies lacked comparative data compared with standard colonoscopy, and definitions of false positives and negatives varied widely. Overall, the evidence was considered to be sparse, inconsistent, and often derived from abstracts with high risk of bias.

False positives for CADe were usually defined as lesions flagged by the technology as polyps that, on review, endoscopists did not consider to be polyps. Studies reporting on false positives with AI in colonoscopy show that most systems (including Discovery™, ENDO-AID™, ENDOANGEL®, EndoScreener®, and GI Genius™) produce relatively few false alerts per procedure, typically fewer than one per colonoscopy. However, these rates may be higher in certain populations, such as those with Lynch syndrome.

False negatives were seldom reported.

Further information on CADe-based diagnostic accuracy data is detailed in section 3.2.2.1.1.13 of the DAR.

Other CADe results

Findings such as adenomas per colonoscopy and adenoma miss rate were consistent with the ADR. [redacted]. The other results relating directly to CADe functionality are reported in the DAR in sections 3.2.2.1.1.2 to 3.2.2.1.1.12 and include adenomas per colonoscopy, by size, miss rate and by different categories such as hyperplastic and non-neoplastic polyps.

Results of CADx

The EAG reported studies of CADx tools showed inconsistent diagnostic accuracy, with some reporting higher sensitivity (but lower specificity) than endoscopists alone, while others finding no benefit or worse performance. However, the evidence base was limited and the EAG identified several methodological concerns. For example, some trials evaluated AI in fully autonomous mode rather than as an adjunct to the clinician, others omitted low confidence endoscopist diagnoses, and many failed to classify serrated lesions as potentially precancerous. The EAG considered the evidence on CADx to be too limited to base strong conclusions on.

A full discussion on the results for each technology is reported in the DAR in section 3.2.2.1.2.

Other results

Number of polyp removal procedures

Polyp removal outcomes for AI-assisted colonoscopy were reported by 2 studies. An RCT of EndoScreener® showed a higher biopsy rate compared to standard colonoscopy (1.04 vs 0.64 biopsies per procedure), while a high-risk-of-bias study for GI Genius™ found a significantly higher per-patient polypectomy rate, but no significant difference per polyp resected. Overall, AI technologies may increase biopsy or polypectomy rates, though the evidence remains limited and variable.

Unavailable outputs (CADx)

Some technologies showed a ‘no prediction’ output when unable to confidently classify polyps, with rates varying across platforms. These were low for CAD EYE® (1.3%) and higher for GI Genius™ (5 to 20.5%). These outputs reflect confidence limitations rather than technical failures, and overall, the evidence base on reliability remains sparse. The impact of unavailable outputs was not a feature of the economic model.

Usability and acceptability

Some data on healthcare professionals’ views of AI-assisted colonoscopy, mainly from abstracts and surveys, were identified. The technologies were generally seen as helpful for polyp detection and reassurance, although there were concerns around procedural time, cost, and potential over-reliance. There was cautious optimism about their future role, especially if supported by strong clinical and cost-effectiveness data.

Adverse events

No obvious difference in adverse events was identified in the DAR (section 3.2.2.1.3).

Subgroup analyses of population

The EAG conducted subgroup analyses based on colonoscopy indication and endoscopist experience, as outlined in the protocol. For colonoscopy indication, studies were grouped by dominant patient categories and supplemented with within-trial subgroup data where available, though inconsistent reporting and mixed populations limited interpretability.

The EAG reported that, while some trends emerged, such as a possible negative impact of GI Genius™ in Lynch syndrome patients, these findings were inconsistent across technologies and based on limited data, making firm conclusions difficult.

Most studies that included mixed populations lacked within-trial subgroup analyses, limiting interpretation. Overall, the EAG concluded that the evidence does not suggest strong differences in AI performance across subgroups,

though subtle effects cannot be ruled out. Larger, stratified trials are needed to clarify whether AI technologies perform differently across patient populations.

Subgroup analysis of operator experience

Subgroup analyses based on endoscopist experience were prespecified in the protocol and explored where feasible, particularly in relation to ADR and APC. For endoscopist experience, various definitions were reviewed and refined with expert input, but analyses were often constrained by the small number of studies and limited variation across interventions.

Few studies reported outcomes separately by experience level, and those that did often lacked stratification at randomisation, undermining reliability. While some data suggest CADe may benefit less experienced endoscopists more, other analyses show the opposite, and definitions of experience varied widely across trials. Additionally, a meta-analysis was identified that concluded there is no strong evidence that CADe efficacy is modified by skill level.

6. Resource use outcomes

6.1 Procedure time

The results from the available studies suggested that the AI technologies may increase procedure times compared with standard colonoscopy. However, the differences were small, at less than 1 to 2 minutes difference in duration in most analyses.

[redacted]

6.2 Effect on surveillance intervals

Some studies reported on how AI technologies affect post-colonoscopy surveillance intervals, with limited and mixed evidence. CADe may reduce missed adenomas, potentially leading to shortened (but more appropriate) intervals, while CADx shows high agreement with expert diagnosis in assigning intervals, especially in resect-and-discard or diagnose-and-leave contexts. Overall, AI does not appear to worsen surveillance interval

decisions, but the evidence base is sparse, and it could lead to increased surveillance colonoscopy workload.

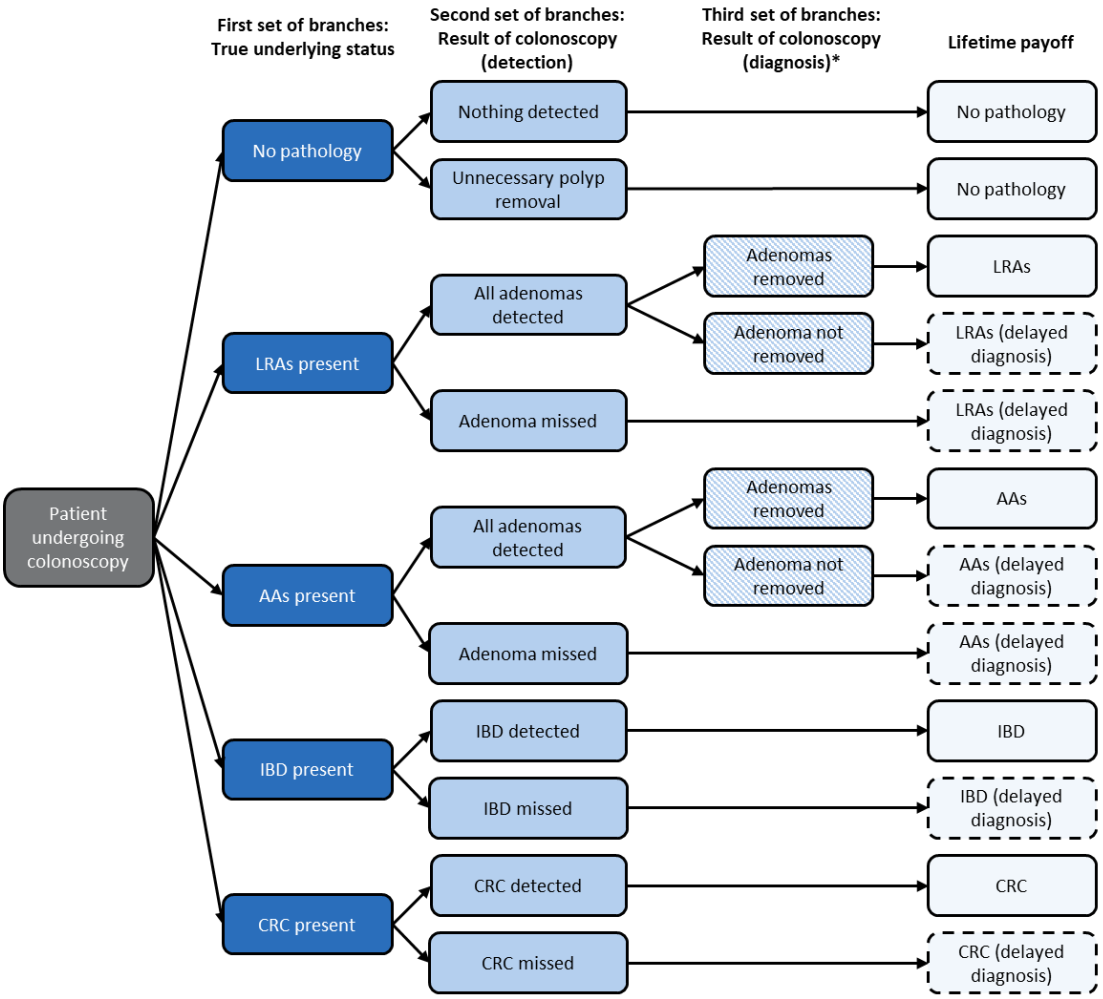
7. Health economic evidence

The EAG performed a systematic review which identified 9 existing economic evaluations of AI-assisted colonoscopy (DAR section 4.1). The EAG reported the identified models relied on unvalidated assumptions and inputs and were not generalisable to the UK. Consequently, the EAG developed a *de novo* cost-utility model comparing 8 CADe/CADx technologies which had cost data (Argus®, CAD EYE®, Discovery™, EMIS™, ENDO-AID™, EndoScreener®, GI Genius™, MAGENTIQ-COLO™) plus colonoscopy compared with standard colonoscopy alone in eligible patients. The model was developed in line with the NICE reference case.

7.1 Health economic model

The EAG developed a decision tree model to simulate outcomes from the baseline colonoscopy, drawing on methods from the previous NICE diagnostic appraisals *Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care* (DG56) and *PillCam COLON 2 for investigation of the colon through direct visualisation* (DG10083). In the base case, the economic model focussed on the CADe functionality of the technologies only. The model is illustrated schematically in figure 3.

Figure 3. Schematic of the EAG model.



In the first branch, the model assigns a cohort of eligible people to one of five 'true disease' states, namely no pathology (or non-adenomatous polyps), low-risk adenomas, advanced adenomas, IBD, or CRC using a hierarchal system based on the most severe finding (so for instance, a person with advanced adenoma and CRC would be classed as having CRC).

The second and third branches capture the outcomes of colonoscopy, with the second branch capturing whether polyps or adenomas are detected, and the third branch capturing whether the detected polyps/adenomas are correctly diagnosed (with or without AI-assistance according to if the comparator or intervention is being used). It should be noted that, in the base case, the third level of branch determining if adenomas are removed or not is not used because it's assumed all identified polyps would be removed in line with current

UK practice. This was only used in scenario analyses exploring CADx functionality and alternative polyp management strategies, where *in situ* diagnosis could impact resection or histological examination decisions.

At the end of the decision tree, lifetime pay offs are applied to people in each of the final health states to reflect long term health-related costs and quality of life. These were ultimately derived from the MiMiC-Bowel individual patient simulation model developed by the Sheffield Centre for Health and Related Research (SCHARR) (Thomas et al. 2020). However, the values used in the model for this assessment were taken directly from a previous NICE HealthTech assessment, DG10083, which was set in a similar, but not identical population (patients who were symptomatic of suspected CRC (stratified by FIT thresholds) and surveillance populations. The long-term outcomes were aggregated total costs (covering follow-up and surveillance colonoscopies, IBD management, and CRC treatment) and life years gained (LYGs) as well as quality-adjusted life-years (QALYs) derived from combining LYGs with EQ-5D utility metrics. Separate costs and QALY estimates were generated for screening and surveillance cohorts to reflect their distinct clinical pathways.

For patients whose adenomas or CRC are initially missed or misdiagnosed, the model assumes eventual diagnosis after a delay that allows disease progression. An alternative set of long-term costs, QALYs, and LYGs captures the impact of this deferred detection. The delay's effect on outcomes is treated identically whether caused by non-detection or misclassification, since subsequent follow-up protocols do not differ.

For full details on the EAG's model structure, see section 4.2.1 of the DAR.

Population

The population included in the model was in line with the scope, featuring individuals from all the 5 diagnostic pathways who required colonoscopy for screening, surveillance or because they are symptomatic (see figure 1). In the base case, these groups were not analysed separately because there was a lack of evidence for this. That is, the population was a mix case of all patients

eligible for colonoscopy, in line with the population for most studies informing the clinical inputs.

The only population characteristics used directly in the decision tree were the proportion of patients in each ‘true disease state’ at baseline, i.e. the prevalence of LRAs, AAs, IBD and CRC at the time of colonoscopy. The EAG used data from 2 published studies to determine these inputs, which were epidemiological studies from a screening population and a surveillance population. There were no data identified on symptomatic populations. From this, a weighted average was used to calculate the overall prevalence of disease states in the base case, using the assumption that people who received colonoscopy following screening accounted for 10.6% of colonoscopies performed.

Other population characteristics, including population age at baseline, proportion of males and prevalence of CRC stage at screening for patients with underlying CRC, were used indirectly in the MiMiC-Bowel model to generate long-term outcomes and delayed diagnosis penalties, but these could not be varied within the economic model, as this would require generating a new set of results from the MiMiC-Bowel model. The EAG recognised this inability to conduct subgroup analyses is a key limitation of the model.

Model inputs

Detection of polyps (CADe)

Sensitivity of standard colonoscopy was calculated using the adenoma miss rate (AMR) from Zhao et al. 2019, which reported the AMR for low-risk adenomas was 0.29 (95% CI 0.25 to 0.35) and for high-risk adenomas was 0.10 (95% 0.03 to 0.20).

For the AI technologies, ADR was used as a proxy for sensitivity to determine the effectiveness of each AI technology in identifying the true pathology. This was calculated by multiplying the sensitivity (1-AMR) for standard colonoscopy by the RR for ADR from the meta-analyses (table 6). In cases

where the sensitivity exceeded 100%, an upper cap was applied, implying perfect (100%) sensitivity. Where distinct RRs for low-risk adenomas and advanced adenomas were unavailable, a single ADR estimate was applied across both states which is potentially favourable to the intervention. This is because AI technologies may have a greater impact in detecting smaller/lower-risk polyps compared with larger/higher-risk polyps (table 3 and 4).

The EAG performed scenario analyses to explore the impact of these simplifying assumptions.

Table 6. Diagnostic accuracy inputs

Intervention	Sensitivity LRA	Sensitivity AA	Notes
Standard colonoscopy	0.71	0.9	-
Argus	0.78	0.99	Overall ADR used for LRA and AA
CAD EYE	0.83	1	Sensitivity AA capped at 1. All-adenoma ADR used as proxy for LRA
Discovery	0.72	0.92	Overall ADR used for LRA and AA
ENDO-AID	0.96	1	Sensitivity AA capped at 1.
EndoScreener	0.88	1	Overall ADR used for LRA and AA. Sensitivity AA capped at 1.
GI Genius	0.93	0.9	-
MAGENTIQ-COLO	0.89	1	Overall ADR used for LRA and AA. Sensitivity AA capped at 1.

Diagnosis of polyps (CADx)

Diagnostic accuracy was not considered in the base case, as a ‘resect all polyps’ management strategy was assumed. However, CADx data was used in the scenario analyses in diagnose-and-leave and resect-and-discard management strategies.

Adverse events

The model included colonoscopy complications including perforation, bleeding and death which were related to diagnostic colonoscopy and therapeutic removal of polyps. These were assumed to occur at a fixed rate (different for therapeutic or diagnostic colonoscopy) and weren't altered by AI detection. However, as AI results in greater detection of polyps, and their resection, the technologies were associated with an increased rate of adverse events in the base case.

Health related quality of life (HRQoL)

HRQoL was measured in quality-adjusted life-years (QALYs), derived from LYG and EQ-5D utilities, and was applied to the model in two ways. Firstly, consistent with the MiMiC-Bowel model, a one-off QALY loss was applied for colonoscopy complications (perforation and bleeding). Patients who died during the procedure accrued no further QALYs.

Secondly, long-term QALY payoffs were drawn from DG10083, calculated separately for screening and surveillance colonoscopies, then combined in the base case using NHS proportions (with subgroup analyses retaining the distinct values). These values are reported in Table 31 of the DAR (section 4.2.1.9.2). Long-term QALY gains assume all follow-up colonoscopies use standard (non-AI) procedures, so any accuracy benefits from AI aren't captured beyond the initial colonoscopy. The EAG stated this was done for pragmatic reasons.

Costs

Costs of standard diagnostic and therapeutic colonoscopy were taken from NHS reference costs. AI costs per procedure were calculated for each technology, described in section 4.2.10.1.2 of the DAR (listed in Table 33). Long-term cost payoffs were drawn from DG10083 and updated to 2023/24 prices using the provisional NHS Cost Inflation Index. These costs were calculated separately for screening and surveillance colonoscopies and then combined in the base case based on NHS screening versus surveillance proportions.

7.2 Model results

Base case

The base case results were generated using probabilistic analysis through the application of 1,000 simulations. A £30,000/QALY threshold was used for the calculation of incremental net health benefit (NHB). The EAG used NHB to present some of their results because they considered this was easier to interpret than incremental cost-effectiveness ratios (ICERs), as, for instance, sensitivity and scenario analyses gave results in a different quadrant of the cost-effectiveness plane.

In the base case, all the technologies that were assessed for cost-effectiveness (with 2 technologies not being assessed because they did not have cost data) were found to be less costly and more effective (dominate) than standard colonoscopy (Table 4), except for Discovery™, which had an ICER of £8,669 which is within the cost effectiveness threshold. All the AI interventions showed very small impacts on costs and QALYs, under £110 and 0.007 QALYs respectively.

The EAG also reported deterministic analysis which closely aligned with the probabilistic results. The cost-effectiveness acceptability curves (CEACs) show about a 50% chance of cost-effectiveness at typical willingness-to-pay thresholds. The EAG stated the results should be considered with caution, considering the small changes in incremental cost and QALY values observed. Incremental cost-effectiveness planes, CEACs and NHB convergence plots for all the technologies are reported in the DAR Appendix.

Table 4. Base case results for CADe for the 8 technologies undergoing cost-effectiveness assessment.

Technology	Total Costs	Total QALYs	Total LYG	Incremental costs	Incremental QALYs	Incremental LYG *	ICER (£/QALY)	Incremental NHB
Colonoscopy without AI	£3,171.62	10.981	14.061	N/a				
Argus®	£3,127.81	10.984	14.065	-£43.81	0.004	0.003	Dominant	0.005
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dominant	0.007
Discovery™	£3,180.32	10.982	14.061	£8.70	0.001	0.000	£8,669.76	0.001
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dominant	0.003
ENDO-AID™	£3,098.39	10.985	14.068	-£73.23	0.004	0.007	Dominant	0.007
EndoScreener®	£3,082.52	10.986	14.068	-£89.10	0.006	0.007	Dominant	0.009
GI Genius™	£3,126.46	10.982	14.065	-£45.16	0.002	0.004	Dominant	0.003
MAGENTIQ-COLO™	£3,081.36	10.987	14.069	-£90.26	0.006	0.007	Dominant	0.009

Footnote: * Undiscounted total and incremental LYG is presented to aid interpretability; all other results are discounted at a rate of 3.5% per year.

Abbreviations: AI, artificial intelligence; EMIS™, Endoscopic Multimedia Information System; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year; SW, south-west.

Sensitivity analyses

The EAG did deterministic sensitivity analyses, including tornado diagrams, that showed that long-term QALY payoffs for low-risk and advanced adenomas were overwhelmingly the key drivers of NHB for most AI colonoscopy interventions. Discovery™ was found to be additionally sensitive to the diagnostic accuracy RR for advanced adenomas, whilst GI Genius™ was largely insensitive to all inputs except the low-risk adenoma QALY pay off. This highlighted how small absolute QALY gains amplified the influence of payoff estimates and detection accuracy parameters, especially when RRs were near one with wide uncertainty in those technologies with limited evidence.

Subgroup analysis

Where data allowed, the EAG performed subgroup analyses for screening, symptomatic, surveillance, and Lynch syndrome surveillance populations.

In most of these subgroups and for most technologies, the AI-technologies remained dominant or cost-effective. However, GI Genius™ was dominated in the Lynch syndrome surveillance subgroup whilst Discovery™ was dominated in the ‘any surveillance’ subgroup. The results are presented in Table 42 in section 4.2.2.3 of the DAR. These results should be treated with particular caution, as the incremental costs and QALYs are very small, and the informing evidence base (and sample sizes) were reduced compared with the overall cohort.

Scenario analysis

The EAG did a range of scenarios to explore resection strategy (diagnose-and-leave or resect-and-discard), alternative methods of calculating technology sensitivity, and alternative scenarios for colonoscopy follow up. The results are reported in Table 43, section 4.2.2.4 of the DAR.

In the ‘resect-and-discard’ scenario, included as it is beginning to be implemented by the Bowel Cancer Screening Programme (BCSP), the findings suggested that the addition of this strategy had a negligible impact on cost-effectiveness results. This implies that switching from resect-all to resect-

and-discard using the AI technologies does not significantly alter QALYs or costs and would support the idea that resect-and-discard could be a viable strategy for use of the CADx function. All the other scenarios had little impact, including the diagnose-and-leave scenario, with incremental NHBs remaining tightly clustered around zero (approximately –0.006 to 0.015), with any quadrant flips, particularly for Discovery™, driven by the extreme proximity of QALY gains to zero and random sampling noise. Given this high degree of uncertainty, the scenario results warrant cautious interpretation.

8. Equality considerations

The final scope (page 20) and Equality Impact Assessment describe equality considerations for this assessment. Population subgroups are discussed in section 2.1.2 of the DAR. The EAG noted that whilst all the included studies adhered to the NICE scope, most studies excluded key subgroups such as IBD, familial adenomatous polyposis, Lynch syndrome, and prior CRC. Thus, analysis and interpretation of these subgroups could be an issue for equality.

The EAG also raised concerns that AI colonoscopy algorithms might not have been adequately developed or validated for patients with IBD or hereditary risk syndromes, with the reporting of training data being poor and most studies excluding these groups. While a few Lynch syndrome cohorts are represented and exploratory subgroup analyses suggest AI performance may be consistent, the evidence is too sparse to draw reliable conclusions.

9. Key points, limitations and considerations

9.1 Diagnostic accuracy

Key points

- The EAG-conducted meta-analyses that excluded high-bias trials consistently show AI colonoscopy systems improve ADR (a key metric of polyp detection and input of the economic model), although the size and certainty of this effect varied by technology and their supporting evidence bases.

- Evidence beyond ADR is scarcer and more varied but indicates that several AI systems may boost detection of both advanced and non-advanced adenomas, including smaller lesions, SSLs and hyperplastic polyps. However, these outcomes are generally more uncertain.

- Diagnostic accuracy data for AI-assisted polyp characterisation (CADx) are limited, with mixed sensitivity results compared with an endoscopist diagnosis alone, using histology as the reference standard.

- AI assisted colonoscopy does not significantly reduce or lengthen procedure times.

Limitations

- No studies report AI impacts on long-term outcomes (mortality, non-AE morbidity, HRQoL) or waiting-list effects, requiring a linked evidence approach in the economic model.

- Key high-risk groups (IBD, Lynch syndrome, familial adenomatous polyposis, prior CRC, family history) were mostly excluded and algorithm training populations are poorly reported, leaving uncertainty about AI performance in these subgroups.

- The studies were heterogenous in terms of design, setting, population, and operator skill, which may limit the confidence and generalisability of the meta-analyses.

- Evidence for AI-assisted polyp characterisation (CADx) is limited by autonomous use without an endoscopist, often missing a comparison to endoscopist optical characterisation alone, exclusion or misclassification of SSLs, and high-confidence-only analyses, reducing clinical applicability.

Considerations for committee:

- The volume and quality of clinical and diagnostic evidence for each technology varies considerably.

- Conventional diagnostic measures such as sensitivity and specificity were generally not reported for CADe. ADR was used as the key efficacy outcome by the EAG. Other diagnostic yield measures were also reported for some technologies.

- In general, there was insufficient evidence to understand any differences in the diagnostic efficacy of CADe in specific subpopulations (symptomatic, screening, surveillance) or key high-risk groups. However, these populations may differ in terms of pretest probability, clinical presentation, management needs and prognosis.

- The evidence for the detection of SSLs, which are more challenging to detect and diagnose, is less robust but these lesions can also develop into CRC. The evidence for CADx was generally of lower quality and more uncertain, with no technology showing unequivocal benefit. The data were unsuitable for pooled analysis.

- Are there any implementation issues we should consider, such as operator deskilling?

9.2 Health economic evidence

Key points:

- In the base case, all AI-assisted colonoscopy technologies (CADe) were either cost-saving or cost-effective compared to standard colonoscopy, though their impacts on costs and quality-adjusted life years (QALYs) were small. It should be noted that these results are population level data, and there may be very important benefits for some individuals (such as an individual avoiding a missed diagnosis of an adenoma, which may progress to cancer before the correct diagnosis).

- The EAG advised that the results are very uncertain due to the small effect sizes involved. They estimated there was approximately 50%

probability of CADe being cost-effective across interventions at usual cost effectiveness thresholds.

- The modelled impact of the resect-and-discard scenario had a negligible impact suggesting that it was a viable strategy for the use of CADx.

- Most other scenarios showed negligible effects and high uncertainty, again warranting cautious interpretation.

Limitations:

- The economic analysis was constrained by variable availability and quality of data. Not all AI technologies could be included due to missing technology pricing data.

- The model relies heavily on proxy outcomes, particularly the ADR, as no long-term 'end-to-end' studies were found. Long-term outcomes are assumed to be directly linked to ADR through extrapolation of known disease processes.

- Adenoma Detection Rate Relative Risk (ADR RR) was used as a proxy for AI detection accuracy. This gave rise to values of sensitivity of 100% which were capped at this value (so assumed perfect sensitivity). Per-patient Adenoma Miss Rate Relative Risk (AMR RR) would be more direct but was only available for one intervention.

- The long-term 'pay offs' were not modelled by the EAG, who instead inputted cost and benefit data directly from DG10083 which in turn used the MiMiC-Bowel individual patient simulation model. However, this assumed the populations of the assessments were similar and reduced the ability of the EAG to account for long-term uncertainties.

- In the base case, the model used a blended population which may not accurately reflect the true case mix of populations in the diagnostic pathway observed in practice.

- The model assumed that after the index test, AI was not used for any future colonoscopies. This may have underestimated both benefits and costs, making the overall impact on cost-effectiveness uncertain.

Considerations for committee:

- Are the economic model structure, assumptions and clinical and cost parameters suitable to answer the decision question (see final scope) for this assessment?

- Are there any other potential system benefits that are not captured by the economic model, that could generate improvements in QALYs not accounted for?

- Are there any risks that are not captured by the economic model that might result in QALY loss?

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Appendix A Abbreviations

ADR	Adenoma detection rate
AMR	Adenoma miss rate
APC	Adenoma per colonoscopy
BCSP	the Bowel Cancer Screening Programme
CEAC	Cost-effectiveness acceptability curve
CRC	Colorectal cancer
EAG	External assessment group
DAR	Diagnostic assessment report
FIT	Faecal immunochemical test
HRQoL	Health-related quality-of-life
IBD	Inflammatory bowel disease
IRR	Incidence rate ratio
ICER	Incremental cost-effectiveness ratio
KPI	Key performance indicator

LYG	Life-years gained
NMB	Net monetary benefit
QALY	Quality-adjusted life year
RCT	Randomised controlled trial [delete if not needed]
RR	Risk ratio
VCE	Virtual chromoendoscopy

NICE National Institute for Health and Care Excellence

Health Tech Programme

Artificial intelligence software to help detect and characterise colorectal polyps

Professional organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 13 pages.

Any confidential information provided should be underlined and highlighted. Please underline all confidential information, and separately highlight information that is 'commercial in confidence' in blue and all that is 'academic in confidence' in yellow.

About you **1. Your name**	Tom Lee
2. Name of organisation	Joint Accreditation Group, Royal college of Physicians
3. Job title or position	Chair, National Endoscopy Database
4. Are you (please select Yes or No):	An employee or representative of a healthcare professional organisation that represents clinicians? Yes or No A specialist in the treatment of people with this condition? Yes or No A specialist in the clinical evidence base for this condition or technology? Yes or No Other (please specify):
5a. Brief description of the organisation (including who funds it).	The JAG oversees accreditation of endoscopy services in the UK
5b. Has the organisation received any funding from any company with a technology included in the evaluation in the last 12 months? [Please refer to the final scope for a full list of technologies included]. **If so, please state the name of company, amount, and purpose of funding.**	No
5c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The aim of treatment for colorectal polyps

6. What is the main aim of CADe and CADx technologies? (For example, initial diagnosis, clinical monitoring, treatment triage assessing stages of disease progression or risk stratification.)	CADe- reduce variation on lesion detection between endosocpists. CADx- optimise resect and discard strategies
7. In your view, is there an unmet need for patients and healthcare professionals in the detection and characterisation of colorectal polyps?	yes

What is the expected place of the technology in current practice?

8. How are colorectal polyps currently managed in the NHS?	Optical diagnosis Standard is for all polyps to be sent for histological assessment
9a. Are any relevant clinical guidelines we should be aware of, and if so, which?	BSG Adenoma Surveillance Guideline BCSP guidance on resect and discard
9b. Is the pathway of care well defined? Does it vary or are there differences of opinion between	Well defined

professionals across the NHS? (Please state if your experience is from outside England.)	
9c. What impact would the technology have on the current pathway of care?	Contribute to increased polyp detection- may need more time allowed for increased polypectomy rate. Facilitate introduction of resect and discard strategies.
10a. Will the technology be used (or is it already used) in the same way as current care in NHS clinical practice?	Yes
10b. How does healthcare resource use differ between the technology and current care?	Potential increased cost and time utilisation due to increased lesion detection. Offset by reduced interval cancer rate.
10c. In what clinical setting should the technology be used? (For example, primary or secondary care, specialist clinics.)	Secondary care endoscopy services Private and independent endoscopy service Community based diagnostic services.
10d. What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.)	Equipment- Financial Training of endosocpists
11a. Do you expect the technology to provide clinically meaningful benefits compared with current care?	Yes

11b. Do you expect the technology to increase length of life more than current care?	Potentially
11c. Do you expect the technology to increase health-related quality of life more than current care?	Potentially
12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?	More benefit in Bowel cancer screening population

The use of the technology

13. Will the technology be easier or more difficult to use for healthcare professionals than current care? Are there any practical implications for its use (for example, additional clinical requirements, factors affecting patient acceptability or ease of use or additional tests or monitoring needed.)	Can make colonoscopy more challenging- this can be eased be training/ upskilling
14. Do you consider that the use of the technology will result in any	Potentially- through reduction in reduced interval cancer rate

substantial health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculation?	
15. Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how might it improve the way that current need is met?	Yes- currently there is no technology that reduces the variation in quality between endosocpists.
16. Does the use of the technology address any particular unmet need of the patient population?	It can mitigate against endoscopist fatigue
17. Are there any side effects or adverse effects associated with the technology and how do they affect the patient's quality of life?	no

Sources of evidence

17a. Do studies on use of the technology reflect current UK clinical practice?	yes

17b. If not, how could the results be extrapolated to the UK setting?	
17c. What, in your view, are the most important outcomes, and were they measured in trials?	Number of adenomas and number of polyps per procedure
17d. If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?	yes
17e. Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently?	no
18. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence?	no
19. How do data on real-world experience compare with the available data? Are you aware of any ongoing studies?	Consistent increase in lesion detection

Equality

20a. Are there any potential equality issues that should be taken into account when considering these technologies?	no
20b. Consider whether these issues are different from issues with current care and why.	no

Key messages

21. In up to 5 bullet points, please summarise the key messages of your submission.	• NICE appraisal of AI polyp detection is timely • clarity of impact on meaningful patient outcomes will be key • Health economic evaluation should account for the cost of implementation and upkeep of the technology • Consideration of impact on endoscopy quality assurance using KPIs will need to be borne in mind • •

Thank you for your time.

Please log in to your NICE Docs account to upload your completed submission.

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BMJ TAG

Artificial intelligence software to help detect and characterise colorectal polyps [GID-DG10118]

Diagnostics Assessment Report

October 2025

Source of funding

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Produced by:	BMJ Technology Assessment Group (BMJ-TAG)
Authors:	Steve Edwards, Director of Health Technology Assessment, BMJ-TAG, London Nicole Downes, Senior Clinical Evidence Analyst, BMJ-TAG, London Sophie Ip, Senior Health Economist, BMJ-TAG, London Victoria Wakefield, Principal Clinical Evidence Analyst, BMJ-TAG, London Clare Dadswell, Clinical Evidence Manager, BMJ-TAG, London Isaac Mackenzie, Health Economist, BMJ-TAG, London Tracey Jhita, Health Economics Manager, BMJ-TAG, London
Correspondence to:	Steve Edwards, BMJ-TAG, BMJ Group, 5th Floor, 90 Whitfield Street, London W1T 4EZ, UK.
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This review has been registered on PROSPERO under registration number CRD42024586541.

Contribution of authors:

Steve Edwards	Project lead: supervised the production of the final report; critical appraisal of the clinical evidence; critical appraisal of the economic evidence; and provided feedback on all versions of the report. Guarantor of the report
Nicole Downes	Devised and carried out the literature searches for clinical and diagnostic evidence; contributed to study selection, data extraction and critical appraisal of the clinical evidence; carried out clinical analyses; wrote the background, decision problem and clinical sections of the report; and contributed to discussion and conclusion sections of the report
Victoria Wakefield	Assisted with project coordination
Clare Dadswell	Contributed to study selection, data extraction and critical appraisal of the clinical evidence; and validated clinical analyses
Sophie Ip	Devised and carried out the economic literature searches; study selection; data extraction; critical appraisal of the economic evidence; development of the conceptual model; development of the economic model; performing economic analyses; writing the economic sections of the report; and contributed to discussion and conclusion sections of the report
Isaac Mackenzie	Contributed to study selection; data extraction; critical appraisal of the economic evidence; development of the economic model; and performing the economic analysis
Tracey Jhita	Quality assurance of the economic model.

All authors read and commented on draft versions of the EAG report.

All commercial in confidence data and information are highlighted in [redacted].

All academic in confidence data and information are highlighted in yellow and underlined 'academic in confidence'

All depersonalised data and information are highlighted in magenta and underlined [redacted]

Changes to the original report

The original diagnostics assessment report was dated 11/09/2025. The report was subsequently revised based on stakeholder comments; the edits made are detailed in the table below. Alongside the revised version, the External Assessment Group (EAG) has also prepared an addendum to the report, which includes the results of economic analyses using an updated cost for the GI Genius™ technology, and additional scenario analyses requested by stakeholders.

Location in report	Description of change
Scientific Summary; Section 4.2.3.1; Section 6.1; Section 6.4	Update of the discussion of economic analysis results, to reflect updates in the diagnose-and-leave scenario results
Section 1.1.1	Clarification of the description of eligibility criteria for screening and surveillance colonoscopies (these criteria are only applicable to patients without symptoms)
Section 1.1.2	Correction in the description of national screening programmes to acknowledge the differing approach in Northern Ireland
Section 1.2.1	Update to reflect the existence of a BCSP pilot using an alternative FIT result threshold
Table 4; Section 3.2.1.10; Section 3.2.2.1.2; Table 24; Table 38; Table 44; Appendix 9.10	Updates to acknowledge the availability of a CADx functionality for MAGENTIQ-COLO™
Section 4.2.1.11	Update to the source for the median waiting time, to reflect the average value over a year rather than a single month
Section 4.2.1.12; footnotes of all figures in Appendix 9.12.2Additional DSA results	Correction in the description of the assumed SE in the absence of reported data (updated from 10% to 20%)
Table 43, Table 72	Correction of errors in the results for all diagnose-and-leave scenarios (1a, 1b, 3a and 3b)
Table 68	Clarification of the source used for the APC mean difference input for Argus®
Table 68	Correction of an error in the 95% CI for the specificity of high-confidence diagnoses for colonoscopy without CADx

Abbreviations: APC, adenomas per colonoscopy; BCSP, bowel cancer screening programme; CADx, computer-aided diagnosis; CI, confidence interval; FIT, faecal immunochemical test; SE, standard error.

Abstract

Background

Colorectal cancer (CRC) is the fourth most common cancer in the UK, accounting for 10% of UK cancer-related deaths. In the UK, colonoscopy for CRC screening may be indicated through an age-based national screening programme, or for people with symptoms associated with CRC or CRC risk factors. Artificial intelligence (AI) technologies with polyp detection and/or characterisation functions aim to support endoscopists by increasing polyp detection and improving polyp characterisation, respectively, which may ultimately reduce the risk of CRC.

Objectives

To assess whether the addition of specific AI-supported colonoscopy technologies to colonoscopy represents a clinically- and cost-effective use of National Health Service (NHS) resources compared to standard colonoscopy without AI.

Methods

A *de novo* systematic literature review (SLR) was performed in September 2024 and updated in June 2025. Searches included electronic databases and grey literature sources. Adenoma detection rate (ADR) and diagnostic accuracy data are key clinical outcomes for the assessment of the detection and characterisation functions of the AI technologies, respectively. Other detection-based outcomes and outcomes such as procedure duration, impact on surveillance intervals and adverse events are also captured. Subgroup analyses for colonoscopy indication and endoscopist experience were performed. A *de novo* economic model was developed to assess the cost-effectiveness of AI technologies compared to colonoscopy without AI. The model used a lifetime horizon and an NHS and personal social services (PSS) perspective.

Results

Clinical data from 70 studies were included, covering all 10 technologies of interest. ADR was increased for all technologies compared to standard colonoscopy, although results were not statistically significant for Argus®, [redacted] or Discovery™. The impact on polyp characterisation is uncertain, with mixed results across studies and concerns about analyses or a lack of comparator data. Procedure durations may increase slightly with AI, and there are no concerns that AI increases adverse events. No data for long-term outcomes

were available. Subgroup analyses provide no robust evidence of a differential effect of AI technologies across colonoscopy indication or endoscopist experience subgroups. Specific populations at a higher risk of CRC are not well represented by the included studies.

The economic analysis suggested that the introduction of all technologies would result in increased quality-adjusted life years (QALYs) and reduced costs (with the exception of Discovery™, which led to increased costs, and an incremental cost-effectiveness ratio [ICER] of £8,670) compared to colonoscopy without AI. However, as the benefits of AI technologies are consistently small, the results are uncertain, and are unlikely to correspond to meaningful changes for patients or service provision.

Conclusions

Despite increased uncertainty for certain technologies, there is some evidence for all technologies of an improved ADR with AI, with no major concerns about impacts on procedure durations or adverse events, compared to colonoscopy without AI. Further research into the impact on polyp characterisation and long-term outcomes, effects across colonoscopy indication and endoscopist experience subgroups, and impact in certain higher risk groups, is required. The cost-effectiveness of the AI technologies is also uncertain, with incremental results too small to suggest tangible benefits.

Abstract word count: 500

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The protocol for the systematic review is registered on PROSPERO (registration number CRD42024586541).

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Scientific summary

Background

Colorectal cancer (CRC) is the fourth most common cancer in the UK, with more than 44,000 new cases annually and accounting for 10% of all UK cancer-related deaths. Factors including older age, lifestyle factors, other bowel conditions and the presence of benign colorectal polyps can increase an individual's risk of CRC. Colorectal polyps are lesions within the colon or rectum that are usually harmless, but some types have the potential to develop into CRC over time. Treatment and prognosis of CRC depend on multiple factors, including the location and disease stage, cancer cell grading, results of genetic and other tests, and patient fitness. Treatment for most patients involves surgery where feasible, with the option of chemotherapy or radiotherapy (or chemoradiotherapy) where deemed appropriate.

CRC symptoms are not always present and screening and surveillance programmes exist with the aim of detecting CRC, or colorectal lesions that may develop into cancer, earlier. Colonoscopy is considered to be the gold standard for the detection of these lesions. During colonoscopies, detected lesions can be removed and sent for histological testing to determine their characteristics. The aim of screening and surveillance colonoscopies is to identify and remove lesions at a higher risk of developing into CRC, including adenomas and other polyps such as serrated polyps.

In the UK, individuals aged between 50 and 74 years are invited to undergo screening for CRC as part of the national screening programme; those with a positive faecal immunochemical test (FIT), which detects the presence of blood in the stool, will be offered a colonoscopy. Higher risk groups may be invited for earlier and more frequent surveillance, which includes those with:

- a strong family history of CRC;
- hereditary conditions such as Lynch syndrome or familial adenomatous polyposis (FAP);
- inflammatory bowel disease (IBD);
- a personal history of CRC;
- adenomatous or serrated polyps identified on a previous colonoscopy.

Outside of these programmes, colonoscopies can also be performed if there are symptoms or signs suggestive of CRC. Collectively, these pathways to colonoscopy aim to identify and remove lesions that may develop into CRC before this occurs, or to detect existing CRC as early as possible.

Technologies using artificial intelligence (AI) to support the detection of colorectal polyps during colonoscopies have been developed. This computer-aided detection (CADe) functionality aims to increase the number of polyps that are detected and removed to reduce the individual's risk of CRC in the future. Some technologies also have a computer-aided characterisation (CADx) function, which aims to support optical diagnosis by endoscopists and subsequent decisions about which polyps need to be removed and sent for histological testing.

Objectives

To assess whether the addition of specific AI-supported colonoscopy technologies to colonoscopy represents a clinically- and cost-effective use of National Health Service (NHS) resources compared to standard colonoscopy procedures without these AI technologies. Technologies outlined as relevant in the National Institute for Health and Care Excellence (NICE) final scope include Argus®, CAD EYE®, CADDIE™, Discovery™, ENDO-AID™, ENDOANGEL®, Endoscopic Multimedia Information System (EMIS™), EndoScreener®, GI Genius™, MAGENTIQ-COLO™ and WISE VISION®; however, WISE VISION® was removed from this assessment in February 2025 given it was to be withdrawn from the UK market.

Methods

A *de novo* systematic literature review (SLR) was performed, including searches of electronic databases (MEDLINE, Embase, Cochrane Central Register of Controlled Trials [CENTRAL] the Cochrane Database of Systematic Reviews [CDSR]) and other sources, including clinical trial registries, recent conferences, health technology assessment (HTA) body websites, bibliographies of relevant SLRs and submissions provided by manufacturers of technologies included in this assessment. Searches were initially conducted in September 2024, with an update performed in June 2025.

Randomised controlled trials (RCTs) with full text publications were prioritised where available, but non-randomised studies and abstracts were considered where data were not available for particular interventions, populations or outcomes. Any study using any of the AI technologies listed above in any colonoscopy population was considered for inclusion, providing the technology was applied prospectively during real-time colonoscopies. A comparison against standard colonoscopy without AI was required for CADe studies, while for CADx, any study reporting data for any of the prespecified AI technologies was considered for inclusion. Where available, data for the AI technologies when

used to support endoscopist judgement (adjunct use) were prioritised over data relating to the AI technology's prediction without endoscopist input (autonomous use).

Records from electronic databases were screened independently by two reviewers in the title and abstract and full text screening stages, with discussion to resolve conflicts. Records from other sources were screened by a single reviewer. Data extraction and quality assessment for each study was performed by one reviewer, with validation by a second reviewer. Clinical analyses were performed by one reviewer, with a second reviewer performing validation. Meta-analyses for each individual AI technology compared to standard colonoscopy were performed for each outcome where possible; meta-analyses were not performed for diagnostic accuracy data, as there were either very limited data or a lack of similarity between studies in terms of methods and analyses performed. Subgroup analyses to explore the impact of different indications for colonoscopy and different levels of endoscopist experience or expertise on results were performed, where possible.

Adenoma detection rate (ADR) is the key outcome included in this assessment for the CADe function of technologies. It is a key performance indicator for colonoscopies, and a higher ADR has been linked to a reduced risk of CRC development following a previous colonoscopy negative for CRC. For CADx, diagnostic accuracy measures are the key outcomes; these indicate the accuracy of AI technologies (with or without endoscopist input) for polyp characterisation (e.g. classification as adenoma or non-adenoma), with histological assessment used as the reference standard. A wide range of other outcomes are covered in this assessment, including other polyp detection outcomes (such as other adenoma-based outcomes and outcomes relating to serrated lesions) and outcomes such as impact on procedure durations, surveillance intervals and adverse events, and patient and endoscopist opinions.

A *de novo* economic model was developed to assess the cost-effectiveness of the AI technologies included in the final scope for which a price was available (Argus®, CAD EYE®, Discovery™, ENDO-AID™, EMIS™, EndoScreener®, GI Genius™, MAGENTIQ-COLO™), compared to colonoscopy without AI. The population considered in the model base case was a mixed population of all patients eligible and suitable for colonoscopy, although subgroup analyses were performed for technologies with relevant data available. The economic model considered a lifetime horizon, and an NHS and personal social services (PSS) perspective.

In the model base case, a resect-all polyp management strategy was assumed, in line with current UK clinical practice, although alternative approaches (resect-and-discard and diagnose-and-leave) were considered in scenario analyses. The impact of CADx functionalities was also considered in

exploratory analyses for the technologies for which relevant data were available (CAD EYE® and GI Genius™).

The model used a decision tree structure, with branches corresponding to patients' underlying true disease state; correct or incorrect detection of patients' true disease state; and complete or incomplete removal of all identified adenomas. Results from the clinical analyses described above were used to parametrise the probability of entering each decision tree branch. The long-term outcomes for patients in each branch (i.e. long-term costs, survival, and quality-adjusted life years [QALYs]) were informed by general population norms, and the MiMiC-Bowel model, an existing microsimulation model developed for economic evaluation of screening strategies for CRC.

Costs and QALYs were discounted at a rate of 3.5% per annum. As well as costs, QALYs and life years gained (LYG), the model also estimated the number of colonoscopies required to reach a correct diagnosis. An exploratory analysis was conducted to estimate the potential impact of introducing AI technologies on waiting times for colonoscopy procedures. All results were generated probabilistically. The impact of uncertainty was further examined through a range of scenario analyses and deterministic sensitivity analyses (DSAs).

Results

In total, 70 independent studies were included in the clinical review; most reported data solely for the CADe function of technologies but 16 reported some CADx data. At least one study meeting the requirements of this review was identified for all interventions, including ADR data for each. Of note, the trial covering EMIS™ was described as [redacted] ADR results suggest a benefit of all of these AI technologies compared to standard colonoscopy, although results were not statistically significant for Argus®, [redacted] or Discovery™. Similar results were observed for the outcome of adenomas per colonoscopy (APC). Most other detection-based outcomes were reported by fewer studies and for fewer interventions, but there is some more limited evidence for a possible increase in the detection of specific categories of adenomas separately (i.e. advanced and non-advanced, or different size categories), sessile serrated lesions and non-neoplastic/hyperplastic polyps, and a reduction in adenoma miss rate, with certain AI technologies. For GI Genius™, data from a non-randomised trial were included as supportive evidence, given it was a fairly large trial

conducted in a UK setting within multiple NHS centres. Evidence from this trial [redacted]

While some differences in the impact of AI-supported technologies on ADR across particular colonoscopy indication and endoscopist experience and expertise subgroups were noted in some analyses (for example, some analyses suggest larger increases in ADR with AI-supported colonoscopy in symptomatic compared to screening or surveillance populations, or in endoscopists with less experience compared to those that are more experienced), the opposite was observed in other analyses. Based on this and when considering limitations such as difficulty separating into subgroup categories and lack of stratification at randomisation, there is a lack of robust evidence within this assessment to support a difference in outcomes across these subgroups.

The results suggest potential for increased procedure times with AI-supported colonoscopy compared to standard colonoscopy, although the extent of this may be small at less than 1 to 2 minutes difference in most analyses. Although it is unclear how robustly they were assessed and monitored in the included studies, no obvious difference in adverse events was identified in this assessment. No relevant data for the impact of AI-supported colonoscopy on longer term outcomes such as mortality, morbidity and health-related quality of life were identified from studies included in the clinical review.

Mixed results for CADx functionalities (reported as diagnostic accuracy measures) are noted; some studies suggest improved sensitivity (and reduced specificity) when AI is used compared to endoscopist optical diagnosis alone, while others report the opposite, no notable difference, or do not report comparative data. Furthermore, CADx data are reported by fewer studies and concerns about the analysis or the use of the technology exist; this includes the fact that some studies:

- only report results when the AI technology is used autonomously (not as an adjunct to endoscopist judgement);
- exclude final diagnoses made with low-confidence by endoscopists (with or without adjunct AI use);
- do not capture serrated lesions as potentially harmful polyps.

Certain groups undergoing colonoscopy in UK clinical practice are not well represented by the trials included in this assessment, including those with hereditary conditions such as Lynch syndrome and FAP, those with prior CRC and those with IBD. This, combined with the fact that these groups were often excluded from data used to train the AI technologies, means it is difficult to conclude whether

similar impacts of the AI technologies included in this assessment would be observed in these populations.

The economic analyses demonstrated that the introduction of all AI technologies considered would be expected to result in a small increase in LYG and QALYs, and a small decrease in costs (with the exception of Discovery™, which would result in a small increase in costs). The incremental net health benefit (NHB) was positive for all technologies, assuming a willingness-to-pay threshold of £30,000/QALY.

However, the External Assessment Group (EAG) notes that the incremental differences are consistently small across technologies; cost savings are all around £100 per patient or less, and no technology shows a QALY increase of more than 0.007 (around 2.5 days in perfect health). The EAG considers that these incremental differences are unlikely to have a meaningful impact on either patient quality of life or service provision. Furthermore, the results are unstable due to the small incremental QALYs and high level of uncertainty in many of the parameters in the model.

Very similar results were observed for population subgroups, and for the resect-and-discard and diagnose-and-leave polyp management strategies. =

Conclusions

RCT data suggest that the use of the AI technologies included in this assessment may increase the detection of adenomas and other polyp types during colonoscopy when compared with standard colonoscopy, with the potential for a small increase in procedure duration and limited impact on the occurrence of adverse events. For GI Genius™, [redacted]. Evidence to conclude whether the CADx functionality of certain AI technologies may be beneficial for improving endoscopist optical diagnosis is uncertain; further research in this area, addressing limitations of currently available studies outlined above, may be beneficial.

Similarly, evidence to determine whether the impact of these AI technologies differs across colonoscopy indications and endoscopist experience subgroups is associated with limitations, meaning it is not possible to draw robust conclusions from this assessment. Further RCTs powered to detect differences between subgroups (and stratified for them at randomisation) using more clinically relevant categories may improve the ability to conclude the impact of these factors in the future. Studies covering populations that are commonly excluded from existing trials of these

technologies, such as those with prior CRC, hereditary conditions that increase CRC risk and IBD would allow insight into whether AI technologies are likely to have a similar impact in these groups, and studies investigating longer term outcomes such as mortality, morbidity and health-related quality of life would allow an assessment of whether the impact of the technologies on detection rates translates into impacts on longer term outcomes.

The economic analyses suggest that using AI technologies could slightly increase QALYs and decrease costs for the average patient; however, caution should be used in interpreting these results, due to the small incremental costs and QALYs, and the high levels of parameter uncertainty.

Scientific Summary Word Count: 2398

Plain English summary

This assessment reviewed the benefits, risks and costs of 10 artificial intelligence (AI) technologies that support clinicians to detect and characterise colorectal polyps. Some polyps have a risk of developing into colorectal cancer (CRC). These technologies aim to improve the detection and characterisation of polyps, increasing the earlier removal of higher risk polyps to reduce the risk of CRC.

Medical journals and other publications were searched to identify evidence on how well each technology works. Clinical data were available for all 10 technologies and results indicate that all are likely to increase the detection of adenomas (one type of higher risk polyp), although the results for some technologies were less certain. Currently, evidence for the polyp characterisation functions of some technologies is considered to be limited.

This assessment also considered whether these technologies are likely to be considered good value for money for the NHS. The analysis found that all technologies may improve some patients' health, and all technologies except one may reduce overall NHS spending. However, these changes were very small, and are unlikely to be meaningful for most patients.

In summary, while there is more uncertainty for some technologies, there is some evidence that all 10 technologies improve polyp detection. However, the impact on polyp characterisation is uncertain. It is also unclear whether these technologies are likely to be good value for money for the NHS.

Plain English Summary Word Count: 228

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Definition of terms

Adenocarcinoma	A type of cancer that starts within glands lining an organ, in this case the lining of the colon or rectum.
Adenoma	A type of polyp that is non-cancerous but has the potential to develop into cancer over time.
Adenoma-carcinoma pathway	A pathway that is key in the development of colorectal cancer and describes the process through which normal cells develop into non-cancerous adenomas and, subsequently, into cancer over time.
Adenoma detection rate (ADR)	Calculated by dividing the total number of colonoscopies where at least one adenoma was detected by the total number of colonoscopies performed. ADR is a key performance indicator during colonoscopy, with a higher ADR linked to a reduced risk of colorectal cancer (CRC) development following a previous colonoscopy that was negative for CRC. A similar calculation can be used to calculate detection rates for other polyp types, such as polyp, advanced adenoma, non-advanced adenoma, non-neoplastic/hyperplastic polyps and sessile serrated lesion detection rates.
Adenoma miss rate (AMR)	Calculated from studies with tandem designs (i.e. initial colonoscopy procedure followed by a second colonoscopy procedure) by dividing the total number of adenomas found on a second colonoscopy by the total number of adenomas found in both the initial and the second colonoscopy. A similar calculation can be used to calculate miss rates for other polyp types, such as polyp miss rate. Of note, one study in this review calculated this outcome differently, with adenomas identified by experts used as the denominator and those found by trainees used as the numerator.
Adenomas per colonoscopy (APC)	Calculated by dividing the total number of adenomas identified across all colonoscopies by the total number of colonoscopies performed. A similar calculation can be used to calculate per colonoscopy values for other polyp types, such as polyp, advanced adenoma, non-advanced adenoma, non-neoplastic/hyperplastic polyps and sessile serrated lesions per colonoscopy.
Adenomatous	Having the characteristics of an adenoma.
Adjunct	Used as a supplement to something else rather than alone; in this context, it is used to refer to artificial intelligence technologies being used as an adjunct to endoscopist judgement.
Adjuvant treatment	Treatment given after the main treatment or approach with the aim of reducing the risk of the disease returning or spreading, such as chemotherapy given after surgery to remove cancer.
Adverse event	Unintended negative effects (e.g. side effects/complications) of a treatment or medical procedure
Algorithm	A digitalised set of instructions or rules used to perform specific tasks or functions; in this context, algorithms included within the artificial intelligence technologies allow the technologies to interpret information and perform polyp detection and polyp characterisation functions, for example.
Autonomous	The ability to operate independently; in this context, it is used to refer to autonomous judgements made by the artificial intelligence technologies without considering input or validation from an endoscopist.
Biopsy	Procedure involving the removal of a small sample of body tissue to allow further examination; for example, under a microscope.
Budget impact analysis	An analysis to estimate the overall change in expenditure resulting from a decision to make a change in a healthcare system.

Comparator	A technology against which a new technology is compared, often the existing standard of care.
Computer-aided polyp characterisation (CADx)	Some artificial intelligence technologies for colonoscopy include this function, which involves the technology analysing polyps during the colonoscopy and predicting the type of polyp it is likely to be (e.g. whether it is an adenoma, non-adenoma or whether no prediction is possible). The prediction is done during the colonoscopy before any tissue is removed.
Computer-aided polyp detection (CADe)	The main function of all artificial intelligence technologies included in this assessment, which involves the technology assessing a video feed during the colonoscopy and flagging areas that may be polyps and require further review. The aim is to increase the number of polyps detected so that all potential polyps can be assessed and decisions about removal made
Cost-comparison analysis	A comparison of costs for two technologies, assuming that the clinical benefits are equal.
Cost-effectiveness acceptability curve	A graph which shows the probability that an intervention will be cost-effective at different willingness-to-pay thresholds.
Cost-effectiveness analysis	A comparison of costs in monetary units with outcomes in quantitative non-monetary units (for example, reduced mortality or morbidity).
Cost-utility analysis	A type of cost-effectiveness analysis that compares costs in monetary units with clinical outcomes in terms of their utility, usually to the patient, measured in quality-adjusted life years (QALYs).
Definitive treatment	The main treatment decided on for a specific patient; for example, surgery to remove colorectal cancer.
De novo	Something new that is developed from the beginning, rather than an existing template being updated or adapted.
Deterministic sensitivity analysis	Involves changing one or more parameters within the economic model to assess the extent of any impact on the results of the analysis.
Diagnose-and-leave	A potential strategy for some polyps identified during colonoscopy that would involve leaving them *in situ* rather than resecting. Usually reserved for polyps where a high confidence diagnosis is made by the endoscopist, and the diagnosis is that it is a polyp with a limited risk of progression to colorectal cancer.
Diagnostic accuracy	The ability of a test to correctly distinguish between a target condition and the absence of the target condition. It is usually assessed using various measures, including sensitivity and specificity.
Diagnostic (or symptomatic) colonoscopy	Colonoscopies that are scheduled based on the presence of symptoms or other factors indicating that colorectal cancer may be present.
Deterministic sensitivity analysis (DSA)	Changes to a particular economic model input are made to assess the impact it has on the results of the economic evaluation.
Diminutive (polyps)	Term used to refer to small polyps. Most studies define polyps sized ≤5 mm as diminutive, but this may differ slightly across studies, with some defining it at polyps sized 1 to 4 mm.
Dominant	In an economic analysis, a technology is dominant if its adoption results in lower costs and greater benefits than an alternative.
Dye-based chromoendoscopy (DCE)	Procedure that can be applied during colonoscopy to improve visualisation of the lining of the colon and rectum and improve the ability to detect polyps and suspicious areas. This version involves the application of a physical dye to stain the mucosa.
Dysplasia	Abnormal growth and differentiation, in this case relating to cancer cells.

Economic evaluation	Process of assessing the costs and clinical effects of interventions compared to alternative options.
ENDOCUFF VISION™	A device or cap that is attached to the end of a colonoscope with the aim of improving the visualisation of the bowel during colonoscopy by increasing the total surface area of the visual field.
Ex vivo	Performed outside of the living body.
False negative	An incorrect result of a test where the test indicates that a disease or an abnormality is not present when in fact it is present.
False positive	An incorrect result of a test where the test indicates that a disease or an abnormality is present when in fact it is not present.
Faecal immunochemical test (FIT)	A home-based test used to screen for CRC, which detects the presence of blood in the stool.
Familial adenomatous polyposis	Genetic condition that increases the risk of colorectal and other types of cancer. It causes the development of hundreds or thousands of adenomatous polyps within the bowel, which increases the risk of colorectal cancer development considerably.
Health-related quality of life	Outcome assessing the impact of health on an individual's ability to live a fulfilling life.
Heterogeneity	The presence of differences or diversity. In this context, differences between included studies may be identified, such as populations included or level of endoscopist experience.
Histopathology/histology	Visual and microscopic examination of biopsies or other tissues removed from patients to support with diagnosis.
Hyperplastic (polyp)	A common, non-cancerous and usually small growth that is thought to be at a lower risk for colorectal cancer development.
Indication for colonoscopy	The primary reason that someone is undergoing colonoscopy; for example, as part of a national screening programme or because symptoms are present.
Inflammatory bowel disease	Term used to describe inflammatory conditions of the bowel that cause inflammation, pain, discomfort and other symptoms and can also be associated with an increased risk of colorectal cancer. This includes Crohn's disease and ulcerative colitis
Incremental cost-effectiveness ratio (ICER)	Summary measure that represents the economic value of one intervention compared to another and is usually the main output of economic evaluations. Calculated by dividing the difference in total costs by the difference in the chosen health outcome, commonly quality-adjusted life years (QALYs). ICERs are usually compared against an established willingness-to-pay (WTP) threshold.
Incremental net health benefit (NHB)	Summary measure, similar to the ICER, which measures the impact of an intervention on overall population health by assuming that the monetary costs of a new technology can be converted into 'lost health'. The value of the incremental NHB is dependent on the WTP threshold. A positive incremental NHB suggests that the intervention has a net positive effect on overall population health, while a negative incremental NHB suggests that the intervention decreases population health.
In vivo	Performed inside of the living body.
Intervention	A technology of interest in an assessment of clinical or cost-effectiveness.
Key performance indicator	Quantifiable measure that can be used to assess performance. In this context, adenoma detection rate is a key performance indicator for endoscopists during colonoscopies, with the achievement of specific rates being desirable.

Life years gained (LYG)	The additional years for which a patient is expected to survive from baseline in an economic analysis.
Linked-colour imaging	Endoscopic image-enhancing technique that can be applied during colonoscopies to enhance colour contrast to aid with the identification and assessment of polyps in this context.
Lynch syndrome	Genetic condition linked to the development of specific cancers, including early colorectal cancer.
Meta-analysis	Statistical method used to combine the results of multiple, independent studies reporting on the same comparison and outcome.
Microsimulation	A technique used in health economic modelling in which treatment pathways and outcomes are simulated for individual patients.
Narrow-band imaging	Endoscopic image-enhancing technique using blue/green wavelength light that can be applied during colonoscopies to enhance visualisation of the mucosa to aid with assessment of polyps in this context.
Neoadjuvant treatment	Additional treatment applied before the main treatment or approach, with the aim of improving the effectiveness of the main treatment, such as chemotherapy given before surgery to shrink the cancer and facilitate surgical removal as the main treatment.
Neoplasia/neoplastic	Abnormal and uncontrolled growth of cells or tissues/cells or tissues that exhibit abnormal and uncontrolled growth.
Net health benefit	Summary statistic representing the impact of the introduction of a new intervention on population health. A positive value suggests that overall population health would be increased due to the new intervention, and a negative value indicates that any health benefits do not outweigh health losses resulting from healthcare that ceases to be funded as a result of funding the new treatment.
Optical diagnosis	In the context of colonoscopy, this refers to the characterisation or diagnosis of polyps based on visualisation by the endoscopist with or without the support of artificial intelligence technologies. It does not refer to the results of any histopathology testing.
Parallel RCT	A type of clinical study where patients are randomised to different groups and where the aim is that they receive only one of the treatment options included in the study.
Pathogenesis	Process and mechanisms through which a disease develops.
Polyp (colorectal)	Small growths on the lining of the large intestine (colon) or rectum. Usually harmless, but can sometimes lead to colorectal cancer.
Polypectomy (colorectal)	Process of removing polyps via various methods. Usually done during colonoscopy, but occasionally surgery may be required.
Pre-malignant	Something that has a high risk of becoming cancerous, usually based on specific observed characteristics, if left untreated.
Publication bias	Bias that may be introduced when the results of a study impact whether it is published or not. For example, studies with statistically significant results may be more likely to be published than those with non-significant results.
Quality-adjusted life year (QALY)	Summary outcome measure used to quantify the effectiveness of a particular intervention. A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale).

Reference standard	In the diagnostic context, this refers to the test or assessment considered to be the best available for determining the presence or absence of a condition or disease. For example, for the characterisation of polyps, histological assessment is considered to be the reference standard.
Resect-and-discard	A potential strategy for some polyps identified during colonoscopy that would involve removing them but not sending for subsequent histopathological testing. Not widely used in the UK yet, but could apply where a high confidence diagnosis is made by the endoscopist and the diagnosis is that it is a polyp with a limited risk of progression to colorectal cancer.
Risk ratio	A measure comparing the likelihood of an event occurring in an 'exposed' group compared to an 'unexposed' group; in this context, generally the 'exposed' group consists of patients undergoing colonoscopy with AI, and the 'unexposed' group consists of patients undergoing colonoscopy without AI.
Scenario/sensitivity analysis	Exploring the impact of changing a particular input to an alternative or analysing something in a different way, to assess the impact it has on the results.
Screening colonoscopy	Colonoscopy performed when there is not necessarily any concerns that an individual has colorectal cancer. For example, national screening programmes invite anyone over a certain age to undergo screening for colorectal cancer, which involves colonoscopy if the results of an initial stool test are positive.
Sensitivity	A measure of diagnostic accuracy that indicates how good a test is at identifying people with disease. Calculated relative to the reference standard by dividing the number of patients with disease detected on both the new test and the reference standard (true positives) by the total number of patients with disease detected on the reference standard (true positives + false negatives).
Serrated lesions/polyps	Type of polyp with a serrated or saw-toothed appearance under a microscope. While the pathway is not as well characterised as that for adenomas, some are thought to be associated with a risk of colorectal cancer development.
Specificity	A measure of diagnostic accuracy that indicates how good a test is at identifying people without disease. Calculated relative to the reference standard by dividing the number of patients with no disease detected on both the new test and the reference standard (true negatives) by the total number of patients with no disease detected on the reference standard (true negatives + false positives).
Statistical heterogeneity	Differences in the results across multiple studies reporting the same outcome for the same comparison; for example, within a meta-analysis.
Subgroup analysis	Statistical method of assessing whether or not results for a comparison differ between specific groups; for example, whether an intervention may have a larger impact in one population compared to another.
Surveillance colonoscopy	Colonoscopies performed to follow-up specific groups of patients at a set time-point based on guidelines, such as those with prior polyps removed or prior colorectal cancer or those with hereditary conditions at an increased risk of colorectal cancer.
Surveillance interval	In the context of colonoscopy, this refers to the time-point at which a person should have another colonoscopy and will depend on findings from the previous colonoscopy as well as other factors such as presence of risk factors for colorectal cancer.
Systematic literature review	A structured, rigorous and transparent process through which relevant evidence is identified for inclusion in clinical and economic reviews.
Tandem study	A study that involves patients undergoing more than one treatment or assessment within a particular study, in contrast to parallel trials where each patient only undergoes one of the options. For example, in this assessment, tandem studies

	refer to those patients that had a standard colonoscopy as well as a colonoscopy supported by artificial intelligence.
Therapeutic colonoscopy	A colonoscopy where an action is performed rather than solely visualising the bowel, which may include removal of polyps or biopsies
Virtual chromoendoscopy (VCE)	Application of electronic imaging enhancements during colonoscopy to enhance contrast and support with the characterisation of polyps. It is an alternative to chromoendoscopy using physical dyes.
Willingness-to-pay (WTP) threshold	The amount that a healthcare system is willing to pay to achieve an additional QALY (i.e., one year in perfect health) in the patient population. In NICE evaluations, a threshold of £20,000-£30,000 is generally used.

List of Abbreviations

AA	Advanced adenomas
AACR	American Association for Cancer Research
AAMR	Advanced adenoma miss rate
ACPGBI	The Association of Coloproctology of Great Britain and Ireland
ADR	Adenoma detection rate
AE	Adverse event
AGA	American Gastroenterological Association
AI	Artificial intelligence
AMR	Adenoma miss rate
APC	Adenomas per colonoscopy
APDW	Asian Pacific Digestive Week
AQuAS	Agència de Qualitat i Avaluació Sanitàries de Catalunya
ASCO	American Society of Clinical Oncology
BBPS	Boston Bowel Preparation Scale
BCSA	Bowel Cancer Screener Accreditation
BCSP	Bowel Cancer Screening Programme
BLI	Blue-light imaging
BMJ	British Medical Journal
BSG	British Society of Gastroenterology
CAD	Canadian dollars
CADe	Computer-aided detection
CADTH	Canadian Agency for Drugs and Technologies in Health
CADx	Computer-aided characterisation
CCE	Colon capsule endoscopy
CDA-AMC	Canada's Drug Agency
CDC	Centers for Disease Control and Prevention
CDSR	Cochrane Database of Systematic Reviews
CEAC	Cost-effectiveness acceptability curve
CENTRAL	Cochrane Central Register of Controlled Trials
CI	Confidence interval
CKS	Clinical Knowledge Summary
CMS	Centers for Medicare & Medicaid Services
CPU	Central processing unit
CRC	Colorectal cancer
CRD	Centre for Reviews and Dissemination
CSR	Clinical study report
CT	Computed tomography
CTC	CT colonography

DA	Diagnostic accuracy
DAR	Diagnostic Assessment Report
DCE	Dye-based chromoendoscopy
DDW	Digestive Disease Week
DHTC	Danish Health Technology Council
DR	Detection rate
DRSP	Diminutive rectosigmoid polyp
DSA	Deterministic sensitivity analysis
EACR	European Association for Cancer Research
EAG	External Assessment Group
EMIS™	Endoscopic Multimedia Information System
EMR	Endoscopic mucosal resection
EPCAM	Epithelial cell adhesion molecule gene
ESCP	European Society of Coloproctology
ESGE	European Society of Gastrointestinal Endoscopy
ESMO	European Society for Medical Oncology
EU	European
FAP	Familial adenomatous polyposis
FDA	US Food and Drug Administration
FIT	Faecal immunochemical test
GI	Gastrointestinal
GIRFT	Gastroenterology Get It Right First Time
HCP	Healthcare professional
HD	High-definition
HD-WLE	High-definition white-light endoscopy
HDWL	High-definition white-light
HRA	High-risk adenoma
HRQoL	Health-related quality of life
HTA	Health technology appraisal
HTW	Health Technology Wales
IBD	Inflammatory bowel disease
ICTRP	International Clinical Trials Registry Platform
iFOBT	Immunochemical faecal occult blood test
ICER	Institute for Clinical and Economic Review OR incremental cost-effectiveness ratio
IHE	Swedish Institute for Health Economics
INAHTA	International Network of Agencies for Health Technology Assessment
IRR	Incidence rate ratio
ITT	Intention to treat
JAG	Joint Accreditation Group
JPY	Japanese Yen

LCI	Linked-colour imaging
LRA	Low-risk adenomas
LS	Lynch syndrome
LYG	Life years gained
MA	Meta-analysis
MD	Mean difference
MDR	Medical Device Regulation
MeSH	Medical Subject Headings
M-H	Mantel-Haenszel
MHRA	Medicines and Healthcare products Regulatory Agency
MLH1	mutL homolog 1
MRI	Magnetic resonance imaging
MSH2	mutS homolog 2
MSH6	mutS homolog 6
NA or N/A	Not applicable
NAIAD	Nationwide study of Artificial Intelligence in Adenoma Detection
NBI	Narrow-band imaging
NHB	Net health benefit
NHS	National Health Service
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Care Excellence OR NBI International Colorectal Endoscopic criteria
NIHR	National Institute for Health and Care Research
NPV	Negative predictive value
NR	Not reported
NSC	UK National Screening Committee
OR	Odds ratio
PDR	Polyp detection rate
PET	Positron emission tomography
PHE	Public Health England
PICO	Population intervention comparator outcome
PMR	Polyp miss rate
PPC	Polyps per colonoscopy
PPV	Positive predictive value
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROMS	Patient-reported outcome measures
PSA	Probabilistic sensitivity analysis
PSS	Personal Social Services
QALY	Quality-adjusted life year
RAM	Random access memory

RCT	Randomised controlled trial
RoB 2	Cochrane risk of bias tool for randomised trials
RR	Risk ratio
SD	Standard deviation
SEER	Surveillance Epidemiology and End Results
SIGN	Scottish Intercollegiate Guidelines Network
SLR	Systematic literature review
SMC	Scottish Medicines Consortium
SPS	Serrated polyposis syndrome
SSL	Sessile serrated lesion
TNM	Tumour, node and metastasis staging
UC	Ulcerative colitis
UK	United Kingdom
UKCA	UK Conformity Assessed
UKCGG	United Kingdom Cancer Genetics Group
USA	United States of America
USD	United States dollars
USMSTF	US Multi-society Task Force on Colorectal Cancer
VAT	Value-added tax
VCE	Virtual chromoendoscopy
WHO	World Health Organization
WLE	White-light endoscopy
WLI	White-light imaging
YHEC	York Health Economics Consortium

1 Background

1.1 Description of health problem

1.1.1 Brief statement describing the health problem

Colorectal cancer (CRC), or bowel cancer, is defined as cancer found anywhere within the large bowel, which includes the colon and the rectum. Various genetic, lifestyle and other factors are thought to increase the risk of CRC.[7-9] This includes the presence of colorectal polyps, which are lesions within the large bowel that are usually harmless but have the potential to develop into CRC.[7-10] During colonoscopies, most colorectal polyps detected will usually be removed and sent for testing.[9, 10] Symptoms such as rectal bleeding or a change in bowel habits are among those associated with CRC but symptoms are not always present.[7-9] Colonoscopies can be scheduled if indicated based on patient signs or symptoms, or as part of national screening or surveillance programmes for those without symptoms.[7-9] CRC is the fourth most common cancer in the UK, with over 44,000 new cases each year, and accounts for 10% of all UK cancer-related deaths. It is the second most common cause of cancer-related death; the earlier it can be diagnosed, the better the chances of survival.[8, 11, 12]

1.1.2 Aetiology, pathology and prognosis

The cause of CRC is often unknown but it will vary between patients; the following genetic changes, lifestyle factors, health conditions, environmental and other factors are thought to increase the risk of CRC development:[7-9, 13]

- Older age;
- Smoking;
- Alcohol consumption;
- Being overweight or obese;
- Poor diet;
- Lack of physical activity;
- Family history of CRC;
- Inflammatory bowel disease (IBD);
- Hereditary conditions such as Lynch syndrome and familial adenomatous polyposis (FAP);
- The presence of benign colorectal polyps.

While bowel cancer can affect people of any age, increasing age has been linked to a higher risk of CRC, with an age >50 years often cited as the threshold above which risk generally increases.[7, 8] Bowel Cancer UK reports that more than 90% of all new cases are diagnosed in people over the age of 50 years.[8] National screening programmes such as the one in the UK, which screen people above a certain age for bowel cancer (between age 50 and 74 years in England, Scotland and Wales, and between age 60 and 74 years in Northern Ireland),[14, 15] are designed with this age-based risk in mind.

Lifestyle factors such as smoking and alcohol consumption, diet, physical activity and weight are also thought to be linked to someone's risk of CRC. General advice is that stopping or reducing smoking and alcohol consumption, having an active lifestyle and maintaining a healthy body weight, including a balanced diet that is high in fibre and low in foods that are high in fat or sugar and red or processed meats, should reduce the risk of CRC.[8, 9]

A strong family history of CRC means someone's risk of CRC is considered to be increased, with 5-10% of all bowel cancers thought to be caused by a faulty gene that can be passed down through families.[8, 9] A strong family history may be defined as a close relative (such as a parent, sibling or child) being diagnosed with CRC before the age of 50 or multiple close relatives (such as a parent and grandparent or two siblings) being diagnosed at any age. The presence of this risk factor may mean someone qualifies for earlier screening within the UK, depending on the number and age of affected relatives.[8, 9] Not all of the genes that may be linked to CRC risk have been identified yet, but there are some specific inherited conditions (including Lynch syndrome and FAP) that are known to be associated with a substantially increased risk of CRC and it is important that these conditions are diagnosed as soon as possible to allow enhanced monitoring and risk management via specific surveillance programmes and prevention strategies for individuals diagnosed with these conditions.[8, 9, 13]

The presence of other bowel conditions such as IBD (including conditions such as ulcerative colitis and Crohn's disease) has also been linked to an increased risk of CRC, and screening at a younger age compared to the general population may be recommended in people with these conditions. It is also recommended that people with a history of prior bowel cancer are followed up at specific time points (1 and 4 years post-treatment).[9]

Another factor that can influence how frequently someone undergoes screening tests such as colonoscopies is the presence of colorectal polyps, which are small growths on the lining of the colon or rectum.[7-9] Unless they are associated with symptoms, these will usually be incidental findings on colonoscopies, for example when colonoscopies have been arranged for other indications or as part

of the screening or surveillance programmes for CRC within the UK. While most are harmless, some types of polyp have the potential to develop into cancer over time and so many of them will be removed during colonoscopy procedures.[10] Polyps that are classified as "adenomatous" are of most concern and the adenoma-carcinoma pathway is key to understanding the pathogenesis of CRC. However, other pathways leading to cancer development are thought to exist, including other types of polyps such as serrated lesions.[16, 17] Collectively, polyps that are considered at risk of developing into cancer may be termed "premalignant" polyps.[17] Therefore, thorough investigation and identification of colorectal polyps during colonoscopies, with removal of polyps of concern, is key to reducing the risk of future CRC development in patients with polyps. Furthermore, additional follow-up colonoscopies may be scheduled at varying intervals (for example at 1 or 3 years post-polyp removal) for those with polyps removed on their last colonoscopy; this may depend on how many polyps were removed, their size and how abnormal they were.[9]

Once diagnosed with CRC, the prognosis depends on the disease stage. CRC is staged using the TNM system and by a number system which separates patients into stages 0 to 4, with stage 0 referring to carcinomas *in situ* that are very unlikely to have spread and stage 4 indicating CRC that has spread to other parts of the body such as the liver or lungs. Statistics reported by Cancer Research UK for patients in England diagnosed between 2016 and 2020 and followed up to 2021 show that 5-year survival reduces with increased stage, dropping from ~90% surviving at least 5 years at stage 1 to ~85%, ~65% and ~10% at stages 2, 3 and 4, respectively.[9] Therefore, earlier diagnosis of CRC or earlier removal of polyps with the potential for CRC development is key to improving CRC outcomes.[8, 12]

1.1.3 Epidemiology and incidence

Cancer Research UK reports that, based on data between 2017 and 2019, there are over 44,000 new cases of CRC in the UK each year, making it the fourth most common cancer in the UK.[11] Based on Cancer Registration Statistics data reported on National Health Service (NHS) Digital, CRC was also the fourth most common cancer within England in the year 2020. Given breast and prostate cancer make up two of the four most common cancers (which mostly affect females and males, respectively), CRC is the third most common cancer diagnosis for males and females when separated, accounting for 13% and 11% of total new diagnoses, respectively.[18] Of CRC cases diagnosed within England in 2020, over half of those with sufficient staging information were diagnosed at later stages (stage 3 or 4) in both males and females.[18] Similar observations were made in Wales based on data from 2021.[19] CRC accounts for ~10% of all UK cancer-related deaths with

approximately 16,800 deaths annually based on data from 2017 to 2019, making it the second most common cause of cancer-related death in the UK.[11]

CRC incidence and mortality is reported to be higher within older age groups, with more than 4 in 10 new diagnoses in the UK being in those >75 years and ~58% of CRC-related deaths occurring in this age group,[11] and more than 90% of diagnoses estimated to be in those over 50 years of age.[8] National screening programmes based on age, such as the NHS Bowel Cancer Screening Programme (BCSP), screen for CRC in the age group that is at the highest risk of CRC with the aim of identifying cases at an earlier stage and improving prognosis or removing premalignant polyps that may develop into CRC in the future. The minimum age for the NHS BCSP has in recent years been lowered from 60 to 50 years.[9, 12, 14]

1.1.4 Impact of health problem

1.1.4.1 Significance for patients in terms of ill-health (burden of disease).

A diagnosis of CRC may impact patients in various ways, including a direct, physical impact of the CRC as well as effects of treatment, an increased risk of mortality and psychological impacts of all of these factors. Similar to other types of cancer, the psychological burden of a cancer diagnosis is likely to be large, with concerns about mortality, finances and continuing to live a normal life likely to occur and potentially extending beyond treatment. Furthermore, treatments for CRC may lead to side effects of varying durations that lead to physical and/or psychological burdens on patients. For example, there might be a requirement for a stoma following surgery or chemotherapy might lead to general ill health and an increased risk of infection.[8, 13]

In a 2012 report comparing various patient-reported outcome measures (PROMs) between survivors of CRC and the age- and sex-matched general population from the Health Survey for England 2011, a lower proportion of CRC survivors reported being in perfect health based on EQ-5D. Overall, challenges with regards to the emotional and physical impact of a cancer diagnosis and treatment, and social and financial challenges were mentioned by patients. Specific challenges included concerns about stomas, ongoing issues with bowel and urinary control and an ongoing fear of death or cancer recurrence.[20]

1.1.4.2 Significance for the NHS

As noted earlier, CRC is the fourth most common cancer in the UK meaning it is likely to be associated with a fairly large proportion of the resources used to diagnose and treat different types of cancer. Based on a synthesis of routinely collected healthcare data such as cancer registry data,

hospital episode statistics and published research, a report published in 2010 by the York Health Economics Consortium (YHEC) estimated that the total cost of CRC to the NHS in England was £1.1 billion per year in 2005, which accounts for the cost of diagnosis, treatment and palliative care.[21, 22]

More recently, a prevalence-based cost-of-illness study by the Swedish Institute for Health Economics (IHE) reported that the estimated cost of CRC to the UK economy in 2018 was £1.7 billion; it should be noted that as well as costs to the NHS such as those associated with diagnosis and treatment, it also considers indirect expenses such as inability to work and the provision of informal care to patients by friends and relatives.[23]

1.1.5 Measurement of disease

In the diagnostic or screening pathway for CRC in the UK, colonoscopies are the main imaging method used in the identification of colorectal lesions.[7] Other imaging methods are an option, such as computed tomography (CT) scans of the abdomen, CT colonography (CTC) or, more recently and not yet in widespread use, colon capsule endoscopy (CCE); however, these methods do not allow the removal of identified polyps or biopsies to be taken, so a colonoscopy (or surgery if conditions are too difficult for removal via colonoscopy, as outlined in National Institute for Health and Care Excellence [NICE] guideline IPG503) to obtain tissue for histopathological testing may still be required following these tests.[24] Another type of imaging method that allows polyps to removed or biopsies to be taken is a flexible sigmoidoscopy; this is similar to a colonoscopy but involves examination only up to the lower part of the large bowel rather than all of it.[8, 9]

Polyps that are removed during colonoscopies or flexible sigmoidoscopy (or subsequent surgery, if there are issues with removing during the aforementioned procedures) will be sent for histopathological testing.[8, 9] Feedback from the External Assessment Group (EAG)'s clinical experts and at the scoping workshop for this project was that most identified polyps are removed during a colonoscopy, with the exception of polyps within the rectum that are considered to be hyperplastic. Feedback also indicated that all removed polyps are usually sent for histopathological testing currently in the UK, although after a successful pilot, the BCSP is in the process of rolling out a strategy for certain polyps where an optical diagnosis by the endoscopist would suffice without the need for histopathological testing.[25]

The strategy within the NHS BCSP will allow endoscopists to discard diminutive polyps (≤5 mm) if they have been able to make a high-confidence optical diagnosis themselves during the colonoscopy, rather than sending these polyps for histological testing, and a quality assurance

process will be in place. The NHS BCSP opted to implement this strategy based on the results of the DISCARD 3 study, where it was concluded that it is feasible and safe for screening endoscopists to take this approach for diminutive polyps (≤5 mm) with a high-confidence optical diagnosis and where there is a quality assurance process in place,[26, 27] and following an initial pilot within the NHS BCSP.[26, 27] The roll-out of the new process is ongoing within the NHS BCSP and will require screening endoscopists to undertake optical diagnosis accreditation before they can use this approach; based on updates presented at European Society of Gastrointestinal Endoscopy (ESGE) Days in November 2024 and British Society of Gastroenterology (BSG) LIVE in June 2025, around 8% and 20.8% of endoscopists, respectively, invited to undertake this accreditation had completed the full process ([redacted]). Reductions in histology time and costs associated with histology have already been noted as part of this process, with roll-out expected to complete in 2027.[26] It should be noted that this approach will only be permitted for use in colonoscopies that are performed as part of the NHS BCSP (i.e. it would not be used in patients having a colonoscopy outside of the NHS BCSP pathways) and only for diminutive polyps (≤5 mm) where the endoscopist has been able to make a high-confidence optical diagnosis.

If histology confirms that CRC is present, further tests are performed to stage the cancer to assess its size, where it is located and whether it has spread elsewhere in the body. This process may involve one or more imaging tests such as CT, magnetic resonance imaging (MRI), ultrasound and positron emission tomography (PET)-CT scans.[8, 9] The EAG's clinical experts noted that the TNM system is now used in the UK to stage CRC and has almost exclusively replaced the Dukes' criteria.[9] The TNM system classifies tumours based on the depth and extent of invasion of the tumour itself (T), whether the cancer has spread to nearby lymph nodes (N) and whether the cancer has spread to other parts of the body, or metastasised, (M). Categories within this staging system are summarised in Table 1 below.[8, 9]

The TNM report can also be used to categorise cancers into stages between 1 and 4. Stage 1 refers to cancer that has not spread outside of the bowel wall, stage 2 to cancer that has grown into or through the outer layer of the bowel wall, stage 3 indicates spread to nearby lymph nodes and stage 4 is when the cancer has spread to other parts of the body.[8, 9] Cancer cells are also graded (based on the appearance of cancer cells, i.e. how abnormal they look compared to normal cells) as a result of histopathological testing.[9, 28] Grades are separated into low grade (slow growing) cells and high grade (fast growing) cells. CRC is also divided into different types depending on the type of cell the

cancer starts in (for example, cancers that start in gland cells are termed adenocarcinomas) and where it starts in the bowel (i.e. colon vs rectal cancer).

The EAG's clinical experts noted that these factors all inform decisions about treatment and that the results of genetic profiling of the cancer also make up a large part of the decision-making process currently,[9] including K-RAS, N-RAS and BRAF mutations which are routinely tested for in the UK. Furthermore, the results of other tests such as liver and kidney function tests and assessing for the presence of anaemia will also be performed, and consideration of a patient's general fitness and frailty will also be taken into account when making treatment decisions in discussion with the patient.

Table 1. Categories within the TNM staging system

T stage (tumour)	
T1	Tumour is in the inner bowel layer
T2	Tumour has grown into muscle layer of bowel wall
T3	Tumour has grown into outer lining of bowel wall
T4	Tumour has grown through outer lining of bowel wall
N stage (nodes)	
N0	No lymph nodes contain cancer cells
N1	Cancer cells located in up to three nearby lymph nodes
N2	Cancer cells located in four or more nearby lymph nodes
M stage (metastases)	
M0	Cancer has not spread to other parts of the body
M1	Cancer has spread to other parts of the body, such as the liver or lungs

Abbreviations: TNM, tumour, node and metastasis staging.

1.2 Current service provision

1.2.1 Pathways to colonoscopy

As noted in Section 1.1.5, colonoscopy is the main diagnostic imaging method for the identification and removal of colorectal polyps. There are various pathways through which someone may be referred for a colonoscopy in the UK including the age-based NHS BCSP, referral due to symptoms suggestive of CRC or specific surveillance programmes in populations at increased risk of CRC. Examples of populations at an increased risk of CRC include those with a hereditary risk of CRC, IBD

or who have had colorectal polyps or CRC previously resected. These pathways are summarised in Figure 1 below.

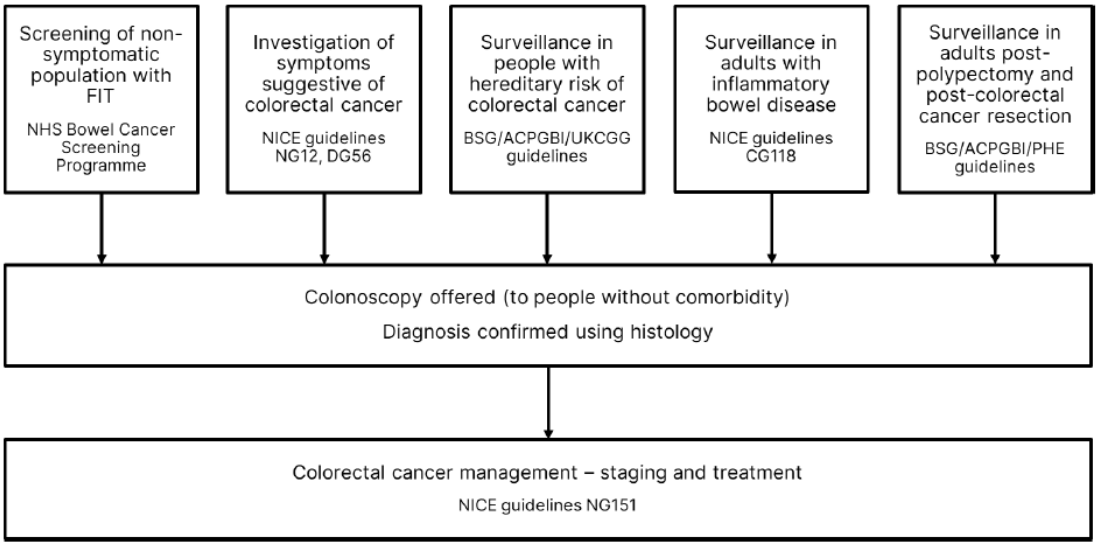
The NHS BCSP invites people between a certain age range to return a faecal immunochemical test (FIT) kit every 2 years to identify the presence of blood in the stool; the age range and threshold for a positive FIT result varies slightly across the UK nations, summarised by the NICE Clinical Knowledge Summary (CKS). For England, the screening programme applied to those aged between 50 and 74 years from 2021, with a threshold of 120 µg of haemoglobin/g of faeces, although a pilot of an 80 µg threshold is taking place in some parts of England.[29, 30] Colonoscopy is offered to people with a positive FIT result. The BCSP also covers colonoscopy for assessment/polypectomy following an abnormal CTC, to check a polypectomy site of a BCSP patient post-polypectomy and for surveillance of a BCSP patient post-polypectomy.[31]

Patients with symptoms suggestive of CRC can be referred for testing via the suspected cancer pathway, the criteria for which are described in Section 1.3 of the NICE guideline on suspected cancer (NG12) and were adapted from Sections 1.1 to 1.4 of the NICE guidance (DG56) on quantitative faecal immunochemical testing for CRC in primary care. A FIT with a threshold of 10 µg of haemoglobin/g of faces is used as part of this pathway but referral should not be excluded on the basis of this alone.[32, 33] The Association of Coloproctology of Great Britain and Ireland (ACPGBI)/BSG 2022 guideline on FIT in patients with signs or symptoms of suspected CRC also provides guidance on this.[34] Patients referred on the suspected CRC pathway should receive a diagnosis or ruling out of cancer within 28 days of referral.[35]

Guidance exists for the surveillance of specific groups of people with an increased risk of CRC. Joint guidance from the BSG, ACPBGI and the United Kingdom Cancer Genetics Group (UKCGG) from 2019 outlines recommendations on colonoscopic surveillance for people with an increased hereditary risk of CRC, which includes people with Lynch syndrome, polyposis syndromes (i.e. where there are >10 polyps in the colon), a significant family history of CRC (defined in Section 1.1.2) or with a diagnosis of CRC under the age of 50 years.[36] Guidance on the colonoscopic surveillance of adults with IBD for signs of CRC is available in NICE guideline (CG118) and the BSG 2019 guideline on the management of IBD in adults.[37, 38] In addition, a 2019 guideline produced jointly by the BSG/ACPBGI/UKCGG on post-polypectomy and post-CRC resection surveillance provides recommendations on the colonoscopic surveillance of people who have undergone removal of adenomatous polyps, serrated polyps or CRC.[17]

Feedback at the scoping workshop for this assessment was that people with Lynch syndrome in England have surveillance as part of the BCSP (performed by screening-accredited endoscopists) but this may not always be the case for other UK nations. Feedback was also that within England there may be variation in terms of whether hereditary high-risk patients (including people with polyposis) have their colonoscopies performed by screening-accredited colonoscopists or not.

Figure 1. Overview of groups offered colonoscopy (reproduced from the NICE final scope)



Abbreviations: ACPCBI, The Association of Coloproctology of Great Britain and Ireland; BSG, British Society of Gastroenterology; FIT, faecal immunochemical test; NICE, National Institute for Health and Care Excellence; PHE, Public Health England; UKCGG, UK Cancer Genetics Group.

1.2.2 Current service cost

Standard colonoscopy without artificial intelligence (AI) technologies results in an average cost to the NHS of £787.00 per procedure for diagnostic colonoscopies (i.e., colonoscopies with no polypectomies performed) and £1,015.00 per procedure for therapeutic colonoscopies (i.e. colonoscopies with at least one polypectomy performed), based on the 2023/24 NHS reference costs. These costs are inclusive of staff time, use of facilities and equipment, and histopathological testing.

1.2.3 Management of disease

Based on feedback from the EAG's clinical experts, standard colonoscopy is currently considered to be high-definition (HD) white-light endoscopy (WLE). It was also noted that the use of narrow-band imaging (NBI), dye-based chromoendoscopy (the application of dye; DCE) and virtual chromoendoscopy (VCE; a method similar to chromoendoscopy but without the use of a physical

dye) are sometimes used to improve visibility of lesions to aid with polyp characterisation and decisions about polyp removal. ENDOCUFF VISION™ was also mentioned as an adjunct technology that is sometimes used to improve visualisation of the bowel and polyp detection rates. However, despite a recommendation for the use of VCE by NICE, DCE and VCE were mentioned as being mostly used in IBD populations and not routinely for all colonoscopies.[39]

Furthermore, ENDOCUFF VISION™ was said to be mostly used in the screening colonoscopy or polyp surveillance settings, aligning with its recommendation by NICE,[40] and may not be consistently used (it is also not appropriate for all patients given it increases the thickness of the scope). At the scoping workshop for this project it was noted that the extent of the use of VCE within the NHS is currently unclear and that ENDOCUFF VISION™ is used within the NHS.[25]

Once polyps have been detected during a colonoscopy, a decision about whether to resect each polyp and send for histopathological testing is made by the endoscopist. Guidance updated in 2024 from the ESGE recommends that all polyps other than diminutive rectosigmoid polyps that are predicted to be non-adenomatous with high confidence are resected.[41] Furthermore, NICE guidance on VCE in colonoscopy recommends that optical diagnosis using VCE is performed for diminutive (size ≤5 mm) polyps rather than resection and histopathology, providing a high-confidence assessment is made and certain criteria on equipment used, expertise of the endoscopist and auditing processes are met.[39] However, as noted in Section 1.1.5, feedback received as part of this project suggests that the general approach within the NHS currently may be for all polyps other than hyperplastic rectal polyps to be removed.[25]

Once resected, the ESGE 2024 guidance recommends the retrieval and histopathological analysis of resected polyps; it indicates that resect-and-discard strategies using real-time optical diagnosis with VCE or DCE for diminutive colorectal polyps should only be performed by experts.[41] This may be slightly more flexible than current clinical practice in the UK but colonoscopies performed within the NHS BCSP will soon make routine use of a resect-and-discard strategy; as noted in Section 1.1.5, feedback was that all resected polyps are usually sent for histopathological testing, but there is an ongoing rollout of a resect-and-discard strategy for colonoscopies performed within the NHS BCSP for diminutive (≤5 mm) polyps where the endoscopist is able to make a high-confidence diagnosis, and where the endoscopist has achieved accreditation (see Section 1.1.5).

Further tests, including scans if CRC is confirmed on histology are outlined in Section 1.1.5. The results of these tests are used to inform treatment decisions in discussion with each patient; the stage, location, genetic results and patient fitness help to determine which options are available and

there may be fewer options in some cases. However, the EAG's clinical experts noted that surgery is usually the first choice where it is feasible, with the option of neoadjuvant, adjuvant or definitive chemotherapy or radiotherapy (or chemoradiotherapy) where deemed necessary.[8, 9] NICE guideline NG151 includes recommendations on the management of local and metastatic CRC, separated into rectal and colon cancer.

1.2.4 Variation in services and/or uncertainty about best practice

Some variation in terms of the NHS BCSP across different UK nations is described in Section 1.2.1. Furthermore, Bowel Cancer Screener Accreditation (BCSA) is noted to differ between the UK nations; England and Wales have a national accreditation and quality standards but screening colonoscopists are approved locally in Scotland. Health Education England and Health Improvement Wales also have accelerated programmes to train suitably registered health professionals to perform colonoscopies. As part of the scoping process for this assessment, experts noted that this could mean there is variation in the experience levels of endoscopists trained through different programmes.

The NHS BCSP is implementing a resect-and-discard strategy based on optical diagnosis by the endoscopist for diminutive polyps (≤5 mm) where the endoscopist has been able to make a high-confidence optical diagnosis (see Section 1.1.5). While the rollout is not expected to complete until 2027, this could lead to differences between BCSP and non-BCSP settings in terms of approach to resection and histopathological testing.

The EAG understands that there is likely to be variation across centres in terms of the use of adjunct technologies or processes such as DCE, VCE and ENDOCUFF VISION™ as part of colonoscopies (Section 1.2.2).

As discussed in Section 1.2.1, there may be differences across the UK nations in terms of whether Lynch syndrome patients have colonoscopy performed by screening-accredited endoscopists, and not all hereditary high-risk patients (such as polyposis) have their surveillance colonoscopy performed by screening-accredited colonoscopists in England.

1.2.5 Relevant national guidelines, including National Service Frameworks

Relevant guidance for colonoscopy and CRC are listed below under specific subheadings and have been cited and discussed in this report as applicable. Of note, recommendations from different health technology appraisal (HTA) groups vary. A recommendation not to use computer-aided polyp

detection (CADe) was made by the Danish Health Technology Council (DHTC) in February 2023, although this was a temporary recommendation to apply only until the first quarter of 2025 given the rapid development of evidence in this area and the potential for future assessment of the computer-aided polyp characterisation (CADx) functionality.[42] More recently, a recommendation that CADe technologies could be used during colonoscopies was made as a result of the Health Technology Wales (HTW) appraisal in 2024.[43] Another appraisal in Spain by the "Agència de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS)" reviewed only GI Genius™ in 2023, but the EAG could not identify whether any recommendations were made as a result of this report. Health Improvement Scotland published advice on the use of artificial intelligence to support endoscopy in April 2025 but only summarised the available evidence rather than making any recommendations about whether or not it should be used,[44] with Canada's Drug Agency (CDA-AMC) also doing similar as part of a rapid review published in December 2024.[45]

Furthermore, ESGE guidance from 2019 included a weak recommendation based on low quality evidence for the possible use of AI technologies to support polyp detection and characterisation assuming acceptable and reproducible accuracy for colorectal neoplasia is demonstrated in high quality multicentre *in vivo* clinical studies.[46]

In 2025, recommendations relating to CADe use in colonoscopy were made by ESGE, the American Gastroenterological Association (AGA) and the British Medical Journal (BMJ) Rapid Recommendations,[47-49] which were all based largely on the same large meta-analysis (pooling all AI technologies as a single CADe intervention) and associated microsimulation model,[50, 51]. All three also considered one or more sources of data on patient and clinician preferences relating to AI use in colonoscopy and/or general gastrointestinal healthcare.[52-54] ESGE were the only group to make a positive recommendation and even this was a weak recommendation, as follows:

- The ESGE position statement in March 2025 included a weak recommendation that most well-informed patients who have already decided to undergo colonoscopy for screening or surveillance would likely favour CADe assistance during colonoscopy. This was said to be based on potential benefits, although limited, on reduction in CRC incidence and mortality. The recommendation made was weak as the evidence was considered to be limited with considerable uncertainty, only small effects on absolute benefits in terms of CRC incidence and mortality obtained from the microsimulation model and potential for patient burden with CADe (such as polyp overdiagnosis and more colonoscopy surveillance). This recommendation only applies to those undergoing primary screening, colonoscopy

following a positive FIT or for polyp surveillance (and not those undergoing colonoscopy for symptoms) based on the search terms used in the systematic review. [47]

- The BMJ's Rapid Recommendations on CADe and CADx in adults undergoing colonoscopy included a weak recommendation against the routine use of CADe colonoscopy in March 2025 based on the small and uncertain impact on critical outcomes of CRC incidence, post-colonoscopy CRC incidence and CRC-related mortality, and the potential for patient burden;[49]
- In April 2025, the AGA made no recommendation for the use of CADe-assisted colonoscopy in adults given the very low certainty of evidence relating to long-term outcomes that were considered critical to decision-making (CRC incidence, CRC mortality and post-colonoscopy CRC), with plans to reconsider this recommendation when long-term evidence is available.[48]

HTA recommendations/reports

- Artificial intelligence (AI)-assisted endoscopy in the detection of gastrointestinal cancer and pre-cancerous lesions – HTW guidance;[43]
- Use of artificial intelligence as clinical decision-support in colonoscopy for the diagnosis of neoplastic disease – DHTC;[42]
- Artificial intelligence for the detection of colorectal precancerous lesions in colonoscopy - AQuAS;[55]
- Artificial intelligence (AI)-assisted endoscopy – Health Improvement Scotland;[44]
- Artificial Intelligence–Assisted Colonoscopy for Detecting Polyps, Adenomas, Precancerous Lesions, and Colorectal Cancer – CDA-AMC.[45]

Recommendations by professional organisations/other groups

- Use of computer-assisted detection (CADe) colonoscopy in colorectal cancer screening and surveillance: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement;[47]
- AGA Living Clinical Practice Guideline on Computer-Aided Detection-Assisted Colonoscopy;[48]
- Computer-aided detection and diagnosis of polyps in adult patients undergoing colonoscopy: a living clinical practice guideline.[49]

Guidance on colonoscopy and polyp resection

- Virtual chromoendoscopy to assess colorectal polyps during colonoscopy – NICE guidance [NG28];[39]

- Endocuff Vision for assisting visualisation during colonoscopy – medical technologies guidance [MTG45];[40]
- Combined endoscopic and laparoscopic removal of colonic polyps – interventional procedures guidance [IPG503];[24]
- Advanced imaging for detection and differentiation of colorectal neoplasia: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2019;[46]
- Colorectal polypectomy and endoscopic mucosal resection: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2024;[41]
- British Society of Gastroenterology position statement on serrated polyps in the colon and rectum;[16]
- Management of the malignant colorectal polyp: ACPBGI position statement.[56]

Guidance on referral from primary care, screening and surveillance

- Suspected cancer: recognition and referral – NICE guideline [NG12];[32]
- Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care – NICE diagnostics guidance [DG56];[33]
- Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected CRC: A joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG);[34]
- NHS Bowel Cancer Screening Programme (BCSP);[29, 31]
- British Society of Gastroenterology position statement on serrated polyps in the colon and rectum;[16]
- Management of the malignant colorectal polyp: ACPBGI position statement;[56]
- BSG/ACPGBI/PHE post-polypectomy and post-colorectal cancer resection surveillance guidelines;[17]
- Guidelines for the management of hereditary colorectal cancer from the British Society of Gastroenterology (BSG)/Association of Coloproctology of Great Britain and Ireland (ACPGBI)/United Kingdom Cancer Genetics Group (UKCGG);[36]
- Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas – NICE clinical guideline [CG118];[37]
- British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults.[38]

Guidance on cancer diagnosis and management

- Colorectal cancer – NICE guideline [NG151];[13]
- Management of the malignant colorectal polyp: ACPBGI position statement;[56]
- In development: European Society of Coloproctology (ESCP) – T1 cancer guideline.[57]

Other national reports/frameworks

- Gastroenterology Get It Right First Time (GIRFT) Programme national specialty report – NHS England;[58]
- Faster diagnosis of cancer – NHS England.[35]

1.3 Description of technology under assessment

1.3.1 Summary of Intervention

At the start of this project, 11 AI-supported colonoscopy technologies were to be appraised in this assessment. Although it was available in the UK at the time of scoping for this assessment, the EAG was informed in February 2025 by NICE that the manufacturers of WISE VISION® had confirmed that the product was to be withdrawn from the UK market and would not be available for use in the NHS. Therefore, this product is no longer covered in this Diagnostic Assessment Report (DAR). The remaining 10 interventions covered in this assessment are listed in Section 2.1.1. These technologies are intended to be used during colonoscopy procedures to assist endoscopists in the detection and/or characterisation of colorectal polyps; some products have a CADe function only while others have CADe and CADx functionalities. The technologies, their regulatory status and intended use as outlined by manufacturers are summarised in Table 44 of Appendix 9.1. This table also summarises any requirements of specific technologies in terms of other equipment, personnel involved or criteria for use, and information on updates and previous versions of the technology.

Manufacturers of most technologies outlined that they can be used in any colonoscopy population, although some mention that they are not ideal for use in certain populations (such as IBD populations) or that they have not been validated in certain populations. They all outlined that they are designed for use as adjunct, supportive tools with the final judgement to be made by endoscopists and it is noted that overreliance on the products should be avoided. Extensive training is not considered to be needed for those that provided manufacturer submissions as part of this

assessment, but some manufacturers offer formal training as part of the product purchase where required.

1.3.2 Identification of important subgroups

The NICE final scope included subgroups based on colonoscopy indication and also identified the need to explore subgroup data based on endoscopist experience and expertise. The EAG has explored these subgroups, as discussed in Sections 3.1.5.2, 3.2.2.1.12 and 3.2.2.1.13.

1.3.3 Current usage in the NHS

Based on discussions with the EAG's clinical experts, the EAG considers that the use of these technologies in the NHS currently may be very individual endoscopist- and centre-dependent. Where they are being used, this is most likely to be with regards to the CADe function rather than CADx, given the latter is a newer function that has emerged and given that most polyps identified are currently being resected and sent for histology (see Section 1.1.5).

In September 2024, the manufacturer of GI Genius™ noted in its submission that the technology is available to the NHS and is in active use throughout the NHS currently; the total number of hospital installations following purchase exceeds 100 devices, with one example provided as GI Genius™ having been purchased and installed in 34 hospitals in England, Wales and Scotland as part of a study funded by the National Institute for Health and Care Research (NIHR; Nationwide study of Artificial Intelligence in Adenoma Detection [NAIAD] study). No other similar statements have been made in submissions by other companies taking part in this assessment.

1.3.4 Anticipated costs associated with intervention

The intervention technologies included in this evaluation are generally available on either an upfront purchase or subscription purchase basis; in the former case, the technology is purchased outright, but an additional maintenance fee is charged on an annual or monthly basis, while in the latter case, the subscription cost is inclusive of the maintenance cost. For two technologies included in this evaluation (GI Genius™ and MAGENTIQ-COLO™), a choice of upfront or subscription purchase is available. For Endoscopic Multimedia Information System (EMIS™), the pricing model is more complex, and includes a per-procedure cost as well as an upfront and maintenance cost; the manufacturer provided an estimated overall cost per procedure for the purposes of this evaluation.

The EAG notes that for two technologies included in the scope of this evaluation (i.e., CADDIE™ and ENDOANGEL®), no price has been provided by the manufacturer, in which case, inclusion in the

economic analysis was not possible. A summary of available prices is given in Table 2. Further details of the costs used for each technology that was able to be included in the economic model are provided in Section 4.2.1.10.2.

Table 2. Technology costs

Technology	List price
Argus®	Upfront cost of £10,000.00 (excluding VAT) £2,000.00/year maintenance cost.
CAD EYE®	[redacted]
Discovery™	Upfront cost of £34,999.99 (excluding VAT). First year maintenance is included in upfront cost; thereafter, £2,265.00/year maintenance cost.
EMIS™	[redacted]
ENDO-AID™	£29,916.00 (including VAT) First year maintenance is included in upfront cost; thereafter, £3,189.00/year maintenance cost.
EndoScreener®	Subscription: £9,750/year (excluding VAT), waived after four years
GI Genius™	Upfront purchase: £42,000 including three years of maintenance. Subscription: £1,750/month including maintenance (including VAT).
MAGENTIQ-COLO™	Upfront purchase: €30,000 including one year of maintenance. Subscription: €1,000/month including maintenance (excluding VAT)

Abbreviations: AI, artificial intelligence; EMIS™, Endoscopic Multimedia Information System; VAT, value-added tax.

The intervention technologies are designed to be used as an adjunct to standard colonoscopy; therefore, all interventions additionally incur the costs of a standard colonoscopy (diagnostic or therapeutic as appropriate), as laid out in Section 1.2.2.

2 Definition of the decision problem

2.1 Decision problem

The decision problem outlined in the National Institute for Health and Care Excellence (NICE) final scope and the External Assessment Group (EAG)'s final protocol, and any deviations between this and the decision problem addressed by the EAG in this report,[25, 59] are outlined in the subsections that follow.

2.1.1 Interventions

The following 11 technologies, which are artificial intelligence (AI) technologies that provide computer-aided polyp detection (CADe) and/or computer-aided characterisation (CADx) functions, are listed in the NICE final scope for this assessment:

- Argus® (Endosoft);
- CAD EYE® (Fujifilm Healthcare UK Ltd.);
- CADDIE™ (Odin Vision);
- Discovery™ (Pentax Medical UK);
- ENDO-AID™ (Olympus Medical Systems Corp.);
- ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.);
- Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC., previously EndoMetric Corporation);
- EndoScreener® (Wision AI);
- GI Genius™ (Medtronic);
- MAGENTIQ-COLO™ (MAGENTIQ-EYE);
- WISE VISION® (NEC Corporation).

As noted in Section 1.3.1, WISE VISION® is no longer included in this assessment given it is no longer available to the National Health Service (NHS). There were no other deviations from the NICE final scope or protocol in terms of the technologies covered by this report, but the EAG notes that the evidence for some technologies is more limited than that for others, with studies identified for each technology outlined in Section 3.2.1. Furthermore, CADDIE™ and ENDOANGEL® could not be

included in the economic analysis, since no cost was provided by the manufacturers. More details of these interventions are presented in Appendix 9.1.

2.1.2 Population including sub-groups

The population relevant to this assessment is any patient undergoing a colonoscopy. The NICE final scope outlines that, where data permits, subgroups based on the following subgroups should be considered:

- Referred for colonoscopy through the NHS bowel cancer screening programme (BCSP);
- Referred for colonoscopy for investigation of symptoms suggestive of colorectal cancer (CRC);
- Referred for surveillance colonoscopy because of a hereditary risk of CRC;
- Referred for surveillance colonoscopy because of inflammatory bowel disease (IBD);
- Referred for surveillance colonoscopy post-polypectomy or post-CRC resection.

No deviations from the NICE final scope in terms of inclusion of studies in this assessment report are noted (all included studies are within a colonoscopy population). However, the EAG notes that the availability of data for certain populations is limited; for example, most studies excluded people with IBD, those with familial adenomatous polyposis (FAP) or other conditions such as Lynch syndrome, and those with prior CRC (see Section 3.3.2 of this report and Section 4 of the Diagnostic Assessment Report [DAR] supplement) and it was difficult to construct subgroups based on the subgroups outlined above given studies were often mixed colonoscopy populations or did not fall well into these categories (see Sections 3.1.5.2 and 3.2.2.1.12).

2.1.3 Relevant comparators

The comparator relevant to this assessment, as outlined in the NICE final scope,[25] is colonoscopy without the use of AI technologies to support polyp detection or characterisation. The EAG accepted any definition of this in the trials identified, which usually aligned with advice received from the EAG's clinical experts that this would typically be high-definition (HD) white-light endoscopy (WLE), with or without the use of adjunct technologies or methods such as dye-based chromoendoscopy (DCE), virtual chromoendoscopy (VCE) or ENDOCUFF VISION™.

2.1.4 Outcomes

The outcomes covered in the NICE final scope, and the availability of data for these outcomes as covered in this report are summarised in 3.1.5.1 and Appendix 9.3. The EAG notes that most data were identified for CADe in the form of detection-based outcomes such as impact on adenoma detection rate (ADR) and adenomas per colonoscopy (APC). Some data were available for other outcomes in the CADe setting, such as impact on surveillance intervals, but this was less common. CADx data were available but mostly for CAD EYE® and GI Genius™, with fewer studies identified and limited overlap between them. CADx data were mostly in the form of diagnostic accuracy against histology as the reference standard, although some data on impact on surveillance intervals and incidence that the technology did not function were available. As expected in the final protocol, no data were available for longer-term outcomes such as mortality, morbidity other than immediate adverse events (AEs) and health-related quality of life (HRQoL), or for potential impact on waiting lists.[59]

2.1.5 Key issues

Various potential issues were noted in Section 2.7 of the EAG's final protocol. Concerns about the potential impact of endoscopist skill and experience on the usefulness of AI technologies in colonoscopy were noted by the EAG's clinical experts and at the scoping workshop for this assessment. The EAG has explored this where possible via subgroup analyses, but it notes that subgroup analyses were difficult to construct and evidence from the literature is still considered to be too limited to support conclusions surrounding this issue (Sections 3.1.5.2 and 3.2.2.1.13).

A concern about algorithms within the AI technologies not being developed, trained or validated on data from people with IBD or hereditary risk factors was raised, meaning there is concern about how well they will perform in these populations. The EAG notes that the reporting of training data for these AI technologies in studies as well as in manufacturer submissions is very limited. It has summarised populations for which there is limited evidence in Section 3.3.2, but it notes that populations such as those with IBD and hereditary risks or polyposis syndromes are not well covered, although some studies for Lynch syndrome specifically are available for certain technologies. The impact of technologies in different colonoscopy indication populations has been explored to some extent through subgroup analyses (to assess whether AI is consistent across these populations), but the EAG considers evidence is too limited to draw robust conclusions (Sections 3.1.5.2 and 3.2.2.1.12).

Impacts of the technologies on workforce and capacity were also highlighted, as it is possible that increased polyp detection with AI technologies may lead to increased polypectomies and increased workload for gastroenterologists and histologists. Conversely, it is possible that the CADx functionality might reduce the number of polypectomies and/or number of polyps sent for histology, if used alongside a polyp management strategy such as "diagnose-and-leave" or "resect-and-discard" (see Section 4.2.1.4.1). The EAG outlined in its protocol that it anticipated indications in the estimated change in numbers of colonoscopies, polypectomies and those related to histopathology would be captured as part of economic modelling. Impact of waiting times was also noted as important to capture if the data permitted; in this assessment, this was captured through an exploratory analysis described in Section 4.2.1.11.

Further risks or issues highlighted either in the NICE final scope/final EAG protocol or feedback from the EAG's clinical and/or patient experts included:

- The risk of overreliance on AI, endoscopist deskilling and hacking;
- Potential variation in the versions of the technology used within clinical trials;
- Limited availability of data for longer term outcomes such as mortality, morbidity and HRQoL.

The risk of overreliance on AI and subsequent endoscopist deskilling was mentioned by the EAG's clinical experts and is also highlighted as a concern in 2019 guidance from The European Society of Gastrointestinal Endoscopy (ESGE).[46] This was also a concern that arose from one of the studies reporting endoscopist opinion before and after use of GI Genius™ (Section 3.2.2.1.7). While it is difficult to assess whether and to what extent this may occur with use of these technologies, the EAG notes that all manufacturers stress the importance of using these technologies alongside endoscopist judgement and that they should not replace endoscopist judgement. Emphasising this point in any recommendations made and including training on this issue may help to alleviate some of this concern, but may not remove the risk of overreliance completely as it could be dependent on individuals.

Hacking is also mentioned in the ESGE 2019 recommendations as a potential concern.[46] The EAG is unable to comment robustly on this risk, but notes that within all manufacturer submissions, it was highlighted that they either do not require patient data to be uploaded to centralised or online

storage, or that only anonymised data may be stored, with the exception of ENDOANGEL® and EndoScreener® for which no submission was received.

Issues surrounding potential differences in versions of the technology are discussed in Section 3.3.2 and the EAG confirms the lack of data for longer term outcomes such as mortality, morbidity and HRQoL from trials included in this assessment, as noted in Sections 2.1.4 and 3.2.2.1.10.

2.2 Overall aims and objectives of the assessment

The purpose of this assessment is to address the following question: "Does the addition of AI-supported colonoscopy technologies to colonoscopy represent a clinically- and cost-effective use of NHS resources?". This has included a systematic literature review (SLR) to identify clinical effectiveness, diagnostic accuracy and safety data on AI-supported colonoscopy technologies compared to standard colonoscopy (Section 3), as well as a review of existing economic analyses and original health economic work through adaptation of an existing economic model to meet the needs of this assessment (Section 4).

3 Assessment of clinical effectiveness

3.1 Method for reviewing effectiveness

The External Assessment Group (EAG) performed a systematic literature review (SLR) of the clinical effectiveness of specific artificial intelligence (AI)-supported colonoscopy technologies, including technologies with computer-aided detection (CADe) and/or computer-aided characterisation (CADx) functionalities (see Section 2.1.1 for a list of included technologies). The aim of the SLR was to identify and include relevant evidence related to clinical effectiveness, diagnostic accuracy, safety and other outcomes outlined in the decision problem (see Section 2.1.4). No additional searches for clinical data for the purpose of economic modelling, for example data informing natural history or progression of disease, were deemed necessary as this information was identified from other sources (as outlined in Section 4.2). The SLR was designed to identify evidence on all 11 interventions initially included in the National Institute for Health and Care Excellence (NICE) final scope,[25] but data relating to WISE VISION® have since been removed from the report given it is no longer available to the National Health Service (NHS; see Section 1.3.1).

3.1.1 Identification of studies

Systematic searches of MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL) and the Cochrane Database of Systematic Reviews (CDSR), as well as grey literature sources including trial registries, conferences and health technology assessment (HTA) databases, were conducted by the EAG. Searches were not limited by study design or language and were designed to pick up randomised as well as non-randomised studies. When designing search strategies, previously published SLRs in this area were reviewed to support identification of relevant terminology. In this regard, the Health Technology Wales (HTW) Evidence Appraisal Report on AI-assisted endoscopy for gastrointestinal cancer was a particularly useful resource.[43] Based on discussions with clinical experts and a review of other SLRs in the area, including the aforementioned HTW report,[43] searches in MEDLINE, Embase, CENTRAL and CDSR were limited to 2010 onwards given these technologies have emerged after this date. Search strategies were designed and produced by one reviewer, with draft strategies for MEDLINE and Embase validated by a second reviewer.

Searches were performed in September 2024 and updated in June 2025, including an opportunity for companies to submit unpublished data. Furthermore, in July 2025, a National Institute for Health and Care Research (NIHR)-funded trial (Nationwide study of Artificial Intelligence in Adenoma

Detection [NAIAD]) provided unpublished data to the EAG for consideration in the review.[60] Preliminary, unpublished results from a second NIHR-funded trial involving the CADDIE™ technology (FORE AI trial) were also provided to the EAG in September 2025;[61] there was insufficient time to formally include this trial in the review and analysis but the EAG also considers the results from this non-randomised, retrospective application of the CADDIE™ technology to be more limited than the two existing RCTs already included for this technology (CADDIE and EAGLE trials) in terms of CADe and CADx functionalities, meaning its omission is not considered to be a limitation of this review. An overview of this study is provided in Section 3.2.1.3.

De novo MEDLINE, Embase, CENTRAL and CDSR searches were performed, with search terms including terms for colonoscopy combined with terms for AI, using a combination of free-text searches and subject headings. Free-text searches for individual product names were also included in these searches, without the need to be combined with other terms for colonoscopy or AI. MEDLINE and Embase searches included lines to exclude animal studies from the search results. For the update in June 2025, date limits were added with the aim of capturing only records added to the databases since the last searches were performed. Furthermore, a correction of an error identified in the MEDLINE search was made in the update search in June 2025 (see footnote of Table 45). Full search strategies for these databases in the original and update searches are presented in Appendix 9.2.1.

Searches for MEDLINE and Embase were performed separately via Ovid, and searches of CENTRAL and CDSR were performed separately via the Cochrane Library. Records from each of these four searches were imported into the freely available version of Rayyan software in September 2024 where they were deduplicated against one another by one reviewer.[62] This process was repeated in June 2025 during the update, with new records also deduplicated against existing records in Rayyan.

Searches of grey literature sources were also performed to identify relevant studies not indexed in the databases searched and to identify ongoing studies. The sources described in the subsections that follow were searched by a single reviewer.

3.1.1.1 Clinical trial/systematic review registries

The following clinical trial and systematic review registries were searched:

- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP);
- Clinicaltrials.gov;

- PROSPERO.

The EAG's search strategy for WHO ICTRP and Clinicaltrials.gov are presented in Appendices 9.2.2 and 9.2.3, respectively, including for the original and update searches. The search strategy for PROSPERO is presented in Appendix 9.2.4; it was identical to the MEDLINE search strategy other than:

- The "sentiment analysis" Medical Subject Headings (MeSH) term could not be located in PROSPERO;
- No search lines to exclude animal studies were included;
- A date limit was not applied;
- An error (described in the footnote of Table 45) in the original MEDLINE search strategy (line 46 of the MEDLINE strategy mistakenly combines line 45 with line 22, whereas the intention was to combine line 45 with line 15) was corrected.

Searches during the update in June 2025 included date limits with the aim of focusing on new records since the original searches.

3.1.1.2 Conference proceedings

The following conference proceedings were searched as part of the original review in September 2024 or the update in June 2025:

- American Society of Clinical Oncology (ASCO) conference abstracts 2022, 2023 and 2024;
- American Association for Cancer Research (AACR) conference abstracts 2022, 2023 and 2024;
- European Society for Medical Oncology (ESMO) conference abstracts 2022 and 2023 (2024 had not occurred at the time of searches taking place);
- European Association for Cancer Research (EACR) Congress abstracts 2022, 2023 and 2024;
- British Society of Gastroenterology (BSG) Annual Meeting/BSG Live abstracts 2022, 2023 and 2024;
- World Congress of Gastrointestinal (GI) Endoscopy (ENDO) abstracts 2022 and 2024;
- Digestive Disease Week (DDW) conference abstracts 2022, 2023, 2024 and 2025;
- European Society of Gastrointestinal Endoscopy (ESGE) Days conference abstracts 2022, 2023, 2024 and 2025;

- The European Society of Coloproctology (ESCP) Annual Conference abstracts 2022,2023 and 2024;
- Asian Pacific Digestive Week (APDW) conference abstracts 2022, 2023 and 2024.

During the June 2025 update, a review of any new ASCO, AACR, ESMO and EACR conferences since September 2024 was not prioritised, given the low yield of relevant abstracts from these cancer-specific conferences in the first search.

3.1.1.3 Health technology assessment bodies

The websites of the following HTA bodies were searched for relevant appraisals, with any relevant studies within these appraisals crosschecked against studies already identified from searches of databases and other sources:

- International Network of Agencies for Health Technology Assessment (INAHTA) Database;
- National Institute for Health and Care Excellence (NICE);
- Scottish Intercollegiate Guidelines Network (SIGN);
- Health Technology Wales (HTW);
- Canada's Drug Agency (CDA-AMC; formerly Canadian Agency for Drugs and Technologies in Health [CADTH]).

For the update searches in June 2025, the inclusion of a date filter was only possible for the INAHTA database and only by year, rather than exact date. Search strategies for these sources are outlined in Appendix 9.2.5.

3.1.1.4 Other sources

Other sources of completed or ongoing studies included the following, which were reviewed in September 2024 and again in June 2025:

- Manufacturer submissions and websites – for manufacturers participating and supplying a submission, the EAG reviewed these submissions for mentions of published and ongoing clinical trials relating to the technologies and considered them for inclusion in the review. Manufacturer websites were also reviewed with the same aim;
- US Food and Drug Administration (FDA) website – the term "colonoscop*" was used to search the FDA website for any relevant records relating to this assessment.

- Reference lists of included papers and of relevant SLRs were reviewed to identify any additional studies that may have been relevant for inclusion in the review.

3.1.2 *Inclusion and exclusion criteria*

Inclusion and exclusion criteria for the SLR are detailed in Table 3 below. Following deduplication, remaining abstracts were screened in duplicate by two independent reviewers in Rayyan software to assess relevance for inclusion in the full text screening stage of this review.[62] Full text screening was performed in duplicate using Microsoft Excel®. At title and abstract and full text screening stages, conflicts between reviewers were resolved following discussions; the involvement of a third reviewer was available but was not required.

As outlined in the protocol for this assessment,[59] the rationale for certain decisions around the exclusion or prioritisation of studies is as follows:

- Only including autonomous AI data when there are no other studies reporting equivalent data for adjunct use of the AI – it is intended that AI technologies will be used in conjunction with endoscopist experience rather than relying on their results alone, which is also emphasised by many of the manufacturers. Studies using the technologies in this way, therefore, better reflect how they will be used in clinical practice and the results of them are more applicable to this situation;
- Excluding studies where the AI technology is applied *ex vivo* to videos or images from colonoscopies – studies of this kind will not capture the impact of the colonoscopy environment on outcomes of using the technology (such as time pressures) or interactions between the technology and the endoscopist that would occur during a colonoscopy. For example, suggestions made by AI technology in real-time may prompt endoscopists to investigate particular areas in more detail. Furthermore, ESGE guidance in 2019 was that for incorporation of AI technology into colonoscopy procedures, *in vivo* evidence should be available.[46]

Table 3. Inclusion and exclusion criteria of the clinical SLR

Factor	Inclusion criteria	Exclusion criteria
Design	RCTs or non-randomised studies were permitted, including single-arm studies if identified for studies reporting diagnostic accuracy data. Studies must have applied the AI technologies to colonoscopies in real-time rather than applying to videos or photographs of colonoscopies that had previously occurred as this best reflects the way in which they will be used in clinical practice. For studies where the focus was not on diagnostic accuracy data (e.g. they focused on outcomes such as ADR or APC rather than reporting sensitivity or specificity data), non-randomised studies were only included if there were no RCTs for that particular intervention and population for key outcomes. An exception to this was the results from the NAIAD trial, which were provided to the EAG and included in the discussion as supportive evidence, given that it is a fairly large non-randomised trial conducted within a UK setting at multiple NHS centres. Conference abstracts were only considered for inclusion where information was not available from any full text publications for an intervention, population or key outcome.	While SLRs and MAs were included up until full text screening to allow reference lists to be searched for relevant primary studies, the reviews themselves were excluded after this had taken place. Studies applying AI technologies to videos or photographs rather than live colonoscopies were excluded (i.e. *ex vivo* rather than *in vivo*).
Population	Any human population undergoing colonoscopy.	Animal studies and human populations not undergoing colonoscopy are excluded.
Interventions*	The following AI-supported colonoscopy technologies prespecified in the NICE final scope have been included:[25] • Argus® (Endosoft); • CAD EYE® (Fujifilm Healthcare UK Ltd.); • CADDIE™ (Odin Vision); • Discovery™ (Pentax Medical UK); • ENDO-AID™ (Olympus Medical Systems Corp.); • ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.); • Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC., previously EndoMetric Corporation); • EndoScreener® (WISION AI); • GI Genius™ (Medtronic); • MAGENTIQ-COLO™ (MAGENTIQ-EYE); • WISE VISION® (NEC Corporation).	Any alternative AI-supported colonoscopy technologies not listed in the NICE final scope have been excluded from this review. Evidence for the AI technology used as an adjunct to endoscopist judgement was prioritised; if evidence for key outcomes from at least one study per intervention and population was identified, studies reporting results for AI when used alone (autonomous AI) were excluded, as adjunct use aligns with how the technologies are expected to be used in clinical practice.

	They could be used with or without the use of VCE, dye-based chromoendoscopy or ENDOCUFF VISION™.	When a diagnostic accuracy study compared adjunct AI use with an autonomous AI group, only the adjunct AI group was included in the report.
Comparators	Colonoscopy performed without the use of AI-supported colonoscopy technologies (i.e. standard colonoscopy). This could be with or without the use of VCE, dye-based chromoendoscopy or ENDOCUFF VISION™. Diagnostic accuracy studies did not necessarily need to have a relevant comparator arm to be included.	Any other comparator.
Reference standards (diagnostic accuracy studies)	For diagnostic accuracy studies of CADe (i.e. for polyp detection) and CADx (i.e. for polyp characterisation), the most relevant reference standards are considered to be: • CADe – standard colonoscopy; • CADx – histology. Other reference standards could be considered where available and if data using the preferred reference standard was scarce.	NA
Outcomes	Outcomes listed in the NICE final scope,[25] alongside examples of specific outcomes matching these in the included studies, are presented in Table 57.	Studies with no outcomes falling into categories of outcomes listed in NICE final scope.[25]
Other	No limits on language were applied. For one study that was open access, Google Translate was used to facilitate understanding of the paper to assess inclusion.	NA

*WISE VISION® studies were eligible for inclusion at the time of the review but have since been removed from the report given the discussion in Section 1.3.1.

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided characterisation; EAG, External Assessment Group; MAs, meta-analyses; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NICE, National Institute for Health and Care Excellence; RCT, randomised controlled trial; SLR, systematic literature review; VCE, virtual chromoendoscopy.

3.1.3 Data abstraction strategy

Data for each included study were extracted by a single reviewer into standardised data extraction templates, with validation of extractions performed by a second reviewer and discrepancies resolved by discussion. A third reviewer was available in the event of unresolved discrepancies but this was not required. Study design details, baseline characteristics and details on patient disposition were extracted into Microsoft Excel® templates and outcome data were extracted into Microsoft Word® templates. Templates for data extraction and complete data extracted from included studies are not

included here (a summary of key information is presented in Section 4 of the Diagnostic Assessment Report [DAR] supplement) but can be provided on request. As well as outcome data, information relating to study design, colonoscopy procedure requirements, the AI technology used, comparator details, reference standards (where applicable), participant characteristics, funding sources and participant disposition were extracted.

A large number of outcomes tended to be reported in each study, for example, as well as key performance indicators such as overall adenoma detection rate (ADR) being reported by most studies, many studies also reported ADR broken down by size, location and morphology categories, with similar observed for many other detection-based outcomes. The EAG took a comprehensive approach to outcome extraction and extracted any data fitting outcome categories in the NICE final scope.[25] As described further in Section 3.1.5, given the large number of outcomes, some prioritisation in terms of analysis was required due to time constraints and in order to focus the report and facilitate decision-making; the EAG consulted with specialist committee members on this project to ensure that the most useful outcomes reported in studies from their perspective were included in this report. For subgroup data, in line with the NICE final scope and the final protocol for this assessment, the EAG only reported subgroup data for different colonoscopy indication populations and different levels of endoscopist experience or expertise, however it happened to be defined in each trial.[25, 59]

Data were preferentially extracted for the intention-to-treat (ITT) populations where reported. Data on adverse events (AEs) were limited and were extracted as reported in each study. Raw data and unadjusted or adjusted effect estimate data were extracted from studies; for non-diagnostic accuracy studies, raw data were used where possible in analyses given there were no concerns about the need to use adjusted data from the randomised controlled trials (RCTs) included and not all studies reported adjusted data (see Section 3.1.5). Authors of studies were contacted for any missing information that would be useful for analysis as well as to ask whether any information was available for colonoscopy indication population subgroups if not already reported. This information has been incorporated where possible, but if there was no response it has been assumed that it is not available.

While the EAG noted in its protocol that it would include information on sensitivity and specificity of technologies when tested in validation datasets of images or videos where reported by included studies, this was ultimately not considered useful as it was rarely reported in studies and, where it

was reported, different values were cited given different validation datasets were used. Furthermore, given these validations are not reflective of how the technologies are intended to be used in UK clinical practice (as they are based on images and videos rather than during a real-time colonoscopy), the EAG considered this information would not add value to the information already included in this report.

3.1.4 Critical appraisal strategy

For full-text publications, study quality was assessed by a single reviewer and validated for agreement by a second reviewer, with discussion of any disagreements. A third reviewer was available to resolve outstanding disagreements if needed, but this was not required. Risk of bias was assessed for each study at the study level, with the assessment based on the primary outcome defined in each trial. RCTs focusing on non-diagnostic accuracy data were assessed using Version 2 of the Cochrane risk of bias tool for randomised trials (RoB 2).[63] The quality of diagnostic accuracy studies was assessed using QUADAS-2.[64] An overview of the quality assessment at the study level for each study is presented in Section 3 of the DAR supplement.

For three non-randomised studies, the only relevant data were from a questionnaire delivered to clinicians and/or patients. A list of limitations associated with these outcomes from these studies were collated rather than a formal quality assessment, as a suitable checklist could not be identified.[53, 65, 66] Quality assessment of any abstracts included was not performed given very little information is available on which to base critiques; these abstracts should be considered to be at a higher risk of bias and uncertainty given the limited information that is available from them; this included data for the single Argus® study included (see Section 3.2.1.1), as the additional information identified in the instructions for use manual did not include further methodological details compared to the abstract.[67, 68] The EAG also took the same approach for data provided by the manufacturer as part of the June 2025 update for an Endoscopic Multimedia Information System (EMIS™) trial, as very limited details about the study and results were provided.[69] Furthermore, the EAG explored the use of the ROBINS-I checklist to assess the risk of bias of the included non-randomised NAIAD trial,[60, 70] but considered that there was not enough information provided to be able to complete this robustly, and most of the domains would have been marked as unclear. Therefore, the EAG also considers the data provided from this trial to be at a higher risk of bias.

3.1.5 Methods of data synthesis

3.1.5.1 Outcome prioritisation

A summary of outcomes for each outcome category listed in the NICE final scope that were prioritised for analysis following discussions with specialist committee members, is presented in Table 57 of Appendix 9.3.

As part of the prioritisation process, the EAG listed detection and procedural outcomes extracted from studies that it thought should be prioritised and deprioritised and asked specialist committee members to suggest others that might be deprioritised, or to indicate whether any deprioritised outcomes should be prioritised instead. Following this, the EAG took the comprehensive approach of including all outcomes suggested to be a priority by at least one committee member in the main DAR or a separate DAR supplement, unless it was only prioritised by one committee member and the rationale provided was not specifically related to the use of AI technologies. Where an outcome was not prioritised by most specialist committee members but where there was considered sufficient rationale to include it in the report, it has been included.

Detection and procedural outcomes that are key to the EAG's economic model, were highlighted by the specialist committee members as key or that were reported by a large number of included studies have been prioritised in the main report (Section 3.2.2.1.1), while others have been included in the DAR supplement. Most extracted outcomes have been included in the report or supplement, with the exception of some that were rarely reported or that were not thought to provide additional useful information when discussed with specialist committee members overall. These exceptions were:

- the proportion of patients with at least two adenomas;
- total number of neoplastic lesions, sessile serrated lesions (SSLs) and hyperplastic polyps (as a combined outcome) divided by the number of excisions;
- outcomes broken down by morphology (for example, non-polypoid vs polypoid);
- adenoma miss rate (AMR) broken down by visible/invisible on initial colonoscopy.

Various types of outcomes have been extracted under the, "measures of ability or accuracy to detect polyps or cancer" outcome listed in the NICE final scope.[25] Detection rate outcomes (such as ADR) are usually calculated by dividing the number of patients with at least one of the specific polyp types by the total number of colonoscopies performed. Per colonoscopy outcomes, such as adenomas per

colonoscopy (APC), are calculated by dividing the total number of polyps of a specific type identified across all colonoscopies by the total number of colonoscopies performed. Outcomes such as AMR, which are obtained from tandem studies and are calculated by dividing the total number of adenomas identified on the second colonoscopy (and therefore missed on the first one) by the total number of adenomas identified in both colonoscopies, are also reported.

Diagnostic accuracy data were scarcely reported for studies looking at the impact of AI technologies on polyp detection (CADe) but some studies do report this with the reference standard being unclear, or others report limited information such as false positives (areas flagged by AI as a lesion but not deemed to be one on endoscopist review). This is not unexpected given it is difficult to obtain an appropriate reference standard to calculate these measures given that standard colonoscopy is currently the gold standard for polyp detection. However, a number of studies reported diagnostic accuracy data for polyp characterisation (CADx) for certain interventions.

Data for procedural outcomes such as withdrawal time and total procedural time were identified and considered relevant for inclusion under the, "Measures related to healthcare resource use" category outlined in the NICE final scope.[25] There were also some data considered appropriate for "number of polyp removal procedures", "incidences that the technology does not function", "impact on decision making" and "ease of use/acceptability of the technologies to healthcare professionals" outcomes listed in the NICE final scope; however, these were reported by only a handful of studies at most and in some cases reported in different ways across studies. No relevant outcome data were identified to inform mortality or health-related quality of life (HRQoL).

A number of studies included in the report covered the acceptability of AI use in colonoscopy to patients. In addition, the EAG received expert input from a patient representative regarding the use of AI technologies and general concerns about colonoscopy, and a submission from Bowel Cancer UK was received. This information has been discussed in Section 3.2.2.1.9. The only data related to morbidity that was identified was the reporting of AEs, which was most often immediate procedural AEs only and most studies reported that there were "no complications" in both trial arms (see Section 3.2.2.1.8).

3.1.5.2 Data synthesis

As outlined in the final protocol, data have been analysed or reported separately for each intervention listed in the protocol with no pooling of data for different interventions. Summary data

extraction tables are presented in Section 4 of the DAR supplement, with results of analyses presented in Section 3.2.2.1 of this report or in the DAR supplement. A summary of included studies is provided in Section 3.2.1.

For analyses of non-diagnostic accuracy data, such as data from RCTs comparing dichotomous (e.g. ADR) or continuous (e.g. APC) outcomes, meta-analyses have been performed for each intervention in Review Manager.[71] On review of the included studies, the EAG considers that there is a high likelihood of clinical and methodological heterogeneity within the trials (for example, based on differences in populations included, adjunct technologies used and endoscopist experience or expertise). Therefore, random effects models have been preferred for the analyses. For GI Genius™, results from the non-randomised NAIAD trial have been considered alongside the RCT meta-analyses, given the difference in study design and risk of bias,[60] rather than meta-analysing both together. While most non-randomised studies were excluded if data were available from RCTs for the same outcomes, the EAG considered it important to discuss the results of this trial given it is a fairly large study in a UK setting across multiple NHS centres; it is not included in the economic model given the EAG's preference for RCT data, but it is discussed as a supportive source of evidence in Section 3.2.2.1.10.

Furthermore, the EAG's main analyses for these outcomes exclude studies considered to be at high risk of bias unless no other studies were available for a particular intervention OR the study at high risk of bias covered a population that was not well covered in studies at a lower risk of bias (such as patients with inflammatory bowel disease [IBD]). This approach of excluding studies at a higher risk of bias is in line with guidance in Section 7.6.2 of the Cochrane Handbook for Systematic Reviews of Interventions version 6.5.[72] This led to the exclusion of six RCTs from the main analyses across interventions, but sensitivity analyses with these studies included have been performed (see Section 3.2.2.1.14).[2, 73-77] Where these studies reported outcomes not covered by any other studies, the data has been included in the report. Scholer *et al.* 2024 and Gong *et al.* 2020 have also been listed as suitable inputs for colonoscopy indication subgroups in the economic model,[2, 75] given no other studies provided data for the symptomatic colonoscopy indication for CAD EYE® and ENDOANGEL® interventions (see Appendix 9.8).

Dichotomous outcomes have been presented as risk ratios (RRs), unless event rates in the whole study were <1.0%, in which case Peto odds ratios have been used. For AEs, it was often the case that zero events in both study arms were reported; Forest plots for AEs have been presented using risk

difference given estimates are not calculable for RRs or Peto odds ratios for studies with zero events in both arms. Outcomes reported as continuous measures, for example means with standard deviations (SD) for each trial arm have primarily been analysed as a continuous outcome, with mean differences used as the effect measure. For APC, an additional analysis for each intervention was performed, with it analysed as an incidence rate ratio (IRR). This was performed as it was identified as a suitable input for a scenario in the economic model (see Section 4.2.1.6). Calculation of the IRR requires the total number of adenomas across all colonoscopies to be divided by the total number of colonoscopies in each arm. The EAG used this information to calculate rate ratios using the MedCalc tool.[78] Where these data were not available, either an unadjusted IRR reported in the paper was used in the meta-analysis, or the total number of adenomas were estimated by multiplying the mean per colonoscopy value in each treatment arm by the number of colonoscopies, which was then used to calculate an IRR. Due to time constraints, this additional analysis was only performed for the APC outcome and not for other similar outcomes such as polyps per colonoscopy or sessile serrated lesions per colonoscopy.

Some studies had multiple arms that met the criteria for inclusion under intervention (AI-supported colonoscopy) and/or comparator (standard colonoscopy) colonoscopies outlined in the NICE final scope.[25] For example, one study included two CAD EYE® groups and two standard colonoscopy groups (one with and one without the use of ENDOCUFF VISION™) and another study covering ENDO-AID™ was similar.[79, 80] In these cases, outcome data from the separate arms were combined into a single CADe arm and a single standard colonoscopy arm, as the use of ENDOCUFF VISION™ is possible within UK clinical practice, although it may be variable (see Section 1.2.2). This was done by totalling events and number analysed for dichotomous outcomes and through use of an online calculator that is based on formulae and methods reported in Sections 6.2.9, 6.5.2.10 and 23.3.4 of the Cochrane Handbook for Systematic Reviews of Interventions for continuous outcomes.[72, 81]

Raw data from RCTs have been included in meta-analyses rather than adjusted or unadjusted effect estimate data where reported, given there were no major concerns about using unadjusted data from RCTs and it was more commonly reported than adjusted data. Where raw data were not reported but effect estimates such as RR with 95% confidence intervals (CIs) were, the generic inverse variance method was used to ensure all studies could be included in meta-analyses of the same outcome for each intervention. For tandem studies reporting outcomes such as ADR or APC, data for the first randomised intervention only was included in the meta-analyses as this better aligns with the parallel non-tandem studies, and also aligns with the approach in the HTW report.[43]

The EAG's main analyses were performed within the whole/mixed colonoscopy population regardless of endoscopist experience; as prespecified in the final protocol, subgroup analyses based on colonoscopy indication population and endoscopist experience and expertise were performed.[59] For colonoscopy indication, the EAG's approach was to report any within-trial subgroup analyses however they had been reported in the trial, as well as to separate whole studies into specific subgroups based on which indication most patients within each trial were categorised under. Additional analyses where whole studies categorised based on the majority were combined with within-trial subgroup data for studies that reported it were also explored, as were variations of these analyses where only studies with >80% of participants falling into a specific category were included. Categories included were loosely based on those included in Table 1 of the NICE final scope but had to be adapted in some cases given studies often separated populations in a different way. Further details of the categories used in the subgroup analyses are provided in Section 3.2.2.1.12.

For endoscopist experience and expertise subgroup analyses, the EAG reviewed the various ways that individual studies defined experience or expertise and proposed some potential strategies for exploring via subgroup analyses. These were then reviewed by specialist committee members as part of this appraisal and any feedback was used to add to or alter the way in which they were explored. The following approaches were considered by the EAG for each intervention, although it should be noted that many were not feasible for many interventions given the limited number of studies or the limited variation in terms of colonoscopy indications covered within a specific intervention:

- Any analyses performed within individual trials regarding expertise or experience to be reviewed;
- Comparison between colonoscopies performed by screening-accredited endoscopists and those without this accreditation (if reported by studies);
- Separation of studies including only non-trainees, only trainees or a mix of trainees and non-trainees (as defined in the study);
- Separation into expert/experienced and non-expert/less experienced based on the definitions used within each trial (for example, some studies may define experienced endoscopists as those with >2,000 colonoscopies while others might have a lower threshold or use a different factor to define experience);
- Separation of studies based on baseline ADR of the endoscopists participating – a threshold of 40 to 50% or 45% was suggested by two specialist committee members as useful for

separating between Bowel Cancer Screening Programme (BCSP)-level endoscopists and non-BCSP endoscopists.

A similar approach to using whole studies and within-trial subgroup data, as well as exploring whole studies categorised based on the majority and where >80% were within a certain subgroup, was followed where data allowed. More details on the subgroup analyses for endoscopist experience are provided in Section 3.2.2.1.13.

In reality, subgroup analyses for population and endoscopist experience/expertise were difficult to construct and to interpret; specialist committee members themselves noted that subgroup analyses for endoscopist experience were likely to be difficult given the variation between studies and it was rarely possible to separate studies in the most clinically useful way, which may be based on a baseline ADR threshold of 40% before study enrolment, given this is likely to separate screening and non-screening endoscopists (Section 3.2.2.1.13). The wide variation in methods to define experience or expertise, and the different ways of separating populations for colonoscopy indication subgroup analyses, coupled with the fact that there was often only one or two studies within each category means the EAG considers these analyses to be exploratory. The EAG prioritised ADR and APC for subgroup analyses as these were usually the most commonly reported outcomes across interventions.

Sensitivity analyses for specific meta-analyses were performed were deemed necessary, for example where data from two studies of a trial had been combined into a single arm this was explored and where there was a concern about a study given its comparator was slightly different to other studies. Sensitivity analyses including studies at high risk of bias were also explored, as the default was to exclude them. Due to time constraints, sensitivity analyses were explored for ADR and APC outcomes only. These data are presented in Section 3.2.2.1.14.

Data that could not be meta-analysed are reported narratively and/or in tables throughout the report. This included quantitative data such as data reported as medians or means, or as means without a measure of variance, qualitative data such as clinicians' thoughts on the usefulness of AI technologies or other data that only applied to the AI colonoscopy arm, such as incidence that it did not function.

Furthermore, no meta-analyses of diagnostic accuracy data were performed by the EAG. Diagnostic accuracy data were scarcely reported for CADe but for CADx there were some studies reporting

data, particularly for CAD EYE® and GI Genius™ technologies. However, on review of the studies in terms of population, outcomes reported, analysis methods and use of the AI technology (i.e. adjunct or autonomous), the EAG considered that the overlap was too limited; there are large concerns about heterogeneity and the meta-analysis of these data is not considered to be robust or meaningful at this stage. Instead, the EAG has reported CADx diagnostic accuracy data from each study separately in Section 3.2.2.1.2 and Section 1.13 of the DAR supplement. The following observations contributed to the EAG's concerns about heterogeneity:

- Population included – some included anyone undergoing colonoscopy while others required the presence of at least one polyp of a specific type (e.g. at least one diminutive rectosigmoid polyp);
- Analysis methods – some included high- and low-confidence diagnoses in the analysis while others only included high-confidence diagnoses, and SSLs were treated differently in different analyses (i.e. adenomatous in some, non-adenomatous in others, or excluded completely);
- Overlap of outcomes within interventions was limited – in most cases only two studies for the same intervention and outcome were available, with the only category with more than this being an analysis where AI is used autonomously rather than as an adjunct, which does not align with the expected use of the technology in clinical practice.

3.2 Results

3.2.1 Quantity and quality of research available

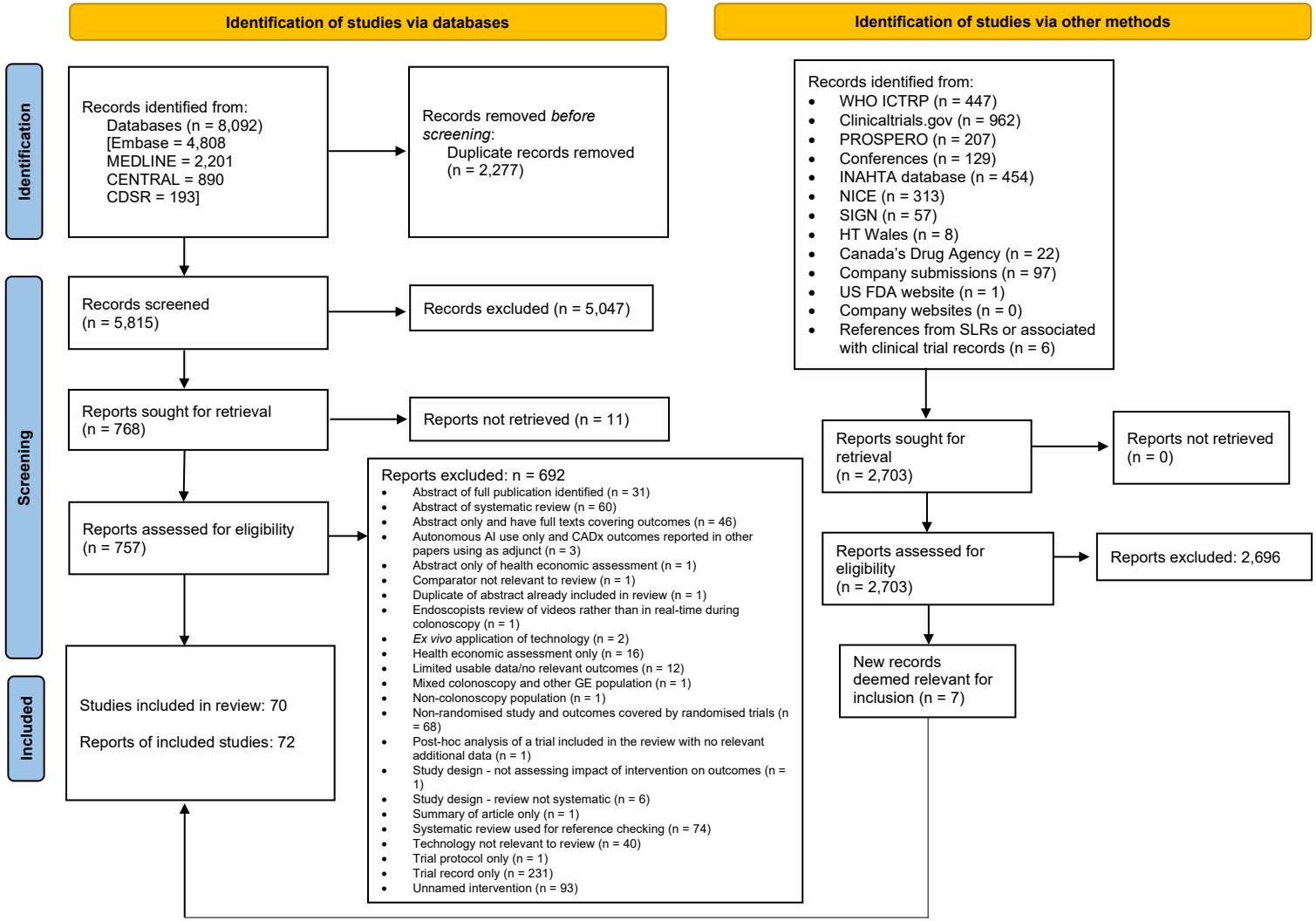
A Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow diagram outlining the identification, inclusion and exclusion of records at different stages of the clinical SLR process is presented in Figure 2. The EAG conducted the original database searches on 4 September 2024 and updated these searches on 11 June 2025. Across the original and update searches, a total of 8,092 records were retrieved, with 5,815 records screened in the title and abstract review after deduplication. Of these, 768 records were carried forward into the full text assessment stage of this review. After full text assessment, 65 records (reporting on 65 separate studies) identified from database searches were included in the review after WISE VISION® records had been excluded; 11 records were not retrieved either because they could not be retrieved or it was concluded from a later review of the abstract or a short preview of the article that it was not likely to be relevant to

the review, and 692 records were excluded. Records excluded from the database searches are presented in Section 5 of the DAR supplement, along with the rationale for exclusion.

Of note, three studies were ultimately excluded as they reported data for AI technologies when used autonomously and other studies covered the same outcomes for these technologies when used as an adjunct to endoscopist judgement.[82-84] This preference in terms of a hierarchy of evidence was specified in the review protocol.[59] In addition, in line with the review protocol,[59] 68 non-randomised studies were excluded given randomised trials covering the same outcomes were identified. Trial records and SLRs were used as a way of identifying publications for inclusion in the review but were excluded at the full text stage of the assessment (at the extraction stage, trial records were checked for included studies to identify any useful additional information).

Grey literature searching led to the identification of 2,703 records overall, which were reviewed by a single reviewer. This led to the inclusion of only 7 additional records (once WISE VISION® papers were excluded) given the vast majority had either already been identified through database searching, were trial records only with no associated publications or they were deemed not to be relevant or not a priority for inclusion in the review. Of these, 1 was from searches of conference proceedings and 6 were from manufacturer submissions (2 published abstracts, 2 clinical study reports provided by the manufacturers, 2 documents provided by the manufacturers providing preliminary results and limited additional information for a published abstract identified in the instructions for use provided by the manufacturer). Overall, a total of 70 studies (from 72 records) were included in the review after the exclusion of WISE VISION® records.

Figure 2. PRISMA flow diagram of records included in the clinical systematic literature review



Abbreviations: AI, artificial intelligence; CADx, computer-aided characterisation; CDSR, Cochrane Database of Systematic Reviews; CENTRAL, Cochrane Central Register of Controlled Trials; FDA, US Food and Drug Administration; GE, gastroenterology; HT Wales, Health Technology Wales; INAHTA, International Network of Agencies for Health Technology Assessment; NICE, National Institute for Health and Care Excellence; PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses; SIGN, Scottish Intercollegiate Guidelines Network; SLR, systematic literature review; WHO ICTRP, World Health Organization International Clinical Trials Registry Platform.

The following rules were applied in terms of prioritisation of studies for inclusion, as outlined in the review protocol,[59] assuming they matched the decision problem in terms of population, intervention, comparator and outcomes:

- All RCTs identified were included;
- Non-RCTs were only included for diagnostic accuracy outcomes or if they reported other outcomes not covered by RCTs (the exception being the NAIAD trial which provided data to the EAG and is a fairly large trial in a UK setting involving multiple NHS centres);
- Abstracts were only included if they reported outcome data that were not reported in any full text publication or if they covered a population or technology not well represented in full text publications;
- Trial records and SLRs were used as a way of identifying publications for inclusion in the review but were excluded at the full text stage of the assessment (at the extraction stage, trial records were checked for included studies to identify any useful additional information);
- Where outcomes were covered by studies using the AI technology as an adjunct to endoscopist judgement, studies (or specific outcomes from studies) using autonomous AI covering the same outcomes were not included.

Table 4 provides a brief overview of studies prioritised for inclusion in the clinical part of this assessment, broken down by each intervention, with a brief summary of evidence available for each intervention provided under the subheadings within this section of the report. Further details are presented in data extraction tables in Section 4 of the DAR supplement, including an overview of key baseline characteristics, inclusion and exclusion criteria and other comments on the studies. Studies that were excluded but that were highlighted by companies as being particularly useful, or were excluded because AI was used autonomously (with data for the same outcomes available from other studies using it as an adjunct to endoscopist judgement) or following removal of WISE VISION® from this report, are listed Section 5 of the DAR supplement.

Methods used for quality assessment are described in Section 3.1.4. An overview of the quality assessment at the study level for each study is presented in Section 3 of the DAR supplement, with broad comments on the quality of studies for each intervention made under the subheadings below. Overall, the EAG notes that most of the studies included for polyp detection were rated as having "some concerns" using the Cochrane risk of bias tool for randomised trials (RoB 2) tool.[63]

All studies had the common issue of being unblinded given the nature of the intervention requiring endoscopists to be aware of it, which the EAG considers may introduce some bias given decisions are likely to be affected by the technology. While the aim of AI technologies is to support endoscopist judgement, it is possible that different levels of reliance would be placed on AI and could introduce bias in some cases. Given the risk of bias associated with this is difficult to quantify, studies were not considered to be at a high risk of bias for this, particularly as it was clear in most studies that pathologists assessing histology were blinded to intervention assignment. Other concerns that were noted in multiple studies were concerns about randomisation, missing data, deviations from interventions and selection of the reported result, although these were most often only considered to be slight concerns if it was not considered likely to have a large impact.

A number of studies considered to be at a high risk of bias were identified. If these studies did not cover populations excluded from other trials, such as IBD, and where data were available for the same outcome from studies at a lower risk of bias, the EAG's approach was to remove these studies from the primary analyses and to explore the impact using sensitivity analyses with these studies included.[2, 73-76] Sensitivity analyses were performed for ADR and APC outcomes (Section 3.2.2.1.14). This is in line with guidance in Section 7.6.2 of the Cochrane Handbook for Systematic Reviews of Interventions version 6.5.[72] Where these studies reported outcomes not covered by any other studies, the data have been included in the report. For example, data from Scholer *et al.* 2024 and Gong *et al.* 2020 are not included in the main or subgroup ADR analyses,[2, 75] but have been listed as suitable inputs for the symptomatic subgroup in the economic model given a lack of other trials representing this subgroup for CAD EYE® and ENDOANGEL® interventions (see Section 9.8).

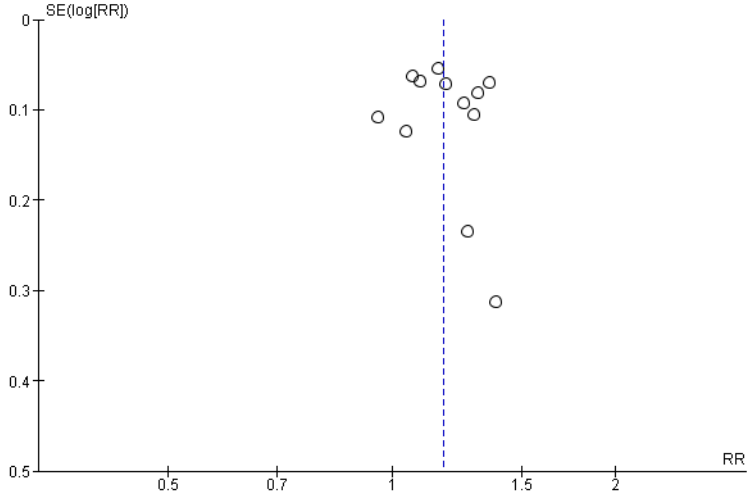
For CADx studies, there was only one included across all interventions with no concerns in terms of risk of bias based on QUADAS-2, with others having various limitations such as being used autonomously rather than as an adjunct to endoscopist experience, classification of SSLs as hyperplastic or non-adenomatous and/or inclusion of only diagnoses that were made with high confidence by the endoscopist with or without AI.

An additional concern for all studies, which was highlighted by the EAG's clinical experts and at the scoping workshop for this project, was the Hawthorne effect.[85] This is where the knowledge of being observed, for example as part of a clinical trial, can lead to a change in how someone performs something; in this case, it might lead to changes in how an endoscopist performs the colonoscopy, such as taking longer to complete the procedure and being more cautious than they might be in

normal clinical practice, potentially leading to higher ADRs (or other outcomes) than might normally be seen. However, it is also likely to impact both treatment arms in the RCTs, meaning it is unclear to what extent this may bias effect estimates.

A formal statistical assessment of publication bias was not performed for most meta-analyses in this assessment given it is recommended that tests for funnel plot asymmetry, used to assess publication bias, are not performed unless there are at least 10 meta-analysed studies (see Section 13.3.5.4 of the Cochrane Handbook for Systematic Reviews of Interventions version 6.5),[72] which was only the case for the ADR and APC (when analysed as an IRR) analyses for the CAD EYE® intervention; however, the denominator for the APC IRR analysis was number of polyps rather than number of patients, so the funnel plot for this outcome has not been reviewed for evidence of publication bias. There are 12 studies included in the CAD EYE® ADR meta-analysis. The funnel plot appears to be largely symmetrical with the exception of study spread in the lower section of the graph, as there is some representation on the lower right-hand side of the plot but not the lower left-hand side (Figure 3). However, the EAG considers this insufficient to make conclusions about whether or not publication bias is present and has commented further on the potential for publication bias based on methods used and trial records identified below.

Figure 3. Funnel plot for ADR outcome in CAD EYE® vs standard colonoscopy meta-analysis



Abbreviations: ADR, adenoma detection rate.

The EAG notes that the exclusion of data from conference abstracts unless no other data were available from full text publications for a particular outcome and intervention may increase the risk of publication bias to some extent; however, it considers this to be a necessary limitation in this assessment given the time constraints on the project and given data from abstracts are associated with fewer details in terms of methodology and would be considered to be at a higher risk of bias in this review (see Section 3.1.4). Conversely, this assessment permitted the inclusion of unpublished data submitted by manufacturers, for example, the data provided by Odin Vision for "CADDIE" and "EAGLE trials" of the CADDIE™ technology, which may reduce the risk of publication bias compared to systematic reviews relying solely on published data; however, it should be noted that it was up to manufacturers whether they provided any data from unpublished studies.

The EAG considers there may be some concerns about publication bias for this topic area based on a review of clinical trial records where a publication has not yet been identified. Of those that were due to complete by 2022 at the latest, the EAG identified at least 16 trial records that did not appear to have a publication associated with them as of January 2025; however, the EAG notes that there could be other reasons for this, such as trials being discontinued or trial numbers not being cited in publications. Despite this, the EAG considers it possible that publication bias is a risk associated with evidence in this topic area.

Table 4. Summary of studies prioritised for inclusion in the clinical review

Study (country, sites) – trial name CADe or CADx, Adjunct/autonomous	Population	Intervention*	Comparator*	Endoscopist experience	Study design	Reference standard (if applicable)
Argus® (Endosoft)						
CADe studies						
Strapko 2023[67, 68] (USA, single site) CADe, adjunct use	Adults undergoing screening, surveillance or diagnostic colonoscopy	Argus®-assisted colonoscopy (n=344)	Standard colonoscopy without Argus® (n=342)	Not reported	Parallel RCT Abstract + limited information from instructions for use manual only	NA
CADx studies						
None – not described as a function of Argus®						
CAD EYE® (Fujifilm Healthcare UK Ltd.)						
CADe studies						
Aniwan 2023[79] (Thailand, single site) CADe, adjunct use	Asymptomatic adults 50-75 years undergoing routine screening colonoscopy or following positive FIT	CAD EYE®-assisted colonoscopy (n=620)†	Standard HD colonoscopy using white light (n=625)†	7 staff attendings, 10 trainees. Average baseline ADR 33%.	Parallel RCT	NA

Desai 2024[86] (USA, 12 sites) CADe, adjunct use	≥45 years undergoing screening or surveillance colonoscopy for history of polyps (surveillance interval ≥3 years)	CAD EYE®-assisted colonoscopy (n=509)	Standard HD colonoscopy (n=522)	≥1000 colonoscopies, baseline ADR 25 to 40%	Parallel RCT	Histology (for some DA measures of CADe function)
Djinbachian 2024[87] (Canada, single site) CADe, adjunct use	45 to 80 years undergoing elective colonoscopy for screening, surveillance or diagnosis purposes	CAD EYE®-assisted colonoscopy with water exchange and caecal retroflexion (n=229)	Standard colonoscopy with no CAD EYE®, water exchange or caecal retroflexion (n=238)	Board-certified gastroenterologists (n=4) or trainees (n=1)	Parallel RCT	NA
Hiratsuka 2025[88] (Japan, single site) CADe, adjunct use	≥20 years scheduled for lower gastrointestinal endoscopy (screening, symptomatic and surveillance colonoscopies)	CAD EYE®-assisted colonoscopy (n=48)	Standard colonoscopy (n=46)	Expert (≥10 years' experience) and non-expert (<10 years' experience) endoscopists included. ~40% procedures performed by experts.	Tandem RCT	NA
Huneburg 2023[89] (Germany, single site) – CADLY trial CADe, adjunct use	≥18 years with LS and MLH1, MSH2 or MSH6 pathogenic germline variant with 10-36 months since last colonoscopy	CAD EYE®-assisted colonoscopy (n=50)	Standard HD white-light colonoscopy (n=46)	Experienced in LS endoscopic surveillance (>1000 total colonoscopies, >300 in LS patients)	Parallel RCT	NA

Miyaguchi 2024[90] (Japan, single site) CADe, adjunct use	≥20 years undergoing colonoscopy due to positive FIT, abdominal symptoms or for follow-up of colon polyps	CAD EYE®-assisted colonoscopy (n=400)	Standard HD colonoscopy with white-light imaging and LCI (n=400)	Experts and trainees, experts defined as >1000 colonoscopies and trainees as <1000 colonoscopies	Parallel RCT	NA
Nakashima 2023[3] (Japan, single site) CADe, adjunct use	21 to 81 years undergoing primary endoscopic screening for CRC, following a positive FIT of occult blood or patients with colorectal neoplasia undergoing endoscopic resection	CAD EYE®-assisted colonoscopy (n=207)	Standard HD colonoscopy with white-light imaging (n=208)	Experienced. Board-certified trainers of the Japan Gastroenterological Endoscopy Society or board certified fellow of the Japan Gastroenterological Society	Tandem RCT	NA
Rondonotti 2022[91] (Italy, 5 sites) - AIFIT trial CADe, adjunct use	50 to 74 years undergoing colonoscopy as part of CRC screening programme following positive FIT	CAD EYE®-assisted colonoscopy (n=405)	Standard HD white-light colonoscopy (n=395)	Qualified to work in FIT-based screening programme (≥300 colonoscopies per year, caecal intubation rate ≥95%, ADR ≥25%)	Parallel RCT	NA
Scholer 2024[2] (Sweden, 2 sites) CADe, adjunct use	40 to 90 years undergoing colonoscopy for cancer screening, alarm symptoms or other reasons such	CAD EYE®-assisted colonoscopy (n=98)	Standard HD white-light or LCI colonoscopy (n=95)	Experienced (≥400 prior colonoscopies) and inexperienced (<400 prior colonoscopies) endoscopists included	Parallel RCT‡	NA

	as positive faecal occult stool test, polyp surveillance, hereditary CRC and diarrhoea					
Tiankanon 2024[4] (Thailand, 3 sites) CADe, adjunct use	Asymptomatic, 50 to 75 years undergoing routine screening colonoscopy or screening following a positive FIT	CAD EYE®-assisted colonoscopy (n=400)	Standard HD white-light colonoscopy (n=400)	Baseline ADR ≥35% (from ≥100 prior screening colonoscopies in mixed population of primary colonoscopies and following positive FIT). Average baseline ADR was 42.6%. Includes attending physicians and fellows under supervision	Parallel RCT	NA
Yamaguchi 2024[92] (Japan, 3 sites) CADe, adjunct use	≥20 years scheduled for colonoscopy following positive FIT or for surveillance following colonic polypectomy	CAD EYE®-assisted colonoscopy (n=113)	Standard colonoscopy (n=118)	Performed by trainees (third/fourth year physician with up to 20 prior colonoscopies) back-to-back an expert (>5000 colonoscopies), who performed resections and could assist with insertion and performed observation separately to the trainee.	Parallel RCT with tandem procedures performed by experts	NA
Zimmermann-Fraedrich 2025[93] (Germany, 12 sites)	≥50 years undergoing screening	CAD EYE®-assisted	Standard colonoscopy (n=815)	Experienced examiners (not defined)	Parallel RCT	NA

CADe, adjunct use	colonoscopy (age cut-offs 50 years for men and 55 years for women) or diagnosis colonoscopy (including polyp follow-up and symptom evaluation)	colonoscopy (n=812)				
CADx studies						
Djinbachian 2024[5] (Canada, single site) CADx, adjunct use	45 to 80 years undergoing colonoscopy (screening, surveillance or diagnostic)	CAD-EYE®-assisted optical diagnosis (n=179 polyps)	NA – autonomous AI assessment reported in paper but not extracted given adjunct AI assessment prioritised from this paper	Between 1 and >30 years' experience with optical diagnosis. Procedural volume 300 and 1500 colonoscopies per year. All participated in previous optical diagnosis-based studies.	Parallel RCT	Histology
Li 2023[94] (Singapore, 4 sites) CADx, autonomous use	≥40 years undergoing colonoscopy for evaluation of clinical signs and symptoms, polyp surveillance or screening for CRC with at least one polyp detected	Autonomous CAD-EYE® optical diagnosis (n=661 polyps)	Endoscopist optical diagnosis alone (n=661 polyps)	Followed training programme involving use of image-enhanced endoscopy for polyp characterisation	Prospective non-randomised	Histology

Picardo 2023[95] (Australia, single site) CADx, autonomous use	IBD patients undergoing surveillance colonoscopy	Autonomous CAD-EYE® optical diagnosis (n=61 lesions)	Endoscopist optical diagnosis alone (n=61 lesions)	Not reported	Non-randomised Abstract only	Histology (resected) or expert consensus (non-resected pseudopolyps)
Rondonotti 2023[96] (Italy, 4 sites) – ABC trial CADx, adjunct use	18 to 85 years undergoing outpatient colonoscopy (symptoms, surveillance, FIT positive and primary screening) with at least one DRSP detected	CAD-EYE®-assisted optical diagnosis (n=550 DRSP)	Endoscopist optical diagnosis alone (n=540 DRSP)	Experts and non-experts included. Experts had undertaken specific training programme, had auditing and monitoring and performed optical diagnosis on regular basis according to ESGE curriculum.	Prospective non-randomised	Histology
Sato 2024[97] (Japan, 3 sites) CADx, adjunct use	20 to 85 years scheduled to undergo colonoscopy following positive FIT, for symptoms, screening or where endoscopist otherwise deemed a colonoscopy necessary	CAD-EYE®-assisted optical diagnosis (n=380 lesions)	Endoscopist optical diagnosis alone (n=380 lesions)	Experts (≥1500 colonoscopies) and non-experts (<1500 colonoscopies)	Prospective non-randomised	Histology
Taghiakbari 2025[98] (Canada, single site)	45 to 80 years undergoing outpatient colonoscopy	CAD-EYE®-assisted optical diagnosis (n=138 diminutive polyps	NA – no comparator assessment reported	Academic endoscopists with training and experience in CADx-assisted and	Prospective non-randomised	Expert video review – polyps resected and

CADx, adjunct use	(indications not reported)	resected and discarded or diagnosed and left)		CADx-unassisted optical diagnosis		discarded or diagnosed and left in place
Studies reporting CADe and CADx data						
Cassinotti 2023[99] (Italy, single site) CADe and CADx; adjunct for CADe, unclear if adjunct use for CADx	Patients with UC undergoing endoscopic surveillance	CAD EYE® + LCI/BLI (n=62; 113 lesions)	WLE and LCI as separate comparators (n=62; 113 lesions)§	Not reported	Non-randomised, prospective tandem study Abstract only	Histology for CADx function
Alali 2025[100] (Kuwait, single site) CADe and CADx, adjunct for CADe, unclear if adjunct use for CADx Note that data for CADx function was not eventually analysed as it was likely autonomous data and other studies using the technology adjunctly reported the same outcomes	≥45 years undergoing average-risk screening or surveillance colonoscopy	Detection: CAD-EYE®-assisted colonoscopy (n=51) Characterisation: CAD-EYE® use, unclear if adjunct to endoscopist judgement or autonomous (n=69 polyps)	Detection: Standard HDWL colonoscopy (n=51) Characterisation: standard HDWL colonoscopy with chromoendoscopy (n=52 polyps)	Experienced endoscopists (≥1000 colonoscopies)	Parallel RCT	Histology for CADx function
Zavyalov 2024[101] (Russia, possibly single site)	Colonoscopies, average 64.3 years (no further details)	Autonomous CAD-EYE® detection/optical diagnosis (n=154 polyps)	Standard colonoscopy/endoscopist optical diagnosis alone (n=87 polyps)	Not reported	Prospective non-randomised	Histology (CADx), unclear for CADe

CADe and CADx, possibly autonomous use for CADe and CADx						
CADDIE™ (Odin Vision)						
CADe studies						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Studies reporting CADe and CADx data						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Discovery™ (Pentax Medical UK)						
CADe studies						
Maas 2024 - Discovery™[104] (Canada, France, Germany, Italy, Netherlands, Russia – 7 sites) – DISCOVERY II trial CADe, adjunct use	≥18 years scheduled for non-iFOBT screening, surveillance or diagnosis colonoscopy	Discovery™-assisted colonoscopy (n=250)	Standard HD colonoscopy (n=247)	>2000 colonoscopies (500 was requirement)	Parallel RCT	NA
CADx studies						

Lopez-Serrano 2024[105] (Spain, single site) – CUDISIA trial CADx, adjunct use	≥18 years at risk of CRC undergoing surveillance colonoscopy for ulcerative colitis	Discovery™-assisted optical diagnosis (n=61 lesions)	VCE with iSCAN assessment optical diagnosis (n=61 lesions)	Endoscopists with extensive experience in DCE and VCE	Prospective non-randomised	Histology
ENDO-AID™ (Olympus Medical Systems Corp.)						
CADe studies						
Gimeno-Garcia 2023[106] (Tenerife, single site) CADe, adjunct use	≥18 years, including patients with colonoscopy for average-risk population screening, post-polypectomy surveillance, rectal bleeding, anaemia, familial CRC screening, change in bowel habits, chronic diarrhoea and suspicion of CRC	ENDO-AID™-assisted colonoscopy (n=185)	Standard HD colonoscopy (n=185)	High and low detectors included (ADR ≥40% and <40%, respectively), with >2000 lifetime colonoscopies	Parallel RCT	NA
Lau 2024[107] (Hong Kong, single site) – ENDOAIDTRAIN trial CADe, adjunct use	≥18 years undergoing elective colonoscopy for screening, surveillance or diagnostic purposes (i.e. symptoms)	ENDO-AID™-assisted colonoscopy (n=386)	Standard HD white-light colonoscopy (n=380)	Trainees (<500 procedures and <3 years' experience) with supervisors present on-site or next-door supervision (supervisors could alert trainees to missed	Parallel RCT	NA

				polyps and assist with caecal intubation and/or resection of polyps)		
Lui 2024[80] (Hong Kong, 2 sites) CADe, adjunct use	≥40 years undergoing elective colonoscopy for screening, surveillance or diagnostic workup	ENDO-AID™-assisted colonoscopy with or without ENDOCUFF VISION™ (n=468)‖	Standard HD white-light colonoscopy (n=214)	Range from 1 to 23 years' experience, historical ADR range 30 to 53%	Parallel RCT	NA
Spada 2025[108] (Italy, 2 sites) – ACCENDO-Colo trial CADe, adjunct use	40 to 85 years undergoing screening (opportunistic or immunological FOBT-based) or surveillance colonoscopy	ENDO-AID™-assisted colonoscopy (n=611)	Standard HD colonoscopy (n= 617)	Experienced endoscopists (>2000 examinations)	Parallel RCT	NA
Vilkoite 2023[73] (Latvia, single site) CADe, adjunct use	≥18 years referred for colonoscopy by the family doctor	ENDO-AID™-assisted colonoscopy (n=194)	Standard colonoscopy with NBI (n=206)	Average 2000 colonoscopy examinations per year between two endoscopists; 8- and 15-years' experience	Parallel RCT‡	NA
CADx studies						
None – not described as a function of ENDO-AID™						
ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.)						
CADe studies						

Gong 2020[75] (China, single site) CADe, adjunct use	18 to 75 years undergoing colonoscopy (for screening, clinical symptoms or surveillance)	ENDOANGEL® - assisted colonoscopy (n=355)	Standard colonoscopy (n=349)	Endoscopy experience of 1 to 3 years with total colonoscopies 1500 to 4000	Parallel RCT‡	NA
Yao 2022[109] (China, single site) CADe, adjunct use	≥18 years undergoing colonoscopy for screening, post-polypectomy surveillance or gastrointestinal symptoms	ENDOANGEL® - assisted colonoscopy (n=268)	Standard HD colonoscopy (n=271)	>2000 screening colonoscopies required	Parallel RCT	NA
Yao 2024[110] (China, 3 sites) CADe, adjunct use	>18 years undergoing diagnostic, screening or surveillance colonoscopy	ENDOANGEL® - assisted colonoscopy (n=227)¶	Standard HD white-light colonoscopy (n=229)¶	Novices (>1 year gastroenterology fellowship experience and no prior experience or training in colonoscopy) performed withdrawal phase (experts performed insertion; ≥5000 colonoscopies)	Tandem RCT	NA
Zhang 2023[76] (China, 3 sites) CADe, adjunct use	18 to 75 years undergoing colonoscopy for diagnosis or screening	ENDOANGEL® - assisted colonoscopy (n=643)	Standard colonoscopy (n=650)	At least 1 year experience and total volume of 100 colonoscopies	Parallel RCT‡	NA
CADx studies						

None – not described as a function of ENDOANGEL®						
Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC., previously EndoMetric Corporation)						
Data provided for EMIS™ trial by manufacturer in 2025[69, 111] (USA, 3 sites but data from single site only provided)	[redacted]	Colonoscopy with real-time feedback with EMIS™ [redacted]	Standard colonoscopy without real-time feedback [redacted]	Not reported	Parallel RCT**	NA
EndoScreener® (WISION AI)						
CADe studies						
Glissen Brown 2022[112] (USA, 4 sites) CADe, adjunct use	≥22 years undergoing colonoscopy for CRC screening or surveillance	EndoScreener® - assisted colonoscopy (n=113)	Standard HD white-light colonoscopy (n=110)	Experienced endoscopists with high baseline ADR (ADR in HDWL-first group was 44.0%)	Tandem RCT	NA

Liu 2020[113] (China, single site) CADe, adjunct use	14 to 90 years undergoing colonoscopy for any indication	EndoScreener® - assisted colonoscopy (n=393)	Standard HD colonoscopy (n=397)	Senior, mid-level and junior endoscopists included	Parallel RCT	NA
Wang 2019[114] (China, single site) CADe, adjunct use	Symptomatic or screening colonoscopies, mean age 50 years	EndoScreener® - assisted colonoscopy (n=522)	Standard HD colonoscopy (n=536)	Senior, mid-level and junior endoscopists included, defined based on number of prior colonoscopies (10,000+, 3000 to 10,000 and 100 to 500, respectively)	Parallel RCT	NA
Wang 2020 (effect of a deep…)[115] (China, single site) - CADe-DB trial CADe, adjunct use	18 to 75 years undergoing diagnostic or screening colonoscopies	EndoScreener® - assisted colonoscopy (n=484)	Standard white-light HD colonoscopy with sham CADe system (n=478)	Senior endoscopists with at least 5 years' experience and at least 1000 colonoscopies per year	Parallel RCT	NA
Wang 2020 (lower adenoma miss…)[116] (China, single site) CADe, adjunct use	18 to 75 years referred for diagnostic, screening or surveillance colonoscopy (prior polypectomy)	EndoScreener® - assisted colonoscopy (n=184)	Standard whit-light HD colonoscopy (n=185)	Experienced endoscopists from division of gastroenterology	Tandem RCT	NA
Wang 2023[117] (China, 4 sites) CADe, adjunct use	18 to 75 years undergoing symptomatic, screening or surveillance colonoscopy	EndoScreener® - assisted colonoscopy (n=636)	Standard white-light HD colonoscopy with observer assistance (n=625)	Endoscopists with >2000 colonoscopy screening performed procedures. In observer group, trainees were observers (100 to 500	Parallel RCT	NA

				procedures, qualified in colonoscopy)		
CADx studies						
None – not described as a function of EndoScreener®						
GI Genius™ (Medtronic)						
CADe studies						
Ahmad 2023[1] (UK, single site) – AI-DETECT trial CADe, adjunct use	60 to 74 years with positive FIT test within NHS BCSP, established history of adenomas attending for surveillance colonoscopy within BCSP or >55 years referred for colonoscopy due to large/multiple adenomas during screening flexible sigmoidoscopy	GI Genius™ - assisted colonoscopy (n=308)	Standard HD colonoscopy (n=306)	Endoscopists working at an NHS bowel cancer screening centre. Between 46 and 109 colonoscopies with ADR between 56 and 80%	Parallel RCT	NA
Engelke 2023[74] (Sweden, single site) CADe, adjunct use	≥18 years having colonoscopy for primary screening, post-polypectomy surveillance, tumour follow-up or work-up for GI symptoms such as bleeding, anaemia, IBD	GI Genius™ - assisted colonoscopy (n=122)	Standard HD colonoscopy (n=110)	Trained endoscopists (no further details)	Parallel RCT‡	NA

	(diagnostic colonoscopy)					
Karsenti 2023[118] (France, single site) – COLO-Genius trial CADe, adjunct use	≥18 years undergoing total colonoscopy	GI Genius™ - assisted colonoscopy (n=1003)	Standard colonoscopy (n=1012)	Endoscopists with >2000 prior colonoscopies	Parallel RCT	NA
Lagstrom 2025[77] (Denmark, 4 sites) CADe, adjunct use	≥18 years undergoing screening following a positive FIT (>100 µg/l), surveillance or diagnostic colonoscopy	GI Genius™ - assisted colonoscopy (n=400)	Standard colonoscopy (n=395)	Experts (>1000 colonoscopies) and non-experts (≤1000 colonoscopies) included	Parallel RCT‡	NA
Levartovsky 2023[119] (Israel, single site) CADe, adjunct use	Colonoscopies in patients with IBD (no further information)	Colonoscopies performed after incorporation of GI Genius™ (n=759)	Colonoscopies performed prior to incorporation of GI Genius™ (n=237)	Conducted at high-volume gastroenterology department	Retrospective Abstract only	NA
Mangas-Sanjuan 2023[120] (Spain, 6 sites) – CADILLAC trial CADe, adjunct use	≥18 years presenting for colonoscopy after positive FIT or for CRC screening	GI Genius™ - assisted colonoscopy (n=1610)	Standard HD colonoscopy (n=1603)	Endoscopist experience unclear, but all are screening colonoscopies	Parallel RCT	NA
Ortiz 2024[121] (Belgium, Germany, Italy, Spain – 17 sites) – TIMELY trial CADe, adjunct use	≥18 years undergoing surveillance colonoscopy for LS (germline variant in MLH1, MSH2, MSH6 or EPCAM)	GI Genius™ - assisted colonoscopy (n=214)	Standard white-light HD colonoscopy (n=216)	ADR ≥20% for screening colonoscopy and ≥35% following positive FIT required. Also required >2000 colonoscopies, and training in optical	Parallel RCT	NA

				diagnosis and chromoendoscopy techniques		
Pinto 2022[122] (Portugal, single site) CADe, adjunct use	Patients with LS undergoing screening colonoscopies (median age 50 years)	GI Genius™ - assisted colonoscopy (n=36)	Standard white-light HD colonoscopy (n=36)	Endoscopy expert (no further details)	Non-randomised, tandem procedures Abstract only	NA
Repici 2020[123] (Italy, 3 sites) – AID trial CADe, adjunct use	40 to 80 years undergoing colonoscopy for primary CRC screening, post-polypectomy surveillance or following a positive FIT	GI Genius™ - assisted colonoscopy (n=341)	Standard HD colonoscopy (n=344)	>2000 screening colonoscopies required. Centres involved in organised CRC screening programme	Parallel RCT	NA
Repici 2022[124] (Italy, Switzerland – 5 sites) – AID2 trial CADe, adjunct use	40 to 80 years undergoing colonoscopy for primary screening (outside regional screening programme), following positive FIT within screening programme, post-polypectomy surveillance and diagnostic	GI Genius™ - assisted colonoscopy (n=330)	Standard HD colonoscopy (n=330)	Non-expert (<2000 colonoscopies lifetime)	Parallel RCT	NA

	colonoscopy for signs/symptoms					
Scholer 2024[2] (Sweden, 2 sites) CADe, adjunct use	40 to 90 years undergoing colonoscopy for cancer screening, alarm symptoms or other reasons such as positive faecal occult stool test, polyp surveillance, hereditary CRC and diarrhoea	GI Genius™ - assisted colonoscopy (n=24)	Standard HD white-light or LCI colonoscopy (n=23)	Experienced (≥400 prior colonoscopies) and inexperienced (<400 prior colonoscopies) endoscopists included	Parallel RCT‡	NA
Seager 2024[125] (UK, 12 sites) – COLO-DETECT trial CADe, adjunct use	≥18 years undergoing planned colonoscopy for GI symptoms, surveillance after prior colonic pathology (polyps, CRC or any other than IBD), due to family history of CRC, or CRC screening	GI Genius™ - assisted colonoscopy (n=1015)	Standard HD colonoscopy (n=1017)	Median 10 years independent, 49.3% BCSP accredited	Parallel RCT	NA
Thiruvengadam 2024[126] (USA, single site) CADe, adjunct use	≥30 years with any colonoscopy indication	GI Genius™ - assisted colonoscopy (n=550)	Standard white-light HD colonoscopy (n=550)	At least 1000 colonoscopies required with baseline ADR ≥25%	Parallel RCT	NA

Wallace 2022[127] (USA, Italy, UK – 8 sites) CADe, adjunct use	≥45 years undergoing screening or surveillance colonoscopy for CRC	GI Genius™ - assisted colonoscopy (n=116)	Standard colonoscopy (n=114)	At least 1000 colonoscopies with ADR between 20 and 40% (or PDR between 30 and 70%)	Tandem RCT	NA
NAIAD trial[60] (UK – [redacted]) CADe, adjunct use	[redacted]	GI Genius™ - assisted colonoscopy [redacted]	Standard colonoscopy prior to GI Genius™ implementation [redacted] Standard colonoscopy after GI Genius™ withdrawn [redacted]	[redacted]	Non-randomised prospective observational trial	NA
CADx studies						
Baumer 2023[128] (Germany, single site) CADx, autonomous use	≥18 years presenting for a diagnostic colonoscopy or planned polypectomy as an inpatient or outpatient	Autonomous GI Genius™ optical diagnosis (n=262 polyps)	Endoscopist optical diagnosis alone (n=262 polyps)	Experience varied from <5 years to >10 years of experience	Prospective non-randomised	Histology
Bernhofer 2025[129] (Austria, single site) – AC-CADx trial CADx, adjunct use	≥18 years undergoing elective colonoscopy by a trainee endoscopist for any reason	GI Genius™ - assisted optical diagnosis (n=630 lesions)	NA – two comparator assessments reported but not relevant to review (autonomous AI	Trainee endoscopists (<500 colonoscopies and no formal optical diagnosis training). Support from experienced	Prospective non-randomised	Histology

			assessment and expert optical diagnosis based on videos only)	endoscopists where required for polypectomies.		
Koh 2024[130] (Singapore, single site) – CO-PILOT trial CADx, autonomous use	Not reported	Autonomous GI Genius™ optical diagnosis (n=616 lesions)	NA – no comparator assessment reported	Accredited trainees and specialists in the endoscopy unit (no further details)	Prospective non-randomised	Histology
Rondonotti 2024[131] (Italy, single site) CADx, adjunct use	18 to 80 years referred for colonoscopy for screening, symptoms or post-polypectomy surveillance and with detection of at least one DRSP	GI Genius™-assisted optical diagnosis (n=376 polyps)	NA – autonomous AI assessment reported in paper but not extracted given adjunct AI assessment prioritised from this paper	Experts and non-experts in optical diagnosis included. Experts defined as dedicated training, prior studies in optical diagnosis, periodical auditing and monitoring according to ESGE curricula. Met ESGE quality criteria and personal experience >300 colonoscopies	Prospective non-randomised	Histology
Hassan 2022[132] (Italy, single site) - CHANGE trial CADx, adjunct use	≥40 years undergoing colonoscopy for primary CRC screening, post-polypectomy surveillance,	GI Genius™-assisted optical diagnosis (n=544 polyps)	NA – autonomous AI assessment reported in paper but not extracted given adjunct AI assessment	Endoscopists >2000 screening colonoscopies, trained in optical diagnosis and participating in prior studies on polyp	Prospective non-randomised	Histology

	symptoms or signs, or following a positive FIT		prioritised from this paper	characterisation with BLI		
Endoscopist opinions on AI only						
Ladabaum 2023[133] (USA, single centre) Unclear if adjunct use or if specific to CADe or CADx (or both)	Participating colonoscopists surveyed after trying GI Genius™	Prior to GI Genius™ use (n=22 colonoscopists)	After GI Genius™ use (n=22 colonoscopists)	Not reported	Not reported Abstract only	NA
Nehme 2023[65] (USA, single centre) CADe, adjunct use	≥18 years undergoing elective outpatient colonoscopy	Prior to GI Genius™-assisted colonoscopy (n=45 clinicians)	Following Genius™-assisted colonoscopy (n=45 clinicians)	Board-certified attending gastroenterologists. Described as having high baseline ADR	Non-randomised	Histology
Olabintan 2025[134] (UK, unclear sites) Possibly CADe use only, adjunct use	Online survey distributed to endoscopists participating in NAIAD trial, which used GI Genius™ technology	n=89 endoscopists completed the survey	NA – no comparator, single group of clinicians received the same survey	Included gastroenterologists, surgeons and nurse endoscopists from UK participating in NAIAD trial	Qualitative online questionnaire Abstract only	NA
Seager 2024[135] (UK, 10 sites) – COLO-DETECT trial CADe, adjunct use	Medical endoscopists, nurse endoscopists, endoscopy nurses and endoscopy unit managers participating within the COLO-DETECT trial	Unclear how many clinicians completed the interviews	NA – no comparator, single group of clinicians took part in interviews	Medical endoscopists, nurse endoscopists, endoscopy nurses and endoscopy unit managers within the COLO-DETECT trial. May have had experience or not with	Semi-structured interviews within COLO-DETECT trial Abstract only	NA

				GI Genius™ during this trial.		
MAGENTIQ-COLO™ (MAGENTIQ-EYE)						
CADe studies						
Maas 2024 – MAGENTIQ-COLO™ [136] (Germany, Israel, Netherlands, USA – 10 sites) CADe, adjunct use	18 to 90 years scheduled for non iFOBT screening or surveillance colonoscopy with last colonoscopy at least 3 years prior	MAGENTIQ-COLO™ -assisted colonoscopy (n=449)	Standard HD colonoscopy (n=467)	ADR between 25 and 40% required	Parallel and tandem RCT	NA
CADx studies						
None identified, despite being listed as a function of the technology						
Endoscopist or patient perspective studies not specific to a particular technology						
Anderson 2024[137] (UK, 3 sites) CADe but unnamed technologies, unclear if adjunct or autonomous use	Endoscopists and unit managers involved in a non-randomised trial of three unnamed CADe systems	n=38 endoscopists and n=8 unit managers completed the survey	NA – no comparator, single group of clinicians took part in interviews	Endoscopists and unit managers	Survey delivered after use of CADe interventions Abstract only	NA
Burton 2025[53] (USA, unclear sites) No AI procedure received, surveying perceptions on AI in colonoscopy	Patients presenting for colonoscopy for any indication	n=112 patients surveyed about perceptions on AI prior to standard colonoscopy procedure	NA – no comparator, single group of patients completed survey	NA	Survey completed by patients prior to colonoscopy procedure	NA

Magahis 2023[138] (USA, single site) No AI procedures performed, surveying perceptions on AI in colonoscopy	First-, second- and third-year GI fellows at a large, urban, academic tertiary care centre	n=10 GI fellows completed the survey	NA – no comparator, single group of clinicians completed survey	GI fellows in first-, second- and third- year at tertiary academic centre	Cross-sectional study with online survey Abstract only	NA
Schmidt 2025[66] (USA, single site) No AI procedure received, surveying perceptions on AI in colonoscopy for polyp detection	Undergoing outpatient screening or surveillance colonoscopy	n=508 patients surveyed about perceptions on AI prior to standard colonoscopy procedure	NA – no comparator, single group of patients completed survey	NA	Survey completed by patients prior to colonoscopy procedure	NA

*n refers to the number of patients analysed, unless otherwise specified to be lesions analysed;

†Four separate groups with (n=308 CAD EYE®, n=315 without CAD EYE®) and without (n=312 CAD EYE®, n=310 without CAD EYE®) ENDOCUFF VISION™ reported but combined into two groups (CAD EYE®-assisted and standard colonoscopy) for the purpose of this analysis;

‡Study was considered to be at a high risk of bias and was not included in primary analyses in this assessment, unless it covered outcomes not covered by other studies;

§Kudo, NICE and Kudo-IBD classifications reported as comparators for diagnostic accuracy data;

‖The ENDOCUFF VISION™ + ENDO-AID™ (n=230) and ENDO-AID™ only (n=238) groups in this study were combined into a single ENDO-AID™ group for the purpose of this analysis;

¶Only the two novice groups (with and without ENDOANGEL®; n=227 and n=229) from this study were included in analyses in this assessment given the third group (expert endoscopists without ENDOANGEL®) is not comparable to either of the other two groups given the endoscopist experience differs and may introduce additional bias into results;

**While randomised in design, only data from one of three sites have been analysed in the preliminary data provided [redacted].

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; BCSP, Bowel Cancer Screening Programme; BLI, blue-light imaging; CADe, computer-aided detection; CADx, computer-aided characterisation; CRC, colorectal cancer; DA, diagnostic accuracy; DCE, dye-based chromoendoscopy; DRSP, diminutive rectosigmoid polyp; EMIS™; Endoscopic Multimedia Information System; EPCAM, epithelial cell adhesion molecule gene; ESGE, European Society of Gastrointestinal Endoscopy; FIT, faecal immunochemical test; FOBT, faecal occult blood test; GI, gastrointestinal; HD, high-definition; HDWL, high-definition white-light; IBD, inflammatory bowel disease; iFOBT, immunochemical faecal occult blood test; LCI, linked-colour imaging; LS, Lynch syndrome; MLH1, mutL homolog 1; MSH2, mutS homolog 2; MSH6, mutS homolog 6; NA, not applicable; NAIAD, Nationwide study of Artificial

Intelligence in Adenoma Detection; NBI, narrow-band imaging; NICE, National Institute for Health and Care Excellence; PDR, polyp detection rate; RCT, randomised controlled trial; UC, ulcerative colitis; VCE, virtual chromoendoscopy; WLE, white-light endoscopy.

3.2.1.1 Argus® (Endosoft)

Evidence identified for Argus® was very limited, with only a single abstract using this technology to support polyp detection identified.[67] Some additional data for the same study was identified from the instructions for use manual provided by the manufacturer,[68] which has been included as an additional record for this study. This study compares Argus® with standard colonoscopy via a parallel RCT in a mixed colonoscopy population (screening, surveillance or diagnostic colonoscopy), with limited details on methods reported and only ADR reported as an outcome. A number of other abstracts were highlighted in the manufacturer's submission, but these were not considered relevant to this assessment as they involved use of the technology on artificial colon structures (see Section 5 of the DAR supplement). Given that data were only available in abstract form and that no additional data on methods was available from the instructions for use document, this is considered to be at a high risk of bias.

3.2.1.2 CAD EYE® (Fujifilm Healthcare UK Ltd.)

CAD EYE® was one of the two technologies (alongside GI Genius™) with a relatively high number of publications identified for inclusion in this review compared to other interventions (21 studies). This included 12 studies (10 parallel RCTs and two tandem RCTs) assessing the CADe function,[2-4, 79, 86-93] six studies assessing the CADx function (five prospective non-randomised and one RCT),[5, 94-98] and three studies that assessed CADe and CADx functions (two prospective non-randomised and one parallel RCT; only CADe data from one of these were included given CADx data were autonomous, with other studies reporting the same outcomes when used as an adjunct instead).[99-101] For those reporting CADe data, 11 of the 12 studies were considered to have "some concerns" in terms of risk of bias, with a "high" risk of bias rating assigned to Scholer *et al.* 2024.[2] The latter was excluded from the primary analyses for CAD EYE® based on this. For studies reporting CADx data or CADe and CADx data, Djinbachian *et al.* 2024 was not considered to be at risk of bias.[5] The other included studies were at some risk of bias, due to reasons such as classification of SSLs as non-adenomas, inclusion of only high confidence diagnoses, unclear or questionable exclusions and/or use of the technology autonomously rather than as an adjunct to endoscopist experience. Autonomous data have been included only for outcomes not covered by studies using the technology as an adjunct technology. Zavyalov *et al.* 2024 was considered to be at a higher risk of bias in general given reporting of methods and results was very limited.[101]

Populations included varied across the studies, but most were mixed populations (for example, covering screening and surveillance colonoscopies, or screening, surveillance and diagnostic colonoscopies). Some studies were more specific, for example, focusing specifically on patients with Lynch syndrome or those with a positive faecal immunochemical test (FIT) test as part of a national screening programme. A large number of different outcomes were covered by these studies but these were mostly detection or diagnostic accuracy outcomes, with other outcomes in the protocol not covered.

Comparators for CADe studies were standard colonoscopy, which was often defined as white-light high-definition (HD) colonoscopy but details were sometimes limited. Whether or not other techniques such as use of a cap was permitted varied between studies and was often unclear. In one study, the intervention combined CAD EYE® with other exploratory techniques for polyp detection, including water exchange and caecal retroflexion, with the comparator being colonoscopy without any of these techniques.[87] For CADx, endoscopist optical diagnosis alone was reported as a comparator in most studies, with histology used as the reference standard. However, one study that assessed the accuracy of optical diagnosis in diminutive polyps that were not resected and sent for histology (trialling resect-and-discard and diagnose-and-leave strategies) differed as it used expert video review as the reference standard.[98] In cases where autonomous AI and adjunct AI groups were reported, data for the autonomous AI group were not analysed by the EAG, meaning no comparator was extracted if the study had not also reported an endoscopist optical diagnosis alone group.

Two abstracts were included to cover the IBD population, which was commonly excluded from studies published at the time of this review. Three of the nine studies with some CADx data involved autonomous use of the AI technology rather than as an adjunct to endoscopist judgement (it was unclear in a further two studies); these were included given no data for at least some reported outcomes were available from other studies using the technology as adjunct.

3.2.1.3 CADDIE™ (Odin Vision)

Evidence identified for CADDIE™ included two clinical study reports (CSR) provided by the manufacturer of this technology. One trial (EAGLE) assessed the CADe function only and the other (CADDIE) assessed the CADe and CADx functions and neither has been published as a full text publication yet.[102, 103] Both trials were parallel RCTs and used the technology as an adjunct to endoscopist judgement for CADx and/or CADe assessment.

[redacted]

[redacted] Both trials were considered to have "some concerns" in terms of risk of bias.

Outcomes covered for CADe were mostly detection and procedural outcomes during colonoscopy, [redacted]

As noted in Section 3.1.1, in September 2025, preliminary, unpublished data from the FORE AI trial covering the CADDIE™ technology were provided to the EAG.[61] This study was not considered for formal inclusion in the review given it arrived close to the submission of the report; however, the EAG considers this study to be associated with considerable limitations meaning it would not have been a key component of the report had there been sufficient time to include it. These limitations include the retrospective identification of CADe detections with the endoscopist blinded to these during the procedure, which is not reflective of how the technology would be used in clinical practice, and the non-randomised study design. Data from two RCTs (CADDIE and EAGLE trials) using the technology with endoscopist awareness of CADe output were already available and included in the review,[102, 103] which the EAG considers to be more robust and clinically relevant sources of information. A further limitation noted by the authors was that the FORE AI trial did not use the latest version of the CADDIE™ system, an issue which could apply to other trials included in this review (see Section 3.3.3). Nonetheless, a brief summary of this study and its results are described below.

FORE AI involved the retrospective use of CADDIE™ to analyse colonoscopy videos for CADe and CADx functions. It involved a subset of videos taken from participants in the CONSCOP2 RCT, which used HD white-light imaging (WLI) screening colonoscopies (with or without dye-based

chromoendoscopy). The CADe analysis involved an evaluation of [redacted] colonoscopy videos, with CADe detections reviewed retrospectively by Joint Accreditation Group (JAG)-certified endoscopists to confirm whether a polyp was detected and the CADe detection could be considered a true positive. Results for CADe were [redacted], with the use of CADDIE™ being associated with [redacted] compared to standard colonoscopy, with [redacted], outcomes which were not reported for the aforementioned RCTs. While [redacted], the differences between CADe and standard colonoscopy [redacted].

For CADx, a total of [redacted] resected polyps were analysed, with cancerous lesions and polyps that did not [redacted] excluded. Analysis for CADx was based on autonomous use of the technology for classifying into adenoma or non-adenoma polyps, which is a limitation given the technology would be used as an adjunct to endoscopist judgement in clinical practice. A total of [redacted] polyps were analysed based on endoscopist optical diagnosis alone, and histology was used as the reference standard for CADx and endoscopist diagnoses. Autonomous CADDIE™ had a negative predictive value (NPV) of [redacted] based on [redacted] diminutive rectosigmoid polyps (DRSPs) analysed, which was reported to be [redacted] endoscopists at [redacted] when analysing [redacted] DRSPs. Furthermore, in terms of surveillance interval assignment, CADDIE™ analysis led to [redacted] agreement with histology, with agreement being [redacted] for endoscopist assessment alone. The NPV results for DRSPs are [redacted] from FORE AI compared to the CADDIE RCT that also reported on the CADx functionality of CADDIE™, as results there suggested the NPV value for CADDIE™ was [redacted] NPV for endoscopist optical diagnosis alone ([redacted]. Surveillance interval agreement was [redacted] in the CADDIE trial compared to FORE AI, with values [redacted] for CADDIE™-assisted and endoscopist alone optical diagnosis. Given the limitations described by the authors themselves in FORE AI (retrospective analysis and autonomous use rather than in conjunction with the endoscopist), the EAG considers the CADx results from the CADDIE RCT are likely to be more robust and clinically relevant.

3.2.1.4 Discovery™ (Pentax Medical UK)

Two studies, one assessing CADe and the other CADx, for Discovery™ were identified, in the form of an RCT and prospective non-randomised study, respectively.[104, 105] The comparator for CADe was standard HD colonoscopy and for CADx it was compared to virtual chromoendoscopy (VCE) with iSCAN assessment for optical diagnosis, with histology used as the reference standard and the technology appearing to be used as an adjunct to endoscopist judgement. Detection outcomes, procedure duration outcomes and diagnostic accuracy data were covered by these studies, with other protocol outcomes not covered for this intervention. The CADe study had a broad population in terms of colonoscopy indication (non-immunochemical faecal occult blood test [iFOBT] screening, surveillance or diagnosis), while the CADx study was specific to those undergoing surveillance colonoscopy for ulcerative colitis. For the risk of bias rating, "some concerns" were noted for the CADe element. For diagnostic accuracy data, the EAG considers this study to be at some risk of bias given the reporting of what is considered to indicate neoplasia on the index test is unclear, and because it may not be relevant to this assessment given a role of CADx for Discovery™ was not outlined by the manufacturer (Table 44).

3.2.1.5 ENDO-AID™ (Olympus Medical Systems Corp.)

Only studies assessing ENDO-AID™ for assisting polyp detection were identified (no CADx function), with five parallel RCTs included in this review.[73, 80, 106-108] All five studies were broad in terms of indication for colonoscopy, including at least two of screening, surveillance and diagnostic colonoscopy categories or not specifying further than "colonoscopy referrals". Standard colonoscopy was the comparator and appeared to be white-light HD colonoscopy in most cases, although one study mentioned the use of NBI. Some permitted the use of add on devices or techniques while others did not, or reserved them only for characterisation. Detection outcomes and procedure duration outcomes, and some information on missed polyps or false positives, were covered by these studies, with other protocol outcomes not covered for this intervention. In terms of risk of bias, four studies were considered to have "some concerns", while Vilkoite *et al.* 2023 was considered to be at "high" risk of bias overall.[73] The latter was excluded from the primary analyses for ENDO-AID™ based on this.

3.2.1.6 *ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.)*

Four studies (three parallel RCTs and one tandem RCT) assessing ENDOANGEL® for assisting polyp detection (no CADx function) were included in this review.[75, 76, 109, 110] All four studies were mixed colonoscopy populations, with three covering screening, diagnostic and surveillance colonoscopies, and the fourth covering diagnostic or screening colonoscopies. Limited details for standard colonoscopy were often provided but two studies mentioned HD colonoscopy, with one mentioning white-light HD colonoscopy. Detection outcomes and procedure duration outcomes, and some information on missed polyps or false positives and impact on surveillance intervals were covered by these studies, with other protocol outcomes not covered for this intervention. Zhang *et al.* 2023 and Gong *et al.* 2020 were considered to be at "high" risk of bias,[75, 76] while only "some concerns" were noted for the other two studies. The two studies at high risk of bias were excluded from the primary analyses for ENDOANGEL®.

3.2.1.7 *Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC, previously EndoMetric Corporation)*

In the June 2025 update, EndoPerv LLC. provided the EAG with preliminary data from an EMIS™ trial, and additional information from a paper previously identified in the original database searches was paired with this information to support with data extraction on the components of the technology.[69, 111] Only very limited details were provided but the manufacturer confirmed that the data related to clinical trial record NCT05241210, with preliminary data from one of three sites provided. Despite being an RCT, the EAG notes that the manufacturer described [redacted], which have contributed to there being a [redacted] for the real-time feedback and no real-time feedback groups ([redacted]). It should be noted that the technology used in this specific trial is described as [redacted] This means it differs considerably to the other technologies included in this review.

Procedures were performed in patients undergoing [redacted]. Otherwise, there is almost no information on baseline characteristics, intervention and comparator details and study methods. Therefore, it has not been possible to perform a risk of bias assessment but the EAG has included the outcome data provided and considers this information to be at a high risk of bias. Of note, only data for ADR and ADR with inclusion of sessile and tubulovillous polyps are available, with some brief comments on endoscopist opinions on the technology, and the preliminary data provided are only from one of three sites that participated in the trial.

3.2.1.8 EndoScreener® (WISION AI)

Six studies (four parallel RCTs and two tandem RCTs) assessing EndoScreener® for assisting polyp detection (no CADx function) were included in this review,[112-117] all of which were considered to have "some concerns" in terms of risk of bias. All studies were mixed colonoscopy populations with slight variations between studies; three included either any colonoscopy indication or covered symptomatic/diagnostic, surveillance and screening colonoscopies, while the other three covered a combination of screening and surveillance colonoscopies or screening and symptomatic/diagnostic colonoscopies. Standard colonoscopy was reported to be HD in all studies, with white-light mentioned in most. Information on the use of additional devices or techniques was not reported in most cases, but some mentioned the use of chromoendoscopy once polyps had been detected. Detection outcomes and procedure duration outcomes, and some information on missed polyps or false positives and endoscopist fatigue levels, were covered by these studies, with other protocol outcomes not covered for this intervention.

3.2.1.9 GI Genius™ (Medtronic)

Alongside CAD EYE®, GI Genius™ was the other technology with a relatively large number of publications identified for inclusion in this review compared to other interventions (24 studies). This included 15 studies (three non-randomised [two prospective, one retrospective], eleven parallel RCTs and one tandem RCT) assessing the CADe function,[1, 2, 60, 74, 77, 118-127] five studies assessing the CADx function (all prospective non-randomised),[128-132], two studies that reported on endoscopist opinion before and after using the technology (non-randomised), and two studies that reported

endoscopist perceptions after having used GI Genius™ or not in UK-based NAIAD and COLO-DETECT trials[65, 133-135]

Of the CADe studies, nine were considered to have "some concerns", while six, including two abstracts, were considered to be at high risk of bias.[2, 60, 74, 77, 119, 122] Engelke *et al.* 2023, Scholer *et al.* 2024 and Lagstrom *et al.* 2025 were excluded from the primary analyses given they covered similar populations to most other studies, but information from Pinto *et al.* 2022 and Levartovsky *et al.* 2023 was retained, given they covered IBD populations, which were excluded from most studies. The remaining study at a high risk of bias was the NAIAD trial.[60] Data provided to the EAG were included in the review despite covering outcomes already covered by RCTs as it was a fairly large UK-based study of CADe outcomes before, during and after withdrawal of GI Genius™ in a large number of UK hospitals. While it has been included, the EAG considers the data from the RCT analyses for this intervention to be more robust, but has included it as a source of supportive evidence in Section 3.2.2.1.10. As discussed in Section 3.1.4, a formal quality assessment of this trial was explored but not performed given the limited details available to complete this accurately.

All five CADx studies had some possible risk of bias; Rondonotti *et al.* 2024 and Hassan *et al.* 2022 were a better match to the protocol in terms of representing adjunct use of the technology, but there were concerns about the classification of SSLs and the main analyses excluding low-confidence diagnoses. Bernhofer *et al.* 2025 also represented adjunct use of the technology, but it was specific to trainee endoscopists and information about how SSLs were treated in the analysis was also unclear. While Baumer *et al.* 2023 classified SSLs as adenomatous, it excluded polyps where no AI prediction could be made and represented autonomous rather than adjunct use. Similarly, Koh *et al.* 2024 used the technology autonomously and there are concerns about the limited information provided for patient selection and the exclusion of "no prediction" results from the analysis. Overall, Baumer *et al.* 2023 and Koh *et al.* 2024 are considered to be less relevant to the review given the autonomous use, but have been included for outcomes not covered by the other studies. The four studies reporting on endoscopist opinion were considered to be at high risk of bias.

Populations included varied across the studies, but most were mixed populations (for example, covering screening and surveillance colonoscopies, or a broader population of screening, surveillance and diagnostic colonoscopies). Some studies were more specific, for example, focusing specifically on patients with Lynch syndrome or those that would fall within the NHS BCSP. A large number of different outcomes were covered by these studies but these were mostly detection or

diagnostic accuracy outcomes, with some more limited information on outcomes such as acceptability to clinicians, false detections or missed lesions and impact on surveillance intervals.

Comparators for CADe studies were standard colonoscopy, which was often defined as HD colonoscopy (white light sometimes mentioned) but details were sometimes limited. One study mentioned the use of linked-colour imaging (LCI) as an alternative to white light during standard colonoscopy procedures depending on endoscopist preference and one retrospective study compared results from before implementation of GI Genius™ to after its implementation instead. Whether or not other techniques such as the use of a cap was permitted was often unclear but two studies noted that they could be used. Where reported, the use of techniques such as magnification or chromoendoscopy was only permitted for characterisation purposes once polyps had been detected.

For CADx, endoscopist optical diagnosis alone was reported as a comparator in one study. In the other four studies, a comparator was not extracted as part of this review either because one was not reported, there was only a comparison between adjunct GI Genius™ use and autonomous GI Genius™ use (the latter was not prioritised for inclusion in this review in the presence of adjunct data) or between trainee optical diagnosis with GI Genius™ during colonoscopy and expert optical diagnosis based on video review. Histology was used as the reference standard in all five CADx studies. Three of the five studies with some CADx data reported data for its use as an adjunct to endoscopist judgement, with the other two comparing autonomous use of GI Genius™ to endoscopist optical diagnosis alone or not including a relevant comparator; the latter were included given they covered at least one outcome not covered by the adjunct use studies.

The remaining four non-randomised, survey-based studies were included given they gave some (albeit limited) insight into endoscopist opinions on the technology before and after its use or following participation of clinicians in a GI Genius™-based trial. Three of these were abstracts and the other a full text publication that also reported on some detection outcomes (detection outcomes from this study were not included in the analysis given RCT evidence was available for these outcomes). One of the included CADe studies was also only an abstract; it was included as it covered Lynch syndrome, a population often excluded from other included studies, and also provided some diagnostic accuracy data not covered in a full text publication covering the patients with Lynch syndrome.

3.2.1.10 MAGENTIQ-COLO™ (MAGENTIQ-EYE)

Only a single study assessing MAGENTIQ-COLO™ for assisting polyp detection was included in this review,[136] which was considered to have "some concerns" in terms of risk of bias. This was an RCT that included four groups; two received only one of the two interventions and the other two groups received both assessments in a tandem process (one received MAGENTIQ-COLO™-assisted colonoscopy first and the other had standard colonoscopy first). Indications for colonoscopy in this study were those scheduled for non iFOBT screening or surveillance colonoscopy (with last colonoscopy at least 3 years prior). The comparator was reported to be standard HD colonoscopy and the use of distal devices was excluded. Detection outcomes and procedure duration outcomes were covered by this study but other protocol outcomes were not covered. No studies covering the CADx function, which is described as being a feature of this technology (Table 44 of Appendix 9.1), were identified.

3.2.1.11 Endoscopist or patient perspective studies not specific to a particular technology

An additional four studies that covered patient and/or endoscopist perspectives on AI use in colonoscopy but were either not specific to a technology or the technology was not named were included in the review to cover these outcomes. This included two clinician-based surveys, with one focusing on endoscopists and unit managers involved in a non-randomised trial of three unnamed CADe systems and the other surveying first-, second- and third-year gastrointestinal fellows at a large, urban, academic tertiary care centre where no specific technology had been used.[137, 138] The remaining two studies focused on patient perspectives, with surveys completed prior to colonoscopy procedures and procedures not involving the use of any AI technology. [53, 66]

The two clinician-based studies were only available as abstracts and considered to be at a high risk of bias. While the patient-based studies were available as full texts, a formal quality assessment was not performed as a suitable checklist could not be identified. Instead, a summary of the limitations associated with each of these studies was collated.

3.2.1.12 Ongoing studies

The EAG reviewed results from searches of clinical trial registries and statements in manufacturer submissions about ongoing clinical trials to identify ongoing trials that may be published in the next few years and would be relevant to this assessment. These are included in Table 58 of Appendix 9.4. Of records identified from clinical trial records, only those with a scheduled completion date from

2024 onwards are included unless otherwise mentioned by the manufacturer as an ongoing trial. Only those with relevant comparators are included here.

3.2.2 Assessment of clinical effectiveness

3.2.2.1 Critical review and synthesis of information

This section outlines the evidence available for each outcome listed in the NICE final scope; a table summarising results across interventions is presented for each outcome included in this DAR. More detail is provided per intervention, including Forest plots, for the key outcome of ADR given it is used in the economic model (see Section 4.2.1.6) and it is a key performance indicator in colonoscopy that has been linked to risk of interval colorectal cancer (CRC).[139] A similar level of detail for other outcomes included in this report has been included in a separate DAR supplement. The DAR supplement also contains a summary of results for other outcomes analysed as part of this assessment but that are not considered to be as clinically important or are reported more sparingly than those presented in the main report.

Table 57 in Appendix 9.3 outlines the outcomes from included studies that were prioritised for analysis and how they align with outcomes specified in the NICE final scope. It also outlines which outcomes have been prioritised for inclusion in the main report and which are included in a separate DAR supplement. A summary of risk of bias assessments across interventions is included in Section 3.2.1, with full risk of bias tables for each study presented in Section 3 of the DAR supplement.

3.2.2.1.1 Measures of ability or accuracy to detect polyps of cancer

3.2.2.1.1.1 Adenoma detection rate

ADR is the key outcome used in the economic model and was the most widely reported outcome across studies of all interventions, with some data available for all interventions for this outcome. It refers to the number of patients with at least one adenoma detected, of all patients undergoing colonoscopy. A higher ADR among endoscopists has been linked to a lower risk of interval CRC and this link is widely accepted within the colonoscopy field.[139] Results across interventions are summarised in Table 5 below and results per intervention are provided under relevant subheadings.

Table 5. Summary of analyses performed for ADR across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
Argus® (Endosoft)				
1 parallel RCT (abstract), 686 participants[67, 68]	144/344 (41.86 %)	130/342 (38.01%)	RR 1.10 (0.92 to 1.32)	• Single study • Abstract + instructions for use manual only, limited details to base quality assessment on (assume higher risk)
CAD EYE®				
12 RCTs (2 tandem, 9 parallel, 1 parallel with tandem procedures performed by experts), 7708 participants*[3, 4, 79, 86-93, 100]	1939/3844 (50.44 %)	1662/3864 (43.01%)	RR 1.17 (1.11 to 1.24)	• Some statistical heterogeneity suggested (I^2 = 28% and point estimates vary)
CADDIE™				
[redacted]	[redacted]	[redacted]	[redacted]	NA
Discovery™				
1 parallel RCT, 497 participants[104]	96/250 (38.40 %)	93/247 (37.65%)	RR 1.02 (0.81 to 1.28)	• Single study
Endoscopic Multimedia Information System (EMIS)™				
1 sequential RCT, [redacted] participants[69]	[redacted]	[redacted]	[redacted]	• Single study • [redacted]
ENDO-AID™				
4 parallel RCTs, 3046 participants†[80, 106-108]	889/1650 (53.88 %)	595/1396 (42.62%)	RR 1.25 (1.16 to 1.35)	NA
ENDOANGEL®				
2 RCTs (1 tandem, 1 parallel), 995 participants‡[109, 110]	104/495 (21.01 %)	77/500 (15.40%)	RR 1.36 (1.04 to 1.78)	NA
EndoScreener®				

6 RCTs (2 tandem, 4 parallel), 4663 participants[112-117]	716/2332 (30.70 %)	573/2331 (24.58%)	RR 1.24 (1.13 to 1.37)	NA
GI Genius™				
9 RCTs (1 tandem, 8 parallel), 10,913 participants (overall colonoscopy population)[§1, 118, 120, 121, 123-127]	2923/5452 (53.61 %)	2566/5461 (46.99%)	RR 1.18 (1.07 to 1.30)	• Substantial statistical heterogeneity suggested (I^2 = 83% and point estimates vary) • Results from the non-randomised NAIAD trial [redacted] (see Section 3.2.2.1.10)[60]
1 retrospective study (abstract), 996 participants[119] (IBD patients)	30/759 (3.95%)	15/237 (6.33%)	RR 0.62 (0.34 to 1.14)	• Single study • Retrospective comparison before and after introduction of technology • Abstract only, limited details to base quality assessment on (assume higher risk) • ADR noticeably lower in each arm compared to other studies across all interventions
MAGENTIQ-COLO™				
1 RCT (parallel and tandem arms), 916 participants[136]	167/449 (37.19 %)	138/467 (29.55%)	RR 1.26 (1.05 to 1.51)	• Single study

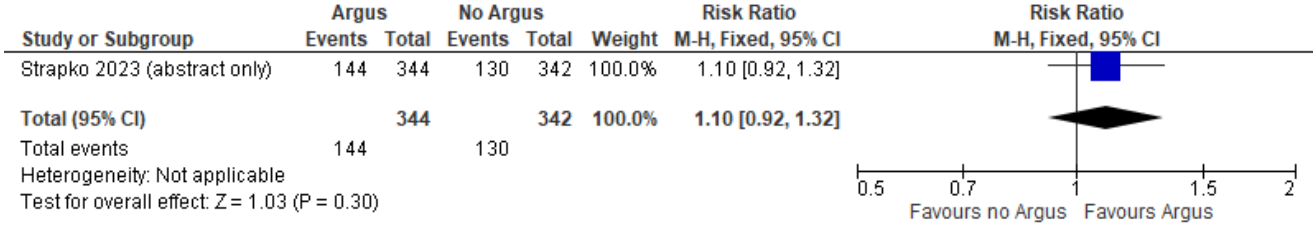
*Scholer *et al.* 2024 excluded from primary analysis due to high risk of bias[2]; †Vilkoite *et al.* 2023 excluded from primary analysis due to high risk of bias;[73] ‡Gong *et al.* 2020 excluded from primary analysis due to high risk of bias;[75] §Engelke *et al.* 2023, Scholer *et al.* 2024 and Lagstrom *et al.* 2025 excluded from primary analysis due to high risk of bias[2, 74, 77]

Abbreviations: ADR, adenoma detection rate; CADe, computer-aided detection; CI, confidence interval; IBD, inflammatory bowel disease; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial; RR, risk ratio.

Argus®

A single abstract reporting ADR for this technology was identified, covering screening, surveillance and diagnostic colonoscopies, with endoscopist experience not reported.[67, 68] As an abstract rather than a full publication, with minimal additional details available from the instructions for use manual also covering this study, this result is assumed to be at a high risk of bias given the limited information available (see Section 3.1.4). Results suggest a slight but non-statistically significant benefit of Argus®-supported colonoscopy (p-value 0.30), with a higher ADR in this arm compared to standard colonoscopy (Figure 4).

Figure 4. ADR in Argus® studies

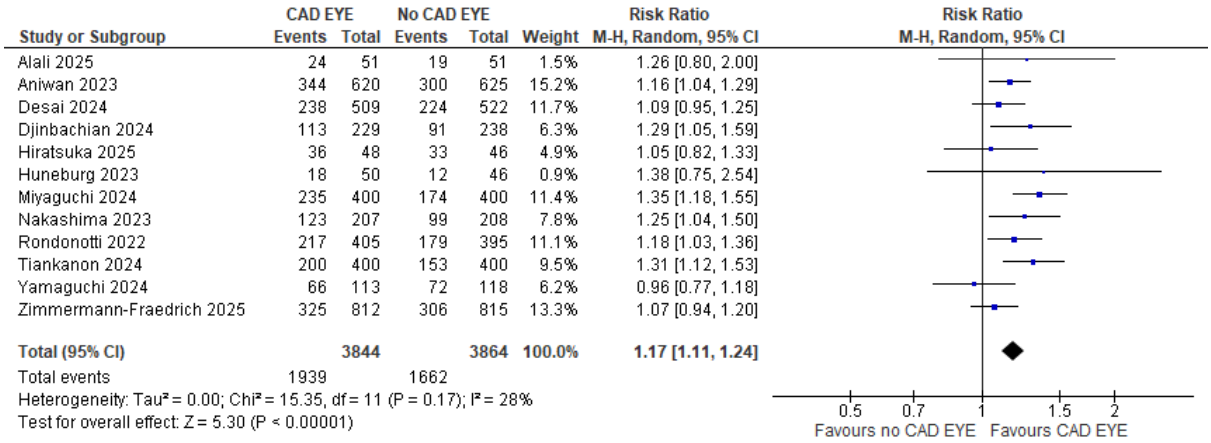


Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

CAD EYE®

Twelve RCTs reporting ADR for this technology compared to standard colonoscopy were identified, with one high risk of bias study (Scholer *et al.* 2024) excluded from the primary meta-analysis.[2-4, 79, 86-93, 100] Populations included in studies varied but included screening in general, screening following a positive FIT test, surveillance colonoscopies (including following previous polypectomy), surveillance in Lynch syndrome patients and colonoscopies due to symptoms. Endoscopist experience also varied, ranging from no requirements to only including endoscopists meeting certain criteria, such as at least 1000 prior colonoscopies, a certain number of years' experience or qualified and participating in national screening programmes. Results suggest a higher (statistically significant; p-value <0.00001) ADR with CAD EYE® (Figure 5). There is some indication of statistical heterogeneity based on the I^2 value and visual differences in point estimates.

Figure 5. ADR in CAD EYE® studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

CADDIE™

Two RCTs reporting ADR for this technology compared to standard colonoscopy were meta-analysed.[102, 103]

[redacted]

Figure 6. ADR in CADDIE™ studies

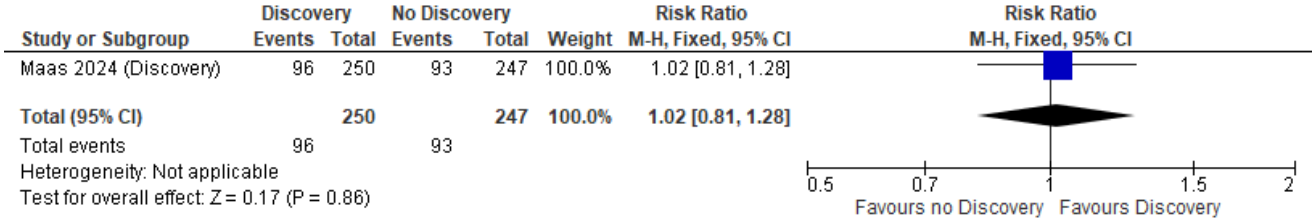
[redacted]

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Discovery™

A single RCT reporting ADR for this technology compared to standard colonoscopy was identified.[104] The population was those scheduled for non-iFOBT screening, surveillance or diagnosis colonoscopy and endoscopists included had performed at least 2000 prior colonoscopies. Results suggest a slightly higher ADR with Discovery™ compared to standard colonoscopy but this was not statistically significant (p-value 0.86) and the RR was very close to 1.0 (Figure 7).

Figure 7. ADR in Discovery™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Endoscopic Multimedia Information System (EMIS)™

EndoPerv LLC. provided ADR data from a study comparing EMIS™ with no EMIS™.[69, 111] Information provided was very limited, but the manufacturer confirmed that the data provided were preliminary data from one of three sites involved in a sequential RCT (NCT05241210). These data are considered to be at a high risk of bias given the limited details provided, but were included in the absence of no other data for this technology. The population included those undergoing [redacted], and endoscopist experience requirements were not reported. Results suggest a [redacted] ADR with EMIS™ (RR [redacted]; Figure 8).

Figure 8. ADR in EMIS™ studies

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; EMIS™, Endoscopic Multimedia Information System; M-H, Mantel-Haenszel.

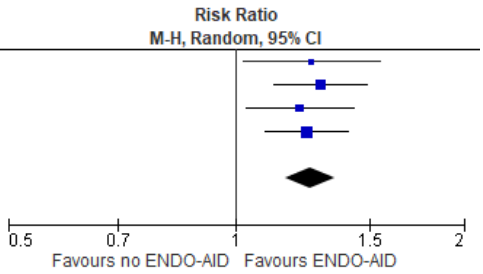
ENDO-AID™

Five RCTs reporting ADR for this technology compared to standard colonoscopy were identified, with one study considered to be at high risk of bias (Vilkoite *et al.* 2023) excluded from the primary meta-analysis.[73, 80, 106-108] Populations were similar, with all four analysed covering screening, surveillance and symptomatic colonoscopies or screening and surveillance colonoscopies. Endoscopist experience varied; two did not appear to have any criteria for inclusion, one included experienced endoscopists with >2000 prior colonoscopies and the other was specifically trainee endoscopists with supervisors present. Results suggest a higher (statistically significant; p-value <0.00001) ADR with ENDO-AID™ (Figure 9). Results across studies are similar based on point estimates, with no evidence of statistical heterogeneity.

Figure 9. ADR in ENDO-AID™ studies

Study or Subgroup	ENDO-AID Events	ENDO-AID Total	No ENDO-AID Events	No ENDO-AID Total	Weight	Risk Ratio M-H, Random, 95% CI
Gimeno-Garcia 2023	102	185	81	185	13.3%	1.26 [1.02, 1.55]
Lau 2024	222	386	169	380	29.0%	1.29 [1.12, 1.49]
Lui 2024	263	468	99	214	21.2%	1.21 [1.03, 1.43]
Spada 2025	302	611	246	617	36.5%	1.24 [1.09, 1.41]
Total (95% CI)		**1650**		**1396**	**100.0%**	**1.25 [1.16, 1.35]**
Total events	889		595			

Heterogeneity: Tau² = 0.00; Chi² = 0.36, df = 3 (P = 0.95); I² = 0%
Test for overall effect: Z = 5.80 (P < 0.00001)



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

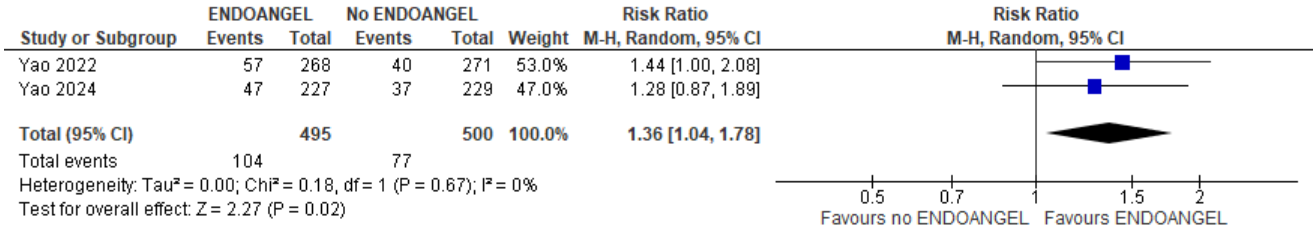
ENDOANGEL®

Three RCTs reporting ADR for this technology compared to standard colonoscopy were identified, with one excluded from the primary meta-analysis as it was considered to be at high risk of bias (Gong *et al.* 2020).[75, 109, 110] The population in both analysed studies covered screening, symptomatic and surveillance colonoscopies. Endoscopist experience varied; one covered more experienced endoscopists (requirement for at least 2000 prior colonoscopies), while the other was performed by

novices supported by experts with at least 5000 prior colonoscopies, where required for aspects other than polyp detection. Results suggest a higher (statistically significant; p-value 0.02) ADR with ENDOANGEL® (

Figure 10), with no statistical heterogeneity based on the I^2 value.

Figure 10. ADR in ENDOANGEL® studies

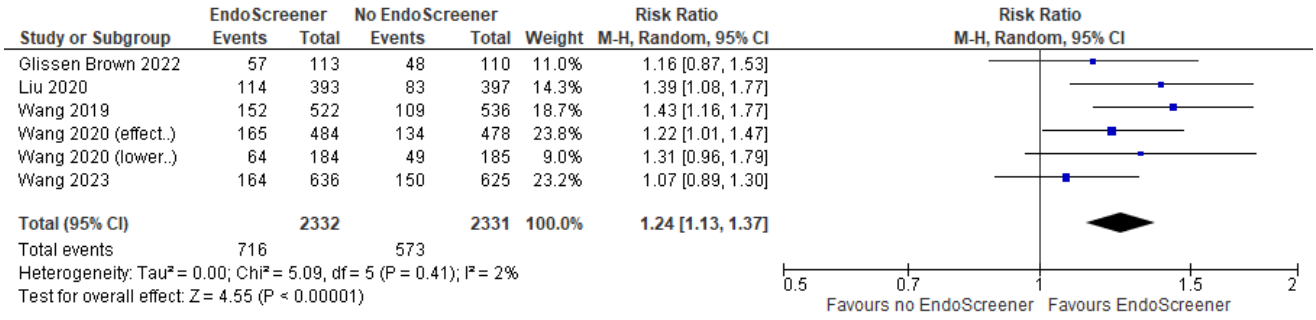


Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

EndoScreener®

Six RCTs reporting ADR for this technology compared to standard colonoscopy were meta-analysed.[112-117] Populations covered by each study varied but included screening, surveillance and symptomatic colonoscopies. Endoscopist experience varied; two included senior as well as more junior endoscopists and four were specific to more experienced endoscopists, with definitions of experienced varying (for example, requirement for at least 1000 or 2000 prior colonoscopies, described as having a high baseline ADR or described as experienced with no definition provided). Results suggest a higher (statistically significant; p-value <0.00001) ADR with EndoScreener® (Figure 11). Despite some slight variation, point estimates appear to be generally similar and there is no evidence of statistical heterogeneity.

Figure 11. ADR in EndoScreener® studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

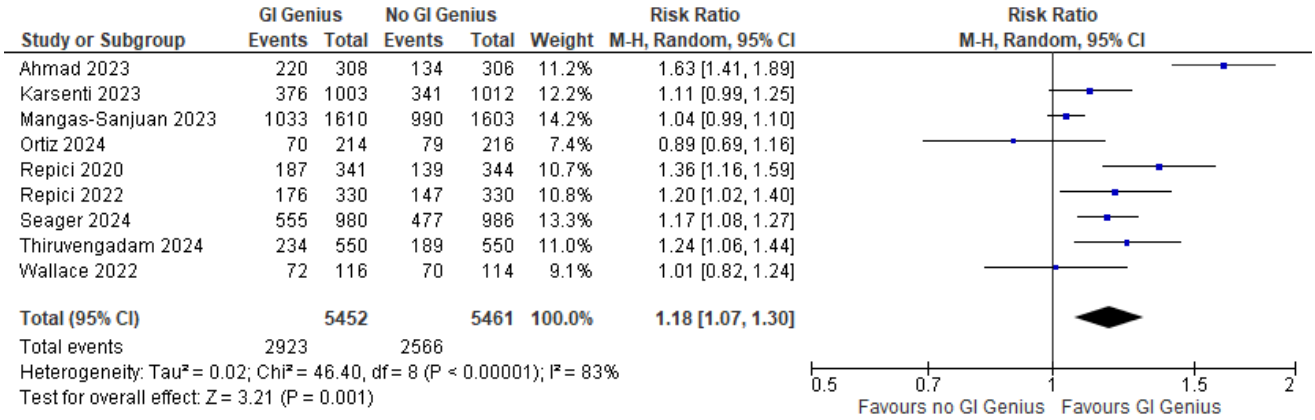
GI Genius™

Eleven RCTs reporting ADR for this technology compared to standard colonoscopy were identified, with three excluded from the primary meta-analysis given they were considered to be at a higher risk of bias (Engelke *et al.* 2023, Scholer *et al.* 2024 and Lagstrom *et al.* 2025). [1, 2, 74, 77, 118, 120, 121, 123-127] Populations covered by each study varied but included screening (general and following a positive FIT test), surveillance and symptomatic colonoscopies, as well as surveillance specifically in Lynch syndrome patients. Endoscopist experience varied, with some appearing to include no requirements for endoscopists, some requiring a certain number of procedures (for example, at least 2000 prior colonoscopies) and/or a certain baseline ADR (such as a baseline ADR of at least 25%) and one study specific to colonoscopies performed as part of a national screening programme. One study only included non-expert endoscopists (defined as <2000 prior colonoscopies) and for some there was limited reporting of endoscopist requirements. Results suggest a higher (statistically significant; p-value 0.001) ADR with GI Genius™ (Figure 12). There is notable variation between studies based on point estimates and evidence of substantial statistical heterogeneity based on the I^2 value of 83%.

[redacted] (see Section 3.2.2.1.10)

Furthermore, given most RCTs excluded patients with IBD, a single abstract reporting on a non-randomised comparison of ADR before and after implementation of GI Genius™ in the IBD population (no further information) was included to capture this population.[119] Endoscopist experience was unclear for this study, but it was performed in a high-volume gastroenterology department. Results suggest a lower (not statistically significant; p-value 0.13) ADR with GI Genius™ in this population (Figure 13); however, event rates are much lower than rates reported for the overall colonoscopy population from RCTs and these data are considered to be at a higher risk of bias given the non-randomised study design as well as limited information available only in abstract form.

Figure 12. ADR in GI Genius™ studies – RCTs (mixed colonoscopy population)



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

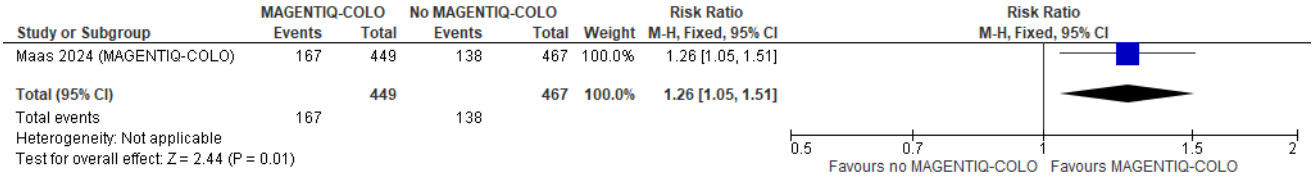
Figure 13. ADR in GI Genius™ studies – non-randomised (IBD population)

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; IBD, inflammatory bowel disease; M-H, Mantel-Haenszel.

MAGENTIQ-COLO™

A single RCT reporting ADR for this technology compared to standard colonoscopy was identified. [136] The population was non-iFOBT screening or surveillance colonoscopies (within the last three years for surveillance colonoscopies) and endoscopists had an ADR between 25 and 40%. Results suggest a higher (statistically significant; p-value 0.01) ADR with MAGENTIQ-COLO™ compared to standard colonoscopy (Figure 14).

Figure 14. ADR in MAGENTIQ-COLO™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

3.2.2.1.1.2 Advanced adenoma detection rate

Advanced ADR has also been utilised as part of the economic modelling (Section 4.2.1.6). It is calculated in the same way as ADR, with advanced adenomas usually defined as those ≥10 mm in size, or with a villous component, high-grade dysplasia or intramucosal cancer (although this may vary very slightly between studies). This outcome is less commonly reported across studies, with evidence only available for five of the 10 interventions and from fewer studies. Results across interventions are summarised in Table 6 below. Event rates are much lower for this outcome compared to overall ADR, explaining the increased 95% CIs observed for this outcome.

Across interventions, there is a trend based on point estimates for an increased advanced ADR with AI for all analyses other than GI Genius™ (RR = 1.00); however, no statistically significant differences were identified and heterogeneity between studies was an issue for most analyses. Overall, the impact of AI technologies on advanced ADR appears to be smaller and less certain compared to overall ADR, and the lower event rates observed for this outcome may be contributing to the increased uncertainty for these analyses. For GI Genius™,

[redacted]

(see Section 3.2.2.1.10). Further details in terms of results per intervention, including forest plots, are presented in Section 1.1 of the DAR supplement.

Table 6. Summary of analyses performed for advanced ADR across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
8 RCTs (1 tandem, 7 parallel), 6481 participants[3, 4, 79, 86, 87, 89, 91, 93]	321/3232 (9.93%)	275/3249 (8.46%)	RR 1.18 (0.98 to 1.44)	• Some statistical heterogeneity suggested (I^2 = 30% and point estimates vary)
CADDIE™				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
ENDO-AID™				
4 parallel RCTs, 2988 participants[80, 106-108]	176/1620 (10.86%)	120/1368 (8.77%)	RR 1.12 (0.86 to 1.45)	• Some statistical heterogeneity suggested (I^2 = 21% and point estimates vary)
ENDOANGEL®				
2 RCTs (1 tandem, 1 parallel), 995 participants[109, 110]	16/495 (3.23%)	12/500 (2.40%)	RR 1.35 (0.64 to 2.82)	• Some heterogeneity noted based on visual differences in point estimates
GI Genius™				
6 parallel RCTs, 9683 participants[118, 120, 123-126]	866/4835 (17.91%)	863/4848 (17.80%)	RR 1.00 (0.92 to 1.08)	• Results from the non-randomised NAIAD trial [redacted] (see Section 3.2.2.1.10)[60]

Abbreviations: ADR, adenoma detection rate; CADe, computer-aided detection; CI, confidence interval; IBD, inflammatory bowel disease; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial; RR, risk ratio.

3.2.2.1.1.3 Non-advanced adenoma detection rate

Non-advanced ADR is also reported by some studies, but less commonly than ADR and advanced ADR. It is calculated in the same way as ADR, reporting the number of patients with at least one adenoma not considered to be an advanced adenoma divided by the total number of colonoscopies. Evidence for this outcome is only available for three of the 10 interventions. Results across interventions are summarised in Table 7 below. It has been used in the economic model where reported (Section 4.2.1.6).

For all interventions that data are available for, point estimates suggest an increased non-advanced ADR compared to standard colonoscopy, which is statistically significant for the ENDO-AID™ and GI Genius™ analyses, and no statistical or visual heterogeneity was noted for the only meta-analysis (GI Genius™). Overall, the impact of AI technologies on non-advanced ADR similar to that observed for overall ADR if not slightly larger, although these results are based on fewer studies and are not available for all interventions. For GI Genius™, [redacted] (see Section 3.2.2.1.10). Further details in terms of results per intervention, including forest plots, are presented in Section 1.2 of the DAR supplement.

Table 7. Summary of analyses performed for non-advanced ADR across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
ENDO-AID™				
1 parallel RCT, 312 participants[106]	85/155 (54.84%)	64/157 (40.76%)	RR 1.35 (1.06 to 1.70)	• Single study
ENDOANGEL®				
1 parallel RCT, 539 participants[109]	53/268 (19.78%)	37/271 (13.65%)	RR 1.45 (0.99 to 2.13)	• Single study
GI Genius™				
3 parallel RCTs, 2445 participants[123, 124, 126]	499/1221 (40.87%)	383/1224 (31.29%)	RR 1.31 (1.17 to 1.45)	• Results from the non-randomised NAIAD trial [redacted] (see Section 3.2.2.1.10)[60]

Abbreviations: ADR, adenoma detection rate; CADe, computer-aided detection; CI, confidence interval; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial; RR, risk ratio.

3.2.2.1.1.4 Adenoma detection rate separated by size

Given that the impact of AI-supported technologies was expected to differ depending on the size of polyps, with feedback from the EAG's clinical experts and at the scoping workshop for this project

suggesting that AI might only increase the detection of smaller, less clinically significant polyps rather than larger polyps, the EAG has presented meta-analyses for ADR within different size categories here. These outcomes refer to the number of patients with at least one adenoma of a specific size divided by the total number of colonoscopies. Results across interventions are summarised in Table 8 below. Evidence for different size categories was available for six of the 10 interventions included in this assessment.

Overall, the EAG notes that point estimates across interventions and size categories suggest that the impact of AI on increasing ADR relative to standard colonoscopy may be lower for larger sized polyps; across analyses, point estimates are generally larger in the ≤5 mm and 6-9 mm (or <10 mm) categories compared to the ≥10 mm category, with some evidence that the impact is larger in the ≤5 mm category compared to the 6-9 mm category as well. While this trend is noted, it is not consistent across all analyses as a trend was not observed for the ENDOANGEL® analysis. Furthermore, the EAG has concerns about drawing firm conclusions from these data given the number of events drops substantially for the largest size category of ≥10 mm, and often for the 6-9 mm category as well, and this may impact the ability to detect a difference between interventions. It also notes that even for the smallest size category, many of the analyses do not indicate statistically significant differences between AI-supported and standard colonoscopy. Further details in terms of results per intervention, including forest plots, are presented in Section 1.3 of the DAR supplement.

Table 8. Summary of analyses performed for ADR separated by size categories across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - ≤5 mm or <5 mm				
3 parallel RCTs, 3458 participants[86, 91, 93]	569/1726 (32.97%)	492/1732 (28.41%)	RR 1.16 (1.05 to 1.29)	NA
CAD EYE® - 6 to 9 mm				
2 parallel RCTs, 2427 participants[91, 93]	263/1217 (21.61%)	233/1210 (19.26%)	RR 1.12 (0.96 to 1.31)	NA
CAD EYE® - <10 mm				
1 parallel RCT, 1245 participants[79]	280/620 (45.16%)	248/625 (39.68%)	RR 1.14 (1.00 to 1.30)	• Single study
CAD EYE® - ≥10 mm				

3 parallel RCTs, 3672 participants[79, 91, 93]	207/1837 (11.27%)	194/1835 (10.57%)	RR 1.06 (0.88 to 1.28)	• Some heterogeneity suggested (point estimates vary)
CADDIE™ - ≤5 mm				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - 6 to 9 mm				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - ≥10 mm				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
Discovery™ - ≤5 mm				
1 parallel RCT, 497 participants[104]	77/250 (30.8%)	67/247 (27.13%)	RR 1.14 (0.86 to 1.50)	• Single study
Discovery™ - 6 to 9 mm				
1 parallel RCT, 497 participants[104]	28/250 (11.2%)	38/247 (15.38%)	RR 0.74 (0.46 to 1.15)	• Single study
Discovery™ - ≥10 mm				
1 parallel RCT, 497 participants[104]	14/250 (5.60%)	14/247 (5.67%)	RR 0.99 (0.48 to 2.03)	• Single study
ENDO-AID™ - ≤5 mm or <5 mm				
2 parallel RCTs, 1076 participants[106, 107]	236/541 (43.62%)	152/535 (28.41%)	RR 1.53 (1.30 to 1.80)	NA
ENDO-AID™ - 5 to 10 mm or 6 to 9 mm				
2 parallel RCTs, 1076 participants[106, 107]	166/541 (30.68%)	133/535 (24.86%)	RR 1.24 (1.02 to 1.50)	NA
ENDO-AID™ - >10 mm or ≥10 mm				
2 parallel RCTs, 1076 participants[106, 107]	24/541 (4.44%)	31/535 (5.79%)	RR 0.73 (0.28 to 1.88)	• Substantial statistical heterogeneity suggested (I^2 = 67% and point estimates vary)
ENDOANGEL® - ≤5 mm				
2 RCTs (1 tandem, 1 parallel), 995 participants*[109, 110]	87/495 (17.58%)	66/500 (13.20%)	RR 1.33 (0.99 to 1.79)	NA
ENDOANGEL® - 6 to 9 mm				
2 RCTs (1 tandem, 1 parallel), 995 participants*[109, 110]	29/495 (5.45%)	14/500 (2.80%)	RR 1.96 (0.87 to 4.42)	• Some statistical heterogeneity suggested (I^2 = 33% and point estimates vary)
ENDOANGEL® - ≥10 mm				
2 RCTs (1 tandem, 1 parallel), 995 participants*[109, 110]	9/495 (1.82%)	7/500 (1.40%)	RR 1.30 (0.49 to 3.46)	• Some heterogeneity

				suggested (point estimates vary)
GI Genius™ - ≤5 mm				
3 parallel RCTs, 4558 participants[120, 123, 124]	985/2281 (43.18%)	866/2277 (38.03%)	RR 1.13 (1.05 to 1.21)	NA
GI Genius™ - 6 to 9 mm				
3 parallel RCTs, 4558 participants[120, 123, 124]	410/2281 (17.97%)	360/2277 (15.81%)	RR 1.14 (1.00 to 1.29)	• Some statistical heterogeneity suggested (I^2 = 49% and point estimates vary)
GI Genius™ - <10 mm or ≤10 mm				
1 parallel RCTs, 660 participants†[124]	143/330 (43.33%)	120/330 (36.36%)	RR 1.19 (0.99 to 1.44)	NA
GI Genius™ - >10 mm or ≥10 mm				
3 parallel RCTs, 4558 participants†[120, 123, 124]	505/2281 (22.14%)	478/2277 (20.99%)	RR 1.05 (0.94 to 1.17)	• Some heterogeneity suggested (point estimates vary)

*Gong *et al.* 2020 excluded from primary analysis due to high risk of bias;[75] †Engelke *et al.* 2023 excluded from primary analysis due to high risk of bias[74]

Abbreviations: ADR, adenoma detection rate; CADe, computer-aided detection; CI, confidence interval; NA, not applicable; RCT, randomised controlled trial; RR, risk ratio.

3.2.2.1.1.5 Sessile serrated lesion detection rate

SSL detection rate was in at least one study for eight of the 10 interventions covered in this assessment. It has been included in this report given clinical expert feedback that this type of lesion can be important in terms of potential to develop into cancer and that the pathway through which this occurs may differ compared to that of adenomas. An exact definition of this was often not provided but will have been based on histology results in most cases. Results across interventions are summarised in Table 9 below. The proportion of patients with at least one SSL was notably lower compared to the proportion with at least one adenoma across all analyses.

Overall, point estimates for most interventions for this outcome suggest an increased SSL detection rate with AI-supported colonoscopy compared to standard colonoscopy, but this was not statistically significant in any analyses. There is also notable variation between studies for all analyses that included more than one study, suggesting increased uncertainty about the impact of AI on this outcome. The EAG considers this uncertainty is likely due to the lower number of events compared

to other outcomes such as ADR; often there is only a difference of two or three events between interventions within individual studies so there is less data on which to base effect estimates. The EAG considers that while it is likely that all interventions improve SSL detection rate based on point estimates, there is uncertainty with regards to the extent of this impact given the low number of events and lack of statistically significant differences for all analyses. For GI Genius™, [redacted] (see Section 3.2.2.1.10). Further details in terms of results per intervention, including forest plots, are presented in Section 1.4 of the DAR supplement.

Table 9. Summary of analyses performed for SSL DR across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
7 parallel RCTs, 6066 participants*[79, 86, 87, 89-91, 93]	198/3025 (6.55%)	172/3041(5.66%)	RR 1.20 (0.91 to 1.59)	• Some statistical heterogeneity suggested (I^2 = 32% and point estimates vary)
CADDIE™				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
Discovery™				
1 parallel RCT, 497 participants[104]	46/250 (18.40%)	30/247 (12.15%)	RR 1.51 (0.99 to 2.32)	• Single study
ENDO-AID™				
3 parallel RCTs, 2676 participants[80, 107, 108]	261/1465 (17.82%)	119/1211 (9.83%)	RR 1.39 (0.95 to 2.03)	• Substantial statistical heterogeneity suggested (I^2 = 60% and point estimates vary)
ENDOANGEL®				
1 parallel RCT, 539 participants[109]	1/268 (0.37%)	1/271 (0.37%)	Peto OR 1.01 (0.06 to 16.21)	• Single study • Very few events
EndoScreener®				
1 parallel RCT, 790 participants[113]	3/393 (0.76%)	1/397 (0.25%)	Peto OR 2.76 (0.39 to 19.64)	• Single study • Very few events
GI Genius™				

5 parallel RCTs, 5069 participants*[1, 123-126]	246/2530 (9.72%)	192/2539 (7.56%)	RR 1.27 (0.97 to 1.66)	• Some statistical heterogeneity suggested (I^2 = 44% and point estimates vary) • Results from the non-randomised NAIAD trial [redacted] (see Section 3.2.2.1.10)[60]
MAGENTIQ-COLO™				
1 RCT (parallel and tandem arms), 916 participants[136]	27/449 (6.01%)	18/467 (3.85%)	RR 1.56 (0.87 to 2.79)	• Single study

*Scholer *et al.* 2024 excluded from primary analysis due to high risk of bias.[2]

Abbreviations: CADe, computer-aided detection; CI, confidence interval; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; OR, odds ratio; RCT, randomised controlled trial; RR, risk ratio; SSL DR, sessile serrated lesion detection rate.

3.2.2.1.1.6 Significant polyp detection rate

One study for GI Genius™ reported a slightly different outcome of significant polyp detection rate, which was defined as the number of patients with at least one adenoma or SSL divided by the total number of colonoscopies.[1] This differs from ADR as ADR usually includes adenomas only, or adenomas and carcinomas, and does not consider SSLs, which are also thought to be linked to cancer development (see Section 1.1.2).

[redacted] These data have been reported here given the clinical importance of adenomas and SSLs already noted earlier in terms of potential for development into cancer. The GI Genius™ study involved endoscopists involved in the NHS BCSP and covered those aged 60 to 74 years with a positive FIT test within the NHS BCSP, an established history of adenomas attending for surveillance colonoscopy within the BCSP or >55 years referred for colonoscopy due to large/multiple adenomas during screening flexible sigmoidoscopy.

[redacted] The EMIS™ study included patients undergoing

[redacted] and the experience of endoscopists was not reported.

The results indicate a statistically significant increase in detection rate with GI Genius™ compared to standard colonoscopy (p-value 0.03). The difference was less notable compared to when ADR from this study was considered (significant polyp detection rate, RR 1.11; ADR, RR 1.63).

[redacted] While results for EMIS™ were [redacted] in that the point estimate suggests [redacted] with EMIS™, the results for this analysis [redacted] Results are presented in Table 10. See Section 1.5 of the DAR supplement for forest plots.

Table 10. Summary of analyses for neoplastic and significant polyp detection rate

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CADDIE™ - neoplastic detection rate				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
Endoscopic Multimedia Information System (EMIS)™ - adenomatous, sessile or tubulovillous polyp detection rate				
1 sequential RCT, [redacted] participants[69]	[redacted]	[redacted]	[redacted]	• Single study • Includes adenomatous, sessile and tubulovillous polyps in the detection outcome • [redacted]
GI Genius™ - significant polyp detection rate				

1 parallel RCT, 614 participants[1]	244/308 (79.22 %)	219/306 (71.57%)	RR 1.11 (1.01 to 1.21)	• Significant polyps include adenomas or SSLs • Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio; SSLs, sessile serrated lesions.

3.2.2.1.1.7 Adenoma miss rate

Data for AMR were available for five of the 10 interventions covered in this assessment. This outcome involves the use of tandem procedures (one colonoscopy followed by another) to calculate how many adenomas were missed on the first colonoscopy. Results are expressed as AMR on a per lesion basis, i.e. the number of lesions detected in the second colonoscopy (and, therefore, missed on the first colonoscopy) divided by the total number of adenomas detected in the first and second colonoscopies. Data are also infrequently reported on a per-patient basis, i.e. the number of patients with at least one adenoma missed on the first colonoscopy (number of patients with at least one on the second colonoscopy divided by the number of patients with at least one adenoma on the first or second colonoscopy). Results across interventions are summarised in Table 11 below.

For analyses of AMR on a per lesion basis, results for all five interventions for this outcome indicated a statistically significant benefit of AI-supported colonoscopy in terms of reducing the AMR compared to standard colonoscopy, including two separate analyses for CAD EYE® given one study was not meta-analysed with the other two studies due to differences in the methods used to calculate AMR (two based on tandem procedures with AI-supported and standard colonoscopy, one with the tandem procedure performed by experts whereas trainees performed the first procedure). Similar trends were also observed when reported on a per-patient basis for EndoScreener® and GI Genius™, but it was not statistically significant in the EndoScreener® analysis. When expressed as a mean per-patient AMR for MAGENTIQ-COLO™, a statistically significant benefit was also observed. Overall, there appears to be evidence of a benefit of AI-supported technologies on reducing the AMR compared to standard colonoscopy, although data are only from one or two studies per intervention and not all interventions have data for this outcome. Further details in terms of results per intervention, including forest plots, are presented in Section 1.6 of the DAR supplement.

Table 11. Summary of analyses performed for AMR across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - per lesion – denominator is total adenomas on both colonoscopies				
2 tandem RCTs, 509 participants[3]	41/270 (15.19%)	66/232 (28.45%)	RR 0.53 (0.38 to 0.76)	• Not-meta-analysed with Yamaguchi *et al.* 2024 as method of calculating AMR differed • Note one is whole colonoscopy and one is rectosigmoid only
CAD EYE® - per lesion – denominator is total adenomas found by experts				
1 parallel RCT with tandem procedures performed by experts, 483 participants[92]	54/211 (25.59%)	105/272 (38.60%)	RR 0.66 (0.50 to 0.87)	• Not-meta-analysed with Nakashima *et al.* 2023 and Hiratsuka *et al.* 2025. as method of calculating AMR differed
ENDOANGEL®- per lesion				
1 tandem RCTs, 456 participants[110]	16/85 (18.82%)	45/103 (43.69%)	RR 0.43 (0.26 to 0.71)	• Single study
EndoScreener® - per lesion				
2 tandem RCTs, 592 participants[112, 116]	54/313 (17.25%)	93/264 (35.23%)	RR 0.48 (0.26 to 0.88)	• Substantial statistical heterogeneity suggested (I^2 = 75% and point estimates vary)
EndoScreener® - per-patient				
1 tandem RCT, 144 participants[116]	14/78 (17.95%)	17/66 (25.76%)	RR 0.70 (0.37 to 1.30)	• Single study
GI Genius™ - per lesion				
1 tandem RCT, 230 participants[127]	38/246 (15.45%)	80/247 (32.39%)	RR 0.48 (0.34 to 0.67)	• Single study
GI Genius™ - per-patient				
1 tandem RCT, 230 participants[127]	29/116 (25.00%)	52/114 (45.61%)	RR 0.55 (0.38 to 0.80)	• Single study
MAGENTIQ-COLO™ - per lesion				
1 RCT (tandem arms), 127 participants[136]	11/59 (18.64%)	16/45 (35.56%)	RR 0.52 (0.27 to 1.02)	• Single study
MAGENTIQ-COLO™ - mean per-patient AMR				

1 RCT (tandem arms), 127 participants[136]	Mean 0.64 (SD 0.47)	Mean 0.81 (SD 0.37)	MD -0.17 (-0.32 to -0.02)	• Single study

Abbreviations: AMR, adenoma miss rate; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial; RR, risk ratio.

3.2.2.1.1.8 Adenomas per colonoscopy

APC is an alternative adenoma-based measure that provides an average number of adenomas in each colonoscopy, calculated by dividing the total number of adenomas identified across all colonoscopies by the total number of colonoscopies performed. It can be analysed as a continuous outcome by combining mean and SD for each arm within each study, which is how it was initially analysed in this assessment. Analyses based on mean differences have been utilised in the economic model (see Appendix 9.10.3). However, as part of the economic model, an alternative analysis as an IRR (calculated by using the total number of adenomas in each arm as the numerator and the total number of colonoscopies in each arm as the denominator) was identified as a potential scenario analysis for the economic model. Results of APC as an IRR are, therefore, also presented. Results across interventions are summarised in Table 12 below, with nine of the 10 interventions in this assessment covered.

The EAG notes that results for APC are generally in line with those observed for ADR, with statistically significant benefits of AI-supported colonoscopy compared to standard colonoscopy identified for most interventions when analysed as mean and SDs and as an IRR. The only analyses that were not in line with this were those for Argus®, Discovery™ and ENDOANGEL®; the lack of a statistically significant benefit for Discovery™ was in line with results for ADR (Section 3.2.2.1.1.1), with point estimates for both outcomes suggesting no overall difference compared to standard colonoscopy. Argus® results were in line with the ADR results in that point estimates suggested a benefit of the technology, but it was not statistically significant. Results for ENDOANGEL® were not consistent with results for ADR; this discrepancy may be partially due to one study in the ADR analysis not reporting APC data, meaning sample size is reduced and uncertainty increased in the APC analyses. The point estimates for the ENDOANGEL® APC analyses suggest a trend towards a benefit of the technology in increasing APC.

Overall, evidence for most technologies this outcome is available for suggests that AI-supported colonoscopy increases APC compared to standard colonoscopy, with the exception of Discovery™,

which is consistent with ADR results for this technology. Some heterogeneity, either statistical or based on visual differences in point estimates, were noted for CAD EYE®, [redacted], EndoScreener® and GI Genius™ analyses. For GI Genius™, [redacted] Further details in terms of results per intervention, including forest plots, are presented in Section 1.7 of the DAR supplement.

Table 12. Summary of analyses performed for APC across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
Argus® - mean and SD				
No formal analysis possible[67, 68]	• Instructions for use manual reports higher mean APC value with Argus®-assisted colonoscopy compared to standard colonoscopy (difference of 0.107) • Abstract + instructions for use manual only, limited details to base quality assessment on (assume higher risk)			
Argus® - IRR				
1 parallel RCT (abstract + instructions for use manual), 686 participants[67, 68]	Rate 0.42	Rate 0.38	IRR 1.16 (0.97 to 1.39)	• Single study • Abstract + instructions for use manual only, limited details to base quality assessment on (assume higher risk)
CAD EYE® - mean and SD				
9 RCTs (1 tandem, 1 parallel with tandem procedures performed by experts, 7 parallel), 5891 participants[3, 4, 79, 86, 87, 90-92, 100]	Mean 1.10	Mean 0.89	MD 0.24 (0.16 to 0.31)	• Some heterogeneity suggested (point estimates vary)
CAD EYE® - IRR				
12 RCTs (2 tandem, 1 parallel with tandem procedures performed by experts, 9 parallel), 7708	Rate 1.06	Rate 0.86	IRR 1.22 (1.14 to 1.31)	• Some statistical heterogeneity suggested (I^2 = 44% and point estimates vary)

participants[3, 4, 79, 86-93, 100]				
CADDIE™ - mean and SD				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
CADDIE™ - IRR				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
Discovery™ - mean and SD				
1 parallel RCT, 497 participants[104]	Mean 0.66	Mean 0.66	MD 0.00 (-0.19 to 0.19)	• Single study
Discovery™ - IRR				
1 parallel RCT, 497 participants[104]	Rate 0.66	Rate 0.66	1.00 (0.80 to 1.25)	• Single study
ENDO-AID™ - mean and SD				
4 parallel RCTs, 2988 participants[80, 106-108]	Mean 1.38	Mean 0.87	MD 0.45 (0.39 to 0.52)	NA
ENDO-AID™ - IRR				
4 parallel RCTs, 2988 participants*[80, 106-108]	Rate 1.32	Rate 0.85	IRR 1.56 (1.42 to 1.71)	• Some statistical heterogeneity suggested (I^2 = 34%)
ENDOANGEL® - mean and SD				
2 RCTs (1 tandem, 1 parallel), 995 participants†[109, 110]	Mean 0.27	Mean 0.21	MD 0.07 (0.00 to 0.13)	NA
ENDOANGEL® - IRR				
2 RCTs (1 tandem, 1 parallel), 995 participants†[109, 110]	Rate 0.27	Rate 0.20	IRR 1.31 (1.00 to 1.71)	NA
EndoScreener® - mean and SD				
1 tandem RCT, 223 participants[112]	Mean 1.19	Mean 0.90	MD 0.29 (-0.18 to 0.76)	• Single study
EndoScreener® - IRR				
6 RCTs (2 tandem, 4 parallel), 4663 participants[112-117]	Rate 0.54	Rate 0.36	IRR 1.50 (1.32 to 1.70)	• Some statistical heterogeneity suggested (I^2 = 47% and point estimates vary)
GI Genius™ - mean and SD				
9 RCTs (1 tandem, 8 parallel), 10,957 participants[1, 118, 120, 121, 123-127]	Mean 1.36	Mean 1.12	MD 0.23 (0.17 to 0.30)	• Some heterogeneity suggested (point estimates vary) • Results from the non-randomised NAIAD trial [redacted] (see Section 3.2.2.1.10)[60]
GI Genius™ - IRR				

9 RCTs (1 tandem, 8 parallel), 10,957 participants‡[1, 118, 120, 121, 123-127]	Rate 1.40	Rate 1.16	IRR 1.23 (1.14 to 1.32)	• Substantial statistical heterogeneity suggested (I^2 = 70% and point estimates vary)
MAGENTIQ-COLO™ - mean and SD				
1 RCT (parallel and tandem arms), 916 participants[136]	Mean 0.70	Mean 0.51	MD 0.19 (0.04 to 0.34)	• Single study
MAGENTIQ-COLO™ - IRR				
1 RCT (parallel and tandem arms), 916 participants[136]	Rate 0.70	Rate 0.51	IRR 1.37 (1.16 to 1.63)	• Single study

*Vilkoite *et al.* 2023 excluded from primary analysis due to high risk of bias;[73] †Gong *et al.* 2020 excluded from primary analysis due to high risk of bias;[75] ‡Engelke *et al.* 2023 and Lagstrom *et al.* 2025 excluded from primary analysis due to high risk of bias.[74, 77]

Abbreviations: APC, adenomas per colonoscopy; CADe, computer-aided detection; CI, confidence interval; IRR, incidence rate ratio; MD, mean difference; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial; SD, standard deviation.

3.2.2.1.1.9 Advanced adenomas per colonoscopy

Evidence for three of the 10 interventions was available for advanced APC, calculated by dividing the total number of advanced adenomas identified across all colonoscopies by the total number of colonoscopies performed. Results across interventions are summarised in Table 13 below. This outcome has been analysed using mean and SDs per treatment arm.

Results from two studies meta-analysed for CAD EYE® and a single study for ENDO-AID™ suggest small but statistically significant increases in advanced APC with AI-supported colonoscopy compared to standard colonoscopy, with no obvious heterogeneity noted for the CAD EYE® analysis. By contrast, a very small non-statistically significant difference where the point estimate suggests reduced advanced adenomas per colonoscopy with GI Genius™ compared to standard colonoscopy was observed from a meta-analysis of two studies. This suggests that it is possible that the AI technologies increase the number of advanced APC but this was not a consistent observation across technologies and the reporting of this outcome by substantially fewer studies and availability for only two interventions potentially limits the conclusions that can be made for this outcome. Further details in terms of results per intervention, including forest plots, are presented in Section 1.8 of the DAR supplement.

Table 13. Summary of analyses performed for advanced APC across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
2 parallel RCTs, 2045 participants[4, 79]	Mean 0.13	Mean 0.09	MD 0.04 (0.01 to 0.07)	One additional parallel RCT also reports median values for advanced adenomas per patient as median values, with identical median and IQR reported for both treatment arms.[93]
ENDO-AID™				
1 parallel RCT, 682 participants[80]	Mean 0.20	Mean 0.10	MD 0.10 (0.09 to 0.11)	• Single study

GI Genius™				
2 parallel RCTs, 3643 participants[120, 121]	Mean 0.24	Mean 0.26	MD -0.02 (-0.05 to 0.02)	NA

Abbreviations: APC, adenomas per colonoscopy; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NA, not applicable; RCT, randomised controlled trial.

3.2.2.1.1.10 Adenomas per colonoscopy separated by size

As for the ADR outcome (see Section 3.2.2.1.1.4), the EAG has presented APC separately for different size categories as reported in included studies. These data have been analysed as means and SDs per arm in each study. Results across interventions are summarised in Table 14 below. Evidence for different size categories was available for four of the 10 interventions included in this assessment.

Similar to results for ADR by size, point estimates across interventions and size categories suggest that there may be a trend towards reduced increases in APC with AI in larger compared to smaller size categories. For APC, the most notable difference appears to be between ≤5 mm and 6-9 mm or ≥10 mm categories, with analyses for the ≤5 mm category often being statistically significant but other size categories not. While there is some suggestion based on this evidence that the impact of AI on APC may vary according to size category, the EAG considers the evidence may not be strong enough to draw firm conclusions given the substantial heterogeneity noted for some analyses. Further details in terms of results per intervention, including forest plots, are presented in Section 1.9 of the DAR supplement.

Table 14. Summary of analyses performed for APC separated by size categories across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - ≤5 mm				
1 parallel RCT, 800 participants[90]	Mean 0.75	Mean 0.48	MD 0.27 (0.13 to 0.41)	• Single study
CAD EYE® - 6 to 9 mm				
1 parallel RCT, 800 participants[90]	Mean 0.34	Mean 0.24	MD 0.10 (0.00 to 0.20)	• Single study
CAD EYE® - <10 mm				

1 parallel RCT, 800 participants[91]	Mean 0.92	Mean 0.75	MD 0.17 (0.03 to 0.31)	• Single study
CAD EYE® - ≥10 mm				
2 parallel RCTs, 1600 participants[90, 91]	Mean 0.22	Mean 0.18	MD 0.04 (-0.00 to 0.09)	NA
CADDIE™ - ≤5 mm				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - 6 to 9 mm				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - ≥10 mm				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
ENDO-AID™ - ≤5 mm or <5 mm				
3 parallel RCTs, 1760 participants[80, 106, 107]	Mean 0.99	Mean 0.53	MD 0.40 (0.38 to 0.42)	• Some heterogeneity suggested (point estimates vary)
ENDO-AID™ - 5 to 10 mm or 5-9 mm or 6 to 9 mm				
3 parallel RCTs, 1760 participants[80, 106, 107]	Mean 0.36	Mean 0.28	MD 0.06 (-0.05 to 0.17)	• Substantial statistical heterogeneity suggested (I^2 = 77% and point estimates vary)
ENDO-AID™ - >10 mm or ≥10 mm				
3 parallel RCTs, 1760 participants[80, 106, 107]	Mean 0.12	Mean 0.09	MD 0.03 (-0.07 to 0.14)	• Substantial statistical heterogeneity suggested (I^2 = 98% and point estimates vary)
GI Genius™ - ≤5 or <5 mm				
3 parallel RCTs, 4743 participants[120, 121, 126]	Mean 0.69	Mean 0.56	MD 0.15 (0.05 to 0.24)	• Some statistical heterogeneity suggested (I^2 = 38% and point estimates vary)
GI Genius™ - 5-9 mm or 6 to 9 mm				
3 parallel RCTs, 4743 participants[120, 121, 126]	Mean 0.28	Mean 0.26	MD 0.02 (-0.02 to 0.06)	NA
GI Genius™ - <10 mm				
2 parallel RCTs, 1345 participants[123, 124]	Mean 2.07	Mean 1.56	MD 0.27 (0.12 to 0.42)	
GI Genius™ - ≥10 mm				

5 parallel RCTs, 6088 participants[120, 121, 123, 124, 126]	Mean 0.13	Mean 0.13	MD -0.00 (-0.02 to 0.02)	NA
MAGENTIQ-COLO™				
No formal analysis possible[136]	Mean values and p-values reported for ≤5, 6-9 and ≥10 mm analyses suggest similar benefits of AI in lower size categories (statistically significant increases compared to standard colonoscopy) but not for the largest size category			

Abbreviations: AI, artificial intelligence; APC, adenomas per colonoscopy; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NA, not applicable; RCT, randomised controlled trial.

3.2.2.1.1.11 Sessile serrated lesions per colonoscopy

SSL per colonoscopy was also reported by a number of studies, including at least one study for six of the 10 interventions covered in this assessment. This is calculated by dividing the total number of SSLs identified across all colonoscopies by the total number of colonoscopies performed. Results across interventions are summarised in Table 15 below. This outcome has been analysed using mean and SDs per treatment arm.

Overall, point estimates for most interventions for this outcome suggest an increase in SSLs per colonoscopy with AI-supported colonoscopy compared to standard colonoscopy; however, the mean difference for most analyses if very small (less than 0.05) and only statistically significant in CAD EYE® and ENDO-AID™ analyses. The outcome is also reported by relatively few studies for each intervention, with the most being three studies for GI Genius™ and all other analyses apart from CAD EYE® including only one study. The EAG considers that while it is possible that interventions covered here may increase SSLs per colonoscopy, the extent of this is likely to be very small if it is a true effect and there is substantial uncertainty associated with this. Further details in terms of results per intervention, including forest plots, are presented in Section 1.10 of the DAR supplement.

Table 15. Summary of analyses performed for SSL per colonoscopy across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
2 parallel RCTs, 1831 participants[86, 90]	Mean 0.11	Mean 0.07	MD 0.03 (0.00 to 0.06)	NA
CADDIE™				

[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
Discovery™				
1 parallel RCT, 497 participants[104]	Mean 0.30	Mean 0.19	MD 0.11 (0.00 to 0.22)	• Single study
ENDO-AID™				
1 parallel RCT, 682 participants[80]	Mean 0.65	Mean 0.30	MD 0.35 (0.33 to 0.37)	• Single study
EndoScreener®				
1 tandem RCT, 223 participants[112]	Mean 0.12	Mean 0.10	MD 0.02 (-0.08 to 0.12)	• Single study
GI Genius™				
3 parallel RCTs, 2144 participants[1, 121, 126]	Mean 0.18	Mean 0.17	MD 0.02 (-0.02 to 0.06)	NA

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NA, not applicable; RCT, randomised controlled trial; SSL, sessile serrated lesion.

3.2.2.1.1.12 Non-neoplastic and hyperplastic polyp detection rates

Data relating to non-neoplastic or hyperplastic polyp detection rates have been used in the economic model, as outlined in Section 4.2.1.6. These represent polyps that are less clinically significant and may be useful in terms of assessing whether AI is likely to increase the number of these detected compared to standard colonoscopy, which could increase workload. Therefore, these results are summarised below in Table 16. Results are only available for four interventions, with only up to three studies reporting this outcome for any intervention. Nonetheless, results suggest an increased non-neoplastic or hyperplastic detection rate with AI compared to standard colonoscopy, although differences are not all statistically significant. Further details in terms of results per intervention, including forest plots, are presented in Section 1.11 of the DAR supplement.

Table 16. Summary of analyses for non-neoplastic polyp and hyperplastic polyp detection rates

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - non-neoplastic/hyperplastic polyp detection rate				
3 parallel RCTs, 2523 participants[89, 91, 93]	332/1267 (22.20%)	268/1256 (21.34%)	RR 1.21 (1.04 to 1.41)	• Some statistical heterogeneity suggested (I^2 = 6%

				and point estimates vary)
ENDO-AID™ - non-neoplastic resection/detection rate				
2 parallel RCTs, 1078 participants[106, 107]	248/541 (45.84%)	162/537 (30.17%)	RR 1.51 (1.29 to 1.76)	NA
ENDOANGEL® - non-precancerous polyp detection rate				
1 parallel RCT, 539 participants[109]	126/268 (47.01%)	94/271 (34.69%)	RR 1.36 (1.10 to 1.67)	• Single study
GI Genius™ - non-neoplastic polyp detection rate				
3 parallel RCTs, 2445 participants[123, 124, 126]	247/1221 (20.23%)	226/1224 (18.46%)	RR 1.09 (0.93 to 1.29)	NA
GI Genius™ - non-neoplastic polyp resection rate				
1 parallel RCT, 460 participants*[123]	68/262 (25.95%)	57/198 (28.79%)	RR 0.90 (0.67 to 1.22)	• Proportion with no adenoma or SSL with at least one resection • Single study

*Lagstrom *et al.* 2025 excluded from primary analysis due to high risk of bias.[77]

Abbreviations: CADe, computer-aided detection; CI, confidence interval; NA, not applicable; RCT, randomised controlled trial; RR, risk ratio; SSL, sessile serrated lesion.

3.2.2.1.1.13 Detection-based diagnostic accuracy data

Although rare, some studies did report some detection-based outcomes as diagnostic accuracy data, which are summarised narratively across interventions. This included outcomes such as sensitivity and specificity for polyp detection, or more limited reporting of false positives and/or false negatives with the AI technology. These outcomes have not been used in the economic modelling.

Based on the discussion below, the EAG considers that this information is of limited use. In particular, the diagnostic accuracy data discussed is associated with a high risk of bias and the impact on polyp detection is better assessed through outcomes such as ADR. While information on false positives and negatives by the technology functioning autonomously is useful, this is not how the technologies should be used according to manufacturers, and a low rate of false positives are noted per colonoscopy. While data on false positives according to histology following resection may be more useful, results vary in terms of the direction of effect even across studies covering the same intervention, outcomes are defined differently across different studies and very few studies report this type of data. Further details in terms of results per intervention, including forest plots and tables of results, are presented in Section 1.12 of the DAR supplement.

Sensitivity and specificity for polyp detection

Data on sensitivity and/or specificity for polyp detection was available from one study each for CAD EYE®, Discovery™, ENDOANGEL® and GI Genius™. It likely refers to the ability of the systems to detect polyps autonomously, without input from an endoscopist. The evidence for all interventions other than GI Genius™ suggests fairly high sensitivity values (>80% for all apart from GI Genius™ and >90% for studies reporting on CAD EYE® and Discovery™);[76, 101, 105] the sensitivity value reported for the GI Genius™ study was 68.4% and was specific to a Lynch syndrome population.[122] Data for specificity and/or accuracy were only reported for CAD EYE® (84.0% and 93.0%, respectively) and the patient level analysis available from one ENDOANGEL® study (specificity 100.0% for AI and non-AI groups),[76, 101] with others only reporting sensitivity.[105, 122]Comparative data against standard colonoscopy were only available for Discovery™ and ENDOANGEL® (for other interventions, all available studies only reported data for the AI technology, with no comparative data available), with an increased sensitivity reported for the AI technology in both cases.[76, 105] Analyses were in general colonoscopy populations for CAD EYE® and ENDOANGEL®,[76, 101] but were more specific for studies reporting these data for Discovery™ and GI Genius™ (ulcerative colitis and Lynch syndrome, respectively).[105, 122] Overall, the EAG considers that these data are extremely limited and notes that the impact of AI on detection of polyps is best assessed using outcomes such as ADR, as presented in Section 3.2.2.1.1.1. Evidence from all studies reporting this type of data for polyp detection were all considered to be at high risk of bias either based on formal quality assessment or the fact that they were only available from abstracts with limited details available. More details of these data are presented in Section 1.12 of the DAR supplement.

Number of false positives

Data on the number of false positives with AI technologies was available for five interventions (Discovery™, ENDO-AID™, ENDOANGEL®, EndoScreener® and GI Genius™),[104, 107, 112-117, 121, 122, 140] with definitions similar although not identical. Overall, this was usually defined as lesions flagged by the technology as polyps that, on review, endoscopists did not consider to be polyps. Given this was based on autonomous detections by the technology, comparative data were not available. Results mostly suggest few false positives per colonoscopy, with means ranging from 0.1 to 4.1 and all but two studies suggesting less than one false positive per colonoscopy. Data for GI Genius™ were

reported slightly differently as the number of colonoscopies with at least one false positive and were specifically for Lynch syndrome populations, which was 36.0% and 86.0%, respectively, in the two different studies[121, 122]. One suggests that false positives are unlikely to be a large issue but the other reports a high proportion of colonoscopies with at least one false positive. More details of these data are presented in Section 1.12 of the DAR supplement.

Number of false negatives

Some data on false negatives were also available, but only for the EndoScreener® intervention.[112-117] The definition of this varied between studies but was generally defined as polyps detected by the operating endoscopist that did not result in an alert by the AI technology. Five of six studies reported that the system did not miss any polyps,[113-117] with the other reporting a low miss rate of 3/315 polyps,[112] but it is unclear how thoroughly this was assessed during the procedures. While limited in their robustness, they indicate that there may not be a large concern about EndoScreener® missing polyps identified by endoscopists; however, the EAG is unsure how useful this information is given the system would be used alongside endoscopist judgement in clinical practice if recommended. More details of these data are presented in Section 1.12 of the DAR supplement.

Other outcomes

Other outcomes reported included one study reporting the positive predictive value (PPV) of a polyp identified with CAD-EYE®-assisted colonoscopy or standard colonoscopy being confirmed as an adenoma on histology as well as the true histology rate, defined as the percentage of polyps identified that were either adenoma, SSL or large (>10 mm) based on histology.[86] Similar outcomes for [redacted] GI Genius™ were also reported,[103, 121, 127] with false positives defined based on histology and definitions differing slightly between studies. Results across interventions and outcomes were varied, with some suggesting that false positives based on histology (i.e. resected lesions that are not confirmed as an adenoma or other important lesion on histology) may be higher with AI-supported colonoscopy compared to standard colonoscopy (CAD EYE® and data from one of two GI Genius™ studies),[86, 121]

[redacted]

[103, 127] Only the difference from one study (GI Genius™ with more false positives in the AI group) was statistically significant.[121] Therefore, the EAG considers that while it is possible that the use of AI-supported technologies may increase the resection of polyps that are not adenomas or other

clinically important polyps, evidence available to support this is limited given results vary even within the same technology and very few studies report this type of data. More details of these data are presented in Section 1.12 of the DAR supplement.

3.2.2.1.2 Measures of ability to characterise identified polyps

For the AI technologies within this assessment that have CADx as well as CADe functionalities, some diagnostic accuracy data on the ability of these to perform or assist with optical diagnosis performed by the endoscopist are available. This includes some data for four of the 10 interventions assessed as part of this review, meaning some data for three of the four interventions stated by the manufacturers to have some CADx function are available, plus some data for Discovery™ despite CADx not being listed as a function of this technology (see Table 44 of Appendix 9.1).

The EAG has separated these results into the type of polyps being characterised given studies often reported separate data for different sizes or for polyps in different locations. Data for technologies used as an adjunct to endoscopist judgement have been prioritised, with autonomous AI results only included if no studies reported the adjunct equivalent. As described in Section 3.1.5.2, no diagnostic meta-analysis has been performed.

The treatment of SSLs in the analyses is important to consider, as in many cases they have been assumed to be non-neoplastic given the AI technologies currently cannot classify SSLs, and it may be misleading to assume they are non-neoplastic given they are thought to have the potential to develop into cancer. Furthermore, some analyses only include polyps where a high-confidence optical diagnosis could be made by the endoscopist (where the AI technology was used to assist the endoscopist or for assessments performed without the use of AI; see Tables in Section 1.13 of the DAR supplement for studies this applied to). This did not apply for any of the assessments where the AI technology was used autonomously, as the level of confidence is something that is assigned by an endoscopist. However, the EAG notes that some analyses of autonomous AI alone have excluded polyps where the AI returned “no prediction” or where a stable prediction was not achieved, which is considered an additional limitation on top of the technology being used autonomously (see Tables in Section 1.13 of the DAR for studies this applied to).

No rationale was put forward for the inclusion of only polyps diagnosed with high-confidence in these studies; studies tended to resect all polyps where characterisation was attempted in the studies and sent for histological assessment (this was often with the exception of very small

hyperplastic polyps in the rectum, which are often not resected in clinical practice as they are not considered to be a concern [see Section 1.1.5)]. Therefore, the availability of an appropriate reference standard does not differ between low- and high-confidence diagnoses, so it should have been possible to include all polyps resected in the analysis, regardless of endoscopist confidence, and some included studies have done so.

The EAG considers that the accuracy of optical diagnosis performed with or without AI is best assessed on all available polyps, rather than limited to a subset where there is the highest confidence; it is possible that limiting in this way may inflate the accuracy measures obtained given they are likely to be polyps that are less complicated in terms of assigning a diagnosis. While this would be true for assessments with and without AI performed by the endoscopist, it is unclear whether one would be affected more than the other. Furthermore, given polyps that are more difficult to characterise are likely to be an issue in clinical practice, the EAG considers it important that the accuracy of optical diagnosis with and without AI takes account of these polyps.

Results for all polyps and all diminutive (≤5 mm) polyps are discussed in the main report, with tables of results for these assessments presented in Section 1.13.1 of the DAR supplement. A summary of other analyses available in studies is reported in Sections 1.13.2 and 1.13.3 of the DAR supplement, including:

- Diminutive (≤5 mm) polyps divided into rectosigmoid and non-rectosigmoid based on location;
- Diminutive (≤5 mm) polyps divided into proximal and distal location;
- Any polyps divided into left- and right-sided location;
- Polyps ≤10 mm or any sized polyps divided into rectosigmoidal (distal) and proximal location;
- Any rectosigmoid polyps divided into different size categories;
- Any polyps divided into other size categories;
- Specific polyp types including hyperplastic and adenomatous polyps;
- Classification of patients having at least one neoplastic lesion;
- Classification of SSLs into adenomatous or non-adenomatous.

Results for sensitivity, specificity and accuracy have been discussed below, with these prioritised in tables in the supplement as well. However, tables within the supplement also mention NPV values where these were reported or possible to calculate from other data provided.

3.2.2.1.2.1 All polyps

CAD EYE®

For adjunct use of CAD EYE®, data were available from one abstract for classification of any polyps into neoplastic vs hyperplastic categories, which was specific to a population undergoing surveillance for ulcerative colitis,[99] and one full text paper covering a population undergoing colonoscopy for a broad range of indications (positive FIT, symptoms, screening or other).[97] The abstract compares AI-assisted results against endoscopist optical diagnosis alone performed using Kudo, NBI International Colorectal Endoscopic criteria (NICE) and Kudo-IBD classifications. Results indicate increased sensitivity of CAD EYE®-assisted colonoscopy compared to two of the endoscopist optical diagnoses, but not when compared against Kudo-IBD optical diagnosis. The specificity of CAD EYE®-assisted colonoscopy was, however, worse than all three endoscopist optical diagnoses (Section 1.13.1.1 of the DAR supplement).

For the full text paper covering a broad colonoscopy population, CAD EYE®-assisted optical diagnosis was compared with endoscopist optical diagnosis alone (separately for WLI and blue-light imaging [BLI] with or without magnification) for classifying 380 polyps into neoplastic or hyperplastic categories, with SSLs considered to be hyperplastic in line with the AI. Of note, polyps considered by the endoscopist to be whitish diminutive polyps of the rectosigmoid colon were excluded from the analysis, as were invasive cancers or submucosal tumours. Results suggest a slightly higher sensitivity, specificity and overall accuracy of the CAD EYE®-assisted assessment compared to endoscopist optical diagnosis using WLI (sensitivity, 94.3% vs 90.0%; specificity, 71.3% vs 68.8%; overall accuracy, 89.5% vs 85.5%), but results were more comparable when compared against endoscopist optical diagnosis using BLI with magnification (sensitivity, 94.3% vs 94.3%; specificity, 71.3% vs 68.8%; overall accuracy, 89.5% vs 88.9%) or without magnification (sensitivity, 94.3% vs 93.0%; specificity, 71.3% vs 70.0%; overall accuracy, 89.5% vs 88.2%). See Section 1.13.1.1 of the DAR supplement.

Given adjunct data for all polyps were available for a very specific ulcerative colitis population from an abstract and a broad colonoscopy population, autonomous data were only considered for populations not already covered by the adjunct data papers. [100]

One abstract covering IBD patients undergoing surveillance with the technology used autonomously was therefore included, and results from this study suggest a slightly better sensitivity and similar specificity for resected lesions, but the reporting of information in this abstract is limited.[95] See Section 1.13.1.2 of the DAR supplement.

While the data from Sato *et al.* 2024 is considered to be a reasonable source of information on the accuracy of CAD EYE®-assisted optical diagnosis compared to endoscopist optical diagnosis alone in terms of categorisation of any polyps, it should be noted that it is not without its limitations, as SSLs were classified as hyperplastic polyps in the analyses which is not how they would be classified in clinical practice.[97]

CADDIE™

[redacted]

Discovery™

For adjunct use of Discovery™, some limited data were available from one study reporting on the classification of any polyps into dysplasia and non-dysplasia categories.[105] The population covered surveillance colonoscopy in patients with ulcerative colitis at risk of CRC. AI-assisted optical diagnosis results were compared against VCE-assisted optical diagnosis. Results indicate the same sensitivity

values for both assessments, with specificity slightly lower in the Discovery™ assessment (Section 1.13.1.4 of the DAR supplement). However, these results are based on only 48 resected polyps and it is unclear whether this is currently a function of Discovery™ given a CADx function was not outlined by the manufacturer, as summarised in Table 44 of Appendix 9.1. SSLs are considered non-dysplastic in this analysis and it does not limit to high confidence optical diagnoses.

GI Genius™

For adjunct use of GI Genius™, data were available from one study for classification of any polyps into adenomatous and non-adenomatous categories.[132] The population included colonoscopy for primary CRC screening, post-polypectomy surveillance, following a positive FIT or for symptoms or signs of CRC. No comparator data has been extracted, as the only comparison was against autonomous use of GI Genius™ for polyp characterisation. The study included endoscopists with >2000 prior colonoscopies, training in optical diagnosis and participation in prior studies on polyp characterisation. Results indicate a sensitivity of 82% and a specificity of 93.1% GI Genius™-assisted optical diagnosis (Section 1.13.1.5 of the DAR supplement). SSLs were considered adenomatous in the analysis and the analysis included high and low confidence optical diagnoses as judged by endoscopists (an alternative including only high confidence diagnoses as judged by endoscopists is also reported but is not preferred by the EAG). Given data for adjunct GI Genius™ use for all polyps was available from one study, data for all polyps from studies using autonomous GI Genius™ were not prioritised for inclusion.

3.2.2.1.2.2 All diminutive (≤5 mm) polyps

CAD EYE®

For adjunct use of CAD EYE®, data were available from one study for classification of any diminutive polyps (≤5 mm) into adenoma, hyperplastic and serrated histologies.[5] The population included colonoscopy for screening, surveillance and diagnostic purposes and the main analysis was with any confidence diagnoses (as judged by the endoscopist) included. No comparative data were extracted given the only comparison available was autonomous use of CAD EYE®. Results indicate a sensitivity of 83.6% and a specificity of 63.8% (Section 1.13.1.6 of the DAR supplement). The analysis allowed

for SSLs to be classified as its own group. Sensitivity analyses for accuracy based on confidence of diagnosis, as well as versions with SSLs excluded, were available but not presented here as the main analysis is considered to be the most robust by the EAG.

In addition, a separate study assessing CAD EYE®-assisted optical diagnosis was included that also implemented resect-and-discard and diagnose-and-leave strategies.[98] The study presents results of the diagnostic accuracy of CAD EYE®-assisted optical diagnosis for polyps that underwent one of these strategies in terms of classification into adenomatous or non-adenomatous categories; given no histology was performed for these polyps, the reference standard was based on an expert video review of the polyps by three endoscopists, which may be a more limited reference standard but it is likely the only option given the study did not collect the histology for polyps considered eligible for resect-and-discard or diagnose-and-leave strategies. Furthermore, the study does not report a comparison against endoscopist optical diagnosis alone.

The population was reported to be outpatient colonoscopy with no further details provided, and endoscopists had training and experience in CADx-assisted and -unassisted optical diagnosis. Results indicated near identical values for sensitivity and specificity (89.9% and 89.8%, respectively), with a value of 89.9% for overall accuracy, based on 138 polyps where one of the two strategies was applied. When considering the resect-and-discard and diagnose-and-leave strategies separately, sensitivity increased and specificity reduced within the resect-and-discard analysis (93.3% and 73.9%, respectively) but overall accuracy was similar to the main analysis (88.8%), with the opposite observed within the diagnose-and-leave strategy analysis in terms of sensitivity and specificity (25.0% and 100.0%, respectively) and a similar but slightly higher overall accuracy (92.5%). However, given the reduction in polyp number analysed in these two sub-analyses (98 and 40 polyps, respectively, for resect-and-discard and diagnose-and-leave strategies), the results of these are considered to be less robust than the main analysis.

CADDIE™

[redacted]

[redacted]

GI Genius™

Two studies reporting data for adjunct use of GI Genius™ in the classification of any diminutive polyps (≤5 mm) into adenomatous or non-adenomatous were included.[131, 141] Populations were similar, with both covering CRC screening, post-polypectomy surveillance and symptomatic colonoscopies. In both studies, the only comparison was against autonomous GI Genius™ classification, which were not prioritised for extraction in this review given adjunct data are most relevant. SSLs were considered to be non-adenomatous in both studies but one included any confidence diagnosis as assessed by the endoscopist and the other was specific to high confidence diagnoses made by the endoscopist. This difference is unlikely to be a large contributor to the observed differences in terms of sensitivity and specificity between the two studies (sensitivity, 78.6% vs 94.8%; specificity, 94.0% vs 58.9 Section 1.13.1.8 of the DAR supplement), as a scenario analysis from Hassan *et al.* 2022 only including high confidence diagnoses did not change results substantially.[132] It is likely that other factors contribute to the differences observed for these studies. As noted previously, the EAG has a preference for data from any confidence diagnoses to be analysed, meaning the data from Hassan *et al.* 2022 may be slightly more appropriate.[132]

3.2.2.1.3 Measures related to healthcare resource use

Outcomes related to procedure time have been included in this report under measures related to healthcare resource use outlined in the NICE final scope.[25] While data on insertion time (or caecal intubation time), withdrawal time (or inspection time) and total procedure time were identified, only results for withdrawal time and total procedure time have been included in the report, given AI technologies were only used during the withdrawal phase of the procedure and should not have impacted the insertion or caecal intubation time.

For withdrawal time, some studies excluded time to perform washing and polypectomies from calculations, with others also excluding time spent performing diagnosis and magnifying observations or simply describing as “interventions” or “biopsies” with no further details. For other studies, it was unclear whether or not polypectomies or other procedures were excluded from the

calculation of the withdrawal time as it was not explicitly mentioned . Further information on the definition of total procedure time was most commonly not reported but the EAG assumes that in these cases no exclusion of polypectomies or other interventions from this outcome applied. The only exception was one study for GI Genius™, which only reported total procedure time in those where no polypectomies were performed.[125] Data have been meta-analysed and presented as mean differences with SD where possible, but in some cases only median values or means without a measure of variation were reported. A summary of results is presented in Table 17 and Table 18, with results per intervention including forest plots presented in Sections 1.14 and 1.15 of the DAR supplement. Data are available for eight interventions for withdrawal time and five interventions for total procedure time.

3.2.2.1.3.1 Withdrawal or inspection time

Considering the evidence across all interventions, the EAG notes that while it is possible that withdrawal time may increase slightly compared to standard colonoscopy, differences for all interventions appear to be small and often are less than one minute. Results are summarised in Table 17 below, with further details in terms of results per intervention, including forest plots, presented in Section 1.14 of the DAR supplement. For GI Genius™,

[redacted] (see Section 3.2.2.1.10).

Table 17. Summary of analyses performed for withdrawal time across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - three excluded washing, polypectomies or other, and four unclear				
7 RCTs (2 tandem, 1 parallel with tandem procedures performed by experts, 5 parallel), 3920 participants[3, 79, 86, 89, 90, 92, 100]	Mean 10.21 minutes	Mean 9.83 minutes	MD 0.19 (0.01 to 0.37)	• Some heterogeneity suggested (point estimates vary) • Further data as median values available from 4 RCTs suggest similar results[4, 91, 93, 101]

CADDIE™ - unclear if washing, polypectomies or other excluded				
[redacted]	• [redacted]			
Discovery™ - "interventions" excluded, not further defined				
No formal analysis possible[104]	• Data as median values available from 1 RCT suggest slightly a slightly higher duration for Discovery™-assisted colonoscopy			
ENDO-AID™ - one excluded polypectomy and other interventions, one excluded "interventions (not further defined), two unclear				
4 parallel RCTs, 2988 participants[80, 106-108]	Mean 10.38 minutes	Mean 9.95 minutes	MD 0.21 (-0.10 to 0.52)	• Some statistical heterogeneity suggested (I^2 = 32% and point estimates vary)
ENDOANGEL® - one is withdrawal time "without operation", one refers to "clean" withdrawal time				
2 RCTs (1 tandem, 2 parallel), 995 participants[109, 110]	Mean 8.65 minutes	Mean 8.34 minutes	MD 0.28 (-0.26 to 0.81)	• Some statistical heterogeneity suggested (I^2 = 31% and point estimates vary)
ENDOANGEL® - not defined but assumed to include interventions such as polypectomies, as "without operation" analysis above reported separately to this				
1 parallel RCT, 539 participants[109]	Mean 10.52 minutes	Mean 9.71 minutes	MD 0.81 (0.10 to 1.52)	• Single study
EndoScreener® - "biopsies" excluded, no further details				
4 parallel RCTs, 4071 participants[113-115, 117]	Mean 6.61 minutes	Mean 6.48 minutes	MD 0.12 (0.04 to 0.21)	• Further data as median values available from 2 RCTs suggest similar results[112, 116]
EndoScreener® - analyses where "biopsies" are not excluded, no further details				
4 parallel RCTs, 4071 participants[113-115, 117]	Mean 7.46 minutes	Mean 7.00 minutes	MD 0.46 (0.35 to 0.58)	• Further data as median values available from 2 RCTs suggest similar results[112, 116]
GI Genius™ - two included biopsies and/or polypectomies, one excluded polypectomies and other "interventions" and one only analysed patients with no polypectomies required				
4 RCTs (1 tandem, 3 parallel), 5047 participants[120, 124, 125, 127]	Mean 11.21 minutes	Mean 10.64 minutes	MD 0.51 (0.05 to 0.98)	• Substantial statistical heterogeneity suggested (I^2 = 64% and point estimates vary) • Further data as median values available from 5 RCTs not considered to be at high risk of bias suggest similar results[1, 118, 121, 123, 126] • Results from the non-randomised NAIAD trial [redacted]

				[redacted] (see Section 3.2.2.1.10)[60]
MAGENTIQ-COLO™ - with and without interventions separately, not further defined				
No formal analysis possible[136]	• Data as median or mean values (without SD) available from 1 RCT suggest very similar values for both interventions			
Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial; SD, standard deviation.				

3.2.2.1.3.2 Total procedure time

Total procedure time is reported by fewer studies and for fewer interventions compared to withdrawal time; however, results that are available are similar to those for withdrawal time, with results suggesting that while it is possible that total procedure time may increase slightly compared to standard colonoscopy, differences for all interventions are likely to be less than one or two minutes. The only outlier is one abstract covering an IBD population for GI Genius™, where procedure time appears to be four minutes shorter based on median values compared to standard colonoscopy. Results are summarised in Table 18 below, with further details in terms of results per intervention, including forest plots, presented in Section 1.15 of the DAR supplement. For GI Genius™, [redacted] (see Section 3.2.2.1.10).

Table 18. Summary of analyses performed for total procedure time across interventions

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - assume no interventions such as polypectomies excluded				
2 parallel RCTs, 1127 participants[86, 89]	Mean 20.95 minutes	Mean 20.15 minutes	MD 0.74 (-0.30 to 1.79)	An additional tandem study reporting observation time suggest similar, with median durations being almost identical for the first examination, but increased in the group receiving CAD EYE® for their second

				procedure compared to standard colonoscopy.[88]
CADDIE™ - assume no interventions such as polypectomies excluded				
[redacted]	• [redacted]			
Discovery™ - assume no interventions such as polypectomies excluded				
No formal analysis possible[104]	• Data as median values available from 1 RCT indicate identical values for both interventions			
EndoScreener® - assume no interventions such as polypectomies excluded				
2 parallel RCTs, 1848 participants[113, 114]	Mean 12.95 minutes	Mean 12.56 minutes	MD 0.40 (-0.01 to 0.81)	NA
GI Genius™ - study reporting means only assessed in patients with no polypectomies performed (same did not apply to studies reporting medians)				
1 parallel RCT, 720 participants[125]	Mean 23.97 minutes	Mean 22.50 minutes	MD 1.47 (0.09 to 2.85)	• Single study • Further data as median values available from 2 RCTs and 1 non-randomised study suggest similar results apart from one abstract in an IBD population which suggests a shorter procedure time in the GI Genius™ group[1, 119, 126] • Results from the non-randomised NAIAD trial [redacted] (see Section 3.2.2.1.10)[60]

Abbreviations: CADe, computer-aided detection; CI, confidence interval; IBD, inflammatory bowel disease; MD, mean difference; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial.

3.2.2.1.4 Number of polyp removal procedures

Number of polyp removal procedures was an outcome listed in the NICE final scope but has only been reported explicitly by one study for one intervention.[25] This was an RCT for EndoScreener® that reported a higher number of biopsies with EndoScreener®-assisted polyp detection compared to standard colonoscopy (501 vs 308 biopsies), leading to per colonoscopy values of 1.04 and 0.64 biopsies for the respective groups (total 484 vs 478 procedures, respectively).[115] Furthermore, a second study, which was at a high risk of bias but has been included here given no other data for this outcome for GI Genius™ were available, reports a higher polypectomy rate when assessed on a per-

patient basis (number of patients with at least one polypectomy; RR 2.04, 95% CI 1.40 to 2.96). This difference was statistically significant, but when assessed on a per-polyp basis (polyps resected divided by total polyps identified), the difference was not statistically significant (RR 1.07, 95% CI 0.92 to 1.26).[74]

This indicates that the use of EndoScreener® and GI Genius™ is likely to increase the number of biopsies or polypectomies during procedures compared to standard colonoscopy, which may not be unexpected based on clinical expert feedback provided to the EAG. While, based on clinical experience, the number of polypectomies is likely to increase with the use of any AI technology in this assessment, the amount of evidence available is limited, with one study reporting no measure of variation.

3.2.2.1.5 Incidences that the technology does not function

Data on issues with the functioning of the AI technologies are not often reported in the included studies but has been covered in some cases.[96, 102, 103, 125, 128-132] A summary of the data reported for this outcome is provided in Table 19. Only two studies report on issues when used for polyp detection, but both report no issues with functioning of the technology itself.[102, 125]

The only other data included for this outcome is the incidence of a technology not being able to provide an optical diagnosis at all, or a stable optical diagnosis. For example, technologies may have three outputs when assessing a polyp for characterisation using CADx, including adenoma, non-adenoma or "no prediction", with the latter being used when it cannot distinguish between an adenoma or non-adenoma. Results for this type of outcome below show that the incidence of this "no prediction" output may vary between technologies; it appears fairly low for the study that reports this information for CAD EYE® (1.3),[96] with the percentages reported for GI Genius™ being higher than this (ranging from ~5.0 to ~20.5%).[128-132] However, this is not necessarily a malfunction of the technology, but more a limitation of how much confidence the technology may add to an endoscopist's final judgement.

Table 19. Summary of data available for functioning of AI technologies

Study	CADe or C	Outcome	Number of polyps or	Result

	A Dx use		procedures	
CAD EYE®				
Rondonotti 2023 – ABC study[96, 131, 132]	CADx	Ability to provide a stable optical diagnosis	596 polyps	CAD EYE® alone (autonomous) was unable to characterise 8/596 polyps (1.3%) that could be retrieved, and characterisation was unstable for 47/596 polyps (7.9%).
CADDIE™				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
GI Genius™				
Seager 2024 – COLO-DETECT study[125]	CADe	Incidences where technology does not function	1003 procedures	No occasions where GI Genius™ itself failed to operate or malfunctioned during a procedure
Baumer 2023[128]	CADx	Ability to provide a stable optical diagnosis	290 polyps	A result of "no prediction" was returned by GI Genius™ for 17 polyps (5.9%), including 14 polyps that were assessed as undifferentiated and 3 polyps where there was no stable conclusion of the analysis process.
Bernhofer 2025[129]	CADx	Ability to provide an optical diagnosis	Unclear, all polyps in colon	Output of "no prediction" was returned by GI Genius™ for 19.6% of all lesions in the entire colon, with this applying to 13.8% of rectosigmoid lesions
Hassan 2022 – CHANGE study [132]	CADx	Ability to provide an optical diagnosis	544 polyps	GI Genius™ optical diagnosis not feasible in 1.4% (4/295) of rectosigmoid polyps ≤5 mm, 4.6% (22/476) ≤5 mm polyps within the whole colon and 5.1% (28/544) polyps of any size within the whole colon.
Koh 2024[130]	CADx	Ability to provide an optical diagnosis	820 polyps	Output of "no prediction" returned for 20.5% of all polyps with a CADx characterisation
Rondonotti 2024[131]	CADx	Ability to provide an optical diagnosis	480 diminutive polyps	AI output was obtained for all 480 diminutive polyps but "no prediction" was the output in 89/480 (18.5%). Endoscopist was able to provide an outcome in all 480 diminutive polyps but this was only high confidence when assisted by the AI system in 392 cases (81.7%)

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CADx, computer-aided characterisation; CSR, clinical study report.

3.2.2.1.6 Impact on decision making

Some data considered to be relevant to this outcome in the NICE final scope were identified in the form of the impact of the AI technologies on the predicted surveillance intervals for patients following the colonoscopy. Only a handful of studies reported this, however, including at least one study for two of the 10 interventions when used in a polyp detection context (CADe) and four interventions when used in a polyp categorisation context (CADx).[5, 96, 98, 103, 110, 125, 127, 132] Results are summarised narratively below, with results per intervention, including forest plots and results tables, presented in Section 1.16 of the DAR supplement.

Results that are available suggest that:

- For the CADe function: linked to the observation that fewer adenomas may be missed with AI-supported colonoscopy compared to standard colonoscopy in studies performing both procedures in tandem (see Section 3.2.2.1.1.7), there were fewer incidences of the surveillance interval needing to be reduced for a particular person (i.e. needing to be seen sooner than originally indicated) based on results of the second colonoscopy when AI was used as the first procedure compared to when standard colonoscopy was the first procedure.[110, 127] While this is likely to be appropriate given the aim is to identify more polyps and adenomas, and assign surveillance intervals based on the details of these, it is likely to lead to an increased surveillance colonoscopy workload, the extent of which is unclear as only a non-significant difference was identified from one RCT;[125]
- For the CADx function: optical diagnosis with AI may not fully align with recommendations that would be made based on histology and use of ESGE and/or US Multi-society Task Force on Colorectal Cancer (USMSTF) guidelines, but it is often fairly high and studies that provide comparative data suggest this is the same or very similar regardless of whether AI is used. Furthermore, one study suggests that in a resect-and-discard or diagnose-and-leave context, surveillance interval agreement is very high between CAD EYE® optical diagnosis (assume adjunct use based on the rest of paper) and expert optical diagnosis. Evidence for this outcome is limited but the evidence that is available does not suggest a large concern

about worsening assessment of surveillance intervals with the use of AI technologies compared to if based on endoscopist optical diagnosis without AI.[5, 96, 98, 103, 132]

3.2.2.1.7 Ease of use/acceptability of technologies to healthcare professionals

Some data on the opinions of healthcare professionals with regards to the ease of use or acceptability of the technologies are available but mostly from abstracts. This information has been summarised narratively here. A more detailed discussion, as well as forest plots related to these data, are presented in Section 1.17 of the DAR supplement. Data are too limited to base strong conclusions on, but may provide some insight into opinions on the technologies. The EAG notes that within BMJ-TAG, an update of a separate review (covering ethical implications of using AI-based technologies for medical image classifications in screening) is underway, which has been commissioned by the NIHR Evidence Synthesis Programme on behalf of the UK National Screening Committee (UK NSC; PROSPERO ID CRD42024599536). While not specific to AI in colonoscopy, general themes relating to AI emerging from this review may also be useful to consider in the colonoscopy setting, although it is not yet published.[142]

Results for quantitative measures of endoscopist experience suggest that there is limited impact of the technologies on comfort during the procedure or performance of technical aspects of the procedure,[113, 121, 125] and results from surveys on the experience of endoscopists with AI including from trials of specific technologies such as GI Genius™ or unnamed technologies, as well as groups that had not necessarily used an AI technology before suggest that while some concerns were noted (such as increased procedural time and distractions, increased risk due to the patient through increased polypectomies, cost and the potential for dependence on the technology), value in the technology was noted given assistance with polyp detection and reassurance that nothing is missed and support with leaving hyperplastic polyps in place, with most respondents considering there to be a role of the technology in the future of colonoscopy but with refinement required.[65, 69, 133-135, 137, 138] Furthermore, one survey of endoscopists that had used GI Genius™ in the UK COLO-DETECT trial highlighted the need for high-quality clinical and cost-effectiveness evidence to support the implementation of these technologies in clinical practice, which was noted as challenging given the lack of evidence available for the impact on long-term outcomes.[135]

In the submission by the JAG, it was reported that use of AI technologies might make the procedure more challenging initially, but that this could be eased through training and upskilling. It also notes

that it might be considered an innovative technology given there is currently no technology that reduces the variation in quality between endoscopists, which these technologies have the potential to do (including improving polyp detection and a role in improving optical diagnosis of polyps). A role in mitigating endoscopist fatigue was also suggested for these technologies in this submission. Feedback from the EAG's clinical experts was that these technologies do not generally require much training as they are straightforward to use, but more may be required for less experienced or trainee endoscopists.

3.2.2.1.8 Adverse events

The reporting of AEs within studies included in this review is limited. Where information on these have been reported, the majority are limited to statements that no events were observed in either arm. Furthermore, this is usually based on the immediate events during the colonoscopy procedure, with only one or two studies mentioning a longer period of follow-up (for example, 30 days) for AE monitoring. The data available for each intervention (seven of the 10 interventions) are summarised narratively in Section 1.18 of the DAR supplement, alongside forest plots where possible. Overall, across interventions, most studies reported zero AEs in either arm of the trial and where events were reported, there are no major concerns that this is higher for AI-supported colonoscopy. The EAG's clinical experts considered it unlikely that the use of AI technologies would increase or decrease the number of AEs occurring during colonoscopy, which the EAG considers is supported by the available evidence, but there are some concerns about how robustly this was measured in most trials.

3.2.2.1.9 Acceptability of tests to patients

Two survey-based studies assessing patient perspectives on the use of AI in colonoscopy were identified from the literature,[53, 66] with a brief comment on patient acceptance of AI use within a CADx-based trial also reported in a third study.[98] In addition, the EAG received expert input from a patient representative regarding the use of AI technologies and general concerns about colonoscopy. A submission from Bowel Cancer UK was also received as part of this project. A summary of information provided as part of these is provided below. Section 8 of the HTW report in this area also provides feedback from patient focus groups, which highlight similar concerns to those discussed below, in addition to the expectation that they would be asked for their consent before the AI technology was used and concerns about data and privacy.[43] Furthermore, as noted in Section 3.2.2.1.7, any general themes relating to the use of AI technologies in an updated review performed

by BMJ-TAG on behalf of UK NSC (PROSPERO ID CRD42024599536) may also be relevant to the colonoscopy setting, although this is yet to be published.[142]

3.2.2.1.9.1 Patients perspectives from the literature

Both survey-based studies of patient perspectives involved a broad range of colonoscopy patients (aged ~20 to ~80 or ~90 years, undergoing colonoscopy for any indication or for screening or surveillance specifically) and delivered surveys to patients prior to their colonoscopy procedure.[53, 66] The colonoscopy procedure itself was not said to involve any of the AI technologies, but patients were surveyed about their opinions on the use of these technologies.

Burton *et al.* 2025 included responses from 112 patients who completed the surveys in the pre-procedural area on the day of the colonoscopy.[53] The survey included closed-ended questions (yes/no) a 5-point Likert scale on the importance of AI use during colonoscopy and were asked to rank their top three reasons for choosing a colonoscopist from a list of options. Almost two thirds of respondents (58.0%) considered the use of AI in colonoscopy to be “very” or “somewhat” important, with only 9.8% considering it “somewhat not important” or “not important at all”, and 65.2% suggested they would choose a colonoscopist using AI over one that did not. In terms of the influence that AI use may have in a patient choosing a colonoscopist, only ~30% included the use of AI in their top three factors for choosing a colonoscopist, with none choosing this as the most important factor and only ~3.0% choosing it as the second most important factor.

Some potential differences between certain demographics and the perceived importance of AI use in colonoscopy were noted, such as familiarity with AI, prior colonoscopy, males and those aged <45 years possibly linked to rating AI use higher as a factor for selecting a colonoscopist, although no statistically significant differences were identified. Overall, the results indicate that a majority of patients may have some interest in the use of AI during colonoscopy and for some it may be a key factor that they consider to be important, but that this is likely to differ and some patients may equally have no interest or have considerable concerns about the implementation of AI during colonoscopy.

Schmidt *et al.* 2025 involved an online survey that was administered in the waiting room prior to the colonoscopy procedure, with 508 patients completing the survey.[66] The survey included closed-ended questions using a 5-point Likert scale, with brief background information on AI in colonoscopy provided and a focus on patient-friendly language. Only 20.4% of respondents considered the use of

AI by physicians in colonoscopy to be “very” or “extremely” important, although 51.1% considered AI was either “very” or “extremely” likely to lead to better health outcomes. When considering procedures performed by the physician alone as opposed to with assistance from CADe, fewer patients were likely to be “very” or “extremely” comfortable when CADe is used (60.8% vs 79.1%), but respondents were generally more comfortable with resect-and-discard and leave *in situ* approaches when physicians were supported with CADx compared to either physician alone or CADx alone (resect-and-discard: ~20%, ~15% and ~21% “very” or “extremely” comfortable with physician alone, CADx alone and physician + CADx, respectively; leave *in situ*: ~20%, ~16% and ~39% “very” or “extremely” comfortable with physician alone, CADx alone and physician + CADx, respectively).

Similar to Burton *et al.* 2025, there was some suggestion that certain demographics may be linked to perceived importance of AI and/or comfort with its use during colonoscopies, with males and those with at least some college education being variables associated with higher perceived importance of AI and males having a higher belief that it would improve health outcomes. A similar link between at least some college education and being more comfortable with CADe for polyp detection was noted. Furthermore, older respondents were generally more comfortable with polyp detection being performed by physicians alone compared to younger patients. AI familiarity was also mentioned as a factor that may impact the perceived importance of AI or comfort with the use of AI technology during colonoscopy. Overall conclusions made in the study were that there is a potential gap in knowledge within the general population in terms of AI and how it is being used in their care currently, that there may be a link between the belief that AI would lead to better health outcomes and increased comfort for AI use during colonoscopies and there is the potential for differences in perceptions on AI use in colonoscopy among patients, such as differences between males and females and an impact of education level. Furthermore, the authors note that education and clear communication about the roles of AI and clinician oversight will be important to provide reassurance that the AI will not replace the physician but will provide support.

In addition, a third study made a very brief statement on the perceived acceptance of patients regarding the use of AI in a trial using CAD EYE® to assist with optical diagnosis. [98] It was noted that 95.0% of 102 patients approached agreed to undergo CADx-assisted optical diagnosis, followed by a resect-and-discard or diagnose-and-leave approach instead of pathology, with only 2 of the 5 that refused participation citing a lack of trust in optical diagnosis and/or CADx as their reason.

Overall, the literature highlights that there is interest among patients in the use of AI during colonoscopy procedures and some may even consider its use to be important in terms of improving health outcomes. However, it also indicates that not all patients share the same perception in terms of importance or comfort with AI-supported procedures, meaning that different patients will have different beliefs and concerns about its use, and education and communication with patients about the impact of AI technologies on the outcomes of colonoscopies and potential downstream health benefits, as well as reassurance that the technologies will not replace clinician judgement, is likely to be important. Some of these themes are replicated in the feedback provided by the EAG's patient representative and submission from Bowel Cancer UK below, particularly the need for patients to be informed about the AI technologies and how they will be used.

3.2.2.1.9.2 EAG patient representative feedback

The patient representative did not have personal experience of colonoscopy but has supported family members through colonoscopy procedures. Many of the issues raised with colonoscopy were comments about general colonoscopy procedures rather than the use of AI during these procedures, but they are issues that are likely to also apply to procedures using AI, and maybe even more important. Areas raised are discussed in the following paragraphs, broadly separated into headings covering communication, technological functioning, waiting lists and waiting for results.

Communication

Communication surrounding colonoscopy was noted as a major concern, with follow-up information provided by some trusts being limited and patients finding it difficult to interpret the results provided to them. For example, it may be unclear what is considered to be a high number of polyps. While this is not specific to AI procedures, it is an issue that may be even more important with AI, given the potential for more polyps to be identified.

Some issues in terms of the lack of communication about the possibility of certain AEs were noted. While this would also apply to procedures performed with AI technologies, it is not expected that this risk would differ for these procedures based on the results discussed in Section 3.2.2.1.8. and given that the use of AI technologies does not require large changes to the procedure, other than perhaps slightly increased procedure time (Section 3.2.2.1.3), as it simply involves incorporation of the technology into a normal procedure and provides visual assistance only.

It was noted that it may be important to explain to patients the way in which the AI technologies are used during the procedures, as the perception of AI may be negative for some and may lead to reluctance. For example, it may be useful to reassure patients that the technologies will be used as an adjunct to endoscopist judgement, without solely relying on the output of the technology and that there are procedures in place to ensure that any polyps not sent for histology (if and when this process is adopted within UK clinical practice) are those where there is high confidence in the diagnosis, to reduce the risk of cancer being missed. Reassurance around the potential concern that the technology is being used to enable less experienced clinicians to perform the procedures, to save money or that it represents a downgrade to the colonoscopy process may also be useful. Furthermore, it highlighting that some polyps identified by AI may be left *in situ* if not considered by endoscopists to be a concern, as per usual colonoscopy procedures without AI, may be worth explaining.

Technological functioning

Experiences with equipment issues, leading to delays in polyp removal, and a lack of communication surrounding this, were also noted. This may be even more of a concern for patients in terms of procedures performed with AI if it was thought that there might be a risk of technical issues with the AI technology that might lead to delays. However, issues with the functioning of technologies may be rare based on the limited evidence discussed in Section 3.2.2.1.5 and the EAG considers that issues with the functioning of the AI technology might not prevent the colonoscopy from going ahead in the same way as an equipment failure would (i.e. it is possible the procedure could go ahead without the use of the AI technology).

Waiting for results

When considering the potential function of AI technologies in supporting optical diagnosis of polyps identified on colonoscopy, the patient representative noted that if it enabled a diagnosis to be provided on the day, rather than waiting for histology results, it would be considered a very valuable result of the technology. This is because there can be anxiety associated with waiting for test results, and receiving a diagnosis on the day may relieve this.

While the EAG acknowledges this point, feedback from the EAG's clinical experts and at the scoping workshop for this project was that all removed polyps are currently sent for histological testing, meaning it would be rare for any diagnosis to be provided before histology results were received.

While this may change if results from a pilot within the BCSP expands and optical diagnoses are used instead of histology in some cases, the EAG considers this potential role of AI-supported optical diagnosis is unlikely to be used in the near future across the whole colonoscopy setting.

Furthermore, in any colonoscopy procedure it is possible that multiple polyps are identified and removed; while endoscopists in the future might have confidence making optical diagnoses of some polyps where they have high confidence (either with or without AI technologies), it is possible that for others histology would still be required to make a confident diagnosis, so it is unclear how many patients would benefit from the potential reduced anxiety associated with waiting for results that these technologies could offer.

Waiting lists

The patient representative highlighted concerns about current waiting lists, with experience of appointments being changed multiple times, and expressed concern about whether the use of AI technologies would increase this further, for example, if it led to increased polyp detection and subsequently increased procedure times for colonoscopy. The EAG notes that evidence in Section 3.2.2.1.3 suggests the possibility of slightly increased procedure times, and concerns raised by physicians using AI technology about increased procedure times are noted in Section 3.2.2.1.7, but the impact of this on waiting lists is not known. This has been explored in the economic model but is considered to be an exploratory analysis only (see Section 4.2.1.11).

However, there was some discussion about the possibility of the optical diagnosis function of some AI technologies potentially reducing resource use, for example, if it meant that it reduced the wait for diagnosis time, with fewer polyps sent for histological assessment. As noted above under "waiting for results", it is unclear whether or when this CADx function would be used in UK clinical practice and it is not possible to work out whether this would outweigh the potential for increased polyp detection with these technologies, which could lead to more polyps being sent for histology.

A question about whether the use of the AI technologies might lead to increased spacing between tests for those that have regular colonoscopies, for example at least two per year; if so, it was noted as a potential benefit given it can be difficult to attend multiple appointments if there is a lack of flexibility around work, particularly with them changing or being cancelled repeatedly. The EAG considers this to be uncertain but potentially unlikely, given that increased detection of polyps likely associated with the technologies is likely to increase the number of people having more regular

follow-ups (based on applicable guidelines and supported by some data reported in Section 3.2.2.1.6).

3.2.2.1.9.3 Bowel Cancer UK submission

Most comments from the submission were based on general issues with colonoscopies that would not be specific to procedures performed with AI technologies, but would likely also apply to these procedures. For example, concerns were issues with the bowel preparation process, anxiety caused by seeing the screening during the procedure and a lack of information and knowledge about technologies currently used. The EAG considers it possible that the latter two points may be even more of a concern with procedures performed using AI, as there is more activity on the screen (for example flashing boxes) during the AI procedures and there may be a concern about the use of an AI technology if its function has not been described to patients.

When considering what they wanted from these new technologies, respondents as part of the Bowel Cancer UK submission noted the following:

- Improvement in colorectal polyp detection by reducing false positives and negatives, improving overall accuracy, removing human error by acting as a level of verification;
- Use alongside the clinician rather than replacing the clinician;
- Important that technologies are cost-effective, taking into account improvements in accuracy, speed and waiting times, as well as use of already scarce resources;
- Information on whether the technologies would improve polyp detection and characterisation in specific populations such as familial adenomatous polyposis (FAP) and serrated polyposis syndrome (SPS) would be useful, as well as other groups such as younger patients and details of the data that the technologies have been trained on.

There was a general expectation that if implemented, the technology should increase the accuracy and speed of diagnosis for colorectal polyps, with it being noted that the technology would likely not experience fatigue like a human endoscopist would. However, some concerns about potential loss of explanation with the use of AI, increased procedure duration and reduced productivity were noted.

The need for thought in terms of implementing into existing pathways was noted, beginning with ensuring that programming is right including training data and the software itself. The need for training requirements to be thought out and properly implemented, with clear guidance on when it

can be considered reliable and what to do in the event that endoscopists and the technology have contrasting views, was highlighted. Finally, a need for transparency regarding these technologies was emphasised, for example whether it would replace clinicians or enhance their practice and allowing patients to understand more about the decision-making functions of this technology.

3.2.2.1.10 Non-randomised NAIAD trial data (GI Genius™)

Data provided from the NAIAD trial to the EAG for GI Genius™ is described here. As noted in the sections earlier, the results of this trial are considered to be [redacted] The trial included three phases which each [redacted], including procedures performed prior to the implementation of GI Genius™ (phase 1), procedures performed with GI Genius™ (phase 2) and procedures performed after GI Genius™ was withdrawn after a period of use (phase 3). The results from all three phases of the trial are presented in Table 20 and Table 21.

For overall ADR, results were presented as an average value per site and per endoscopist, with [redacted] indicating that the use of GI Genius™ in phase 2 [redacted] compared to phase 1 by [redacted]. Similar results were observed for [redacted], but differences between phase 1 and 2 were [redacted]. Interestingly, when GI Genius™ was withdrawn from use in phase 3 of the trial, average ADR values [redacted], but it is possible there is another explanation for this observation. Similar was observed for all outcomes other than SSL DR, where the [redacted].

In terms of impact on procedure length, data from the NAIAD trial for procedures performed with and without GI Genius™ were provided for inspection time (withdrawal time excluding interventions), withdrawal time (including interventions) and total procedure duration. It is unclear in the information provided, but the EAG assumes that the no GI Genius™ group includes procedures from both phase 1 and phase 3. [redacted] Section 3.2.2.1.3, results suggest that GI Genius™ may

[redacted] Results for various subgroups were provided but the only one of relevance to this review was outcomes broken down by expert and non-expert endoscopists. These are briefly mentioned in Sections 1.21 and 1.22 of the DAR supplement.

Table 20. Relevant detection-based outcome data from NAIAD trial (adapted from Tables 2, 5, 6 and 8 of document provided to the EAG by the manufacturer)

Outcome	Phase 1 (prior to GI Genius™ - [redacted])	Phase 2 (GI Genius™ use - [redacted])	Phase 3 (after GI Genius™ withdrawn - [redacted])	p-value*	RR or MD for phase 2 vs phase 1†
ADR – average site, % (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
ADR – average endoscopist, % (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Advanced ADR, % (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Non-advanced ADR, % (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
SSL DR, % (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
APC, mean (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Non-advanced APC, mean (SD)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

*Unclear, but assume for comparison between all three groups;

†When analysed in Review Manager by estimating the number of patients with events from the percentages and number of colonoscopies reported.

Abbreviations: ADR, adenoma detection rate; APC, adenomas per colonoscopy; CI, confidence interval; DR, detection rate; EAG, External Assessment Group; MD, mean difference; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NR, not reported; RR, risk ratio; SD, standard deviation; SSL, sessile serrated lesion.

Table 21. Relevant procedural duration-based outcome data from NAIAD trial (adapted from Table 7 of the document provided to the EAG by the manufacturer)

Outcome	No GI Genius™ use (unclear, possibly phase 1 and phase 3 combined; [redacted])	GI Genius™ use (phase 2; [redacted])	p-value
Inspection time*, mean (SD)	[redacted]	[redacted]	[redacted]
Withdrawal time†, mean (SD)	[redacted]	[redacted]	[redacted]
Total procedure time, mean (SD)	[redacted]	[redacted]	[redacted]

*Inspection time defined as withdrawal time excluding time used for intervention (polypectomy, biopsy or haemostasis)

†Withdrawal time defined as time taken to withdraw the colonoscope from the caecum to the rectum, including time used for polypectomy, biopsy and haemostasis

Abbreviations: EAG, External Assessment Group; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NR, not reported; SD, standard deviation.

3.2.2.1.11 Outcomes not covered

In this review, no evidence was identified from the literature for the following outcomes outlined in the NICE final scope, for any of the interventions covered in this assessment:

- Time to colonoscopy and impact on waiting lists;
- Morbidity (other than AEs);
- Mortality;
- HRQoL.

While this is a limitation of the studies currently available, as no direct impact of the AI technologies on outcomes such as the development of CRC and mortality can be demonstrated, the impact of the technologies on such outcomes have been modelled through alternative methods, as outlined in Section 4.2.1.

3.2.2.1.12 Impact of colonoscopy indication – subgroup analyses

Subgroup analyses performed based on the indication for colonoscopy were prespecified as part of the protocol for this assessment and are summarised here for separate interventions. The EAG performed subgroup analyses for ADR and APC given these were the most commonly reported outcomes across studies within each intervention. The EAG presents its preferred subgroup analysis

for each intervention in Section 1.19 of the DAR supplement; it notes that similar conclusions were made when other variations were explored (for example, only including studies that had >80% of its population categorised into one subgroup). These alternatives are not presented in the DAR supplement but can be provided on request. Studies considered to be at a high risk of bias were not included in these analyses, in line with their exclusion from primary analyses in the overall population. The EAG notes that no included studies reported CADx data separately for different colonoscopy indication subgroups.

Overall, the EAG concludes that while there may be some trends for differences in population within individual studies or meta-analyses, these observations are not consistent or are based on only one study in one of the subgroups, making interpretation challenging. For example, while the analyses for GI Genius™ suggest that the study covering Lynch syndrome (Ortiz *et al.* 2024) may be an outlier in terms of results (a negative impact of the technology on ADR and APC is noted), suggesting the evidence may not support its use in this population, the same observation was not made for the CAD EYE® analysis, which also included one study focusing on Lynch syndrome (Huneburg *et al.* 2023).[89, 121] While it is possible that differences in how well technologies function across different subgroups could exist between technologies, given this inconsistency, the EAG considers that evidence from one study per technology is not sufficient to draw strong conclusions. Similarly, some analyses suggest a slightly better outcome in symptomatic populations compared to screening or surveillance populations, but the opposite or no difference is observed in other analyses.

The difficulty in assigning studies to different subgroups given that most studies included mixed colonoscopy populations and did not provide within-trial analyses, or where these were available but led to breaking of randomisation, means the results of these analyses are considered to be very limited. The general lack of patterns in differences in effects between different populations may be some reassurance that the functioning of the technologies is unlikely to differ widely, but the presence of subtle differences not identified through these analyses cannot be ruled out. Larger studies stratified at randomisation and powered to detect differences in different subgroups would improve the assessment of whether differences are likely to exist. This lack of strong evidence to support a difference in CADe effect between different colonoscopy indications is supported to some extent by a recent SLR and meta-regression;[143] while the studies included were not identical to this SLR due to certain protocol differences and this analysis involved pooling different CADe technologies as a single CADe intervention, even on univariable regression FIT as a colonoscopy indication was “only suggestively associated” with the ADR outcome and did not form part of the

final multivariable meta-regression. Furthermore, the BMJ Rapid Recommendations stated that its SLR where CADe technologies were pooled as a single CADe intervention found "no credible evidence of effect modification by subgroup".[49, 50] Although the ESGE restricted its weak recommendation to screening/surveillance patients, this was likely due to limited representation of other populations in the SLR it based its recommendation on rather than evidence that there are differences.[47, 50] Some exploratory economic analyses have been performed for screening, symptomatic/diagnostic, surveillance and Lynch syndrome surveillance (see Section 4.2.1.1 and Appendix 9.8).

3.2.2.1.13 Impact of endoscopist experience and expertise – subgroup analyses

Subgroup analyses performed based on the level of experience of the endoscopist performing colonoscopies were also prespecified as part of the protocol for this assessment and are summarised here for separate interventions. As for colonoscopy indication, this was assessed for ADR and APC outcomes. The EAG's clinical experts and specialist committee members involved in this assessment noted that the biggest difference might be expected between screening and non-screening endoscopists. A threshold of at least 40 or 45% for baseline ADR before study enrolment was considered to be representative of what would be expected from screening endoscopists by some specialist committee members, and may be the most useful way of separating data based on endoscopist experience. Studies did not often report subgroup analyses based on ADR and overall endoscopist experience was rarely described in this way to allow separation of whole studies for subgroup analyses. Therefore, while the EAG has explored endoscopist experience where possible for each intervention, in most cases these do not represent the most clinically useful way of separating studies.

The EAG's preferred subgroup analyses for each intervention are presented in Section 1.21 of the DAR supplement. For most interventions, studies were categorised into subgroups based on the entry requirements for the study (for example, if a certain level of experience was required or not, such as a specific baseline ADR or a certain number of colonoscopies), taking into account any within trial subgroup data. Where feasible, alternatives exploring the impact when studies and subgroup data were classified based on the group that the majority of the patients were captured by were also performed where possible. It was less feasible to perform analyses classifying studies based on >80% patients within a specific group for these analyses, but where they were possible the conclusions did not differ from those presented in this report (these are not presented in the DAR supplement but

can be provided on request). Studies considered to be at a high risk of bias were not included in these analyses, in line with their exclusion from primary analyses in the overall population.

Only three studies reporting CADx data reported outcomes separately for endoscopists with different levels of experience or expertise using the AI technologies (CAD EYE® and GI Genius™), and one of these did not report data for an assessment based on endoscopist optical diagnosis alone. Therefore, the ability to assess whether differences with AI-assisted optical diagnosis compared to endoscopist optical diagnosis alone may vary across levels of endoscopist experience is limited.

The EAG notes that within the colonoscopy field, there is a suggestion that any benefit of CADe may be larger for less experienced endoscopists compared to those with more experience, such as between screening and non-screening endoscopists. Overall, the EAG concludes that while there may be a trend for larger increases in ADR or APC with AI within endoscopists with less experience in some studies (mostly within some within-trial subgroup analyses), this is not consistent and some analyses suggest the opposite. Furthermore, there was difficulty separating studies into appropriate subgroups due to wide variations in how experience or expertise was defined in trials and in most cases an analysis based on baseline ADR using a threshold of 40%, which may be the most clinically useful way of separating based on endoscopist experience based on feedback from specialist committee members, was not possible.

The EAG considers the evidence to support any differences in CADe benefits between endoscopists with different experience to be limited. In addition to limitations in the ability to group studies, the fact that some trials that reported within-trial subgroup data were not stratified by endoscopist experience, meaning breaking of randomisation has occurred, was an additional limitation. While there may be some evidence to support the idea that the impact of AI on improving ADR and other outcomes may differ depending on endoscopist experience, the direction of effect is inconsistent between studies and meta-analyses, and larger studies stratified at randomisation and powered to detect differences in different subgroups would improve the assessment of whether differences are likely to exist.

While one paper noted that studies showing no effect of CADe on ADR all had a baseline ADR of at least 60% and concluded that benefits of CADe may depend on endoscopist experience or quality, it also acknowledged the limitations of its approach, which was based on the mean ADR in the control group arms of each study rather than a measure of endoscopist performance indicators before

enrolment in the study.[143] In addition, the BMJ Rapid Recommendations on the use of CADe in colonoscopy made a fairly strong statement that, "despite speculations that CADe colonoscopy is most beneficial for novice endoscopists, there is no evidence to support conclusions on its efficacy being modified by the endoscopist's skill level",[49] which was based on its own SLR with CADe technologies pooled as a single intervention.[50] On review of the subgroup analyses considered in this assessment, the EAG did not consider it feasible to explore endoscopist experience subgroups within the economic model (see Section 4.2.1.1), and considers there to be insufficient evidence currently to support a difference in the benefit of CADe between endoscopists with different levels of experience.

3.2.2.1.14 Sensitivity analyses and heterogeneity

Sensitivity analyses were performed to explore the impact of decisions made around analyses on results and heterogeneity observed within the analyses. Due to time constraints, these were only performed for ADR and APC outcomes. Where the impact on results was limited, results are not presented here but can be provided on request. Information was not considered to be reported for enough studies to consider sensitivity analyses based on version of the software or use of additional devices such as ENDOCUFF VISION™ useful.

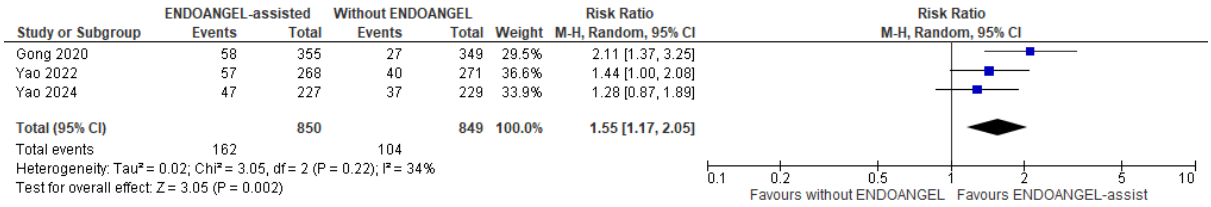
Risk of bias

Where RCTs at high risk of bias were identified, they were excluded from primary meta-analyses if evidence was available from studies at a lower risk of bias. This led to six studies being excluded from the main analyses across interventions.[2, 73-77] Full risk of bias assessments for these studies, indicating the rationale for a high risk of bias rating are presented in Section 3.1 of the DAR supplement. In summary, compared to other studies assigned a lower risk of bias, there were either additional concerns about certain aspects of the trial or there were very limited methodological details reported on key areas such as randomisation and missing data or participant exclusions. For Gong *et al.* 2020, only suspected adenomas were removed and sent for histology, leading to concerns about measurement bias particularly when compared to other studies where most polyps were removed and tested.[75] There was a notable imbalance in endoscopist experience between the AI and non-AI arms and concerns about exclusions post-randomisation for Scholer *et al.* 2024,[2] and for Zhang *et al.* 2023,[76] detection outcomes were confirmed by expert endoscopists rather than histological assessment. Concerns about Vilkoite *et al.* 2023 were mostly due to very limited information provided;[73] these concerns also applied to Engelke *et al.* 2023,[74] with additional

concerns about randomisation for this study given it was based on alternation rather than a random sequence and imbalances are noted for endoscopist experience and completion of colonoscopies. Similarly, Lagstrom *et al.* 2025 used a quasi-randomisation approach where the intervention received was based on the week that patients had the colonoscopy, with some larger imbalances in baseline characteristics noted between trial arms.[77]

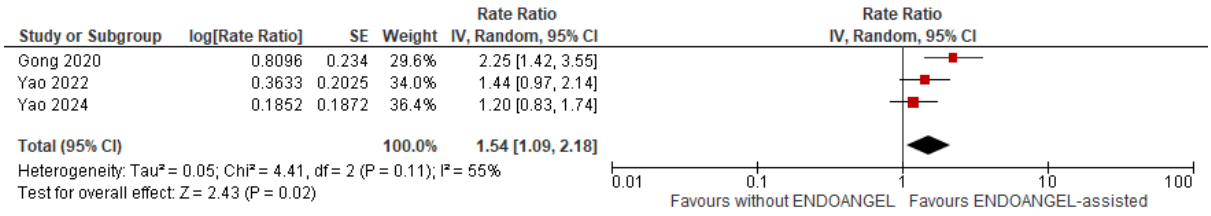
For ADR, the exclusion of high risk of bias studies only had a notable impact on the results for ENDOANGEL®; when Gong *et al.* 2020 was included in the analysis instead (Figure 15),[75] the point estimate increased from 1.36 to 1.55, although both analyses were consistent with a statistically significant benefit of ENDOANGEL® in terms of increasing ADR compared to standard colonoscopy. While no large impact of this sensitivity analysis for APC when analysed as a mean difference was noted for ENDOANGEL®, when analysed as an IRR the difference was more notable (the point estimate increased from 1.31 to 1.54 and was statistically significant when the additional study was included; Figure 16). The inclusion of this study introduced statistical heterogeneity that was not present in the primary analyses.

Figure 15. ADR in ENDOANGEL® studies – with inclusion of Gong *et al.* 2020



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 16. APC analysed as IRR in ENDOANGEL® studies – with inclusion of Gong *et al.* 2020



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Methods of combining data from multiple study arms

Where the EAG combined data from two arms of a study into a single arm for the purpose of meta-analysis (for example, data from the Aniwan *et al.* 2023 study),[79] the method of doing this was explored where possible. The EAG's primary approach was to add the two arms as a single study, by totalling the events and number analysed for each arm (for ADR) or by obtaining a single mean and SD value (see Section 3.1.5.2) for each arm (for APC). The EAG explored an alternative of adding as two separate studies to the meta-analysis (where each had different intervention and control groups, avoiding double counting). Results were almost identical and the EAG's primary approach was retained.

Intervention and comparator arm differences

One of the included studies was notably different in that it included a sham CADe system rather than standard colonoscopy.[115] This was a study included for EndoScreener® and the EAG explored the impact of excluding this study on results for ADR and APC when reported as an IRR. Only a negligible impact on the results was noted on both outcomes and the EAG retained the primary analyses including all studies. In addition, one CAD EYE® trial combined CAD EYE® use with water exchange and caecal retroflexion as a single intervention, with the comparator arm being colonoscopy without any of these interventions.[87] The exclusion of this study from the main CAD EYE® analyses for ADR and APC had only a negligible impact on the results.

Inclusion of only trainee endoscopists

Given the protocol allowed inclusion of colonoscopies performed by endoscopists with any level of experience, studies that only included trainees could be included in the EAG's primary analyses for ADR and APC. Across interventions, three studies were specific to trainees or novices (one each for CAD EYE®, ENDO-AID™ and ENDOANGEL®),[92, 107, 110] and the EAG has explored the impact of excluding these studies on the results. Overall, the EAG notes a limited impact on results, and the EAG has retained all studies in its primary analyses given no exclusion criteria regarding trainee endoscopists were outlined in the protocol for this assessment.

While the exclusion of Yamaguchi *et al.* 2024 for the CAD EYE® analysis did not have a large impact on the effect estimate, the removal of this study substantially reduced the statistical heterogeneity present for ADR and APC when analysed as an IRR (I^2 values from 36% to 10% and 40% to 15%, respectively).[92] A similar impact was observed for the APC analyses as a mean difference; although statistically significant heterogeneity was not present in the primary analysis when analysed as a

mean difference, there was a reduced visual difference in point estimates when Yamaguchi *et al.* 2024 was removed.

The impact of excluding Lau *et al.* 2024 from analyses of ADR and APC when analysed as a mean difference for ENDO-AID™ was negligible.[107] For APC analysed as an IRR, a slightly larger impact was observed but would not change conclusions (IRR changed from 1.63 to 1.56, with statistically significant differences observed for both analyses and no obvious heterogeneity present).

For ENDOANGEL®, only two studies were included in the primary meta-analyses for these outcomes. Exclusion of Yao *et al.* 2024 did have a slight effect on the point estimate for ADR and APC analysed as an IRR; when based solely on data from Yao *et al.* 2022, the point estimate for ADR increased slightly (from 1.36 to 1.44), with wider confidence intervals and a difference that was no longer statistically significant (p-value changed from 0.02 to 0.05).[109, 110] When APC was analysed as an IRR, the point estimate changed slightly, increasing from 1.31 to 1.44. However, results from analyses with and without this study were not statistically significant for this outcome and there was no obvious heterogeneity when both studies were included. For APC analysed as a mean difference, the point estimate remained the same despite the removal of Yao *et al.* 2024, but the result was no longer statistically significant (p-value changed from 0.04 to 0.06). There was no obvious heterogeneity when both studies were included in the analysis.

Comment on heterogeneity in primary ADR and APC analyses

For ADR, notable heterogeneity was identified for CAD EYE® and GI Genius™ primary analyses (Section 3.2.2.1.1.1). For CAD EYE®, this heterogeneity was substantially reduced in the sensitivity analysis described above; i.e. removing studies that only consisted of trainees (Yamaguchi *et al.* 2024).[92] While this is noteworthy, the EAG does not consider the evidence to be robust enough to support the idea that improvements in ADR may be poorer in general in trainee endoscopists, as other studies where the majority of endoscopists were trainees were not consistent with this result (see Section 3.2.2.1.13). A similar effect was observed for the respective APC analysis when analysed as a mean difference, but removal of Yamaguchi *et al.* 2024, did not substantially reduce the I^2 value when APC was analysed as an IRR.

For GI Genius™, no obvious reasons to perform a sensitivity analysis were identified to explore heterogeneity. Furthermore, the subgroup analyses performed for colonoscopy indication and endoscopist experience (Sections 3.2.2.1.12 and 3.2.2.1.13) did not resolve the heterogeneity for

ADR; while one study that is an outlier covers a Lynch syndrome population (Ortiz *et al.* 2024),[121] the other two studies showing less favourable results for ADR (Mangas-Sanjuan *et al.* 2023 and Wallace *et al.* 2022) are not particularly notable in terms of differences compared to other studies for colonoscopy indication or endoscopist experience.[120, 127] A similar effect was observed for APC when analysed as an IRR; statistical heterogeneity was not resolved by the exclusion of Ortiz *et al.* 2024.[121] However, the heterogeneity observed for APC when analysed as a mean difference for GI Genius™ (based on visual differences in point estimates), was resolved when the Ortiz *et al.* 2024 study was disregarded, as APC results for Mangas-Sanjuan *et al.* 2023 and Wallace *et al.* 2022 are more consistent with other studies compared to ADR. [120, 121, 127]

3.3 Discussion

3.3.1 Summary of key results

The EAG conducted an SLR and performed meta-analyses, where appropriate, to assess the clinical and diagnostic evidence available for 11 AI technologies (listed in Section 2.1.1) that can be used to support polyp characterisation and/or detection during colonoscopy procedures. In February 2025, WISE VISION® was removed from this assessment report given it is no longer available to the NHS. The comparator included was standard colonoscopy without the use of these technologies. RCTs published as full papers were prioritised where possible, but non-randomised studies and/or abstracts were included to cover outcomes or populations not covered in the RCTs and a fairly large non-randomised UK-based assessment of GI Genius™ was considered to be useful as supportive evidence alongside RCT data. This led to the inclusion of 70 independent studies overall after initial searches in September 2024 and an update in June and July 2025. Most of the evidence was considered to be at some risk of bias, with some higher risk of bias RCTs as well as non-randomised studies and abstracts being considered at a higher risk of bias. The EAG considers a risk of publication bias in this area is likely but is unable to quantify the potential bias introduced by it. Preliminary results from an additional, non-randomised, retrospective analysis of CADDIE™ was also provided to the EAG in September 2025, while not formally included due to time constraints, the EAG also considers this study to be associated with more limitations compared to the evidence from two RCTs already included for this technology (see Section 3.2.1.3).

Evidence for an impact on ADR, a key performance indicator for colonoscopies which has been linked to interval CRC risk (a higher ADR may reduce interval CRC risk) and which is a key input for the economic model in this assessment,[139] is available for all interventions included in this report. There is evidence that all interventions increase ADR compared to standard colonoscopy, based on meta-analyses excluding RCTs at a higher risk of bias. The extent of this increase varies and evidence is less certain for Argus®, Discovery™ [redacted] given no statistically significant difference was identified and results are based on only a single study. For GI Genius™, results from the UK-based non-randomised NAIAD trial performed at multiple NHS centres [redacted].[60] There was also only one study available for MAGENTIQ-COLO™ but a statistically significant difference was identified. Statistical heterogeneity was an issue for CAD EYE® and GI Genius™ analyses, but this was mostly with regards to the extent of an ADR benefit, with only one or two

studies in each analysis suggesting no ADR benefit with AI based on point estimates. Similar conclusions were made with regards to APC, with data available for all interventions other than EMIS™.

Data available for other detection-based outcomes in this report were more limited, being covered by fewer studies and providing information for fewer interventions. Overall, across interventions, there is some evidence that some of the technologies may increase the detection of advanced adenomas, non-advanced adenomas, adenomas of different size categories (although less consistent for larger adenomas, which may be partially explained by fewer events), SSLs and non-neoplastic/hyperplastic polyps, with similar results observed when per colonoscopy rates for many of these outcomes were available. Tandem studies reporting AMR suggest fewer missed adenomas with AI compared to standard colonoscopy, for five interventions for which this information was available. However, the EAG considers evidence for these outcomes to be more limited given the lack of statistically significant differences for many analyses and reduced number of studies reporting them. For EMIS™, only data for the ADR outcome were available in this assessment.

Similarly, the EAG notes that additional outcomes presented in the DAR supplement are limited in terms of the number of studies reporting them and interventions covered and no strong conclusions can be made based on them; of note, there is some evidence that the AI technologies increase the detection of any polyps and no strong evidence to support a difference in ADR within different areas of the colon, such as proximal compared to distal.

With regards to detection, evidence identified for diagnostic accuracy was extremely limited; there is some evidence that false positives flagged by some of the technologies during the procedure may be relatively low, but it is unclear how robustly this information was captured in the trials. Diagnostic accuracy data on the characterisation functions of four of the technologies were available; overall, the EAG notes that results are mixed (some results suggest improved sensitivity with AI compared to endoscopist optical diagnosis alone, while others suggest no notable difference, a slightly better result for endoscopist optical diagnosis alone or do not report a comparison to endoscopist optical diagnosis alone) and most studies are considered to be limited, either because the technologies are used autonomously, there are concerns about how SSLs are treated in the analyses or the exclusion of low-confidence diagnoses, or no comparison against endoscopist optical diagnosis alone is included. For studies reporting information on surveillance intervals in the CADx setting, results

using AI-supported polyp characterisation were similar to those based on endoscopist optical diagnosis. The EAG considers the evidence available for the characterisation functions of technologies to be more limited currently compared to the detection functions and does not consider it possible to base strong conclusions on this evidence. Of note, two recent meta-analyses of CADx use specifically for diminutive rectosigmoid polyps have concluded that there are no incremental benefits or harms associated with CADx-assisted colonoscopy compared to colonoscopy without CADx, specifically in the context of resect-and-discard or leave *in situ* strategies.[141, 144]

Data on withdrawal and total procedure durations suggest potentially increased length of procedures with the AI technologies compared to standard colonoscopy, but any differences identified are mostly small, up to one or two minutes per colonoscopy only. Although it is unclear how robustly they were assessed in trials, information on AEs and issues with the functioning of technologies suggests no major concerns. Information included in this report on patient and endoscopist opinion suggests that there is a willingness to embrace these technologies, but key concerns would need to be addressed, such as explaining processes to patients, reassurance that it will not replace clinician judgement, relevance to specific populations such as IBD and those with polyposis syndromes such as FAP, and concerns about costs and possible impacts on downstream processes such as histology and waiting lists.

As expected, no data on the long-term impact of using these AI technologies were identified as part of this assessment, such as data on mortality, morbidity other than AEs or HRQoL. While other methods of incorporating long-term outcomes into the economic model have been used, the lack of direct evidence for the impact of these technologies on these outcomes is a limitation, nonetheless. Similarly, no evidence relating to any potential impact on waiting lists was identified.

For polyp detection, the EAG explored subgroup analyses by colonoscopy indication and endoscopist experience and expertise for ADR and APC outcomes. However, these should be considered exploratory and uncertain given difficulties in constructing these subgroups due to differences in definitions between trials and a lack of stratification at randomisation for many within-trial subgroups, and it notes that subgroups exactly mirroring those outlined in the NICE final scope were not always possible. While some possible differences were identified in specific trials or analyses, such as improvements in ADR being larger for less experienced endoscopists or for symptomatic compared to screening or surveillance colonoscopy groups, these were not consistent across studies

or interventions, and the EAG does not consider there to be robust evidence to conclude that differences exist between subgroups. Furthermore, with regards to endoscopist experience, most studies did not separate experience based on the most clinically useful categories; feedback from the EAG's clinical experts and specialist committee members was that separation between screening and non-screening endoscopists would be most clinically useful, with a threshold of 40 to 45% for baseline ADR suggested for separating these groups, and this was rarely available. No data for polyp characterisation was available for colonoscopy indication subgroups and was extremely limited for endoscopist experience, with similar issues as noted for polyp detection and reporting by fewer studies.

3.3.2 Generalisability of clinical trial data to clinical practice in England and Wales

Populations covered by the trials

As described in Section 1.2.1, colonoscopies in the UK may be performed for various indications, including screening via a national screening programme, assessment when symptoms of concern are present, as part of surveillance following prior removal of polyps or as part of surveillance programmes for groups with specific conditions associated with an increased risk of CRC, such as Lynch syndrome, polyposis syndromes, prior family history of CRC, a prior diagnosis of CRC at <50 years of age and IBD. The EAG considers that screening, symptomatic and post-polypectomy surveillance populations are reasonably well covered by the evidence available overall, but this may not be the case for specific interventions; for example the single Discovery™ trial does not cover FIT-based screening and the single trial for MAGENTIQ-COLO™ does not cover FIT-based screening or a symptomatic population.

Evidence for surveillance performed for other indications is more limited; while three studies (one full publication for CAD EYE®, and one full publication and one abstract for GI Genius™) were specific to Lynch syndrome populations, most other trials excluded these patients. For IBD populations, the only evidence available for inclusion in this assessment was from abstracts considered to be at a high risk of bias, including some data for CAD EYE® and GI Genius™. Data reported in these abstracts were limited in terms of outcomes covered as well as methodological reporting. Most other trials excluded patients with IBD from participation. Similarly, most trials excluded patients with a prior history of cancer and polyposis syndromes, although this was sometimes unclear. Patients did not often appear to be excluded based solely on a family history of CRC (i.e. CRC but no FAP syndrome),

but the EAG notes that studies did not report the number of these patients included in the trials. Overall, while there are two full text publications focusing on Lynch syndrome, this only covers two interventions, and data for surveillance in IBD and other surveillance populations is even more limited or not covered at all.

Applicability of trials to clinical practice

Based on feedback from the EAG's clinical experts about colonoscopy procedures in England, for example, processes such as bowel cleansing and equipment used, the EAG has no major concerns that the trials are likely to be unrepresentative of clinical practice; most trials describe the use of HD colonoscopes under white light and similar thresholds for determining poor bowel cleansing were used. While some excluded the use of products such as ENDOCUFF VISION™ which can be used in the NHS, this was not considered unreasonable by the EAG as feedback was that the use of these devices is variable and may be used less often in non-screening colonoscopies based on the recommendation by NICE (NICE MTG45).[40]

Coverage of populations seen in UK clinical practice is described above, but in terms of age and sex, the EAG notes that the trials are reasonably well aligned with estimates provided by the EAG's clinical experts for the UK population; mean or median ages are >40 years in all studies and the split between males and females is roughly 50:50 in most studies. While UK sites were not included in the trials for most interventions, the EAG's clinical experts did not expect large differences in the interventions across countries particularly compared to European populations. At least some European data are available for all technologies with evidence available apart from ENDOANGEL® and EndoScreener®. Some UK sites were included in some trials for [redacted] GI Genius™. While European and UK data for these interventions may be ideal, the EAG is not aware of major concerns about likely differences between countries in terms of the ability of AI to improve colonoscopy outcomes if all other factors (such as colonoscopy indications and endoscopist expertise) are similar.

Based on the factors described above, while coverage of certain populations of interest may be limited, such as surveillance for IBD or other indications such as polyposis syndromes, trials that are available are likely to be a reasonable reflection of UK clinical practice. Furthermore, as part of a submission from the JAG, it was noted that current clinical trials of AI-supported colonoscopy are considered to be reflective of UK clinical practice.

Data used to train AI technologies

As discussed in Section 2.1.5, concerns about algorithms within the AI technologies not being developed, trained or validated on data from people with IBD or hereditary risk factors was raised, with concerns about how well they would perform in these populations. Populations that algorithms were trained on were not reported as part of the trial publications. On review of the manufacturer submissions provided as part of this assessment, the EAG notes that full details of populations included in the data training sets for algorithms are not provided for any technology. However, some information was available for some interventions.

In its development report, Odin Vision reported some demographics for hospitals that were part of the developmental data for CADDIE™, but noted that [redacted]

Other information reported in any documents provided by manufacturers is summarised as follows:

- For Argus®, its instructions for use document advises that the device has not been studied in patients with IBD, a history of CRC or previous colonic resection and that "the device performance may be negatively impacted by mucosal irregularities such as background inflammation from certain underlying disease";
- Submissions for CAD EYE®, GI Genius™ and MAGENTIQ-COLO™ report no contraindications in terms of colonoscopy indication.

The EAG also requested additional information from all manufacturers on data used to train algorithms, including colonoscopy indications covered (i.e. screening, symptomatic/diagnostic, surveillance or other), populations covered (such as whether IBD populations and other populations at a higher risk of CRC were captured), countries that data were included from and basic demographic details such as age, sex, ethnicity and race. Manufacturers for Argus®, CAD EYE®, Discovery™, ENDO-AID™, EndoScreener®, GI Genius™ and MAGENTIQ-COLO™ responded to this

request, although only high-level details were provided by most manufacturers, with some noting that a detailed breakdown was not possible as training data were anonymised:

- Responses from five suggest that screening, symptomatic/diagnostic and surveillance colonoscopies were covered (screening colonoscopy, diagnostic colonoscopy prior to treatment, surveillance colonoscopy after treatment and secondary colonoscopy for abnormal findings were included in training data for CAD EYE®, no indications were excluded for Discovery™ and post-CRC surgery colonoscopies were said to be included for EndoScreener®), although a detailed breakdown was not provided. For GI Genius™, screening and surveillance populations were covered in the training data, with a roughly even split between these for detection and characterisation functions. Training data for ENDO-AID™ [redacted];
- No specific populations were said to be excluded from the training data for Discovery™. Information provided for Argus® indicates a wide range of populations included (including those with a family history of CRC and IBD, among others) but it remains unclear if other populations such as those with polyposis syndromes or prior CRC were covered. Information for GI Genius™ indicates that the device has not been trained in IBD, those with a history of CRC, prior colonic resection, Lynch syndrome or FAP or other polyposis syndromes. Lynch syndrome and polyposis populations were said to be excluded from the dataset for MAGENTIQ-COLO™, but people with prior CRC and IBD were included. For ENDO-AID™, [redacted] Data on this were not available for CAD EYE® or EndoScreener®;
- Training data were reported to be from European countries (Germany, Italy, France, UK, Poland) for Discovery™, from North America for Argus® (USA and Canada) and from multiple continents including Europe for CAD EYE® (Germany, Italy and Japan), EndoScreener® ([redacted]), GI Genius™ (Belgium, Canada, Germany, Italy, Lithuania, The Netherlands, UK and USA) and MAGENTIQ-COLO™ (USA, Israel, The Netherlands, Germany, Spain and India). Training data for ENDO-AID™ were from [redacted];

- Broad age ranges of 18 to 75 years, 23 to 85 years or 18 to 90 years were reported for Argus®. EndoScreener® and MAGENTIQ-COLO™, respectively, with all three covering males and females and White, Black and Asian races. For GI Genius™, mean age of training data was ~62.0 years, males and females were covered (majority male, ~65.0%) and ~92.0% of training data were from White participants, with a smaller proportion (~6.0%) of Black or African American participants and limited coverage of other races. Information could not be provided for Discovery™ as issues with data anonymisation were noted and no information on this was available for CAD EYE®. Similarly, [redacted].

While information on whether or not specific populations were covered in training sets for algorithms is limited, the EAG considers the lack of available studies validating the use of these technologies in IBD or other hereditary risk factor populations during real-time colonoscopies to be the bigger issue; if these were available, this may help to alleviate concerns about these populations potentially not being captured in the training datasets for the technologies. Overall, the EAG considers there to be limited evidence covering these populations and it is unclear how well the technologies are likely to function in these populations.

Versions of technologies used in the trials

One concern raised at the scoping workshop for this assessment was whether or not the same version of the technology was used for all patients within a trial and how comparable the versions of the technology used in the trials are to what is currently available. The EAG notes that the version of the technology used was not always reported in the trials, but where it was reported, it tended to be the same version used for all patients (i.e., only one version number is cited). This is with the exception of the Discovery™ study, where two versions were mentioned. Across studies for a specific technology, different studies did use different versions (for example, some GI Genius™ studies cite version 1.0 whereas others cite version 2.0 and higher). Given many studies do not report the version number used, it is difficult to assess how applicable they are to the current versions of the technology, particularly as some technologies expect to have new versions by the time this project is completed. Sufficient reporting of version number across studies was not considered to be available to consider sensitivity analyses based on software version. The EAG considers this is likely to be an

ongoing issue given the nature of the technologies, but considers that evidence from the included trials should be applicable enough to inform this assessment.

3.3.3 Key issues and uncertainties

The EAG has some concerns about the ADR data included in this review for EMIS™ but it has been used given the lack of any other available evidence. In particular, despite being an RCT, [redacted] The technology, as used in this trial, did [redacted] making it different to the other technologies included in this review and data for only one of three sites included in the full trial were provided to the EAG at this stage.

The EAG considers the evidence base for the use of AI technologies for polyp characterisation to be more limited than that for polyp detection. Many of the studies identified use the technology autonomously rather than as an adjunct to endoscopist experience, do not include a comparison to endoscopist optical diagnosis alone or only include diagnoses that were made with high confidence by endoscopists in the analyses. These cause issues with applicability to clinical practice and difficulty determining whether AI-supported characterisation would be an improvement compared to endoscopist optical diagnosis alone. Furthermore, it should be noted that most technologies are not currently able to recognise SSLs as potentially pre-cancerous polyps, and most analyses either excluded them or categorised them as non-neoplastic/non-adenomatous. While they are non-adenomatous, categorisation of adenomas vs non-adenomas only ignores SSLs and other types of pre-cancerous polyps, and while the technologies should be used alongside endoscopist judgement, the fact that SSLs will not be specifically characterised might introduce a layer of complexity when interpreting results of the technology. Additionally, the EAG notes that the use of the polyp characterisation function of applicable technologies in UK clinical practice may be limited, or its impact on downstream resources may be limited, if alternative polyp resection strategies are not adopted, as currently most polyps are resected, with all resected polyps being sent for histology, although this is in the process of changing within the NHS BCSP.

The lack of evidence for the impact of AI technologies on long-term outcomes such as mortality, morbidity other than AEs and HRQoL from included studies is a limitation, and means that alternative methods of capturing these in the economic model have been required. Similarly, there was no information identified from the clinical evidence about potential impacts on waiting lists.

While subgroup analyses based on colonoscopy indication and endoscopist experience and expertise have been performed, the EAG considers these analyses to be exploratory and associated with substantial limitations. Studies taking these factors into consideration during the design process may improve the ability to draw conclusions on potential differences between subgroups; for example, large trials powered to identify differences in different subgroups and stratified for this at randomisation, using categories that are most clinically relevant such as a baseline ADR of 40 to 45% to separate screening and non-screening endoscopists, may be of benefit.

Given the exclusion of certain populations from most of the included studies, there are some concerns about how applicable results in this assessment are in these patient groups; while there are some specific studies looking at patients with IBD or Lynch syndrome, this is from one or two studies and not for all interventions. Furthermore, populations with a prior history of CRC and polyposis syndromes were excluded from most trials and not covered by any individual studies, and it is unclear how well other populations at a higher risk of CRC are covered, such as those with family history of CRC, as this information was not well reported. Details on which populations the algorithms of these technologies were trained on is also not well reported. Therefore, the EAG considers there is uncertainty about whether a similar impact of technologies on outcomes would be seen for these specific populations.

The EAG understands that the nature of these technologies means they will be continually updated, meaning results from clinical trials may become increasingly unrepresentative of the most recent version of the technology. Sufficient information was not reported to explore this in the current assessment and while the EAG considers it unlikely that updates that substantially worsen the impact on outcomes such as ADR may be unlikely to be rolled out, the EAG notes that it is a potential issue.

The EAG acknowledges the concern raised by its patient representative, clinical experts and from studies reporting on endoscopist opinion on AI technologies about the potential for overreliance on AI. While manufacturers of the technologies emphasise that they should be used as an adjunct to endoscopist judgement, the EAG considers this unlikely to remove all of the risk of overreliance on the technology and notes that this may vary between individuals. The fact that ADR values within [redacted], although the EAG notes this may

not be the only explanation for this observation. The EAG considers it important that training with regards to this aspect is considered, and that any recommendations made as a result of this assessment also emphasise this point.

4 Assessment of cost-effectiveness

4.1 Systematic review of existing cost-effectiveness evidence

4.1.1 Methods

A systematic literature review (SLR) was undertaken in September 2024 to identify existing economic evaluations of artificial intelligence (AI) technologies to aid polyp detection or characterisation in colonoscopy. Searches were conducted over the period 2 to 4 September 2024. Searches of the following sources were conducted:

- MEDLINE (R) ALL (via Ovid);
- Embase (via Ovid);
- Cochrane Database of Systematic Reviews (CDSR; via Cochrane Library);
- Cochrane Central Register of Controlled Trials (CENTRAL; via Cochrane Library);
- International Network of Agencies for Health Technology Assessment (INAHTA) Database;
- NHS Economic Evaluation Database (NHS EED).

Further to the database searches, health technology appraisal (HTA) websites including the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), Canada's Drug Agency (CDA-AMC), and Institute for Clinical and Economic Review (ICER) were searched to identify relevant appraisals. In addition, reference lists of key identified studies, and sources included in the clinical SLR (see Section 3.2.1), were also reviewed to identify any other potentially relevant studies.

The search strategies combined terms capturing the intervention of interest with validated economic evaluation search filters, where available (full details of the search strategies are given in Appendix 9.5). While studies in languages other than English were ultimately excluded, no language restrictions were applied, in order to assess the volume of foreign language studies available. The External Assessment Group (EAG) also reviewed the companies' submissions for additional references, although no economic evaluations were included in the submissions.

Once studies had been identified and duplicate studies removed, a review of the identified studies proceeded as described in Section 3.1.3 and Section 3.1.4. Pre-defined inclusion and exclusion criteria were used to determine whether studies were relevant for inclusion in the SLR (Table 22).

Table 22. Inclusion and exclusion criteria for SLR of economic evaluations

Criteria	Inclusion	Exclusion
Population	People undergoing colonoscopy for detection and diagnosis of colorectal polyps or CRC.	None.
Interventions	Any AI technology, or combination of AI technologies, to be used in tandem with colonoscopy for the detection and/or characterisation of colorectal polyps.	AI technologies for the detection and/or characterisation of colorectal polyps which are not used in tandem with colonoscopy; technologies used in tandem with colonoscopy which do not include an AI element.
Comparators	Colonoscopy without AI technology (potentially including additional technologies such as VCE, dye-based chromoendoscopy or ENDOCUFF VISION™)	None.
Outcomes	Costs per unit outcome (e.g. ICER); QALYs; LYG.	None.
Study design	Economic evaluations including the following: Cost-utility analysis; Cost-effectiveness analysis; Cost-minimisation analysis; Cost-benefit analysis; Cost-consequence analysis; Budget impact analysis.	Commentaries and letters; systematic and non-systematic reviews; study protocols with no results.
Report type	Full text articles; English language.	Abstracts with limited methodological details.

Abbreviations: AI, artificial intelligence; CRC, colorectal cancer; ICER, incremental cost-effectiveness ratio; LYG, life years gained; QALY: quality-adjusted life year; SLR, systematic literature review; VCE, virtual chromoendoscopy.

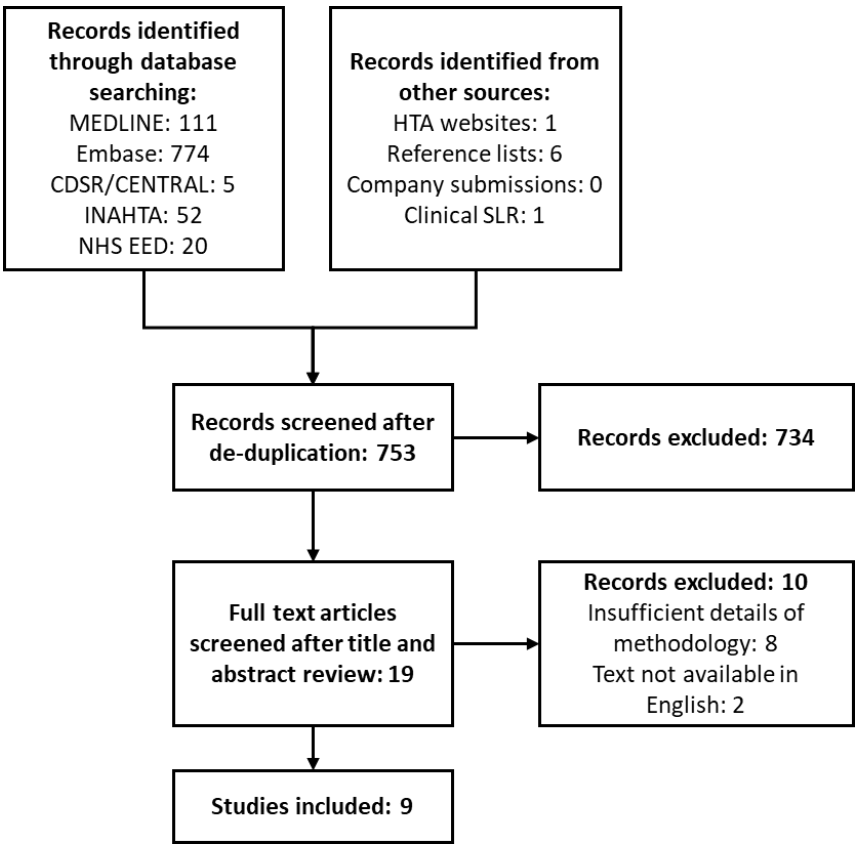
4.1.2 Results

The searches of electronic databases yielded 963 records, giving 753 records in total following deduplication. No additional unique records were identified through searches of HTA websites or review of key studies and manufacturer submissions. Following the assessment of titles and abstracts, 734 records were excluded, leaving 19 records to be assessed at the full-text stage. Following full-text review, 10 further articles were excluded, leaving nine remaining records for inclusion. The EAG notes that six of the included records align with the studies in the SLR of economic evaluations conducted in the 2024 Health Technology Wales (HTW) appraisal of AI-

assisted endoscopy in the detection of lower gastrointestinal cancer and pre-cancerous lesions, with newly identified papers consisting of Chin *et al.* 2023 and Thiruvengadam *et al.* 2024.[43, 126, 145]

The final set of studies included eight journal articles and one HTA report (the HTW 2024 appraisal).[43] These studies included seven studies reporting cost-utility outcomes including the incremental cost per quality-adjusted life year (QALY); while one of these studies, Areia *et al.* 2022, was primarily a cost-comparison and budget impact analysis, cost-utility outcomes were reported in the supplementary materials accompanying the main publication. Two studies identified, Mori *et al.* 2020, and Chin *et al.* 2023, included only cost-comparison and budget impact analyses.[145, 146] The studies covered multiple perspectives; each study considered a different country setting (including Canada, Italy, Japan, Norway, UK and USA). All studies with the exception of Areia *et al.* 2022 took a healthcare payer perspective; Areia *et al.* 2022 considered a societal perspective which incorporated both costs for the health care payer, as well as costs for patients, families and employers.[147] A Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) diagram illustrating this process is shown in Figure 17.

Figure 17. PRISMA diagram for SLR of economic evaluations



Abbreviations: CDSR, Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; HTA, health technology assessment; INAHTA, International Network of Agencies for Health Technology Assessment; NHS EED, NHS Economic Evaluation Database; SLR, systematic literature review.

A summary of the key characteristics of individual included studies is given in Table 23, with further details given in Appendix 9.6. The quality of all included studies was also assessed using the Drummond checklist; details are given in Appendix 9.6.[148]

Table 23. Key features of studies identified in economic evaluation SLR

Study	Study details	Population	Intervention and comparator	Model type	Approach to modelling efficacy and safety
Areia *et al.* 2022[147]	**Study type:** Cost-comparison and budget impact analysis, with cost-utility outcomes reported in supplementary text **Perspective:** USA health care payer and societal **Cost year:** Costs from both 2018 and 2020 were used	Patients undergoing screening colonoscopy aged 50-100 years, with average risk of CRC	**Intervention:** Colonoscopy with CADe (nonspecific) **Comparator:** Colonoscopy without CADe	Markov microsimulation model with lifetime horizon and 1-year cycle length	**Comparator:** Risk of missing adenomas without CADe was calibrated to match the rate of interval CRC reported in an existing observational study (Kaminski *et al.* 2010).[149] **Intervention:** Risk of missing adenomas with CADe was calculated by applying a gradient based on relative ADR; the main text of the article states this was as reported in an SLR (Hassan *et al.* 2021) but supplementary text suggests this was informed by an RCT (Repici *et al.* 2020).[123, 150] **AEs:** Major haemorrhage and perforation were included as potential complications for colonoscopy; rates were informed by an existing observational study (Corley *et al.* 2014).[139]
Barkun *et al.* 2023[151]	**Study type:** Cost-utility analysis **Perspective:** Canadian health care payer **Cost year:** 2022	Patients aged 50+ years, undergoing screening for polyps following a positive FIT result	**Intervention:** Colonoscopy with CADe (GI Genius™) **Comparator:** Colonoscopy without CADe	Cohort Markov model with lifetime horizon and 1-year cycle length	**Comparator:** Risk of missing adenomas without CADe was informed by an SLR of AMRs for small, medium and large adenomas (Zhao *et al.* 2019).[152] **Intervention:** The relative risk of missing adenomas with CADe was informed by the IRR for APC observed in a clinical trial (Repici *et al.* 2020). [123] **AEs:** AEs were not modelled.
Chin *et al.* 2023[145]	**Study type:** Budget impact analysis	All patients eligible for colonoscopy	**Intervention:** Colonoscopy with CADe (GI Genius™)	No formal model presented	**Comparator and intervention:** Polypectomy rate for both comparator and intervention was informed by the cohort study described within the same publication. **AEs:** AEs were not modelled.

	Perspective: Singaporean health care payer (single centre) **Cost year:** Not reported		**Comparator:** Colonoscopy without CADe		
Hassan *et al.* 2023[153]	**Study type:** Cost-utility analysis **Perspective:** Italian health care payer **Cost year:** 2021	Patients aged 50 years, undergoing screening for polyps following a positive FIT result	**Intervention:** Colonoscopy with CADe (GI Genius™) **Comparator:** Colonoscopy without CADe	Same model structure as Barkun *et al.* 2023 (see above).	The approach to modelling efficacy and safety is the same as those used in Barkun *et al.* 2023 (see above).
HTW 2024[43]	**Study type:** Cost-utility analysis **Perspective:** UK health care payer **Cost year:** 2021/2022	All patients eligible for colonoscopy	**Intervention:** Colonoscopy with CADe (nonspecific) **Comparator:** Colonoscopy without CADe	Decision tree with outcomes modelled based on underlying pathology, and outcomes avoided (progression due to delayed diagnosis)	**Comparator:** Comparator efficacy is not explicitly considered; only incremental gains for the intervention are modelled. **Intervention:** The increase in detected adenomas for AI-assisted colonoscopies was assumed equivalent to the observed RR for ADR; input values were sourced from meta-analysis conducted within the same appraisal. **AEs:** Removal of non-neoplastic lesions, bleeding and perforation included as colonoscopy complications; incident rates were aligned with Hassan *et al.* 2023 (see above) for removal of non-neoplastic lesions, and DG56 for bleeding and perforation.[33]
Mori *et al.* 2020[146]	**Study type:** Cost comparison and budget impact analysis **Perspective:** Japanese, English, Norwegian and USA health care payer	Patients with diminutive (≤5mm) rectosigmoid polyps	**Intervention:** Colonoscopy with CADx (EndoBRAIN), coupled with diagnose-and-leave	No formal model presented	**Comparator and intervention:** Polypectomy rate for both comparator and intervention was informed by a clinical trial of the EndoBRAIN AI technology (Mori *et al.* 2018).[154] **AEs:** AEs were not modelled.

	Cost year: Unclear; assumed 2019/2020 based on source given for cost inputs.		polyp management strategy **Comparator:** Colonoscopy without CADx, coupled with resect-all polyp management strategy		
Sekiguchi *et al.* 2023[155]	**Study type:** Cost-utility analysis **Perspective:** UK health care payer **Cost year:** Not reported	All patients eligible for colonoscopy	**Intervention:** Colonoscopy with CADe (nonspecific) **Comparator:** Colonoscopy without CADe	Cohort Markov model with lifetime horizon and 1-year cycle length	**Comparator:** Risk of missing polyps without CADe for each health state was informed by an SLR of AMR (Zhao *et al.* 2019).[152] **Intervention:** The relative risk of missing polyps with CADe was informed by the AMR observed in two clinical trials (Kamba *et al.* 2021 and Wallace *et al.* 2022).[127, 156] **AEs:** AEs were not modelled.
Thiruvengadam *et al.* 2023[157]	**Study type:** Cost-utility analysis **Perspective:** USA health care payer **Cost year:** 2020	Patients aged 45 entering the CRC screening programme	**Intervention:** Colonoscopy with CADe (nonspecific) **Comparator:** Colonoscopy without CADe	Markov microsimulation model with lifetime horizon and 1-year cycle length	**Comparator:** A range of ADRs was modelled, informed by quintiles observed in Corley *et al.* 2014.[139] The sensitivity of colonoscopy based on adenoma size and ADR were estimated by calibrating to data linking ADR and interval CRC (Corley *et al.* 2014).[139] **Intervention:** The relative increase in ADR was derived from a meta-analysis of ADRs for colonoscopy with AI (Hassan *et al.* 2021).[150] **AEs:** Bleeding, perforation and death following perforation were modelled as complications of colonoscopies; rates were sourced from a previous cost-effectiveness model of CRC screening (Ladabaum *et al.* 2019).[158]

Thiruvengadam *et al.* 2024[126]	**Study type:** Cost-utility analysis **Perspective:** USA health care payer **Cost year:** 2020	Patients aged 45 entering the CRC screening programme	**Intervention:** Colonoscopy with CADe (GI Genius™) **Comparator:** Colonoscopy without CADe	Same model as Thiruvengadam *et al.* 2023 (see above)	**Intervention:** The relative increase in ADR was derived from values reported in the RCT described in the same publication. **Comparator and AEs:** The same inputs were used as in Thiruvengadam *et al.* 2023 (see above).

Abbreviations: AE, adverse event; ADR, adenoma detection rate; AI, artificial intelligence; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; FIT, faecal immunochemical test; IRR, incidence rate ratio; RCT, randomised controlled trial; RR, risk ratio; SLR, systematic literature review.

4.1.2.1 Interventions, comparators and populations

The studies identified all focused on the detection of polyps during colonoscopy, with the exception of Mori *et al.* 2020, which considered characterisation of polyps.[146] Of the studies focusing on detection, four studies considered a colonoscopy with a generic computer-aided detection (CADe) technology,[43, 147, 155, 157] while four studies considered the CADe functionality of the GI Genius™ technology.[126, 145, 151, 153] No other individual technologies were included as interventions.

The comparator in all eight detection-related studies was 'standard' colonoscopy without AI technology. The intervention and comparator in Mori *et al.* 2020 included both the technology used as well as the polyp management strategy; the intervention was colonoscopy with the EndoBRAIN computer-aided characterisation (CADx) technology, coupled with a diagnose-and-leave management strategy for polyps, while the comparator was 'standard' colonoscopy without AI technology, coupled with a 'resect-all polyps' management strategy. [146]

The studies also considered a variety of patient populations. Five of the CADe studies considered patients entering a colorectal cancer (CRC) screening programme, although the characteristics of the patient cohorts (e.g., patient sex, patient age and true prevalence of adenomas and CRC) [126, 151, 153, 155, 157] differed between studies, since general population characteristics and CRC screening guidelines differ between countries. One study considered any patients undergoing a screening colonoscopy aged 50-100 years with an average risk of CRC,[147] and two studies considered a population including all patients eligible for colonoscopy.[43, 145]

The only study which considered CADx, Mori *et al.* 2020, considered a patient population encompassing all patients with diminutive (≤5 mm) rectosigmoid polyps.[146]

4.1.2.2 Model structure

Six of the included studies focusing on polyp detection used a Markov model structure.[126, 147, 151, 153, 155, 157] The EAG notes that that the same model structure was used, with slightly different inputs, for Thiruvengadam *et al.* 2023 and Thiruvengadam *et al.* 2024, while very similar models appear to have been used in Barkun *et al.* 2023 and Hassan *et al.* 2023; for the latter two studies, it is unclear whether the models differ in only the inputs used, or if there are also minor structural differences between the models.[126, 151, 153, 157] Each of the models included health states corresponding to healthy

epithelium; presence of adenoma, generally subdivided by size, advancement or risk of progression to CRC; presence of CRC subdivided by stage; and death. In all of the models, patients receive a colonoscopy at baseline; patients with adenomas present at baseline have a given probability of detection and removal, after which they progress to the healthy epithelium health state, or failure to detect and remove, which leads to the patient remaining in their baseline health state, and incurring a risk of progression to CRC. Similarly, patients with CRC present at baseline have a given probability of detection, after which they are assumed to receive treatment; patients whose CRC is not detected at baseline have a risk of progression to a more advanced CRC stage before receiving treatment. The benefits of AI-assisted polyp detection are therefore reflected by an increased probability of detection of adenomas and CRC at baseline, leading to reduced risk of advancement.

Three of these models used a Markov microsimulation approach,[126, 147, 157] while the remaining three models used a deterministic cohort Markov approach.[151, 153, 155] All Markov models used a one-year cycle length, and considered a lifetime horizon.

By contrast, the HTW 2024 appraisal used a decision tree approach; it was assumed that all polyps detected by standard colonoscopy without AI would also be detected by colonoscopy with AI, so only the costs and benefits from detection of adenomas or CRC that would be detected only with AI assistance, but not standard colonoscopy, were modelled.[43] Patient outcomes were modelled based on the underlying pathology (low-risk adenoma, high-risk adenoma or CRC) and the potential outcomes avoided (progression and potential delayed diagnosis of CRC).

The model included 'long-term payoff' total costs and QALYs for each decision tree branch which were sourced from the MiMic-Bowel model, a separate microsimulation model of long-term outcomes for bowel cancer screening strategies; this model is broadly similar in structure to the Markov models described above.[6] An analogous approach was used in the NICE diagnostic assessment for quantitative faecal immunochemical testing (DG56).[33] The long-term payoffs were calculated using a lifetime horizon.

Finally, no formal model was presented in either Chin *et al.* 2023 or Mori *et al.* 2020; only costs associated with the initial colonoscopy were considered, and outcomes were directly informed by the estimated number of polypectomies required for the intervention and comparator strategies, directly informed by a cohort study and clinical trial, respectively.[145, 146]

4.1.2.3 *Effectiveness*

For the studies focusing on polyp detection, the baseline sensitivity of colonoscopy without AI was informed by existing meta-analyses of adenoma miss rates (AMRs) in three studies,[151, 153, 155] and derived through calibration of the model to match reported post-colonoscopy CRC rates in three other studies.[126, 147, 157] In the case of the HTW 2024 appraisal, the baseline sensitivity of colonoscopy without AI was not explicitly considered, since only the incremental effectiveness of colonoscopy with AI compared to colonoscopy without AI was considered.[43]

The sensitivity of colonoscopy with AI for detecting polyps was modelled using surrogate outcomes; multiple distinct approaches were used. Four studies applied the relative risk for adenoma detection rate (ADR) for colonoscopy with AI compared to colonoscopy without AI,[43, 126, 147, 157] and two studies applied the incidence risk ratio (IRR) of the adenomas detected per colonoscopy (APC) for colonoscopy with AI compared to colonoscopy without AI.[151, 153] These inputs were derived either from existing randomised controlled trials (RCTs),[126, 151, 153, 155] or from SLRs;[43, 157] the source for the inputs for Areia *et al.* 2022 is unclear, since contradictory information is given within the publication and supplementary materials.[147] Finally, one study used the reported AMRs for colonoscopy with AI derived from RCTs directly.[155]

An alternative approach was used in Chin *et al.* 2023; in this study, the effectiveness of colonoscopy was not explicitly considered, and only the number of polypectomies required was used as an input; this was informed directly by the cohort study described in the same publication.[145]

The EAG notes that that none of the identified studies focusing on polyp detection modelled specificity for either the intervention or comparator technology; therefore, potential costs and complications for removing non-adenomatous polyps were not considered.

As well as inputs for the relative effectiveness of colonoscopy with and without AI, all models with a Markov structure also required transition probabilities related to the natural history of CRC. For three studies, these inputs were derived by calibrating model results to data obtained from the Surveillance Epidemiology and End Results (SEER) database,[126, 147, 157] while three other studies obtained transition probabilities from existing economic evaluations for other interventions related to CRC screening.[151, 153, 155]

For the single study identified which considered characterisation of polyps, sensitivity and specificity of the CADx system were derived directly from the accompanying RCT.[146]

4.1.2.4 Costs and utilities

The analyses presented in the included studies generally included costs for colonoscopies and associated procedures (e.g. polypectomy). With the exception of Chin *et al.* 2023 and Mori *et al.* 2020, treatment and monitoring costs for CRC were also included.[145, 146]

The sources used for costs varied between studies, and were generally appropriate for the country context of each analysis. The analyses also calculated the cost per procedure of AI technologies; this was generally based on a one-off cost or subscription cost provided by the relevant manufacturer, scaled by the number of expected colonoscopies for which the technology was expected to be used. The expected number of colonoscopies varied considerably between studies, based on local clinical practice in the country of interest. Sekiguchi *et al.* 2023 did not explicitly consider a single cost for AI technologies and instead considered a range of potential costs in their analysis.[155]

For the cost-utility studies identified, health state utilities were applied based on CRC stage, sourced from previous economic evaluations, or studies of health-related quality of life (HRQoL) in patients with CRC. In some cases, distinct utilities were applied for patients with adenomas compared to healthy patients (e.g., in Barkun *et al.* 2023 and Hassan *et al.* 2023).[151, 153] The EAG notes that that many of the studies presented incomplete information on how utility values were parametrised; in particular, few studies explained what utility values were used for healthy patients, or specified whether age-adjustment of utility values was applied.

Four of the included studies (Areia *et al.* 2022, HTW 2024 appraisal, Thiruvengadam *et al.* 2023, and Thiruvengadam *et al.* 2024) also modelled costs and/or disutilities related to complications associated with colonoscopy.[43, 126, 147, 157] All three studies included haemorrhage and perforation as the key complications of interest, while Thiruvengadam *et al.* 2023 and Thiruvengadam *et al.* 2024 also included costs related to death resulting from colonoscopy.[126, 157]

4.1.2.5 Economic evaluation results

Of the cost-utility studies identified, four studies reported that colonoscopy with AI was dominant compared to colonoscopy without AI (i.e., associated with decreased costs and increased QALYs);

the exceptions to this were the HTW 2024 appraisal and Thiruvengadam *et al.* 2024, which both reported that colonoscopy with AI resulted in increased costs and increased QALYs, and Sekiguchi *et al.* 2023, which reported ranges of incremental cost-effectiveness ratios (ICERs) derived from varying the input cost for the AI technology, and presented a threshold cost to indicate cost-effectiveness.[43, 126, 155]

The studies reporting cost outcomes, Chin *et al.* 2023 and Mori *et al.* 2020, both reported a cost saving for colonoscopy with AI compared to colonoscopy without AI.[145, 146]

All identified studies, with the exception of Chin *et al.* 2023, Mori *et al.* 2020, and Thiruvengadam *et al.* 2024, conducted sensitivity analyses including one-way deterministic sensitivity analysis (DSA) and probabilistic sensitivity analysis (PSA).[126, 145, 146] The EAG notes that that in general, cost-utility results were sensitive to the effectiveness inputs for colonoscopy with AI compared to colonoscopy without AI.

4.1.2.6 Key limitations

The studies identified consistently had several key limitations with regard to modelling methodology as follows:

- All studies related to polyp detection assumed a perfect correlation between relative ADR or AMR, and relative sensitivity of standard and AI-assisted colonoscopy in detecting pre-cancerous polyps. This may not be an accurate reflection of the effectiveness of colonoscopy in practice; e.g., beyond a certain threshold, increasing ADR may not result in a meaningful decrease in risk of disease progression (e.g., progression to higher-risk adenoma, or to post-colonoscopy CRC). This is particularly pertinent since results were generally very sensitive to effectiveness inputs. However, this limitation may be insurmountable since trials for CADe technologies do not report the incidence of progression to higher-risk adenoma or post-colonoscopy CRC (see Section 3.2.2.1).
- Detection rates for CRC were informed by assumptions, since trials for CADe and CADx technologies rarely report CRC detection rates as an outcome, and when they do, the total number of events is limited (see Section 2.3 of the Diagnostic Assessment Report [DAR] supplement).

- The studies related to polyp detection did not make clear their assumptions around how polyps would be managed following detection; in general, it was implicitly assumed that all identified polyps would be removed. Relatedly, no identified studies included costs or complications associated with potentially unnecessary removal of polyps.
- In studies which modelled long-term outcomes, limited details were given regarding how follow-up for patients with adenomas or CRC was modelled. In many cases, limited details were given on the monitoring and treatment requirements for patients in each health state. It is also unclear how subsequent follow-up (e.g. increased colonoscopy surveillance) was modelled within a cohort Markov structure in Barkun *et al.* 2023, Hassan *et al.* 2023 and Sekiguchi *et al.* 2023.[151, 153, 155]
- The cost of AI technologies per procedure were generally informed by broad assumptions around the frequency of use and maximum lifetime of the technologies.
- Many of the existing studies (Barkun *et al.* 2023, Chin *et al.* 2023, Hassan *et al.* 2023, Mori *et al.* 2020, and Sekiguchi *et al.* 2023) excluded consideration of complications of colonoscopy, without providing justification for doing so.[145, 146, 151, 153, 155]

The studies identified also have the following limitations with regard to their applicability to the current assessment:

- Only two studies identified considered a UK perspective.[43, 146] However, the EAG notes that one of these, the HTW appraisal, only takes into account the patient population in Wales; therefore, while the sources for costs and utilities are relevant to a general UK population, baseline characteristics of the patient population and estimated use assumptions for AI technologies may not be applicable beyond the Welsh context.[43]
- The studies identified only considered a non-specific CADe system, with efficacy inputs informed by results aggregated from multiple CADe systems, or the GI Genius™ and EndoBRAIN systems individually; no other technologies within the scope of this diagnostic assessment are represented in any existing economic evaluation. Furthermore, all studies included only a single intervention technology. Therefore, none of the existing models are appropriate for capturing the multiple technologies of interest in this appraisal.
- With the exception of one study, all studies identified considered only the CADe functionalities of AI technologies. The only study that considered CADx functionalities,

Mori *et al.* 2020, used an extremely simplistic analysis, which did not include any costs or outcomes beyond those directly related to the index colonoscopy.[146] Therefore, none of the studies are appropriate for capturing the potential benefits of CADx technology, which are relevant for this appraisal. The EAG considers that the existing studies did not sufficiently interrogate the assumptions around the polyp management strategies; in particular, potential alternatives to the 'resect-all' approach were not considered.

As a result, the EAG considers that none of the economic models presented in the identified studies would address the decision problem for the current assessment.

4.2 Independent economic assessment

Since no existing economic model was identified that addressed the decision problem for the current assessment, the EAG developed a *de novo* economic model addressing the decision problem. The methodology used, and the results of the economic analysis, are presented in the following sections.

4.2.1 Methods

4.2.1.1 Population(s)

The population considered in the economic model was all patients eligible and appropriate for colonoscopy.

Subgroup analyses were performed where appropriate data were available to parametrise intervention effectiveness:

- Patients referred for screening;
- Patients referred due to presence of symptoms;
- Patients referred for any surveillance;
- Patients referred for Lynch syndrome surveillance.

Subgroup data was not available for all interventions considered in the economic model; therefore, subgroup analyses were only possible for a subset of interventions (further details are given in Section 3.2.2.1.12 of this report, and Section 1.19 and 1.20 of the DAR supplement).

Further details of the data available to parametrise the model for each relevant subgroup are given in Sections 1.19 and 1.20 of the DAR supplement.

Full details of the subgroups considered for each intervention are given in Appendix 9.8.

Analyses of subgroups based on the experience/expertise of the endoscopist conducting the colonoscopy were not included, as the EAG considers that such analyses would be of limited relevance. In particular:

- The available data were relatively limited, with different definitions of endoscopist experience used for each technology (see Sections 1.21 and 1.22 of the DAR supplement);
- Results were fairly heterogeneous between trials identified in the clinical SLR, with no clear interpretation of how outcomes related to endoscopist experience (see Section 3.2.2.1.13, and Sections 1.21 and 1.22 of the DAR supplement);
- In clinical practice, use of AI technologies to aid colonoscopies are unlikely to be restricted to a subgroup of endoscopists based on experience;
- In UK clinical practice, endoscopist experience is likely to be related to the context in which the colonoscopy is performed (for example, Bowel Cancer Screening Programme [BCSP] endoscopists conducting screening colonoscopies are likely to have considerably more experience than endoscopists working in other contexts); therefore, there is considerable overlap between patient subpopulation and endoscopist experience.

4.2.1.2 Model structure

The economic model was developed using a decision tree structure, similar to the approach used in existing diagnostic appraisals of related technologies, including DG56 (quantitative faecal immunochemical testing) and DG10083 (PillCam COLON 2).[33, 159]

The decision tree structure was implemented to capture outcomes from the 'index' colonoscopy (i.e., the colonoscopy performed at baseline), which included branches capturing the following:

- Patient's true disease state; in order of increasing severity, the pathologies considered were low-risk adenomas (LRA), advanced adenomas (AA), inflammatory bowel disease

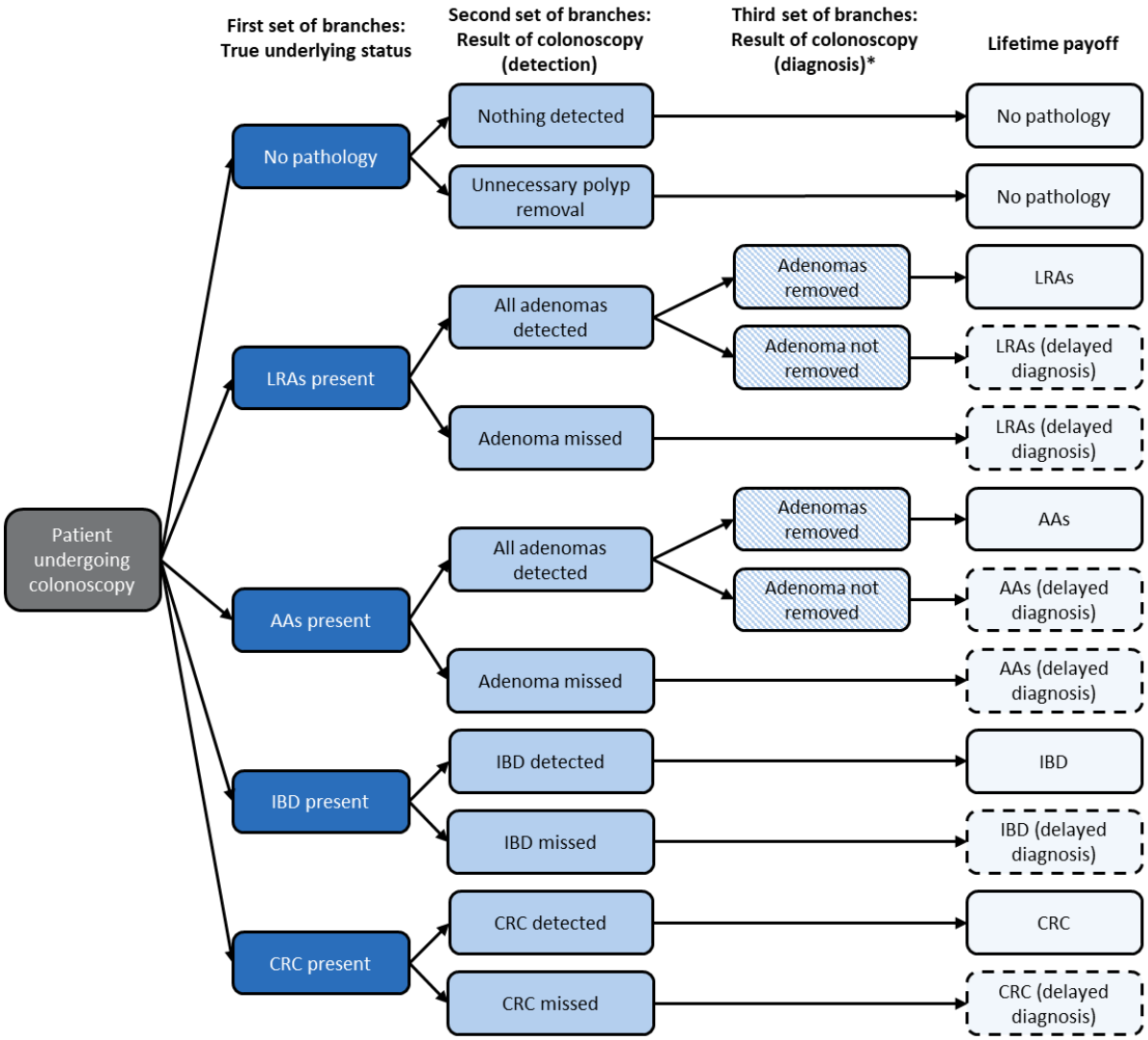
(IBD) and CRC; here, 'adenomas' refers specifically to polyps which are precursor lesions for CRC. Patients were categorised by the most severe pathology present (e.g., a patient with both CRC and adenomas would be included in the CRC category), since the most severe pathology was considered to determine the clinical management of the patient, and hence, long-term costs, survival and HRQoL. Patients with no CRC, IBD or adenomatous polyps were categorised as having no pathology; this would include patients with non-adenomatous polyps only. Note that although the detection of polyps is the focus of colonoscopy, IBD was included as a potential incidental finding.

- Correct detection of a patient's true disease state; for patients with underlying pathologies, this corresponded to correct detection of underlying pathologies (sensitivity), whereas for patients without underlying pathologies, this corresponded to correct assessment of no pathology present (specificity). For patients with underlying pathologies, sensitivity was defined as the probability of detecting the most severe pathology present (e.g., if a patient is in the AA true disease state, if LRA is detected but not AA, they would still be considered to be in the 'adenoma missed' category).
- For patients with adenomas present, the model included the option to consider whether all detected adenomas were removed, or if at least one detected adenoma was not removed, due to misdiagnosis. In the base case, it was assumed that all identified polyps were resected regardless of diagnosis, which is broadly in line with current UK clinical practice; the 'adenoma not removed' branches were therefore redundant in the base case. However, alternative polyp management approaches, which could result in detected adenomas failing to be appropriately removed due to misdiagnosis, were considered in scenario analysis. Further details of the polyp management strategies considered are given in 4.2.1.4.1.

Details of the inputs informing AI technology effectiveness are given in Section 4.2.1.6.

The model structure is illustrated in Figure 18.

Figure 18. Decision tree model structure



Footnote: *The 'adenoma missed' branches are redundant in the model base case, as a 'resect-all' polyp management strategy is assumed.

Abbreviations: AA, advanced adenoma; CRC, colorectal cancer; IBD, inflammatory bowel disease; LRA, low-risk adenoma.

Each branch in the decision tree was assigned the following short-term costs:

- Costs for the colonoscopy procedure were applied, including histopathological testing costs, and including additional costs for polypectomy if appropriate. It was assumed that patients with any adenoma removed would incur costs for a polypectomy during their initial colonoscopy, and a proportion of patients with AA would incur additional costs for a secondary therapeutic colonoscopy, which may be required if a patient has a large

number of adenomas, or adenomas which are technically challenging to remove, due to location or size.

- Costs for the AI technology were applied, if relevant.
- Costs associated with complications of colonoscopy were applied.

One-off disutilities associated with complications of colonoscopy and with delayed diagnosis were also applied.

Longer-term outcomes for each decision tree branch were aligned with DG10083, and were sourced from the MiMiC-Bowel model, a microsimulation model developed for economic evaluation of screening strategies for CRC, or derived from general population norms.[6, 160, 161] These long-term outcomes were applied as an aggregate of total costs, QALYs and life years gained (LYG). Total long-term costs encompassed costs for subsequent colonoscopies (including post-polypectomy and post-CRC surveillance), IBD treatment, and CRC treatment, while total QALYs took into account survival following CRC diagnosis, and HRQoL for patients with CRC. Separate long-term outcomes were generated for the screening and surveillance populations.

This approach was used rather than explicitly calculating the long-term outcomes within the economic model itself, since this would have greatly increased the required complexity. In particular, tracking requirements for varying follow-up periods for subsequent colonoscopies depending on outcomes for the index colonoscopy would not be possible within a straightforward Markov model framework, necessitating either the use of a large number of tunnel states or a simulation approach. On the other hand, the MiMiC-Bowel model is a well-validated model which comprehensively captures all potential outcomes for patients in current UK clinical practice, and has been used for developing BCSP policy.[6, 162] The approach of using the MiMiC-Bowel model to generate long-term costs, QALYs and LYG has been used in previous economic evaluations related to colonoscopy, notably DG56 and DG10083, and in the HTW 2024 appraisal.[33, 43, 159]

For patients with adenomas or CRC that are not appropriately diagnosed (either due to failure to detect the condition, or failure to remove adenomas due to misdiagnosis as non-adenomatous polyps), it was assumed that the underlying condition would ultimately be diagnosed, albeit with a delay, potentially leading to advancement to a more severe underlying condition prior to diagnosis, and increased treatment costs. In these cases, an alternative set of long-term costs, QALYs and LYG

were used, factoring in the delay to diagnosis. It was assumed that the delay and resulting impact on outcomes would be the same, regardless of whether the delay was caused by non-detection or misdiagnosis, as the follow-up for the patient would be the same in both circumstances.

4.2.1.3 Time horizon, perspective and discounting

The perspective used in the model was the National Health Service (NHS) and Personal Social Services (PSS) in England. Time horizon and discounting were applicable only to the long-term outcomes applied to each decision tree branch, sourced from DG10083; these were calculated over a lifetime horizon, including 3.5% discounting of costs and QALYs.[159]

The time horizon, perspective and discounting used in the model were aligned with the reference case.

4.2.1.4 Interventions and comparators

The comparator in the analysis is colonoscopy without AI technology (with or without adjunct technologies such as virtual chromoendoscopy [VCE], dye-based chromoendoscopy [DCE] or ENDOCUFF VISION™).

The interventions considered in the model include the AI technologies commercially available in the UK, and ADR data identified in the clinical SLR (see Section 3.2.2.1.1). These technologies were considered in addition to colonoscopy, with or without adjunct technologies including VCE, DCE, or ENDOCUFF VISION™. Henceforth, interventions will be referred to by the name of the AI technology only.

The EAG notes that in the single trial available for the Endoscopic Multimedia Information System (EMIS™) technology, the functionality used was not technically aligned with the formal definition of CADe [redacted]; further details are given in Section 3.2.1.7.[69, 111] However, for the sake of simplicity, EMIS™ has been included as an intervention in the economic analyses, and is henceforth described as a CADe technology.

A summary of the technologies considered, and the functionalities included for each technology (i.e. CADe and/or CADx) is given in Table 24 below.

Table 24. AI technologies included in the economic model

Intervention	CADe included?	CADx included?
Argus® (Endosoft);	Yes	No
CAD EYE® (Fujifilm Healthcare UK Ltd.)	Yes	Yes
Discovery™ (Pentax Medical UK)	Yes	No*
Endoscopic Multimedia Information System™ (EMIS™; EndoPerv LLC., previously EndoMetric Corporation)	Yes	No
ENDO-AID™ (Olympus Medical Systems Corp.)	Yes	No
EndoScreener® (Wision AI)	Yes	No
GI Genius™ (Medtronic)	Yes	Yes
MAGENTIQ-COLO™ (MAGENTIQ-EYE)	Yes	No†

Footnotes: *CADx data for the Discovery™ system is available only for the ulcerative colitis patient population; furthermore, only data from a single study are available (further details can be found in Section 3.2.2.1.2). Therefore, the CADx functionality of Discovery™ is excluded from the economic analysis. †While a CADx functionality of MAGENTIQ-COLO™ is described by the manufacturer (further details in Table 44 of Appendix 9.1), the CADx functionality of this technology was excluded from the economic model as no CADx data were identified.

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CADx, computer-aided diagnosis; EMIS™, Endoscopic Multimedia Information System.

WISE VISION® was removed from the economic assessment in February 2025 given it is no longer available to the NHS (see Section 1.3.1). CADDIE™ and ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment were excluded from the economic analysis, although data are available for parametrising the effectiveness of these technologies, since no cost for these technologies were provided by the manufacturers.

4.2.1.4.1 Polyp management strategies

Both the intervention and comparator must be considered in the light of the polyp management strategy employed. In the base case, it is assumed that a 'resect-all' polyp management strategy is used for all interventions and comparators (i.e. all detected polyps are resected and sent for histopathological testing). The EAG considers that it is only appropriate to compare the interventions and comparator coupled with the same polyp management strategy, since the decision problem is focused on the AI technologies themselves, rather than the accompanying polyp management strategy.

Based on clinical expert opinion (including discussion at the scoping workshop for this project, and with the EAG's clinical experts), current clinical practice in the UK is that all polyps are removed and sent for histopathological testing, with the exception of rectal polyps which are considered to be hyperplastic, which may be left *in situ* if the endoscopist considers they are sufficiently low-risk for progression to CRC. The EAG considers that an assumption that all polyps are resected is an appropriate simplification of current UK clinical practice, since in general insufficient granularity was available in the identified RCTs in terms of polyp location and characteristics to determine differences in detection and diagnosis of hyperplastic rectal polyps with high confidence.

However, alternative polyp management strategies are available, as follows:

- **Diagnose-and-leave strategy:** polyps that are considered to pose a limited risk for progression to CRC, and are diagnosed with high confidence, are left *in situ* without resection or further follow-up. This avoids unnecessary polyp resections (along with potential associated complications), reducing the requirement for histopathological testing and potentially for additional secondary colonoscopies if many polyps are identified. Patient anxiety may also be reduced as there is no associated wait for confirmatory histopathological testing of the diagnosed polyps, although the EAG notes that there may also be increased anxiety related to the reduction in safeguards by removing the confirmatory testing. A diagnose-and-leave strategy, in which diminutive rectosigmoid polyps which are predicted to be non-adenomatous with high confidence are left *in situ*, is currently recommended in European Society of Gastrointestinal Endoscopy (ESGE) guidelines.[41]
- **Resect-and-discard strategy:** some polyps which are diagnosed with high confidence are resected but not sent for histopathological testing. Similarly to the diagnose-and-leave strategy, this strategy reduces the burden of histopathological testing, and removes the associated wait for a diagnosis, potentially reducing patient anxiety due to uncertainty during the waiting period, in cases where no pathology is present. ESGE guidelines suggest that resect-and-discard strategies for diminutive colorectal polyps should only be used by expert endoscopists.[41]

The EAG notes that the BCSP is currently in the process of rolling out a resect-and-discard strategy in which diminutive (≤5 mm) polyps are diagnosed with high confidence (see Section 1.1.5); however,

this was examined only in a scenario rather than the base case as at the time of writing this strategy only applies to a minority of colonoscopies currently being conducted (i.e. screening colonoscopies conducted by endoscopists with optical diagnosis accreditation).

While it is possible that either or both polyp management strategies described above may ultimately be incorporated in UK clinical practice, neither strategy is currently in widespread use in the UK. Therefore, neither alternative polyp management strategy is included in the base case; however, both strategies, were considered in scenario analyses. Full details of how these scenarios were implemented in the model are given in Appendix 9.10.

4.2.1.4.2 Inclusion of CADe and CADx functionalities

The key functionality of the AI technology considered in the base case was the CADe functionality, while consideration of CADx functionalities was limited to exploratory analyses, coupled with either or both alternative polyp management strategies described above. The reasons for this approach are as follows:

- If a 'resect-all' polyp management strategy is assumed, including CADx functionalities does not make a difference to the overall calculated costs/QALYs; currently, diagnosis does not play a key role in polyp management since essentially all polyps are removed regardless of their characteristics. The main potential benefits of CADx in terms of reducing the number of polypectomies and the burden of histopathological testing are only realised when alternative polyp management strategies are used instead of 'resect-all'. Other benefits of CADx (e.g. reduced patient anxiety due to faster diagnosis) cannot be captured within the standard health economic modelling framework, due to the lack of quantitative evidence informing the impact of these benefits (e.g., the resulting impact of reduced anxiety on a patient's quality of life). Furthermore, the EAG considers that the impact of these benefits is likely to be negligible.
- The available evidence for accuracy of CADx functionalities is limited; of the two AI technologies with available CADx accuracy data for the general patient population (CAD EYE® and GI Genius™), the EAG considers that there are potential issues with many of the relevant trials (e.g., autonomous use of the AI technologies rather than use as an adjunct to endoscopist diagnosis). Further discussion of the available data for CADx technologies can be found in Section 4.2.1.6.2.

4.2.1.5 Population characteristics

The only population characteristics used directly in the decision tree were the proportion of patients in each 'true disease state' at baseline, i.e. the prevalence of LRAs, AAs, IBD and CRC at the time of colonoscopy.

The prevalence of true disease states was informed by two sources: Turvill *et al.* 2021, a diagnostic accuracy study of faecal immunochemical tests conducted in patients referred for CRC screening in 12 secondary care providers in England; and Crispin *et al.* 2013, a registry study of patients undergoing surveillance or screening colonoscopies in Germany.[163, 164] Turvill *et al.* 2021 was considered to be an appropriate source for prevalence of true disease states in the screening population, and Crispin *et al.* 2013 was considered appropriate for the surveillance population.

In the base case, for the LRA, AA and CRC true disease states, a weighted average of prevalences from the two sources was used, to reflect the combination of screening and surveillance colonoscopies in the overall patient populations. The proportion of colonoscopies which are screening colonoscopies was taken to be 10.6%, informed by the most recent Joint Advisory Group on Gastrointestinal Endoscopy (JAG) national census of UK endoscopy services (2023).[165] Since no value for the proportion of patients with IBD was reported by Crispin *et al.* 2013, the value reported in Turvill *et al.* 2021 was used for the overall patient population.[163, 164] The remainder of the patient population was assumed to have no pathology.

The inputs from Turvill *et al.* 2021 were used directly to inform subgroup analyses in the screening population, and the inputs from Crispin *et al.* 2013 were used to inform subgroup analyses in the surveillance population.[163, 164]

The values used in the economic model are presented in Table 25.

Table 25. Prevalence of true disease states

True disease state	Proportion of patients		
	Base case (mixed population)	Screening colonoscopy (Turvill *et al.* 2021)[163]	Surveillance colonoscopy (Crispin *et al.* 2013)[164]
No pathology	0.702	0.774	0.694
LRA	0.189	0.135	0.196
AA	0.075	0.041	0.079
IBD	0.020	0.020	0.020*

CRC	0.014	0.030	0.012

Footnote: * The proportion of patients with IBD was not reported in Crispin *et al.* 2013, so the value was assumed the same as the value reported in Turvill *et al.* 2021

Abbreviations: AA, advanced adenoma; CRC, colorectal cancer; IBD, inflammatory bowel disease; LRA, low-risk adenoma.

Other population characteristics, including population age at baseline, proportion of males and prevalence of CRC stage at screening for patients with underlying CRC, were used indirectly in the MiMiC-Bowel model to generate long-term outcomes and delayed diagnosis penalties, but these cannot be varied within the economic model presented here, as this would require generating a new set of results from the MiMiC-Bowel model.[6] In particular, these underlying population characteristics cannot be changed to align with population subgroups. This is a key limitation of the subgroup analyses conducted using the economic model.

4.2.1.6 Technology effectiveness

4.2.1.6.1 Detection of true disease states

The second set of branches included in the decision tree referred to the probability of detection of the patient's true disease state. If the true disease state was not correctly detected for LRAs, AAs, IBD or CRC, it was assumed that the pathology was missed, and cost and QALY penalties for delayed diagnosis were applied. Therefore, the relevant effectiveness for these branches of the decision tree was informed by the sensitivity of the technology to detecting the underlying pathology. In particular, the probability of failing to detect at least one adenoma was considered. Since sensitivity is not generally reported for CADe technologies, alternative outcomes were used as proxies for sensitivity for the LRA and AA true disease states. Variation in time to diagnosis or risk of adverse outcomes (e.g. risk of progressing to a more severe disease state prior to diagnosis) based on the number of adenomas not detected was not included in the model, since the EAG's clinical experts stated that there is no existing evidence of a link between the number of adenomas missed during a colonoscopy and risk of subsequent adverse outcomes for patients.

For the comparator arm (conventional colonoscopy), the sensitivity was estimated based on the per patient AMR, i.e. the proportion of patients with at least one adenoma present which is not detected, reported in an existing SLR (Zhao *et al.* 2019).[152] The LRA and AA true disease states were parametrised separately for the comparator; the reported advanced adenoma miss rate (AAMR) used for the AA state, while the overall AMR was used for the LRA state, since no specific value for low-risk adenomas was given.

The input values used in the model to calculate comparator sensitivity are given in Table 26 below.

Table 26. Comparator AMR values

True disease state	AMR input value (95% CI)
LRA	0.29 (0.25 to 0.35)
AA	0.10 (0.03 to 0.20)

Abbreviations: CI, confidence interval; AA, advanced adenoma; LRA, low-risk adenoma.

The sensitivity was calculated as follows:

$$Sensitivity\ (comparator) = 1 - AMR\ (comparator).$$

A similar approach has been used in several existing economic evaluations in this area (including Barkun *et al.* 2023, Hassan *et al.* 2023, Sekiguchi *et al.* 2023).[132, 151, 155]

In the base case, the sensitivity of each intervention relative to the comparator was informed by the risk ratio (RR) for the ADR, i.e. the proportion of colonoscopies in which adenomas are detected. The sensitivity for each intervention was calculated as follows:

$$Sensitivity\ (intervention) = RR\ (ADR) \times Sensitivity\ (comparator)$$

In cases where the resulting sensitivity was over 100%, the sensitivity was set to 100%.

Once again, the RRs for each intervention were informed by the clinical SLR and meta-analyses (see Sections 3.2.2.1.1.1 to 3.2.2.1.1.3).

Where appropriate and where data were available, different estimates for ADR were used for patients with an underlying LRA pathology, and patients with an underlying AA pathology. Where only a single estimate of ADR was available encompassing all adenomas, this estimate was used for both the LRA and HRA branch. This assumption is potentially favourable to the intervention, as in practice the additional adenomas detected by CADe tend to be smaller, lower-risk adenomas (see Sections 3.2.2.1.1.2 to 3.2.2.1.1.4). However, this assumption was explored in scenario analyses.

The RR for the ADR was an appropriate proxy for estimating the sensitivity of interventions because it is reasonable to expect that an increase in the proportion of colonoscopies in which an adenoma is detected corresponds to an increase in the probability that the adenomas present are detected (the EAG notes that ADR excludes detection of non-adenomatous polyps, so an increase in ADR cannot be purely attributed to increased detection of non-adenomatous polyps). Furthermore, the ADR was

the most commonly reported outcome across the trials identified in the clinical SLR, and was the outcome for which data was available for the most interventions. This approach was discussed with the EAG's clinical experts, and similar approaches have been used in previous economic evaluations, including Areia *et al.* 2022, Thiruvengadam *et al.* 2023, Thiruvengadam *et al.* 2024, and the HTW 2024 appraisal. [43, 126, 147, 157]

However, the following alternative approaches using other surrogate outcomes were explored in scenario analyses:

- **Scenario 1: Adenoma miss rate (AMR)**

  The sensitivity for interventions was estimated using the RR for per-patient AMR using the following formula:

  $$Sensitivity(intervention) = 1 - RR(AMR) \times AMR(comparator)$$

  In cases where the resulting sensitivity was over 100%, the sensitivity was set to 100%. A similar approach was used in one existing economic evaluation (Sekiguchi *et al.* 2023).[155]

  Relevant data to inform this approach were available only for the GI Genius™ and EndoScreener® technologies. However, per-lesion AMR (i.e. the proportion of adenomas which are not detected) was available for the CAD EYE® and MAGENTIQ-COLO™ technologies; in these cases, RR for per-lesion AMR was used instead of per-person AMR. The per-lesion AMR differs from the per-person AMR in that the number of adenomas per patient differs between patients; a patient with a higher number of adenomas may be more likely to have an adenoma missed; furthermore, the probability of detection of individual adenomas within a single colonoscopy may be correlated (for example, due to the skill level of the endoscopist). However, the EAG considers that the per-lesion AMR is an appropriate alternative for per-person AMR in the context of this scenario analysis. It should also be noted that only AMR for all adenomas was reported, rather than AMR disaggregated by advanced/non-advanced adenomas. Further details of available data are given in Section 3.2.2.1.1.7.

- **Scenario 2: Adenomas per colonoscopy (APC)**

  The sensitivity for interventions was estimated using the incidence rate ratio (IRR) for APC, using the following formula:

  $$Sensitivity\ (intervention) = 1 - (1 - IRR) \times AMR(comparator)$$

  In cases where the resulting sensitivity was over 100%, the sensitivity was set to 100%.

A similar approach has been used in two existing economic evaluations (Barkun *et al.* 2023 and Hassan *et al.* 2023),[151, 153] although in these studies, the IRR value was based on a single trial (Repici *et al.* 2020),[123] and age- and sex-adjusted by fitting a Poisson regression directly to trial data, rather than using an unadjusted IRR value, as calculated in Section 3.2.2.1.1.8.

It should also be noted that only APC for all adenomas was reported, rather than APC disaggregated by advanced/non-advanced adenomas. Further details of available data were given in Section 3.2.2.1.1.8.

For patients with CRC and IBD, sensitivity was assumed the same between intervention and comparator arms, since the interventions under review are intended to detect polyps rather than CRC or IBD. The sensitivity for all arms for detecting CRC was taken to be 93.3% (95% CI: 93.2% to 93.4%), based on Burr *et al.* 2019, a population-based cohort study of patients undergoing colonoscopy in England; the input value used is informed by the observed true positive diagnoses of CRC in 2013, the most recent reported value in the study.[166] The sensitivity for IBD was taken to be 89.2% (95% CI: 86.1% to 91.9%), based on Pera *et al.* 1987, a diagnostic accuracy study of endoscopies in patients with Crohn's disease or ulcerative colitis.[167] The same input values were used in DG10083.[159]

A similar approach has been used in previous related NICE diagnostic appraisals, including DG56 and DG10083,[33, 159] and is also included in this model for consistency; however, the EAG notes that that all identified existing economic evaluations of AI technologies exclude detection and diagnosis of IBD as a separate outcome altogether.[43, 126, 145-147, 151, 153, 155, 157]

Also, where available, the proportion of patients with no underlying pathology undergoing polypectomy was informed by the reported non-neoplastic polyp detection rate (also referred to as the hyperplastic polyp detection rate or non-precancerous polyp detection rate). This is broadly defined as the proportion of patients with at least one polyp removed which was subsequently confirmed to be non-adenomatous by histopathological testing, regardless of their true disease state. It was assumed that this value would be representative of patients with no underlying pathology.

The baseline non-neoplastic detection rate for the comparator was 0.127, in line with DG10083.[159] The input value for interventions was derived by applying the RR derived in the based on the clinical

SLR and meta-analyses, where these could be performed (see Section 3.2.2.1.1.12). Data were only available for the CAD EYE®, ENDO-AID™, and GI Genius™ technologies; if no data were available, in the base case, the proportion of patients undergoing unnecessary polyp removal was assumed to align with the comparator. A scenario was also explored in which the non-neoplastic polyp detection rate was aligned with the ENDO-AID™ technology; this was the technology with the highest non-neoplastic polyp detection rate based on the clinical SLR. This scenario therefore explored a plausible pessimistic estimate for the proportion of patients undergoing unnecessary polypectomy.

A summary of input values used for the comparator and intervention technologies is given in Table 27.

Subgroup analyses were performed for interventions for which ADR was available, based on the clinical SLR; in general, ADR was not reported separately for LRA and AA. The relevant inputs for subgroup analyses are given in Appendix 9.8. Non-neoplastic polyp detection rate was also not reported, and was therefore assumed the same as for the whole patient population. AMR and APC scenario analyses were not performed, as relevant data were generally not available.

Table 27. Detection effectiveness for interventions

Technology	ADR RR (95% CI)*		AMR RR (95% CI)	APC IRR (95% CI)	Non-neoplastic polyp detection rate RR (95% CI)
	LRA	AA			
Argus®	1.10 (0.92 to 1.32)		NR	1.16 (0.97 to 1.39)	NR
CAD EYE®	1.17 (1.11 to 1.24)†	1.18 (0.98 to 1.44)	0.53 (0.38 to 0.76)‡	1.22 (1.14 to 1.31)	1.21 (1.04 to 1.41)
Discovery™	1.02 (0.81 to 1.28)		NR	1.00 (0.80 to 1.25)	NR
EMIS™	[redacted]		NR	NR	NR
ENDO-AID™	1.35 (1.06 to 1.70)	1.12 (0.86 to 1.45)	NR	1.56 (1.42, 1.71)	1.51 (1.29 to 1.76)
EndoScreener®	1.24 (1.13 to 1.37)		0.70 (0.37 to 1.30)§	1.50 (1.32 to 1.70)	NR
GI Genius™	1.31 (1.17 to 1.45)	1.00 (0.92 to 1.08)	0.55 (0.38 to 0.80)‡	1.23 (1.14 to 1.32)	1.09 (0.93 to 1.29)
MAGENTIQ-COLO™	1.26 (1.05 to 1.51)		0.52 (0.27 to 1.02)‡	1.37 (1.16 to 1.63)	NR

Footnotes: *Where only one value is specified for LRA and AA, data were not available for patients separated by LRA and AA

†For CAD EYE®, ADR was reported for advanced adenomas and all adenomas, but not low-risk adenomas. Therefore, the all-adenoma ADR was used as a proxy for LRA

‡AMR defined as AMR per lesion

§AMR defined as AMR per person

Abbreviations: AA, advanced adenoma; ADR, adenoma detection rate; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CI, confidence interval; EMIS™, Endoscopic Multimedia Information System; IRR, incidence rate ratio; LRA, low-risk adenoma; NR, not reported.

The efficacy inputs described above are only applied for the index colonoscopy; for subsequent colonoscopies in the patient's lifetime, since long-term cost and QALY outcomes are sourced from the MiMiC-Bowel model, the effectiveness is assumed the same as a conventional colonoscopy without AI technology. This approach is in line with DG56 and DG10083.[33, 159]

Since AI technologies generally lead to improved polyp detection rates, and thus potentially fewer delayed diagnoses of adenomas, and hence more instances of CRC avoided, this approach is likely to lead to underestimated overall QALYs and overestimated overall costs for intervention technologies compared to hypothetically modelling the effectiveness of AI technologies for all subsequent colonoscopies.

4.2.1.6.2 Diagnosis of true disease states

The third set of branches in the decision tree reflected the diagnosis and subsequent management of polyps following detection. As described in Section 4.2.1.4.2, the 'adenoma not removed' branches are redundant in the base case of the model, in which a resect-all polyp management strategy was assumed, as well as in the scenario analyses considering a resect-and-discard polyp management strategy; however, the functionality to implement these branches was included in the model to facilitate scenario analyses modelling the diagnose-and-leave management strategy. Details of how diagnosis of true disease states was parametrised for each polyp management strategy scenario are given in Appendix 9.10

4.2.1.7 Adverse events

The adverse events (AEs) considered in the model were potential complications of colonoscopy, encompassing bowel perforation, bleeding and death. These are in line with two previous economic evaluations of AI technologies which included AEs (Thiruvengadam *et al.* 2023, Thiruvengadam *et al.* 2024),[126, 157] while the remaining two included bowel perforation and bleeding but not death (Areia *et al.* 2022, HTW 2024 appraisal).[43, 147] The selection of these AEs was also validated by the EAG's clinical experts. The same complications are captured indirectly for future colonoscopies in the long-term QALYs and costs sourced from the MiMiC-Bowel model.[6]

Different incidences of AEs were used for diagnostic colonoscopy (i.e., colonoscopy without polypectomy) and therapeutic colonoscopy (i.e., colonoscopy with polypectomy).

The following patients were assumed to undergo therapeutic colonoscopy:

- Patients with no underlying pathology, but undergoing unnecessary polyp removal;
- All patients with LRAs present;
- All patients with AAs present.

Other patients were assumed to receive a diagnostic colonoscopy.

This is a slight simplification, since it is possible that patients with a true underlying status of LRA or AA may not undergo any polypectomies, due to failure to detect any adenomas at all. However, the proportion of patients in this category is unknown, as relevant data are not generally reported for relevant trials. The probabilities of complications for colonoscopy without polypectomy and for colonoscopy with polypectomy were assumed the same regardless of the technology used; this was considered to be a reasonable assumption since complications are associated with the technique and skill of the endoscopist in performing the colonoscopy rather than technologies used to identify or characterise polyps. This assumption is in line with other existing economic evaluations of AI technologies (Areia *et al.* 2022, HTW 2024 appraisal, Thiruvengadam *et al.* 2023, Thiruvengadam *et al.* 2024).[43, 126, 147, 157]

However, the incidence of complications at the index colonoscopy differed between technologies, since increased detection of polyps would be expected to lead to more polypectomies, if the resect-all or resect-and-discard management strategies are used. Conversely, if the diagnose-and-leave strategy is used, use of CADx would be expected to result in fewer polypectomies overall.

Incidence of complications of colonoscopies were informed by a systematic literature review and meta-analyses of post-colonoscopy complications (Reumkens *et al.* 2016); the same source was used in DG10083 to parametrise incidence of AEs.[159, 168] In this study, death events were defined as deaths due to cardiorespiratory events, perforation or bleeding related to the colonoscopy, which occurred within three months of the colonoscopy. Different incidences were used for diagnostic and therapeutic colonoscopies; the former refers to colonoscopies which do not involve polypectomies, while the latter refers to colonoscopies which involve polypectomies. It was assumed that failed

colonoscopies would not result in complications, as the procedure would be likely to be cut short. A summary of the input values used is given in Table 28.

Table 28. Incidence of colonoscopy complications

Complication	Incidence per colonoscopy (no polypectomy)	Incidence per colonoscopy with polypectomy	Source
Bowel perforation	0.04%	0.08%	Reumkens *et al.* 2016[168]
Bleeding	0.06%	0.98%	
Death	0.003%	0.003%	

4.2.1.8 Long-term survival

Long-term survival of patients following the index colonoscopy was captured via long-term outcomes sourced from DG10083, which in turn were informed by the MiMiC-Bowel model, or, where relevant, generated from general population norms.[6, 159] For patients who were modelled to receive a delayed diagnosis, it was assumed that they would eventually be diagnosed, due to worsening symptoms over time. Therefore, separate input values were generated for patients with a delayed diagnosis. Input values were generated for both patients undergoing colonoscopies for screening or surveillance purposes; similarly to the prevalence of true disease states, a weighted average of these payoffs was used in the model base case, weighted by the proportion of patients undergoing screening vs surveillance colonoscopies in the NHS. The proportion of colonoscopies which are screening colonoscopies was taken to be 10.6%, informed by the 2023 National Census of UK Endoscopy Services.[165] The screening and surveillance outcomes were used to inform subgroup analyses (further details are given in Appendix 9.8). The EAG notes that the screening population has increased long-term survival compared to the surveillance population for all underlying pathologies except CRC, as patients in the screening population are more likely to present with more advanced CRC than patients undergoing routine surveillance.

Further details of the methodology which was used to generate long-term outcomes, including survival, are given in Appendix 9.9. A small proportion of patients were assumed to die as a complication of the index colonoscopy; for these patients, the long-term total life years were set to zero.

A summary of long-term survival outcomes is given in Table 29 below.

Table 29. Long-term LYG

Decision tree outcome	Total long-term LYG		
	Base case (mixed population)	Screening population	Surveillance population
No pathology	14.07	14.59	14.01
LRA	14.07	14.59	14.01
LRA (delayed diagnosis)	14.00	14.58	13.93
AA	14.07	14.59	14.01
AA (delayed diagnosis)	13.43	14.55	13.30
IBD	14.07	14.59	14.01
IBD (delayed diagnosis)	14.07	14.59	14.01
CRC	12.72	10.34	13.00
CRC (delayed diagnosis)	10.42	9.40	10.54

Abbreviations: AA, advanced adenoma; CRC, colorectal cancer; IBD, inflammatory bowel disease; LRA, low-risk adenoma; LYG, life years gained.

4.2.1.9 Health-related quality of life

4.2.1.9.1 Disutilities for complications

One-off QALY losses were applied for complications of colonoscopy (bowel perforation and bleeding); these were aligned with the MiMiC-Bowel model, for consistency.[6] These QALY losses were applied to all patients, including patients dying as a result of colonoscopy, although these patients would not go on to accrue any long-term QALYs. Details of the input values used in the model are given in Table 30.

Table 30. Disutilities for complications

Complication	QALY loss	Source
Bowel perforation	0.00983	Disutility for stomach ulcer/abdominal hernia/rupture, Ara and Brazier 2011, applied for one month.[169]
Bleeding	0.00581	Disutility for major gastrointestinal bleed, Dorian *et al.* 2014, applied for two weeks.[170]

4.2.1.9.2 Long-term QALYs

As described in Section 4.2.1.2, the long-term QALY payoffs for each outcome of the initial decision tree model were sourced from DG10083.[159] Similarly to the total LYG long-term QALYs were generated for both patients undergoing colonoscopies for screening or surveillance purposes; in the base case, a weighted average of these payoffs was used, weighted by the proportion of patients undergoing screening vs surveillance colonoscopies in the NHS, while the screening and surveillance outcomes were used to inform subgroup analyses (further details are given in Appendix 9.8. Further details of the methodology which was used to generate these values are given in Appendix 9.9.

A summary of long-term QALYs is given in Table 31 below. The undiscounted total LYG is presented alongside for comparison; (note that these are the same values presented in Table 29, but these are reproduced here for convenience). Discounted LYG payoffs from the MiMiC-Bowel model are not available.

Table 31. Long-term QALY outcomes

Decision tree outcome	Total long-term QALYs (discounted)			Total long-term LYG (undiscounted)		
	Base case (mixed population)	Screening population	Surveillance population	Base case (mixed population)	Screening population	Surveillance population
No pathology	10.99	11.50	10.93	14.07	14.59	14.01
LRA	10.99	11.50	10.93	14.07	14.59	14.01
LRA (delayed diagnosis)	10.93	11.48	10.86	14.00	14.58	13.93
AA	10.99	11.50	10.93	14.07	14.59	14.01
AA (delayed diagnosis)	10.42	11.34	10.31	13.43	14.55	13.30
IBD	9.82	10.28	9.77	14.07	14.59	14.01
IBD (delayed diagnosis)	9.76	10.22	9.71	14.07	14.59	14.01
CRC	9.11	7.31	9.32	12.72	10.34	13.00
CRC (delayed diagnosis)	7.66	6.71	7.77	10.42	9.40	10.54

Abbreviations: AA, advanced adenoma; CRC, colorectal cancer; IBD, inflammatory bowel disease; LRA, low-risk adenoma; LYG, life years gained; QALY, quality-adjusted life year.

The long-term QALY payoffs were calculated assuming that subsequent colonoscopies after the index colonoscopy are all conventional colonoscopies, without AI technologies; therefore, the potentially improved accuracy of detection of polyps with AI technologies would not be captured for subsequent colonoscopies. The EAG considered that this approach was reasonable, since generating long-term payoffs taking into account AI technology accuracy would have required reruns of the MiMiC-Bowel model for multiple decision tree outcomes and AI technologies, which could not be carried out within the scope of the project. It should also be noted that the resulting QALY estimates may underestimate the true value of QALYs accumulated when AI technologies are used, so the resulting QALY outcomes are conservative. The same approach was also used in DG56, DG10083 and the HTW 2024 appraisal.[33, 43, 159]

4.2.1.10 Resource use and costs

Where appropriate, costs were sourced from the most recent available NHS reference costs (2023/24).[171]

4.2.1.10.1 Colonoscopy costs

All patients incurred a cost corresponding to the index colonoscopy; procedure costs for the index colonoscopy, excluding AI technologies, were derived from the NHS reference costs (2023/24).[171] Separate costs are given for diagnostic and therapeutic colonoscopies. Both costs include costs for histopathological testing resulting from the colonoscopy. However, a cost for histopathological testing was also sourced so that this cost could be deducted for discarded polyps in the resect-and-discard polyp management strategy scenario. Costs for additional services associated with colonoscopies (e.g., bowel preparation and follow-up to confirm results) were not included, both as they were expected to result in a minimal contribution to total costs, and also because the costs would be expected to be identical regardless of the nature of the colonoscopy received.

As for the incidences of AEs, the therapeutic colonoscopy cost was applied to the following patients:

- Patients with no underlying pathology, but undergoing unnecessary polyp removal;
- All patients with LRAs present;
- All patients with AAs present.

The cost for diagnostic colonoscopy was applied for all other patients; any costs for further treatment for patients with IBD or CRC were captured in the lifetime payoffs applied to the relevant decision tree branches.

A proportion of all patients were assumed to undergo an initial incomplete colonoscopy, e.g., due to inadequate bowel preparation, patient discomfort, or technical difficulties. The proportion of patients with an incomplete initial colonoscopy was taken to be 1.1%, in line with the proportion of patients receiving a repeat colonoscopy after incomplete initial colonoscopy, in a five-year audit of colonoscopies conducted at the Royal Liverpool University Hospital between 2005 and 2010 (Britton *et al.* 2015); this was calculated as the proportion of patients who underwent a subsequent test after initial failed colonoscopy (324/10,580), multiplied by the proportion of these patients who underwent a secondary colonoscopy rather than another test (35.8%).[172] It was assumed that a failed test would incur 100% of the costs of a completed diagnostic test. The impact of this assumption was explored in scenario analyses.

A proportion of patients requiring polyp removal were assumed to require a secondary therapeutic colonoscopy; in clinical practice, this may occur if a patient has a large number of polyps requiring removal, or one or more polyps are present which are too technically challenging for the endoscopist to remove (e.g., due to size or location), requiring a follow-up appointment with a more experienced endoscopist. The proportion of patients requiring a secondary therapeutic colonoscopy was aligned with the value used in DG10083;[159] this value was derived from clinical expert estimates. The proportion of patients receiving a secondary therapeutic colonoscopy was applied only to the proportion of patients alive after their initial therapeutic colonoscopy; it was also assumed that no patients without underlying pathology undergoing a therapeutic colonoscopy due to misdiagnosis would require a secondary colonoscopy. In the base case, it was assumed that the proportion of patients requiring a secondary colonoscopy was the same regardless of the technology used; however, the use of CADe technologies may result in a higher detection rate of polyps, potentially resulting in a larger proportion of patients requiring a secondary colonoscopy. The impact of this assumption was explored in scenario analyses. Also in line with DG10083, it was assumed that secondary therapeutic colonoscopies would only be required for patients in the AA true disease state.[159]

The EAG's clinical experts also stated that in rare cases, patients may require surgery to remove particularly intractable polyps; however, this was considered sufficiently uncommon to exclude from the economic model.

A summary of inputs related to costs for colonoscopies is given in Table 32 below.

Table 32. Colonoscopy cost inputs

Input	Value used	Source
Diagnostic colonoscopy cost	£787	NHS reference costs (2023/24), FE32Z – Diagnostic Colonoscopy, 19 years and over (day case)
Therapeutic colonoscopy cost	£1,015	NHS reference costs (2023/24), FE30Z – Therapeutic Colonoscopy, 19 years and over (day case)
Proportion of patients with incomplete first colonoscopy	1.2%	Britton *et al.* 2015[172]
Proportion of patients requiring secondary therapeutic colonoscopy	10.0%	Clinical expert advice

Abbreviations: NHS, National Health Service.

4.2.1.10.2 AI technology costs

For the intervention arms, an estimated cost of the relevant AI per procedure was applied, calculated as follows:

One-off purchases:

$$Cost\ per\ procedure = \frac{1}{Procedures\ per\ year} \times \left(\frac{Upfront\ cost}{Expected\ lifetime\ (years)} + maintenance\ cost\ per\ year\right)$$

Subscription plans:

$$Cost\ per\ procedure = \frac{Cost\ per\ year}{Procedures\ per\ year}$$

For the EMIS™ technology, the manufacturer did not provide a list price, but stated that the expected cost per colonoscopy would be [redacted]. In the absence of a firm list price, the EAG suggests that cost-effectiveness results for EMIS™ are interpreted with caution.

Similarly to the accuracy of interventions, the cost for AI technologies was only applied for the index colonoscopy (see Section 4.2.1.6 for further details), since discounting cannot be correctly applied, as the timing of subsequent colonoscopies varies between patients. This assumption may potentially lead to underestimation of total costs for the AI intervention arm, although AI technologies are priced as one-off costs or subscription costs rather than on a per-unit basis. On the other hand, the potential benefits of AI technologies also could not be applied for subsequent colonoscopies.

The number of procedures per year was informed by the 2023 national census of UK endoscopy services; the mean number of colonoscopies per room over a year was estimated by dividing the total number of colonoscopies in NHS facilities by the total number of rooms in NHS facilities in 2022.[165] The resulting value, 898.05, was used as the relevant model input. Individual technology list prices and maintenance costs were given by the relevant manufacturer, and adjusted to exclude value-added tax (VAT) if necessary, as per the NICE health technology evaluations manual.[173] Costs for the hardware used to run the AI systems was not included, since the same hardware would be required to conduct a colonoscopy without AI technologies. For technologies with an upfront cost including the cost of maintenance for the first year, the subsequent maintenance cost was subtracted from the upfront cost before calculating the cost per procedure. The expected lifetime of the technologies is unknown; in line with the HTW 2024 appraisal, an estimate of four years is used in the model base case, although this is varied in sensitivity analyses. The EAG notes that GI Genius™ and MAGENTIQ-COLO™ are available on both a subscription and upfront purchase arrangement; for these technologies, the subscription cost was used, as they do not rely on any assumption about the lifetime of the technology. Furthermore, the subscription costs are inclusive of maintenance costs, whereas it was unclear what the long-term maintenance costs would be for the upfront purchase framework for these technologies. The EAG notes that the use of an assumption for lifetime of technologies purchased upfront, but not for technologies costed on a subscription model, is a potential source of inconsistency between technologies; however, this is insurmountable, due to the different pricing options available for different technologies, and the impact of the lifetime assumption is explored in scenario analyses.

A summary of the costs used for each AI technology is given below in Table 33.

Table 33. AI technology cost inputs

Technology	List price	Estimated cost per colonoscopy (excluding VAT)
Argus®	Upfront cost of £10,000.00 (excluding VAT) £2,000.00/year maintenance cost	£5.01
CAD EYE®	[redacted]	[redacted]
Discovery™	Upfront cost of £34,999.99 (excluding VAT) First year maintenance is included in upfront cost; thereafter, £2,265.00/year maintenance cost	£12.27
EMIS™	[redacted]	[redacted]
ENDO-AID™	£29,916.00 (including VAT) First year maintenance is included in upfront cost; thereafter, £3,189.00/year maintenance cost	£9.90
EndoScreener®	Subscription: £9,750/year (excluding VAT), waived after four years	£10.86
GI Genius™	Subscription: £1,750/month including maintenance (including VAT)	£19.49
MAGENTIQ-COLO™	Subscription: €1,000/month including maintenance (excluding VAT)	£11.30

Abbreviations: AI, artificial intelligence; EMIS™, Endoscopic Multimedia Information System; VAT, value-added tax.

4.2.1.10.3 Complication costs

Costs for complications used in the model were sourced from appropriate NHS reference costs (aligned with the approach used in DG10083).[159] No additional costs were applied for patients experiencing death, as it was assumed that death would generally occur as a result of other AEs, in the process of receiving treatment; however, a scenario analysis was also conducted in which treatment costs for AEs were excluded for patients dying as a complication of colonoscopy. Details of the costs used are given in Table 34.

Table 34. Colonoscopy complication costs

Complication	Cost	Source
Bowel perforation	£6,348.89	NHS reference costs (2023/24), FF34A-FF34C - Major Large

		Intestine Procedures, 19 years and over (weighted average)[171]
Bleeding	£1,907.02	NHS reference costs (2023/24), FD03A-FD03H - Gastrointestinal Bleed with Multiple/Single/No Interventions (weighted average)[171]
Abbreviations: NHS, National Health Service.		

4.2.1.10.4 Long-term costs

As described in Section 4.2.1.2, the long-term cost 'payoffs' for each outcome of the initial decision tree model were sourced from DG10083 and uplifted from cost year 2022/2023 to 2023/2024 in line with the provisional NHSCII pay and prices index for 2023/2024.[159, 174] Similarly to the total LYG and total QALYs, long-term costs were generated for both patients undergoing colonoscopies for screening or surveillance purposes. In the base case, a weighted average of these payoffs was used, weighted by the proportion of patients undergoing screening vs surveillance colonoscopies in the NHS, while the screening and surveillance outcomes were used to inform subgroup analyses (further details are given in Appendix 9.8).

The EAG notes that that costs for patients with a delayed diagnosis of CRC were in fact lower than costs for patients without a delayed diagnosis, since delayed diagnosis was likely to lead to reduced survival and therefore reduced overall expenditure on treatment.

Further details of the methodology which was used to generate these values are given in Appendix 9.9.

[174]A summary of long-term costs outcomes is given in Table 35 below.

Table 35. Long-term costs

Decision tree outcome	Total long-term costs		
	Base case (mixed population)	Screening population	Surveillance population
No pathology	£0.00	£0.00	£0.00
LRA	£177.24	£0.00	£198.19
LRA (delayed diagnosis)	£727.18	£304.59	£777.11
AA	£674.05	£543.46	£689.49

AA (delayed diagnosis)	£5,842.63	£3,399.46	£6,131.34
IBD	£78,695.55	£81,572.51	£78,355.59
IBD (delayed diagnosis)	£79,587.40	£82,464.36	£79,247.44
CRC	£33,335.44	£31,208.51	£33,586.78
CRC (delayed diagnosis)	£25,673.33	£29,438.37	£25,228.42

Abbreviations: AA, advanced adenoma; CRC, colorectal cancer; IBD, inflammatory bowel disease; LRA, low-risk adenoma.

The long-term costs used assume that subsequent colonoscopies after the index colonoscopy are all conventional colonoscopies, without AI technologies; the EAG considers this to be reasonable, since AI technologies are costed as a one-off acquisition cost, or a flat cost per unit for a set duration, and not on a per-procedure basis. It should also be noted that in the resect-and-discard polyp management strategy scenario, the total long-term costs may be underestimated, since in this scenario, patients are more likely to be incorrectly misdiagnosed than when the 'resect-all' polyp management strategy is used, leading to earlier follow-up than is required. However, this would only have an impact on results if CADx functionalities were considered.

4.2.1.11 Total number of colonoscopies

The economic model also captured the total number of colonoscopies required to arrive at a diagnosis. For patients with a delayed diagnosis of any underlying pathology due to the underlying pathology being missed in an initial colonoscopy, it was assumed that the number of colonoscopies required to reach a diagnosis would be twice the number of colonoscopies required for a patient diagnosed without delay, inclusive of failed colonoscopies and secondary therapeutic colonoscopies, since it is assumed that a patient would have to undergo a second colonoscopy (and potentially a failed initial colonoscopy, or subsequent therapeutic colonoscopy) after re-presenting with symptoms or a positive faecal immunochemical test (FIT) result. Therefore, AI technologies could potentially reduce the total number of colonoscopies required by patients. The EAG notes that the overall number of subsequent colonoscopies in a patient's lifetime after diagnosis could also be affected by the use of AI technologies (for example, increased detection of underlying adenomas could lead to further subsequent surveillance colonoscopies). However, the expected number of colonoscopies was not generated as an output of the MiMiC-Bowel model, and therefore could not be included in this evaluation.

An exploratory analysis was also conducted to explore the potential impact of the decreased number of colonoscopies on waiting times for colonoscopies. The EAG notes that that waiting times are

generally only applicable for diagnostic colonoscopies as a result of a positive FIT test or the presence of symptoms, since colonoscopies for surveillance purposes are generally scheduled well in advance.

The potential impact of introducing AI technologies on waiting times was estimated as follows:

$$Change\ in\ waiting\ time = Proportional\ change\ in\ colonoscopy\ numbers\ per\ patient \times current\ waiting\ time$$

A similar approach has been used in previous diagnostic appraisals (DG56 and DG10083).[33, 159]

The current waiting time was informed by the most recent available NHS England monthly diagnostics data ; the mean of the monthly median waiting times for a diagnostic colonoscopy over the year April 2024-May 2025 was 2.9 weeks.[175]

The EAG acknowledges that this approach is relatively simplistic, and results should be interpreted with caution. In particular, waiting times vary considerably between centres, and wait times for diagnostic colonoscopies may not be affected by an increase in surveillance colonoscopies, since the former are generally conducted through the BCSP while the latter are not.

4.2.1.12 Outcomes

The outcomes included in the economic model were as follows:

- Total and incremental LYG;
- Total and incremental QALYs;
- Total and incremental costs;
- Incremental cost-effectiveness ratio (ICER);
- Incremental net health benefit (NHB);
- Total number of colonoscopies prior to diagnosis
- Total number of diagnostic and therapeutic colonoscopies prior to diagnosis
- Total number of polypectomies for patients with no underlying pathology

An exploratory analysis estimating the potential impact on waiting time for a colonoscopy was also performed.

Both deterministic and probabilistic results were presented. The probabilistic approach varied parameters impacting the decision tree using the source's standard error, if available. However, the model inputs sourced from the MiMiC-Bowel model contributed a significant amount of uncertainty, as only mean values were available. In line with DG56,[33] it was assumed that the standard error of each input corresponded to 20% of the mean value, with all outcomes assumed to have gamma distributions.

A DSA was also conducted to explore the sensitivity of results to individual parameters. Parameters were varied using the 95% confidence intervals in line with good practice.[176] Where confidence intervals were unavailable, an assumed standard error equal to 20% of the mean was used, and the 95% confidence interval was derived from a gamma distribution. In particular, this approach was used for the long-term payoffs, since measures of uncertainty were not available for these inputs.

4.2.1.13 Validation

The economic model was validated as follows:

- Detailed quality assurance of the model (cell-by-cell calculations) by another health economist at BMJ-TAG not previously involved in the project;
- Black box and face validity tests;
- Comparison of key outcomes with existing economic evaluations of similar technologies (e.g., the HTW 2024 appraisal).[43]

Key assumptions and face-validity of the results were also validated with the EAG's clinical experts.

Results of the validation with existing economic evaluations are given in Appendix 9.11.

4.2.1.14 List of assumptions

A summary of key assumptions included in the economic model is given in the tables presented below.

Table 36. Key structural assumptions

Assumption	Justification	Scenario analyses?
Patients with missed conditions (LRA, AA, IBD or CRC) were	It was considered reasonable that patients with underlying conditions would be followed up and correctly	This was not explored in scenario analyses, since an alternative approach was not available.

assumed to be diagnosed after a delay.	diagnosed at a later stage, particularly if their condition worsened. The same approach was used in DG56 and DG10083.[33, 159]	
All detected polyps were assumed to be removed.	This is broadly in line with current UK clinical practice; based on clinical expert opinion, all detected polyps with the potential exception of small rectal polyps would be resected, but reported trial outcomes generally include insufficient granularity to model this directly.	Alternative polyp management strategies (resect-and-discard, diagnose-and-leave) were considered in scenario analyses.
Training of staff in using AI technologies was not considered in the economic model.	Based on the scoping workshop for this project, and feedback from the EAG's clinical experts, adoption of CADe and/or CADx technologies requires minimal additional training for endoscopists, and would not incur additional costs or a 'learning curve' in technology effectiveness as endoscopists learn to use the technology. This is in line with previous economic evaluations of AI technologies.	This assumption was not explored in scenario analyses, as clinical experts were in agreement that training costs and impacts on effectiveness would be negligible.
A fixed proportion of patients with AA were assumed to incur costs for a secondary therapeutic colonoscopy; the proportion was informed by clinical expert input, and was assumed to be the same regardless of the technology used. Patients with LRA were assumed not to require a secondary colonoscopy.	The EAG's clinical experts stated that some patients may require a second therapeutic colonoscopy if they have a large number of polyps requiring removal, or one or more polyps which are technically challenging to remove (e.g., due to large size or location); this is most likely to correspond to patients with AA. The precise proportion of patients requiring a secondary colonoscopy is challenging to define, and may vary considerably between endoscopists; no appropriate data could be identified.	The proportion of patients receiving secondary colonoscopies was varied in scenario analyses (including scenarios with a larger proportion of patients requiring a secondary colonoscopy for AI technologies).
After the initial modelled colonoscopy, for subsequent colonoscopies in a patient's lifetime, costs, sensitivity, specificity and risk of complications were assumed to	This is a simplification, which allows the use of long-term cost and QALY outcomes from the MiMiC-Bowel model, considerably reducing the complexity of the model required. This approach is in line with DG56 DG10083.[33, 159]	Scenario analyses were not feasible, but the long-term outcomes sourced from the MiMiC-Bowel model were varied in sensitivity analyses.

align with those for standard colonoscopy.		

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CADe, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; EAG, External Assessment Group; IBD, inflammatory bowel disease; LRA, low-risk adenoma; QALY, quality-adjusted life year; UK, United Kingdom.

Table 37. Key input assumptions

Assumption	Justification	Scenario analyses?
Effectiveness of technologies was assumed to be independent of the use of non-AI adjunct technologies to aid colonoscopy, including VCE, dye-based chromoendoscopy or ENDOCUFF VISION™.	Based on feedback from the EAG's clinical experts, in practice, use of these technologies is inconsistent between patient populations, centres and individual endoscopists. Trials identified in the clinical SLR also generally included colonoscopies with and without the use of non-AI adjunct technologies. In the absence of more specific available data, it is assumed that the mix of adjunct technologies used in the trials informing model inputs is similar to the use of non-AI adjunct technologies in UK clinical practice, and that estimates of AI technology effectiveness are comparable to UK clinical practice. Furthermore, there is unlikely to be interaction between additional adjunct technologies used, and the relative efficacy of AI technologies. This issue is not explored in any of the existing economic evaluations identified in the economic SLR (see Section 4.1.2.3).	This was not explored in scenario analyses, since an alternative approach was not available.
For detection of polyps, sensitivity (i.e. the probability of detecting all polyps which are present) was assumed to align with 1–AMR for comparator, and derived from relative ADR for interventions.	Sensitivity is not directly reported in existing studies. ADR was used for interventions as this is more commonly reported than AMR or APC. This approach is in line with other existing economic evaluations (e.g., the HTW 2024 appraisal of AI technologies in colonoscopy).[43]	Alternative values for sensitivity of colonoscopy, sourced from alternative existing economic evaluations, were explored.

The probability of detecting IBD and CRC was assumed to be the same as standard colonoscopy for all interventions.	This is a reasonable assumption since CADe technologies are intended to detect polyps rather than IBD or CRC. This approach is also in line with existing economic evaluations (e.g. the HTW 2024 appraisal).[43]	This assumption was not explicitly explored in scenario analyses, although the rates of CRC and IBD detection were varied in sensitivity analyses.
If detection and/or diagnosis outcomes were not available separately for LRA and AA for specific interventions, it was assumed that outcomes were the same for all adenomas.	This assumption is potentially favourable to the intervention, as any increase in adenoma detection due to CADe technology may correspond to smaller (often lower risk) adenomas. However, this assumption was explored in scenario analyses.	A more pessimistic assumption (from the perspective of the intervention technologies) was considered in scenario analyses, in which the outcomes for AA were assumed to be the same as the comparator. Alternative scenarios with input values ranging between the comparator and observed outcomes for all adenomas for the intervention were also considered.
In order to calculate costs per procedure for individual AI technologies with a one-off upfront cost, it was assumed that the average lifetime of an AI technology would be four years.	The expected lifetime of AI technologies is unknown; in the base case, the estimated lifetime is aligned with the value used in the HTW 2024 appraisal.[43]	The expected lifetime of AI technologies was varied in scenario analyses.

Abbreviations: AA, advanced adenoma; ADR, adenoma detection rate; AI, artificial intelligence; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CRC, colorectal cancer; EAG, External Assessment Group; HTW, Health Technology Wales; IBD, inflammatory bowel disease; LRA, low-risk adenoma; SLR, systematic literature review; UK, United Kingdom; VCE, virtual chromoendoscopy.

4.2.1.15 Scenario analyses

The sensitivity of model results to key assumptions was explored in scenario analyses. A summary of the scenario analyses conducted is given in Table 38. In some cases, scenarios were only conducted for a subset of interventions, either because the scenario could not be conducted due to limited data availability, or because the scenario was only applicable to certain interventions.

Table 38. Summary of scenario analyses

Number	Scenario	Details	Relevant interventions
1	Diagnose-and-leave polyp management strategy	In the base case, a resect-all polyp management strategy was assumed. Scenario analyses were explored in which a diagnose-and-leave polyp management	All interventions

		strategy was used for both intervention and colonoscopy without AI. In the first scenario, it was assumed that diagnose-and-leave would be used for all polyps, regardless of confidence in diagnosis, while in the second scenario, it was assumed that diagnose-and-leave would only be applied to polyps diagnosed with high confidence. Details of how these scenarios was implemented are given in Appendix 9.10.	
2	Resect-and-discard polyp management strategy	In the base case, a resect-all polyp management strategy was assumed. A scenario analysis was explored in which a resect-and-discard polyp management strategy was used for both intervention and colonoscopy without AI. Details of how this scenario was implemented are given in Appendix 9.10.	All interventions
3	Diagnose-and-leave polyp management strategy with CADx	In the base case, CADx functionalities were not considered. Exploratory analyses was conducted in which a diagnose-and-leave polyp management strategy was facilitated with CADx functionality for the intervention (both for diagnoses of any confidence level, and for high-confidence diagnoses only). Details of how these scenarios were implemented are given in Appendix 9.10.	Only those interventions with CADx functionality and with data available: CAD EYE® GI Genius™
4	Resect-and-discard polyp management strategy with CAD	In the base case, CADx functionalities were not considered. An exploratory analysis was conducted in which a resect-and-discard polyp management strategy was facilitated with CADx functionality for the intervention. Details of how this scenario was implemented are given in Appendix 9.10.	Only those interventions with CADx functionality and with data available: CAD EYE® GI Genius™
5	Alternative values for sensitivity of detection for colonoscopy without AI	In the base case, the sensitivity of detection for the comparator was informed by AMR values reported in an existing SLR (Zhao *et al.* 2019). An alternative approach was considered in which intervention sensitivity was assumed to be 100%, and colonoscopy without AI sensitivity was calculated by applying ADR RR (similar to the approach used in the HTW 2024 appraisal). The EAG notes that another alternative approach was used in Areia *et al.* 2022, in	All interventions

		which colonoscopy sensitivity was informed directly by reported ADR. The EAG did not consider this approach to be appropriate, since it does not take into account the effect of baseline prevalence of adenomas on the ADR. Another alternative approach was used in Thiruvengadam *et al.* 2023 and Thiruvengadam *et al.* 2024, but the EAG was unable to reproduce this since the input value used was unclear.	
6	CADe sensitivity of interventions calculated using AMR	In the base case, the sensitivity of detection for the interventions was informed by reported ADR RRs. A scenario analysis was conducted in which the AMR RR was used instead. Further details are given in Section 4.2.1.6.1.	CAD EYE® EndoScreener® GI Genius™ MAGENTIQ-COLO™
7	CADe sensitivity of interventions calculated using APC	In the base case, the sensitivity of detection for the interventions was informed by reported ADR RRs. A scenario analysis was conducted in which the APC IRR was used instead. Further details are given in Section 4.2.1.6.1.	CAD EYE® Discovery™ ENDO-AID™ EndoScreener® GI Genius™ MAGENTIQ-COLO™
8	Alternative rate of CRC detection	In the base case, the sensitivity of CRC detection was assumed to be 93.5% for all interventions (Burr *et al.* 2019).[166] The following three alternative approaches were considered: • 100% sensitivity for all technologies; • 90% sensitivity for all technologies; • Sensitivity for interventions calculated by applying AA ADR RR to the colonoscopy without AI sensitivity.	All interventions
9	Alternative rate of IBD detection	In the base case, the sensitivity of IBD detection was assumed to be 89.2% for colonoscopy without AI and all interventions (Pera *et al.* 1987).[167] The following alternative values were considered: • 100% sensitivity for all technologies; • 80% sensitivity for all technologies.	All interventions
10	Alternative approach to parametrising CADe sensitivity for AA	In the base case, for interventions for which ADR RR was not reported separately for AA and LRA, the overall reported ADR RR was used to parameterise CADe sensitivity for both AA and LRA. A pessimistic scenario was	Argus® Discovery™ EMIS™ EndoScreener®

		explored in which the AA sensitivity was assumed to align with colonoscopy without AI.	MAGENTIQ-COLO™
11	Alternative approach to parametrising unnecessary polyp removal	In the base case, for interventions with no data available for the proportion of patients with no underlying pathology undergoing unnecessary polyp removal, alignment with colonoscopy without AI was assumed. A pessimistic scenario was explored in which the relevant input value was instead aligned with the ENDO-AID™ technology.	Argus® Discovery™ EMIS™ EndoScreener® MAGENTIQ-COLO™
12	Alternative costing for failed initial colonoscopies	In the base case, 100% of the diagnostic colonoscopy cost was applied for failed colonoscopies. As an alternative, a scenario was considered in which no costs were applied for a failed colonoscopy.	All interventions
13	Alternative proportion of patients receiving secondary therapeutic colonoscopies	In the base case, 24.8% of patients were assumed to require a secondary therapeutic colonoscopy for all technologies. The following three alternative approaches were considered: • 0% of patients assumed to require a secondary therapeutic colonoscopy for all technologies; • 50% of patients assumed to require a secondary therapeutic colonoscopy for all technologies; • Proportion of patients requiring a secondary colonoscopy for interventions was calculated by applying the ADR RR to the proportion requiring secondary colonoscopy for colonoscopy without AI .	All interventions
14	Alternative expected lifetime of AI technologies	In the base case, AI technologies were assumed to have a lifetime of four years. The following alternative values were explored: • Three years; • Five years; • Ten years.	Argus® CAD EYE® Discovery™ ENDO-AID™
15	Costs for AEs excluded for patients dying as a result of colonoscopy	In the base case, it was assumed that patients who die as a result of colonoscopy would accrue the same AE treatment costs as patients who did not die. A scenario was explored in which AE	All interventions

		treatment costs were excluded for patients who died as a result of colonoscopy.	

Abbreviations: AA, advanced adenoma; AE, adverse event; AI, artificial intelligence; ADR, adenoma detection rate; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; EAG, External Assessment Group; EMIS™, Endoscopic Multimedia Information System; HTW, Health Technology Wales; IBD, inflammatory bowel disease; IRR, incidence rate ratio; LRA, low-risk adenoma; RR, risk ratio.

4.2.2 Results

4.2.2.1 Base case results

The results for the model base case were calculated both deterministically and probabilistically. Probabilistic results are presented in Table 39, while deterministic results are presented in Table 40. Where incremental NHB is presented, a cost-effectiveness threshold of £30,000/QALY was used.

Additional probabilistic results, including plots of probabilistic results in the cost-effectiveness plane and the cost-effectiveness acceptability curve (CEAC), are given in Appendix 9.12.1. Probabilistic results were calculated over 1,000 simulations, which gave appropriate convergence of the resulting incremental NHB for all interventions (convergence plots for each intervention are also given in Appendix 9.12.1). An arbitrarily-selected random seed of 2 was used for all simulations presented in this report, to ensure reproducibility of results, although alternative random seeds gave similar results.

The CEACs and probabilistic analysis convergence plots both consider incremental NHB rather than ICER, as probabilistic simulation results are spread across all four cost-effectiveness plane quadrants, so the incremental NHB is more interpretable than the ICER.

Table 39. Probabilistic cost-effectiveness results

Technology	Total Costs	Total QALYs	Total LYG	Incremental costs vs colonoscopy without AI	Incremental QALYs vs colonoscopy without AI	Incremental LYG vs colonoscopy without AI *	ICER vs colonoscopy without AI (£/QALY)	Incremental NHB vs colonoscopy without AI
Colonoscopy without AI	£3,171.62	10.981	14.061					
Argus®	£3,127.81	10.984	14.065	-£43.81	0.004	0.003	Dominant	0.005
CAD EYE®	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dominant	0.007
Discovery™	£3,180.32	10.982	14.061	£8.70	0.001	0.000	£8,669.76	0.001
EMIS™	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dominant	0.003
ENDO-AID™	£3,098.39	10.985	14.068	-£73.23	0.004	0.007	Dominant	0.007
EndoScreener®	£3,082.52	10.986	14.068	-£89.10	0.006	0.007	Dominant	0.009
GI Genius™	£3,126.46	10.982	14.065	-£45.16	0.002	0.004	Dominant	0.003
MAGENTIQ-COLO™	£3,081.36	10.987	14.069	-£90.26	0.006	0.007	Dominant	0.009

Footnote: * Undiscounted total and incremental LYG is presented to aid interpretability; all other results are discounted at a rate of 3.5% per year.

Abbreviations: AI, artificial intelligence; EMIS™, Endoscopic Multimedia Information System; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year; SW, south-west.

Table 40. Deterministic cost-effectiveness results

Technology	Total Costs	Total QALYs	Total LYG*	Incremental costs vs colonoscopy without AI	Incremental QALYs vs colonoscopy without AI	Incremental LYG vs colonoscopy without AI *	ICER vs colonoscopy without AI (£/QALY)	Incremental NHB vs colonoscopy without AI
Colonoscopy without AI	£3,164.39	10.932	14.042					
Argus®	£3,103.63	10.937	14.047	-£60.76	0.005	0.005	Dominant	0.007
CAD EYE®	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	0.008
Discovery™	£3,164.96	10.933	14.043	£0.57	0.001	0.001	£607	0.001
EMIS™	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	0.003
ENDO-AID™	£3,058.73	10.939	14.050	-£105.66	0.007	0.008	Dominant	0.011
EndoScreener®	£3,073.81	10.938	14.049	-£90.58	0.006	0.007	Dominant	0.009
GI Genius™	£3,116.16	10.934	14.045	-£48.23	0.003	0.003	Dominant	0.004
MAGENTIQ-COLO™	£3,069.97	10.938	14.049	-£94.41	0.007	0.007	Dominant	0.010

Footnote: * Undiscounted total and incremental LYG is presented to aid interpretability; all other results are discounted at a rate of 3.5% per year.

Abbreviations: AI, artificial intelligence; EMIS™, Endoscopic Multimedia Information System; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year;

All interventions gave results with incremental costs and QALYs relatively close to zero (i.e., close to the origin of the cost-effectiveness plane); when considering probabilistic results, all interventions lead to a difference in cost of less than £110 compared to colonoscopy without AI, and a difference in incremental QALYs of less than 0.007 compared to colonoscopy without AI (i.e., a difference of around 2.5 days of perfect health). The EAG notes that the difference in QALYs is generally unlikely to be considered to be clinically meaningful.

All interventions were dominant (i.e. increased QALYs and cost savings compared to the comparator) with the exception of Discovery™, which had both increased QALYs and costs compared to the comparator. However, the EAG considers that since the incremental costs and QALYs are uniformly very close to zero, caution should be used in interpreting these results.

The probabilistic and deterministic results were consistently closely aligned; notably, the calculated ICER for Discovery™ is considerably larger in the probabilistic analysis than the deterministic analysis; this is due to the fact that the incremental QALYs for this intervention are extremely small, so a relatively small change in incremental cost has a major impact on the ICER.

The CEACs generally show that the probability of being cost-effective for either colonoscopy without AI or the intervention quickly converges close to 50% as the willingness-to-pay threshold increases.

For all interventions, the expected number of colonoscopies prior to diagnosis, including disaggregated results for diagnostic and therapeutic colonoscopies, and polypectomies for patients with no underlying pathology, was also considered. Probabilistic results are presented in Table 41. The change in waiting time due to the change in number of colonoscopies was also assessed, although this should be considered as an exploratory analysis, due to the limitations of the analysis conducted; further details are given in Section 4.2.1.11.

Table 41. Probabilistic results: change in number of procedures

	Absolute number of index colonoscopies				Incremental number of index colonoscopies vs colonoscopy without AI				*Change in waiting time (weeks)†*
Technology	**Total***	**Diagnostic**	**Therapeutic**	**Polypectomies with no underlying pathology**	**Total***	**Diagnostic colonoscopies**	**Therapeutic colonoscopies**	**Polypectomies with no underlying pathology**	
Colonoscopy without AI	1.109	0.650	0.447	0.090					
Argus®	1.090	0.650	0.427	0.090	-0.020	0.000	-0.020	0.000	*-0.052*
CAD EYE®	1.077	0.632	0.434	0.108	-0.032	-0.018	-0.013	0.019	*-0.084*
Discovery™	1.106	0.650	0.444	0.090	-0.003	0.000	-0.003	0.000	*-0.009*
EMIS™	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
ENDO-AID™	1.059	0.605	0.442	0.135	-0.051	-0.045	-0.005	0.045	*-0.133*
EndoScreener®	1.066	0.650	0.404	0.090	-0.044	0.000	-0.043	0.000	*-0.115*
GI Genius™	1.064	0.643	0.410	0.098	-0.045	-0.008	-0.037	0.008	*-0.118*
MAGENTIQ-COLO™	1.064	0.650	0.402	0.090	-0.046	0.000	-0.045	0.000	*-0.119*

Footnote: *The total number of colonoscopies includes failed colonoscopies.

†This analysis should be considered to be exploratory.

Abbreviations: AI, artificial intelligence; EMIS™, Endoscopic Multimedia Information System.

The average number of colonoscopies required to reach a diagnosis, including failed colonoscopies, was between 1 and 1.2 for colonoscopy without AI and all interventions, with the total number of required colonoscopies lower for all interventions than colonoscopy without AI. However, the decrease in the expected number of colonoscopies accompanying the introduction of AI technologies was very small (≤ 0.051 decrease for all interventions). This change was driven for all interventions by an overall small decrease in therapeutic colonoscopies. Interventions showed no change in the number of diagnostic colonoscopies or polypectomies for patients with no underlying pathologies, with the exception of CAD EYE®, ENDO-AID™ and GI Genius™, which show a very small decrease in diagnostic colonoscopies and an increase in unnecessary polypectomies. This is due to the fact that these interventions were modelled to have an increase in detection of polyps for patients with no underlying pathologies, who would be wrongly given a therapeutic rather than diagnostic colonoscopy (see Section 4.2.1.6.1 for further details); relevant data were not available for other interventions, so in the base case it was assumed that the polyp detection rate in this patient group would be equal to that of colonoscopy without AI.

The exploratory waiting time analysis suggests that the potential reduction in the number of colonoscopies prior to diagnosis would lead to a negligible reduction in waiting time; for all interventions, the reduction would be less than 0.2 weeks, which is unlikely to have a material impact on service provision.

4.2.2.2 Sensitivity analyses

A deterministic sensitivity analysis was conducted for all interventions to determine the sensitivity of results to individual parameter values. Tornado plots for the NHB, incremental costs and QALYs for each intervention are given in Appendix 9.12.1; the EAG considers NHB to be more informative than tornado plots for the ICER, due to spread of results between the quadrants of the cost-effectiveness plane.

For all interventions except Discovery™ and GI Genius™, the parameters which had the greatest impact on incremental NHB were the long-term QALY payoffs for patients with LRA, with and without delayed diagnosis, and the long-term QALY payoffs for patients with AA. For each of these parameters, changing the value to the endpoints of the 95% CI changed the sign of the incremental NHB (i.e., for one result, the intervention gave a net positive health benefit over colonoscopy without AI, while for the other, the intervention led to a net negative health benefit).

For Discovery™, similar results were seen, albeit diagnostic accuracy RR for colonoscopy with AI in patients with AA had a greater impact on incremental NHB than long-term QALY payoffs for AA. For GI Genius, apart from the long-term QALY payoffs for LRA, all inputs had a relatively small impact on incremental NHB.

The long-term QALY payoffs for LRA and AA were likely the most influential on overall results as the benefits of CADe technologies are concentrated in the avoidance of long-term negative outcomes due to delayed diagnosis of underlying conditions specifically related to polyp detection (i.e., not detecting IBD or CRC). Since the incremental QALYs were very small, changes to the long-term QALY payoffs had a relatively large impact on the incremental QALYs, and hence to the overall ICER and NHB. The same impact was not seen for the long-term QALY payoff for AA for GI Genius™, since the mean ADR RR for AA for this technology is precisely 1. Similarly, the diagnostic accuracy RR for colonoscopy for AI in patients with AA was likely particularly influential on results for Discovery™ as the mean value is very close to 1, but with a much wider CIs than the same parameter for GI Genius™.

4.2.2.3 Subgroup analyses

Subgroup analyses were conducted for the following patient populations, for interventions with sufficient data:

- Patients referred for screening;
- Patients referred due to presence of symptoms;
- Patients referred for any surveillance;
- Patients referred for Lynch syndrome surveillance.

A summary of results of probabilistic analyses are presented in Table 42 below.

Table 42. Subgroup analyses: cost-effectiveness results vs colonoscopy without AI

Subgroup	Technology	Incremental costs (£)	Incremental QALYs	Incremental LYG*	ICER (£/QALY)	Incremental NHB
Full population	CAD EYE®	[redacted]	[redacted]	[redacted]	Dominant	0.007
	Discovery™	£8.70	0.001	0.000	£8,669.76	0.001
	ENDO-AID™	-£73.23	0.004	0.007	Dominant	0.007
	EndoScreener®	-£89.10	0.006	0.007	Dominant	0.009
	GI Genius™	-£45.16	0.002	0.004	Dominant	0.003
	MAGENTIQ-COLO™	-£90.26	0.006	0.007	Dominant	0.009
Screening	CAD EYE®	[redacted]	[redacted]	[redacted]	Dominant	0.001
	ENDO-AID™	-£15.26	0.001	0.000	Dominant	0.002
	EndoScreener®	-£20.14	0.001	0.000	Dominant	0.002
	GI Genius™	-£32.55	0.001	0.001	Dominant	0.002
Symptomatic/ diagnostic	CAD EYE®	[redacted]	[redacted]	[redacted]	£11,434.93	0.001
	Discovery™	-£20.78	0.002	0.000	Dominant	0.002
	ENDO-AID™	-£29.69	0.001	0.001	Dominant	0.002
	EndoScreener®	-£40.42	0.000	0.001	Dominant	0.002
	GI Genius™	-£34.43	0.001	0.001	Dominant	0.002
Lynch syndrome surveillance	CAD EYE®	[redacted]	[redacted]	[redacted]	Dominant	0.096
	GI Genius™	£915.07	-0.068	-0.064	Dominated	-0.098
Surveillance	CAD EYE®	[redacted]	[redacted]	[redacted]	Dominant	0.060
	Discovery™	£132.78	-0.004	0.007	Dominated	-0.009
	ENDO-AID™	-£947.48	0.078	0.094	Dominant	0.110

	GI Genius™	-£365.23	0.040	0.049	Dominant	0.052
	MAGENTIQ-COLO™	-£767.66	0.071	0.084	Dominant	0.097

Footnote: * Undiscounted incremental LYG is presented to aid interpretability; all other results are discounted at a rate of 3.5% per year.

Abbreviations: ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year.

For all interventions compared to colonoscopy without AI, the results were very consistent across the subgroups; the interventions were dominant in all subgroups, with the exception of CAD EYE in the symptomatic/diagnostic subgroup (which had a positive ICER), GI Genius™ in the majority Lynch syndrome surveillance subgroup (which was dominated by colonoscopy without AI), and Discovery™ in the majority surveillance subgroup (also dominated by colonoscopy without AI). The incremental NHB was generally slightly lower in the screening and symptomatic/diagnostic subgroups than in the full population, and slightly higher in the surveillance subgroup (with the exception of Discovery™). This suggests that the cost-effectiveness benefits of the AI technologies may be realised more in patients undergoing surveillance than in other patient populations. This is likely due to the fact that the reduction in total long-term QALYs due to delayed diagnosis is greater for all true disease states in the surveillance population, compared to the rest of the patient population (see Table 32).

For the two technologies with data available for the Lynch syndrome subgroup, CAD EYE® and GI Genius™, different results were observed; for CAD EYE®, incremental QALYs were increased and incremental costs reduced in the Lynch syndrome subgroup compared to the overall patient population, leading to an improved incremental NHB, whereas the opposite was seen for GI Genius™. This reflects the difference in ADR RR between populations for these technologies; the ADR RR is substantially higher for CAD EYE® in the Lynch syndrome subgroup compared to the overall patient population (both LRA and AA), while the reverse is seen for GI Genius™. In particular, GI Genius™ is dominated in the Lynch syndrome subgroup as the observed ADR RR is less than 1.

However, since the incremental costs and QALYs are very small in magnitude across all subgroups and interventions, limited conclusions can be drawn from these analyses.

4.2.2.4 Scenario analyses

The sensitivity of model results to key assumptions was explored in scenario analyses. A summary of the scenario analyses conducted is given in Section 4.2.1.15. A summary of incremental NHB results is for each of these scenarios is given in Table 43. As an alternative, a table of ICERs are presented in Appendix 9.12.3.

Table 43. Scenario analysis results

Scenario	Incremental NHB vs colonoscopy without AI							
	Argus®	CAD EYE®	Discovery™	EMIS™	ENDO-AID™	EndoScreener®	GI Genius™	MAGENTIQ-COLO™
Base case	0.005	0.007	0.001	0.002	0.006	0.009	0.003	0.009
1a. Diagnose-and-leave polyp management strategy	0.003	0.004	0.000	*0.001*	0.007	0.005	0.002	0.006
1b. Diagnose-and-leave (high-confidence) polyp management strategy	0.004	0.005	0.001	*0.002*	0.005	0.007	0.003	-0.007
2. Resect-and-discard polyp management strategy	0.000	0.004	-0.002	*0.002**	0.008	0.011	0.005	0.010
*3a. Diagnose-and-leave polyp management strategy with CADx**	*N/A*	*0.016*	*N/A*	*N/A*	*N/A*	*N/A*	*-0.001*	*N/A*
*3b. Diagnose-and-leave (high-confidence) polyp management strategy with CADx**	*N/A*	*-0.003*	*N/A*	*N/A*	*N/A*	*N/A*	*-0.0015*	*N/A*
*4. Resect-and-discard polyp management strategy with CADx**	*N/A*	*0.004*	*N/A*	*N/A*	*N/A*	N/A	*0.005*	*N/A*
5. Alternative values for sensitivity of detection for colonoscopy without AI	0.007	0.004	0.002	0.004	0.009	0.015	0.003	0.016
6. CADe sensitivity of interventions calculated using AMR	N/A	0.000	N/A	N/A	N/A	0.005	0.006	-0.006
7. CADe sensitivity of interventions calculated using APC	0.015	0.001	0.014	N/A	0.014	0.015	0.014	0.007

8a. Alternative rate of CRC detection: 100% for all technologies	0.005	0.006	0.001	0.002	0.006	0.008	0.003	0.009
8b. Alternative rate of CRC detection: 90% for all technologies	0.005	0.008	0.001	0.002	0.006	0.008	0.003	0.009
8c. Alternative rate of CRC detection: informed by ADR RR	0.006	0.007	0.000	0.003	0.006	0.010	0.003	0.011
9a. Alternative rate of IBD detection: 100% for all technologies	0.005	0.007	0.001	0.003	0.006	0.008	0.003	0.009
9b. Alternative rate of IBD detection: 80% for all technologies	0.005	0.007	0.001	0.003	0.006	0.008	0.003	0.009
10. Alternative values for sensitivity of detection for AA for missing values	0.002	N/A	0.000	0.001	N/A	0.003	N/A	0.003
11. Alternative approach to parametrising unnecessary polyp removal for missing values	0.005	N/A	0.001	0.002	0.006	0.008	N/A	0.009
12. Alternative costing for failed initial colonoscopies: 0% of diagnostic colonoscopy cost	0.005	0.007	0.001	0.003	0.006	0.008	0.003	0.009
13a. Alternative proportion of patients receiving secondary therapeutic colonoscopies: 0%	0.005	0.007	0.001	0.003	0.006	0.008	0.003	0.009
13b. Alternative proportion of patients receiving secondary therapeutic colonoscopies: 50%	0.005	0.006	0.001	0.002	0.006	0.009	0.004	0.010
13c. Alternative proportion of patients receiving secondary	0.005	0.006	0.001	0.002	0.005	0.008	0.003	0.009

therapeutic colonoscopies: informed by ADR RR								
14a. Alternative expected lifetime of AI technologies: three years	0.005	0.007	0.001	N/A	0.006	N/A	N/A	N/A
14b. Alternative expected lifetime of AI technologies: five years	0.005	0.007	0.001	N/A	0.006	N/A	N/A	N/A
14c. Alternative expected lifetime of AI technologies: 10 years	0.005	0.007	0.000	N/A	0.006	N/A	N/A	N/A
15. AE costs removed for patients who die	0.006	0.007	0.001	0.003	0.007	0.009	0.003	0.009

Footnote: *These analyses should be considered to be exploratory

Abbreviations: ADR, adenoma detection rate; AE, adverse event; AI, artificial intelligence; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; EMIS™, Endoscopic Multimedia Information System; IBD, inflammatory bowel disease; N/A, not applicable; NHB, net health benefit.

The scenarios which had the greatest impact on results are the diagnose-and-leave polyp management strategy scenarios (scenarios 1 and 3). For these scenarios, the incremental NHB was generally considerably lower than the base case across all interventions, giving a negative incremental NHB. In all cases, the result was located in the south-west quadrant of the cost-effectiveness plane (i.e. reduced cost and reduced QALYs). This is due to the fact that the sensitivity of detection of polyps was higher for CADe technologies; therefore, the proportion of patients with detected but misdiagnosed polyps was higher. The incremental NHB was slightly higher when only high-confidence diagnoses were considered, as the sensitivity was slightly higher for high-confidence diagnoses than for diagnoses of any confidence level. The same effects were seen independent of whether or not CADx was used, although the addition of CADx generally led to a lower NHB overall. This was due to the fact that sensitivity was generally lower for CADx compared to endoscopist opinion alone, leading to more delays in treatment and hence fewer long-term QALYs for patients overall.

Other scenarios had limited effects on results across interventions; the resulting incremental NHB was consistently numerically close to the base case results (i.e. with very small positive incremental NHB), with some of the differences likely arising from random noise in the generation of the probabilistic results. The EAG notes that in some cases, especially for the Discovery technology, scenarios gave rise to results in a different quadrant of the cost-effectiveness plane compared to the base case; this is purely due to the extreme proximity of the incremental QALYs to zero in the base case for this intervention, resulting in a high level of instability. Overall, this suggests that the assumptions interrogated in each scenario has a relatively small impact on overall results.

It is notable that all scenarios and interventions gave rise to incremental NHB values very close to zero. Excluding the diagnose-and-leave polyp management scenarios, the incremental NHB for all interventions and scenarios lay between -0.002 and 0.015. Similarly to the base case results, in light of the high level of uncertainty and very small incremental costs and QALYs (which may not be clinically significant), the EAG advises caution in interpreting the results of the scenario analyses presented.

4.2.3 Discussion

4.2.3.1 Summary of key results

The EAG conducted an SLR of existing economic evaluations of AI technologies to aid polyp detection or characterisation in colonoscopy. Nine relevant studies were identified, the majority of which were cost-utility analyses of colonoscopy coupled with CADe technologies, compared to colonoscopy without CADe. The EAG did not consider that any existing modelling techniques were appropriate for use in the current project, due to methodological concerns, and lack of relevance to the context of this project.

The EAG therefore developed a *de novo* cost-utility model to inform the economic assessment. The model considered cost-effectiveness outcomes for eight AI technologies (Argus®, CAD EYE®, Discovery™, EMIS™, ENDO-AID™, EndoScreener®, GI Genius™, and MAGENTIQ-COLO™) in combination with colonoscopy, compared to colonoscopy without AI, in patients eligible and appropriate for colonoscopy. The EAG notes that not all AI technologies in the NICE final scope could be included in the economic analysis due to lack of availability of either relevant clinical data or pricing information. The interventions and comparator were considered coupled with a polyp management strategy; in the base case, a resect-all strategy was assumed, while alternatives (diagnose-and-leave, and resect-and-discard) were considered in scenario analyses. The economic analysis primarily considered the CADe functionalities of the interventions, although the impacts of CADx were also investigated in exploratory analyses for the two interventions with available CADx accuracy data (CAD EYE® and GI Genius™).

The results from the economic analysis suggest that, assuming a resect-all polyp management strategy, most AI technologies may contribute to a very slight increase in QALYs and decrease in costs over patients' lifetimes (i.e., colonoscopy with AI technologies dominate colonoscopy without AI); the exception was the Discovery™ technology, which contributed to a slight increase in QALYs and negligible increase in costs. These results are unsurprising in the light of the results of the analysis of clinical effectiveness, which generally suggest that AI technologies may result in a small but often not statistically significant increase in rates of adenoma detection.

However, the EAG notes that there is a very high level of uncertainty in these results, especially given the proximity of the incremental results to zero. There is a considerable amount of uncertainty

in the model inputs derived from the clinical effectiveness analyses, due to potential risk of bias of the studies informing the inputs, heterogeneity of results across different studies, and in many cases, non-statistically significant results. Furthermore, although the scenario analyses show that the results are relatively unaffected by key input assumptions, as demonstrated by the deterministic sensitivity analysis, the results were very sensitive to a small group of model inputs, namely, the long-term QALY outcomes for patients with underlying LRA and AA. The EAG also notes that the incremental QALYs were consistently extremely small across interventions (≤0.007 for all interventions, equivalent to just around 2.5 days in perfect health); these QALY gains are unlikely to constitute a meaningful improvement in patient outcomes. Therefore, the EAG urges caution in the interpretation of these results.

Subgroup analyses were also performed for the screening, symptomatic, surveillance and Lynch syndrome populations. Very similar results were seen for each subgroup compared to the mixed patient population in the base case, although the incremental NHB was generally slightly lower in the screening and symptomatic subgroups than in the surveillance subgroup, potentially suggesting that the benefits of AI technologies may be slightly more fully realised in the surveillance subgroup than in other populations. However, since the incremental QALYs and costs remain very close to zero across all subgroups, these results should also be interpreted with caution.

When considering alternative polyp management strategies, the relevant scenarios suggest that the resect-and-discard polyp management strategy has a negligible impact on results compared to the base case. This is the case across all interventions, both with and without CADx functionalities. This suggests that any conclusions drawn from the base case economic analysis are likely to remain applicable as the resect-and-discard approach is increasingly adopted in the BCSP. The results for diagnose-and-leave without CADx also remain broadly similar to the base case; however, when CADx was included, both technologies analysed (CAD EYE® and GI Genius™) were dominated by colonoscopy without AI (i.e., higher costs and lower incremental QALYs) in the scenario with diagnoses of high confidence only, and GI Genius™ was dominated in the scenario with diagnoses of any confidence level. This is because the input sensitivity of the CADx functionalities was lower than the sensitivity for colonoscopy without AI in these scenarios. However, the EAG would like to reiterate that the scenarios including CADx are exploratory, and the results should be interpreted with caution.

Finally, the model suggests that the introduction of AI technologies would likely lead to a slight decrease in the overall number of colonoscopies per patient required to establish a correct diagnosis, although there may also be a slight increase in the number of unnecessary polypectomies, due to the potential identification of additional non-hyperplastic polyps compared to colonoscopy without AI. There may also be a very slight decrease in waiting time for colonoscopies. However, the EAG considers that the changes in both the number of procedures and the waiting times are both too small to correspond to any meaningful changes in patient experience or care provision.

4.2.3.2 Generalisability of results to clinical practice in England

In general, the EAG considers that the economic analysis is broadly generalisable to clinical practice in England. The model structure has been designed to reflect current clinical practice, while also accommodating practices which are in flux (e.g., the use of alternative polyp management strategies). The model inputs have also been sourced with an NHS and PSS context in England in mind, and well-validated international sources have been used where UK-specific values were not available. However, there are some potential limitations around the generalisability around the inputs sourced from the clinical effectiveness analyses. In particular, the EAG notes that some populations and methodologies in the clinical trials informing model inputs may not be entirely reflective of UK clinical practice (see Section 3.3.2 for more details). More broadly, the economic analysis does not take into account the extent to which the training data used in the development of individual technologies may be relevant to a UK population.

The EAG also notes that the relevance of the economic analyses conducted may change over time, both due to potential future updates in technology, and with changing views on best practice (for example, the ongoing introduction of the resect-and-discard polyp management strategy in the BCSP context). With regard to the former consideration, the EAG considers that it is unlikely that future versions of AI technologies will perform substantially worse than the baselines established in the clinical analysis, but this does not necessarily suggest that cost-effectiveness outcomes will uniformly improve with each update; for example, a technology update which gives an improved overall ADR may still result in a higher detection rate of non-hyperplastic polyps, which could in turn lead to more unnecessary polypectomies and an accompanying higher risk of complications. With regard to changing best practice in the UK, the EAG has mitigated this concern as far as possible through exploring scenario analyses for different polyp management strategies. The similarity of model

results for the resect-all and resect-and-discard strategies suggests that the ongoing introduction of the latter strategy is unlikely to have a major impact on the conclusions drawn in the economic analyses. Overall, the EAG recommends that a cautious approach should be taken in extrapolating the results of the economic analyses presented here both to future AI technology versions, and to circumstances in which clinical practice is different to the approach assumed in this project.

4.2.3.3 Strengths and limitations of analysis

4.2.3.3.1 Strengths of analysis

The EAG's economic analysis addresses several limitations of existing economic analyses of AI technologies for the detection and characterisation of polyps, in particular, the inclusion of multiple AI technologies as independent interventions rather than the consideration of a single non-specific AI technology. The analysis also incorporated novel aspects, including explicit modelling of polyp management strategies, and embedding the impact of CADx functionalities alongside CADe functionalities, which were not included in any of the studies identified in the SLR.

Another key strength of the EAG's economic analysis is the extensive use of clinical inputs informed by the comprehensive analyses presented in the assessment of clinical effectiveness. Where data have not been available to parametrise the model, the EAG has used assumptions which have relatively minor impacts on overall results, as demonstrated by scenario analyses.

Finally, the modelling approach used in the economic analysis is generally consistent with the approach used in previous NICE appraisals for related diagnostic technologies, including DG56 and DG10083, resulting in an interlinked approach to considering diagnostic technologies for CRC.[33, 159] In particular, the results for these economic analyses were comparable to relevant results reported in DG10083 (further details are given in Appendix 9.11).[159] The use of the decision tree structure in all three appraisals also allows the model to incorporate long-term outcomes from the MiMiC-Bowel model, which captures the complexity of different patient pathways in CRC and related conditions, and has been extensively validated, in a manner which would be beyond the scope of the current project.

4.2.3.3.2 Limitations of analysis

A key limitation of the economic analysis was the variable availability and quality of data available to inform model inputs. In particular, not all AI technologies included in the NICE final scope could be

included, due to the lack of either data to inform diagnostic accuracy, or relevant pricing information. The EAG also notes that the model is extremely dependent on proxy outcomes; in particular, no "end-to-end" studies were identified in the SLR of clinical effectiveness data (i.e., long-term outcomes for patients undergoing colonoscopy with AI have not been reported in any of the studies), so long-term outcomes have been assumed to be directly linked to detection and diagnostic accuracy of the index colonoscopy. Furthermore, for the accuracy of detection, the model uses ADR RR as a proxy for the increased rate of adenoma detection for AI technologies, but this is not a direct one-to-one correspondence. The per-patient AMR RR would potentially correspond more directly to the accuracy of detection, but as this was only available for one intervention, the EAG considered that it was more pragmatic to use the ADR RR (which is much more consistently reported) in the model base case. This assumption was examined in scenario analyses, using the per-person AMR for EndoScreener®, and per-lesion AMR for CAD EYE®, GI Genius™ and MAGENTIQ-COLO™; results suggested that the assumption had a minimal impact on outcomes, but given the general lack of AMR data available at present, the potential for bias due to using ADR as a proxy outcome cannot be ruled out.

More broadly, the model relies on several key assumptions and simplifications which could not be avoided, either due to limitations of the model structure, or lack of data. Where possible, these assumptions were explored in scenario analyses, which suggested a minimal impact on results, but some assumptions could not be explored, due to lack of available data. In particular, the assumption that the effectiveness of technologies is independent of the use of non-AI adjunct technologies could not be interrogated, due to a lack of reporting or heterogeneity in the studies informing effectiveness inputs in the model. The other key assumption which could not be varied in the model was the assumption that after diagnosis, the costs and outcomes of subsequent colonoscopies would be aligned with colonoscopy without AI. This assumption may result in a slight underestimation of the potential benefits of AI technologies over a patient's lifetime, but would also be expected to result in underestimation of costs. Therefore, the overall impact of this assumption on the ICER or incremental NHB is uncertain.

Another key weakness of the economic analysis is in the quantification of uncertainty. In particular, for the outcomes sourced from the MiMiC-Bowel model, which include the inputs which have the greatest impact on results (i.e. long-term QALY payoffs for patients with AA and LRA), only point value estimates are available. This is due to the fact that the MiMiC-Bowel model does not output

measures of uncertainty. An alternative approach would have been to rerun the MiMiC-Bowel model with varied input values, and noting the variation in results; however, this would have necessitated a large number of additional analyses which would be beyond the scope of the current project, especially since the MiMiC-Bowel model has not been made publicly available. The EAG has attempted to mitigate this area of uncertainty by assuming that all long-term payoff inputs are gamma distributed, with a standard error equal to 10% of the mean. A similar approach has been used in DG56 and DG10083.[33, 159]

Finally, the EAG notes that many of the key potential benefits and flaws of AI technologies cannot be captured directly in economic analyses. For example, on the one hand, AI technologies may increase the confidence of both patients and endoscopists in the result of a colonoscopy, but use of AI technologies could also potentially lead to overreliance on these technologies, and some patients may be more hesitant to undergo a colonoscopy if they knew an AI technology was being used. Even if data were available to parametrise these effects in the model, it is unlikely that they would have a tangible effect on cost and QALY outcomes. Therefore, these benefits and flaws should be considered qualitatively, alongside the results of the economic assessment, in determining the overall appropriateness of use of AI technologies.

5 Assessment of factors relevant to the NHS and other parties

In terms of implementation, specifications for peripherals to be used alongside the technology, including endoscopes, light source, monitors and other peripherals may differ between technologies based on the instruction manuals. Consideration of this within each centre may be useful to ensure compatibility would not be a problem, depending on equipment already available in the centre.

One of the External Assessment Group (EAG)'s clinical experts mentioned cost as being the major implementation factor to consider. This related to the need to purchase these new technologies and they noted that once purchased, endoscopists would likely want to use the technology as much as possible, rather than just for those with specific colonoscopy indications. The EAG considers this point may be useful to consider alongside the results of colonoscopy indication subgroup analyses in this assessment, for which the EAG considers the evidence to be insufficient to conclude that differences exist across different colonoscopy indications. Given that all technologies (with the exception of Endoscopic Multimedia Information System [EMIS™]) can be obtained on a costing framework independent of the number of procedures performed, as described in Section 4.2.1.10.2, it may not be a sensible use of resources to restrict its use unless there are major concerns that the technology will worsen outcomes such as adenoma detection rate (ADR) compared to standard colonoscopy for that population, or if issues with using it in specific populations become apparent. For example, one of the EAG's clinical experts mentioned that false positives might be increased in someone with inflammatory bowel disease (IBD), which might make the technology too distracting for the endoscopist performing the procedure, in which case the endoscopist might choose not to use the technology. A similar consideration may also be worthwhile when deciding whether only endoscopists with a certain level of experience or expertise should use the technology.

While it considers evidence for computer-aided characterisation (CADx) to be limited currently, the EAG notes that if a potential recommendation for artificial intelligence (AI)-supported polyp characterisation is likely in the future even if not immediately, consideration of technologies that offer both computer-aided detection (CADe) and CADx functionalities would reduce the need for two separate technologies to be purchased and maintained. This is providing both functions of the specific technology were considered to be adequate in terms of clinical and cost-effectiveness.

In terms of the potential for the CADx functionality to reduce costs associated with resection and histopathological testing, this depends on whether alternative polyp management strategies are incorporated into UK clinical practice; while a resect-and-discard strategy is being rolled out within the NHS BCSP, this is only for colonoscopies performed within the NHS Bowel Cancer Screening Programme (BCSP) and only for diminutive (≤5 mm) polyps where an accredited endoscopist has been able to make a high-confidence optical diagnosis (see Sections 2.1.5 and 4.2.1.4.1). Furthermore, any impact of AI technologies on downstream costs when incorporating these alternative polyp management strategies and resources may depend on how confident endoscopists are in using information provided by AI in addition to their own judgement to make decisions about resection and histological testing. The EAG considers that confidence in the use of the technologies is likely to be individual-dependent and might vary depending on endoscopist experience or expertise.

6 Discussion

6.1 Statement of principle findings

This assessment of diagnostic technologies aimed to evaluate the clinical and cost-effectiveness of 11 artificial intelligence (AI) technologies used to support colonoscopy (outlined in Section 2.1.1), with the technologies aiming to provide support for polyp detection (CADe) only or having CADe and polyp characterisation (CADx) functionalities ([redacted]). In February 2025, the number of technologies covered reduced to 10 interventions given WISE VISION® is no longer available within the NHS. A comparison to standard colonoscopy without these AI technologies was made and any colonoscopy population was relevant for inclusion.

A wide range of outcomes from the National Institute for Health and Care Excellence (NICE) final scope are covered in this assessment; however, the External Assessment Group (EAG) considers adenoma detection rate (ADR) to be the key outcome for assessing the impact of the technologies on polyp detection, given it is a key performance indicator for colonoscopies and has been linked to interval colorectal cancer (CRC) risk (a higher ADR may reduce interval CRC risk) and it is the most widely reported outcome across all included studies.[139]. As such, it is a key outcome used in the economic model. Meta-analyses in this assessment indicate that an increased ADR is likely with AI technologies compared to standard colonoscopy, although differences for Argus®, Discovery™ [redacted] were not statistically significant. For GI Genius™, results from the UK-based non-randomised NAIAD trial performed at multiple NHS centres [redacted].[60] Similar conclusions were made when considering adenomas per colonoscopy (APC) and data for adenoma miss rate (AMR) reported by a handful of tandem studies also suggests higher detection of adenomas with AI-supported colonoscopy.

Conclusions made surrounding other detection-based outcomes are more limited; however, the EAG considers there to be some evidence (either in the main report or Diagnostic Assessment Report [DAR] supplement) that the technologies in general may increase the detection of adenomas regardless of advanced or non-advanced classification, size and location, as well as sessile serrated lesions (SSLs) and non-neoplastic/hyperplastic polyps. While effect size may differ for certain

analyses across some of these categories (for example, some results suggest a trend towards larger ADR increases for non-advanced compared to advanced adenomas, or for smaller adenomas compared to larger ones), the EAG does not consider there to be a consistent pattern and does not consider there to be strong evidence of differential impacts across categories particularly when limitations are considered, such as smaller numbers of events for advanced adenomas and large adenomas.

While diagnostic accuracy data for the characterisation functions of four technologies were identified, the EAG considers this to be limited and is unable to draw firm conclusions based on these data. Results are mixed, with some suggesting higher sensitivity with AI vs endoscopist optical diagnosis alone, others suggesting the opposite or no notable difference, and some not reporting a comparison to endoscopist judgement alone. Results from studies using technologies as an adjunct to endoscopist experience, rather than autonomously, have been implemented in the economic model where possible to assess the potential benefit of this functionality (see Section 4.2.1.6.2), but the EAG highlights limitations that apply to most studies, including the technologies being used autonomously without endoscopist input, SSLs being excluded or treated as non-neoplastic and/or the exclusion of low-confidence diagnoses. Of note, two recent meta-analyses of CADx use specifically for diminutive rectosigmoid polyps have concluded that there are no incremental benefits or harms associated with CADx-assisted colonoscopy compared to colonoscopy without CADx specifically in the context of resect-and-discard or leave *in situ* strategies.[141, 144]

Data on duration of procedures suggest a limited impact on withdrawal and total procedure time, with trends for slight increases with AI-supported colonoscopy but generally only around one or two minutes per colonoscopy. No concerns about adverse events with these technologies are noted, and issues with the functioning of the technologies and false positives do not appear to be a large issue; however, it is unclear how robustly these outcomes were assessed in these studies.

While subgroup analyses for colonoscopy indication and endoscopist experience or expertise have been explored in this assessment, the EAG has not been able to make strong conclusions surrounding this. While some trends for higher ADRs with AI are noted in certain groups for some analyses (for example, symptomatic populations compared to screening or surveillance populations, or less experienced compared to more experienced endoscopists), these are not consistent across analyses and in some cases the opposite is suggested. Given difficulties in constructing subgroups

and inconsistencies noted across analyses (see Sections 3.2.2.1.12 and 3.2.2.1.13), the EAG does not consider there to be strong evidence of a differential effect in particular groups. Furthermore, data available for particular patient groups such as those with Lynch syndrome, inflammatory bowel disease (IBD), polyposis syndromes and prior CRC is more limited and it is unclear how well the results of this assessment would apply to these groups. Especially as there is limited information with regards to whether these populations have been covered in the data used to train the algorithms within the technologies. Other than issues with the coverage of certain populations, the EAG considers the included trials to be a reasonable reflection of UK clinical practice, with no major concerns about differences in standard colonoscopy procedures or demographics such as age and sex.

Patients and endoscopists appear to be willing to use these technologies but concerns surrounding the potential for overreliance on AI or replacement of the clinician, impact on costs and downstream workload, and relevance to populations such as those with IBD and polyposis syndromes need to be addressed.

Although not unexpected, the lack of data on long-term outcomes (such as mortality, morbidity other than adverse events and health-related quality of life [HRQoL]) and impact on waiting lists from included studies is a limitation of this assessment, and alternative methods of informing these have been required in the economic model.

An economic analysis was conducted for eight AI technologies for which sufficient clinical and cost data were available (Argus®, CAD EYE®, Discovery™, EMIS™, ENDO-AID™, EndoScreener®, GI Genius™, and MAGENTIQ-COLO™). The costs and benefits of these technologies were assessed in combination with colonoscopy, against a comparator of colonoscopy without AI, using a *de novo* economic model developed by the EAG.

The economic model demonstrates that, if the current resect-all polyp management strategy is used, the use of any of the AI technologies would be expected to result in a slight improvement in survival and HRQoL over an average patient's lifetime, coupled with a very small decrease in costs to the NHS (with the exception of the Discovery™ technology, which would be expected to result in a very small increase in costs). However, the EAG notes that the benefits of the AI technologies are extremely small in magnitude, with no technology leading to a reduction in costs of more than £100, or an

increase in quality-adjusted life years (QALYs) of more than 0.007, or around 2.5 days in perfect health. Similarly, the use of AI technologies may result in a very small reduction in the number of colonoscopies a patient must undergo before receiving a correct diagnosis of their underlying condition, but no technology shows a reduction of more than 0.051 colonoscopies prior to diagnosis for the average patient. This reduction is unlikely to have a meaningful impact on patient experience or service provision, and waiting times for colonoscopy procedures are unlikely to be substantially changed. The EAG also cautions that there is a very high level of uncertainty in these results, due in part to the potential bias and heterogeneity of the studies informing the model inputs.

Very similar results were observed for subgroup analyses, and for resect-and-discard and diagnose-and-leave polyp management strategies. Due to limitations in the available data, it is unclear to what extent these interpretations also apply when CADx functionalities are considered.

6.2 Strengths and limitations of the assessment

A strength of the EAG's clinical analyses is the combination of published data with additional, unpublished data provided by manufacturers as part of this submission. For example, data for CADDIE™ and EMIS™ provided by the manufacturer have been included, which would not have been possible if only published data were considered. The EAG's consideration of data from abstracts for interventions or populations that are not well covered by full text publications may also be considered a strength relative to other reviews in the area, as these commonly only included full text publications.[43, 150, 177, 178] Of note, the consideration of abstracts in this assessment allowed the inclusion of Argus® in the economic model, as clinical data were not available from full text publications at the time of the assessment. Searches were also rerun and the review updated towards the end of the project (in June 2025) to ensure the data included is as up to date as possible before consideration by committee.

Furthermore, it assesses the potential benefit of AI technologies separately against standard colonoscopy, rather than combining all technologies as a single intervention as has been done in many similar reviews including the recent Health Technology Wales (HTW) assessment;[43, 50, 150, 177, 178] the EAG considers this to be a strength given that they are all different technologies with different underlying algorithms, meaning it is plausible that effects could be different across the technologies. While the HTW assessment has captured the costs of the different technologies (using information on costs from the NHS Supply Chain 2024 and from manufacturers, combined with assumptions

about how often each system would be used), incremental cost-effectiveness ratios (ICERs) for each technology compared to standard colonoscopy are not available, with only a single ICER for CADe overall compared to standard colonoscopy.

It is also one of the first health technology assessments (HTAs) to include the CADx element in the review, with many others, including the HTW assessment,[42, 43] only including the CADe functionality. While one Spanish HTA did appear to include the CADx functionality, it is unclear whether any recommendations were made as a result.[55] Furthermore, this assessment prioritises inclusion of CADx studies that are based on real-time colonoscopy data, whereas many other reviews covering CADx include data based on retrospective application of the technologies to recorded videos or photos,[179-181] which the EAG does not consider to be an accurate representation of how the technology will be used in clinical practice. This economic analysis conducted as part of this assessment was also one of the first economic analyses to include CADx functionalities. Furthermore, to the EAG's knowledge, this is the first economic analysis to explicitly consider the impact of using a diagnose-and-leave or resect-and-discard polyp management strategy, which may be a key change to current clinical practice which could be supported by use of CADx technologies. While the EAG does not make any strong conclusions based on CADx data included, it has allowed identification of limitations of currently available evidence that may benefit from being addressed in future studies.

Finally, another key benefit of the economic analysis is the consistency with the approach used in NICE assessments of related diagnostic technologies, including the assessments for quantitative faecal immunochemical testing (DG56) and for the PillCam COLON2 colon capsule endoscopy technology (DG10083). [33, 159]

While not required for the purpose of this assessment, the EAG considers a limitation of the clinical assessment may be the lack of comparisons between individual AI technologies, for example through indirect treatment comparisons. From the perspective of the economic model, a key limitation is the inability to capture some key potential benefits or disadvantages of AI technologies within a standard economic modelling framework (e.g., improved patient confidence as a potential benefit, or endoscopist overreliance on AI technologies as a disadvantage).

6.3 Uncertainties

A key uncertainty in this review is the inability to include CADDIE™ and ENDOANGEL® in the economic model. For both, this is related to no information on costs being available. This means the cost-effectiveness of these technologies cannot be assessed. There are also some concerns about the ADR data used for EMIS™ given [redacted], the technology, as used in this trial, did [redacted] making it different to the other technologies included in this review and data for only one of three sites included in the full trial were provided to the EAG at this stage. However, the data have been used given no other data are currently available for this technology and it was included in the NICE final scope as a relevant technology.[25]

Data currently available for the application of CADx technologies as an adjunct to endoscopist judgement in real-time colonoscopy studies is considered to be limited, as outlined in this assessment. While some adjunct data are available, some outcomes were only reported by studies using the technology autonomously, which is not reflective of how the technology would be used in clinical practice. Furthermore, additional limitations of identified evidence include the fact that studies often do not provide a comparison against endoscopist optical diagnosis alone, only include high confidence diagnoses in the analysis and do not address SSLs in a way that would be useful in clinical practice. As a result, analyses of CADx functionalities using the economic model are considered by the EAG to be exploratory.

As noted in Section 3.3.2, the EAG considers the nature of these technologies in terms of potential for updates may be an ongoing issue. While studies may use the most current version of the technology available at the time of the study, these may become outdated as technologies are developed and updated. While the EAG considers that older studies are still likely to be a useful representation of how the technologies are broadly likely to function, it cannot rule out larger impacts of updates that may occur and this is a factor that should be considered. The impacts of potential updates on cost-effectiveness results also cannot be estimated in advance; given the instability of current results, even a small change in effectiveness due to an update could result in a relatively large change in outcomes.

Section 3.3.2 describes the limited information available on the data used to train algorithms within the technologies. There is uncertainty with regards to the colonoscopy indications covered, particularly whether populations such as those with IBD, polyposis syndromes or other CRC risk factors are covered. This means there is uncertainty as to whether the technologies are likely to function well in these populations, which is compounded by the fact that these populations are only covered by one or two studies included in this assessment or not at all.

No data on long-term outcomes such as mortality, morbidity other than short-term adverse events or HRQoL were identified from studies included in the clinical review. This is a limitation as there is no direct evidence linking the use of AI-supported colonoscopy technologies to improvements in these outcomes, and reliance on the link between ADR and CRC risk is required in this assessment to capture impact on long-term outcomes.[139] This is a particularly notable limitation of the economic model, in which accuracy of a single index colonoscopy is effectively used as a proxy to estimate all long-term patient outcomes.

The EAG notes that the results of its subgroup analyses for colonoscopy indication and endoscopist experience and expertise are uncertain, and the EAG does not draw firm conclusions based on them. This is because while some trends were identified within individual analyses or studies, these were not consistent, in addition to limitations including variation in the way in which subgroups were divided across studies, lack of stratification at randomisation for many within-trial subgroup analyses and only one or two studies being available for certain subgroups. Furthermore, for endoscopist experience and expertise, it was rarely possible to separate this in the most clinically useful way; studies most commonly used the number of prior colonoscopies as a way of classifying experience, rather than separating based on a baseline ADR threshold of 40 to 45%, which may be more clinically useful based on feedback from specialist committee members. The EAG notes that the subgroup analyses in the economic evaluation gave very similar results to the mixed population base case.

Finally, a key element of uncertainty in the economic analyses is the underlying assumptions which could not be avoided without greatly increasing the complexity of the model. In particular, the model sourced long-term patient outcomes from the MiMiC-Bowel model, an existing microsimulation model developed for economic evaluation of screening strategies for CRC; this approach allowed the economic analysis to draw on an existing model which captures the complexity of possible patient pathways after an initial colonoscopy, and has been extensively

validated, in a manner which would be beyond the scope of the current project. However, the use of these long-term patient outcomes necessitated the introduction of several simplifications into the model, including the assumption that all subsequent colonoscopies after the initial diagnosis would be colonoscopies without AI. Since the MiMiC-Bowel model does not produce estimates of uncertainty, assumptions were also required to quantify the uncertainty in the economic analyses.

6.4 Other relevant factors

As noted in Section 3.3.3, in terms of the CADx functionality, most technologies are not currently able to recognise SSLs as potentially pre-cancerous polyps, with them being excluded or classified as non-adenomatous/non-neoplastic in most of the currently available analyses. While technically they would not be considered adenomatous polyps, they are still a clinically relevant polyp type that should not be dismissed. The EAG notes that technologies should be used as an adjunct to endoscopist judgement, which may mean that SSLs are still identified. However, the fact that SSLs will not be specifically characterised by the AI technologies adds complexity in terms of interpreting results of the technology; individuals performing colonoscopies will have to be aware of the limitations of technologies with regards to SSLs and similar lesions and ensure this is taken into account in the decision-making.

The EAG notes that the usefulness and potential impact on downstream resources of the polyp characterisation function of the relevant technologies in UK clinical practice may likely depend on whether or not alternative polyp resection strategies are adopted. Currently most polyps are resected, with all resected polyps being sent for histology, and any impact of CADx technologies may be dependent on whether this changes; while a resect-and-discard strategy is being rolled out for colonoscopies performed within the NHS Bowel Cancer Screening Programme (BCSP), this only applies to diminutive (≤5 mm) polyps where the accredited endoscopist has been able to make a high-confidence diagnosis, and will not be in place for colonoscopies performed outside of the NHS BCSP (see Section 1.1.5). The economic analysis suggests that switching to a resect-and-discard or diagnose-and-leave strategy is unlikely to have a major impact on costs or benefits of AI technologies.

While a large amount of training on how to use the technologies may not be required, based on limited information from the EAG's clinical experts and manufacturer submissions, concerns about the potential for overreliance on the AI technologies has been raised as part of this assessment. While it is clear from manufacturers that technologies should be used as an adjunct to endoscopist judgement, the EAG considers this may be difficult to ensure in clinical practice and may be something worth considering as part of any training as well as within the wording of any recommendations made as a result of this assessment. Additionally, ensuring patients are aware of the way in which AI would be used in this context may provide reassurance for those with any

concerns about its application. The EAG notes that these potential concerns cannot be quantified, and thus have not been captured in the assessment of cost-effectiveness, but should be considered qualitatively in determining the overall appropriateness of use of AI technologies.

7 Conclusions

7.1 Implications for service provision

For the implementation of artificial intelligence (AI) technologies, the External Assessment Group (EAG) notes that peripherals compatible with the technology, including endoscopes, light source, monitors and other peripherals may differ between technologies based on the instruction manuals. Each centre may need to consider this to ensure compatibility is not an issue for particular technologies, depending on equipment already available in the centre.

The EAG received feedback from its clinical experts that, once purchased, endoscopists would likely want to use the technology as much as possible and not limit use to particular colonoscopy indications. Considering this, and the fact that costs for use of AI technologies are generally charged at a flat upfront or subscription rate, rather than on a per-procedure basis, the EAG considers it may not be a sensible use of resources to restrict its use unless there are major concerns that the technology will worsen outcomes such as adenoma detection rate (ADR) compared to standard colonoscopy for that population, or if issues with using it in specific populations become apparent. A similar consideration may also be worthwhile when considering whether only endoscopists with a certain level of experience or expertise should use the technology.

Consideration as to whether AI to support characterisation is likely to be recommended in the future may be important. Even if not immediate, future adoption of computer-aided characterisation (CADx) during colonoscopy (if judged to be clinically useful to support endoscopist decision-making and cost-effective) would mean that AI technologies offering computer-aided detection (CADe) and CADx may be preferable (providing CADe and CADx functionalities of the specific technology are deemed to be clinically and cost-effective), and would require purchasing of two separate technologies (or replacement of the original technology) if a CADe-only technology was purchased in the first instance.

The potential impact of these AI technologies on downstream resources following colonoscopy, such as demand for histology, is uncertain. While AI is likely to increase polyp and adenoma detection, subsequently leading to increased resection and histological testing under current practice which is to send any resected polyps for histology (with the exception of colonoscopies within the NHS Bowel Cancer Screening Programme [BCSP], which is in the process of rolling out a resect-and-discard

strategy for specific polyps once endoscopists are accredited), the extent of this may depend on whether alternative polyp management strategies are adopted in the future within UK clinical practice, such as resect-and-discard or diagnose-and-leave strategies based on optical diagnosis by endoscopists with or without support from AI technologies. As noted, a resect-and-discard strategy is being rolled out for colonoscopies within the NHS BCSP, but this will not apply to colonoscopies performed outside of the NHS BCSP and will only apply to specific polyps.

While the potential impact on waiting lists has been explored by the EAG in this assessment, it should be noted that the results of this should be interpreted with caution, given it is exploratory, and relies on the broad assumption that the change in the number of index colonoscopies is directly proportional to the change in patient waiting time for all centres. The results suggest that the overall number of colonoscopies could potentially decrease with the introduction of any of the AI technologies included in the economic evaluation, although this decrease would be minimal, and would be unlikely to have a tangible effect on waiting times in clinical practice.

7.2 Suggested research priorities

As discussed throughout this report, the EAG considers there to be various limitations related to the clinical evidence base that could be addressed through future research and may help to address some uncertainties within this review, including:

- Further research on the application of CADx technologies during real-time colonoscopies, where the technology is used as an adjunct to endoscopist judgement (AI categorisations alone not used to calculate sensitivity and specificity), with sensitivity and specificity compared to an assessment based on endoscopist judgement alone. Studies should consider diagnoses of any confidence level alongside high-confidence diagnoses in the analysis and sessile serrated lesions (SSLs) should not be considered to be non-neoplastic in the analyses. Classification as neoplastic vs non-neoplastic may be more appropriate than adenomatous vs non-adenomatous, as this would allow SSLs to be captured; endoscopist input may be able to identify at least some of them as potentially neoplastic, even if AI technologies remain unable to categorise them. Prospective diagnostic accuracy studies would be preferable, with a reference standard of histology;
- Randomised controlled trials (RCTs) designed to evaluate differences in the impact of the technologies compared to standard colonoscopy between different colonoscopy indication

and endoscopist experience subgroups may help to reduce uncertainty about potential differences between subgroups. This may include stratifying at randomisation and ensuring they are powered adequately to detect differences between subgroups. For colonoscopy indications, important subgroups include screening, symptomatic/diagnostic and surveillance subgroups, with those with surveillance for Lynch syndrome or other hereditary risk factors potentially separated from surveillance based on prior polypectomies. For endoscopist experience, separation of subgroups based on the baseline ADR of endoscopists before participation in the trial may be most clinically useful, with a threshold of 40 to 45% potentially useful in separating screening and non-screening endoscopists;

- Further RCTs comparing against standard colonoscopy in populations that are not well covered by current trials, including those with Lynch syndrome, polyposis syndromes such as familial adenomatous polyposis (FAP), inflammatory bowel disease (IBD), prior colorectal cancer (CRC) or a family history of CRC would help to address uncertainty about whether AI technologies are likely to function as well as they do in current trials that largely exclude these groups;
- More consistent reporting of outcomes more directly relevant to economic modelling (in particular, per-patient adenoma miss rate [AMR] risk ratio [RR]) would reduce reliance on the ADR as a proxy for outcomes for the accuracy of colonoscopies;
- Research into the long-term impact of these technologies, for example on outcomes such as mortality, morbidity other than adverse events (AEs) and health-related quality of life (HRQoL) may be useful to obtain direct estimates of their impact, which was not available from any of the currently included studies.

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9 Appendices

9.1 Summary of interventions included in this assessment

Table 44. Summary of AI technologies included in this assessment

Name of technology (manufacturer)	Classification*	Function	Intended use	Requirements/specifications
Argus® (Endosoft);	Regulatory approval in process	CADe	Described as a CADe device used in endoscopy to detect abnormal lesions within the GI tract. The device draws attention to images to help with the detection of lesions. It has hardware components that support interfacing with an endoscope. Computer-aided polyp sizing, CADx and natural language processing reporting functions are also reported in the user manual but the manufacturer noted that CADe should be the focus of this assessment.	Device name: Argus® Purpose of the CADe is to help physicians identify potential polyps during colonoscopy procedure. Not intended to be a substitute for the advice of a clinician and proper judgement should always be used, with Argus® recommendations disregarded if deemed clinically inappropriate. Overreliance on the system should be avoided. It is not intended to replace a full patient evaluation or to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis or recommendations of

				treatment/course of action for patients. It is designed to be used by qualified and trained gastroenterologists in adult patients undergoing colonoscopy examination for CRC screening or surveillance purposes. No additional training said to be required by manufacturer, and the system if required for polyp sizing. Minimum workstation requirements, including computer system and monitor requirements are outlined in the instructions for use document. It is only indicated for white-light colonoscopy. Fixed algorithm used. Front-end client application is updated with a single click, triggering process that downloads new version and updates the old version. No previous versions of Argus® were noted at the time of submission but an update to the real-time object detection algorithm was expected by the end of 2024. It has not been studies in patients with IBD, history of CRC or previous colonic resection. Device performance may be negatively impacted by mucosal irregularities such as background inflammation from certain underlying diseases.
CADEYE® (Fujifilm Healthcare	CE class IIa	CADe and CADx	The software detects and characterises areas that are suspected to be colonic polyps in an endoscopic video image from an endoscopic video processor. Results in detection or characterisation modes are presented onto the endoscopic video image in real-time. Characterisation mode includes suggestions about whether a suspected colonic polyp is neoplastic or hyperplastic. It is intended for use as a support for diagnosis during colonoscopy under the supervision of medical professionals.	Product name: Endoscopy Support Program Model: EW10-EC02 (brand name: CAD EYE®) Product intended for use by medical professionals who have received proper training in endoscopic procedures (and optical diagnosis) as the device does not provide information about clinical procedures or any aspects of endoscopic techniques. Suggested training on system involves “appropriate” explanation on quality conditions and limitations of the system prior to the first procedure, with first few

UK Ltd.)				procedures accompanied by clinical application specialist to further explain if necessary. Peripherals to be used outlined in the operation manual. Fixed algorithm used. Updates performed manually with USB stick by authorised technician with consent of physician/customer. No known contraindications reported in operation manual. CADe and CADx may be limited with poor bowel preparation and in water immersion. Version 2 update of CAD EYE® (EW10-EC02) planned with unknown date, possibly within 18 months of manufacturer submission. Additional data training set which is expected to improve detection and have higher accuracy for characterisation.
CADDIE™ (Odin Vision)	CE/UKCA marked (based on manufacturer websit	CADe and CADx	Roles of the product in supporting endoscopists with the detection and characterisation of colorectal polyps in real-time during colonoscopy are described. Additional functions of caecum detection and visible mucosa quantification also described. Characterisation mode classifies into adenoma or non-adenoma and works with VCE images. Endoscopist judgement required.	Device name: CADDIE™ Software intended to be used by trained and qualified healthcare professionals as an accompaniment to video endoscopy. Described as a clinical support tool and not designed to replace optical diagnosis or histopathology. Overreliance on the device should be avoided. Minimal training suggested to be required as fits into standard clinical workflow. Training materials are provided. Minimum system specifications in terms of computer and monitor are outlined in the instructions for use document, including CPU, RAM and resolution requirements. Compatible with endoscopic video processors and scopes equipped with HD or higher image quality resolutions; it has not been tested on systems with less than HD. Compatible with WLI and VCE light modalities. Tested using Olympus video processors with WLI and NBI; performance using other manufacturers' video processors or chromoendoscopy modalities may vary and be negatively affected. Fixed

	e, accessed 23 August 2024)			algorithm used, updates automatically for clients on release. Various updates undertaken already and note that possible others within 18 months of manufacturer submission. Intended to be used on patients >18 years referred for colonoscopy for investigation of colorectal mucosa, regardless of whether for screening, surveillance, symptomatic or diagnosis purposes. This excludes pregnant women for which no clinical evaluation has been carried out. Contraindications: • When colonoscopy is operating on a known or suspected bowel perforation; • Should not be used to assess severity, extent or complications or ulcerative colitis, Crohn's disease or diverticular disease; • Should not be used on patients contraindicated for colonoscopy.
Discovery™ (Pentax Medical	CE class I	CADe	Providing assistance to endoscopists for identification of polyps during colonoscopy; not intended to make or recommend decisions about patient management, diagnosis or therapeutic interventions.	Device name: Discovery™/SAS-M10 Not intended to support diagnosis, or to recommend management or therapeutic decisions; it has a polyp detection function only. Diagnosis is the responsibility of the endoscopist and products used to assist with this. The product should be used as a secondary monitor during endoscopy. Considered to be a very intuitive device with minimal training requirements before use. Need to ensure nursing team know how to toggle audible notifications on/off for individual clinical preference may be a focus.

UK)				The following Pentax Medical video processors are compatible with the product: • EPK-i7000, -i7000A or -i7010 • EPK-i5000, -i5010 or -i5500c. A DisplayPort input connector is also required for the recording device. Fixed algorithm used. Updates only distributed via field technicians. Current version at time of submission is first version of the device. System improvements (version 1.0.4) to improve precision and recall have been made. No planned future updates within 18 months of the submission. No limitations in terms of colonoscopy indications to be used in mentions; note that insufficient bowel preparation is only aspect shown to impact the effectiveness of Discovery™.
ENDO-AID™ (Olympus Medical Syste	CE class I	CADe	Providing assistance to physicians for detection of mucosal abnormalities, such as possible colorectal polyps, during colonoscopy. It is an adjunctive technology and should not be used as a stand-alone method for detection of abnormalities. The system processes signals from the endoscopy video system centre and directs the user's attention to areas of interest for assessment.	Device name: ENDO-AID™ (may also be referred to elsewhere as Endoscopy CAD System or OIP-1) Device intended to assist physicians in detection of mucosal abnormalities during colonoscopy as an adjunctive tool; users should not rely solely on the device for detection. The device has "normal" and "target" modes which can be switched between; the difference between these is the way in which polyp detection is visualised on the screen. Physicians using the technology should be qualified to operate and perform planned endoscopy and endoscopic treatment safely following the relevant guidelines. Basic operational training provided by Olympus to HCPs on how to use ENDO-AID™ during a short session, with refresher training offered if

ms Corp.)				required. Also training on how to select and display different modes available. Manufacturer states that HCPs report a short learning curve of between 5 and 10 cases to become familiar using ENDO-AID™. The Olympus CV-1500 video system centre is compatible with this technology. It is compatible with various Olympus monitors, including OEV321UH, OEV262H and OEV261H models and various video records from Olympus (IMH-200, IMH-20 and IMH-10). Colonoscopes recommended for use are 1500/1200/1100/290/190/185 series. Fixed algorithm used. Updates made using a USB at the front of the device, with users notified of any changes/updates. No previous version of ENDO-AID™ described at time of submission, with no plans to update within 18 months of the submission. Reported to be no known contraindications for use (e.g. in specific colonoscopy indications).
ENDOANGEL® Lower Gastrointestinal En	Uncertain	CADe	Full statement on intended use not available from the manufacturer at the time of protocol development but the manufacturer's website (accessed 28 August 2024) describes ENDOANGEL® as a CADe system for polyps powered by AI. It can be used for polyp identification in the lower digestive tract during endoscopy. It is not intended to replace clinical decision making and results should only be used as a reference.	The manufacturer of ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment is not participating directly in this appraisal and any information has been obtained solely from that available in the public domain. At the time of report write up the website could not be accessed and no information other than that in the previous column is available.

doscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technolo				

gy Co. Ltd .)				
Endoscopic Multimedia Information System (EMIS™; Endo Perv LLC., previo	Regulatory approval in process	CADe	EMIS™ brochure describes it as computer-assisted tool to aid endoscopists in the optimisation of mucosal inspection and detection of colonic mucosal lesions in real-time (includes [redacted] function as well as other functions such as identifying faecal debris, feedback on which quadrants have been inspected during withdrawal, retroflexion detection [redacted]). The study that the manufacturer provided data for in July 2025 [redacted]	Technology name: EMIS™ (software only) Used in real-time during standard WLE examinations only. May be used for upper or lower endoscopy. Not intended to replace clinical decision making. It does not perform any diagnosis and should not be used for any purpose other than its intended use. Overreliance on the output of the system should be avoided. No specific training thought to be required other than how to turn the system on and off. Fixed algorithm used but highly modifiable and customisable regarding needs of customer. [redacted] Unclear how updates incorporated. Many previous versions of the software, with most involving additions or improvements to algorithm speed, or occasional errors. [redacted] The device is not intended to be used with equipment that was not tested against during validation activities. Intended for patients undergoing screening and surveillance endoscopic mucosal evaluations. Good bowel preparation required and remaining faecal debris must be removed by the endoscopist. Quality metrics different for patients with post-surgical abdominal anatomy and IBD. The device has not been studied in patients with IBD; the device performance may be negatively impacted by mucosal

usly EndoMetric Corporation);				irregularities such as background inflammation from certain underlying diseases.
EndoScreener® (Wision AI)	CE class II	CADe	Full statement on intended use not available from the manufacturer at the time of protocol development but the manufacturer's website (accessed 23 August 2024) describes it as a CADe device for colorectal polyps. It uses colonoscopy video stream as the input from an endoscopy device and analyses it in real-time. Output from EndoScreener® involves blue boxes being overlaid onto colonoscopy images to highlight potential polyps.	The manufacturer of EndoScreener® has not submitted any information as part of this assessment any information has been obtained solely from that available in the public domain.
GI Genius™ (Medtronic)	CE class IIb	CADe and CA	Described as an AI-based medical device which processing colonoscopy images containing regions consistent with colorectal lesions such as polyps, including those with flat (non-polypoid) morphology. Characterisation support can be enabled, which enables the software to suggest the possible polyp histology to the user, which includes "adenoma", "non-adenoma" or "no prediction". No prediction is returned when the system is not confident enough to suggest a potential histology. It should be used as an adjunct to colonoscopy and should not replace endoscopist judgement or histopathological assessment.	Device name: GI Genius™ software (current software) and GI Genius™ Module 100 and 200 (current hardware variants) Intended to be used by trained clinicians as an adjunct to white-light colonoscopy to highlight regions with visual characteristics consistent with different types of mucosal abnormalities (such as colorectal polyps). Users should be properly trained on the use of GI Genius™ and should be expert clinicians on lower gastrointestinal endoscopy procedures. Training should be based on the contents of the

		Dx		GI Genius™ user manual. This can be augmented by dedicated training designed in conjunction with clinical end users on a hospital-by-hospital or regional basis where specific training needs have been identified to optimise utilisation and adoption of GI Genius™. The package includes a comprehensive, commissioning training and educational program to support its safe and effective use in clinical practice beyond minimum standard requires. This includes training and education support from a range of materials and approaches, including in person one-to-one training. GI Genius™ software can be installed and operated on third-party hardware that meets certain requirements in terms of CPU, RAM and storage outlined in the user manual. Only the following video processors can be used with the software (use of others may result in underperformance): • Olympus CV-180 EXERA II, CV-190 EXERA III and CV-1500 EVIS X1; • Fujifilm VP-4450HD or VP-7000 ELUXEO; • Pentax EPK-i7000 Video Processor. Version 3.1.0 of the GI Genius™ is planned to be updated within 18 months of the manufacturer submission including retaining of detection and characterisation function, addition of a sizing function as an accessory to the detection function, as well as addition of a non-medical software function to allow data aggregation by healthcare organisations and other optimisation changes to the software. This will lead to software version 4.0 to be traded as ColonPRO™, to be

				submitted for CE certification against MDR in EU and then registered with MHRA. GI Genius™ Module 100 and 200 will be replaced by GI Genius™ Module 300 including improvements to device core elements including various hardware and operating system changes such as keyboard, internal layout and power supply. GI Genius™ Module 300 will be CE marked for EU as class I medical device and registered to MHRA after ColonPRO™ receives its CE certificate. New software can be installed in fielded hardware and user is not obliged to change it. Previous versions of the software have been updated; the first two versions only included the CADe function, with the second version involving retraining of the CADe function. Version 3 added the CADx function. Hardware from the first release has been updated, GI Genius™ Module 100 and 200 currently can operate with third-party software in the future. The intended target population is any person undergoing a screening or surveillance colonoscopy, with no known contraindications currently.
MAGENTIQ-COLO™ (MAGENTI	CE class I	CADe and CADx	Providing assistance to endoscopists performing colonoscopies by assisting with the detection of lesions by highlighting regions with visual characteristics consistent with different mucosal abnormalities that may be seen during a colonoscopy. Identified lesions should be independently assessed by the endoscopist and action taken according to standard clinical practice. It should be used as an adjunctive tool and should not replace histopathological assessment.	Device name: Magentiq Eye Automatic Polyp Detection System (ME-APDS™) or MAGENTIQ-COLO™ Model: AI-DETECT-GI-CU (hardware version 3.0, software version 1.12) Consists of software and a computing device. Intended to be used by endoscopists as adjunct to common colonoscopy procedure, aiming to assist in identifying lesions during colonoscopy. Should not replace histopathological sampling as means of diagnosis. As well as polyp detection it is also reported to provide information about the type and size categorisation

Q-EYE)				functions). [redacted] Users are provided with training as part of the system's deployment process; one training session before using the system is considered to be sufficient. Fixed algorithm used. Updates made by an authorised manufacturer representative in coordination with the user. Reported to be no previous version of the technology at the time of submission. [redacted] Any legally marketed (USA) or CE-mark approved (EU) colonoscopy device can be used with the system. Adults referred for colonoscopy is the intended population, with no contraindications cited.

*Based on information in the NICE final scope from September 2024.

Details reported in this table have been obtained from either the NICE final scope, from documents submitted by the manufacturer or from manufacturer websites.

Abbreviations: AI, artificial intelligence; BBPS, Boston Bowel Preparation Scale; CADe, computer-aided detection; CADx, computer-aided characterisation; CPU, central processing unit; CRC, colorectal cancer; EMIS™, Endoscopic Multimedia Information System; EU, European; GI, gastrointestinal; HCP, healthcare professional; HD, high-definition; IBD, inflammatory bowel disease; MDR, Medical Device Regulation; MHRA, Medicines and Healthcare products Regulatory Agency; NBI, narrow-band imaging; NICE, National Institute for Health and Care Excellence; RAM, random access memory; UKCA, UK Conformity Assessed; VCE, virtual chromoendoscopy; WLI, white-light imaging.

9.2 Literature search strategies

9.2.1 EAG database searches

Table 45. EAG search strategy for Medline via Ovid – clinical SLR – 04/09/24

#	Searches	Results (04/09/24)
1	Colonoscopy/	32,659
2	Sigmoidoscopy/	4,921
3	Proctoscopy/	2,135
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*).tw,kf.	49,554
5	1 or 2 or 3 or 4	64,059
6	Endoscopy, Gastrointestinal/	21,819
7	endoscop*.tw,kf.	268,038
8	6 or 7	273,432
9	exp intestine, large/	151,984
10	lower gastrointestinal tract/	205
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal).tw,kf.	587,177
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).tw,kf.	32,093
13	9 or 10 or 11 or 12	641,888
14	8 and 13	33,941
15	5 or 14	82,428
16	exp Artificial Intelligence/	207,269
17	exp Machine Learning/	74,885
18	Deep Learning/	22,261
19	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*).tw,kf.	59,607
20	AI.tw,kf.	60,878
21	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning)).tw,kf.	186,925
22	Sentiment Analysis/	213
23	("sentiment analysis" or "opinion mining").tw,kf.	2,066
24	Support Vector Machine/	10,826
25	(vector adj2 machine).tw,kf.	24,540
26	neural networks, computer/	54,795
27	((neural or convolut* or artificial) adj2 network).tw,kf.	85,230
28	(CNN or CNNs or ANN or ANNs).tw,kf.	41,098
29	"neural net".tw,kf.	629

30	Natural Language Processing/	7,102
31	(natural adj2 language adj2 process*).tw,kf.	10,461
32	"large language model".tw,kf.	1,049
33	("cognitive computing" or "computer vision").tw,kf.	10,142
34	Image Processing, Computer-Assisted/	144,869
35	Pattern Recognition, Automated/	26,697
36	Image Interpretation, Computer-Assisted/	48,670
37	Diagnosis, Computer-Assisted/	24,510
38	((computer or machine) adj1 (aid* or base* or assist* or support*)).tw,kf.	80,461
39	"CADe".tw,kf.	453
40	"CADx".tw,kf.	307
41	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40	668,045
42	15 and 41	2,450
43	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener).tw,kf.	92
44	(Discovery and Pentax).tw,kf.	2
45	(Argus or EMIS or Endoscopic Multimedia Information System).tw,kf.	1,622
46	45 and 22	0
47	43 or 44 or 46	94
48	42 or 47	2,491
49	exp animals/ not humans/	5,254,851
50	48 not 49	2,441
51	50	2,441
52	limit 51 to yr="2010 -Current"	1,907

Database(s): Ovid MEDLINE(R) ALL 1946 to September 03, 2024.

Note that an error in this search strategy was later identified (line 46 mistakenly combines line 45 with line 22, whereas the intention was to combine line 45 with line 15). The impact of this was reviewed and there was no major impact on the search results. Given much of the deduplication and sifting of database records had already occurred by this stage, updated results from the corrected search strategy were not incorporated into the sift. The search strategy was corrected for the update searches performed in June 2025 (see Table 46).

Abbreviations: EAG, External Assessment Group; SLR, systematic literature review.

Table 46. EAG search strategy for Medline via Ovid – clinical SLR – 11/06/25

#	Searches	Results (11/06/25)
1	Colonoscopy/	33,577
2	Sigmoidoscopy/	4,943

3	Proctoscopy/	2,143
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*).tw,kf.	51,681
5	1 or 2 or 3 or 4	66,321
6	Endoscopy, Gastrointestinal/	22,130
7	endoscop*.tw,kf.	280,239
8	6 or 7	285,637
9	exp intestine, large/	154,395
10	lower gastrointestinal tract/	208
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal).tw,kf.	611,191
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).tw,kf.	32,948
13	9 or 10 or 11 or 12	666,550
14	8 and 13	35,520
15	5 or 14	85,589
16	exp Artificial Intelligence/	239,761
17	exp Machine Learning/	95,790
18	Deep Learning/	29,999
19	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*).tw,kf.	79,536
20	AI.tw,kf.	77,152
21	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning)).tw,kf.	229,247
22	Sentiment Analysis/	214
23	("sentiment analysis" or "opinion mining").tw,kf.	2,449
24	Support Vector Machine/	12,037
25	(vector adj2 machine).tw,kf.	27,527
26	neural networks, computer/	62,326
27	((neural or convolut* or artificial) adj2 network).tw,kf.	96,165
28	(CNN or CNNs or ANN or ANNs).tw,kf.	46,698
29	"neural net".tw,kf.	656
30	Natural Language Processing/	8,110
31	(natural adj2 language adj2 process*).tw,kf.	12,390
32	"large language model".tw,kf.	2,317
33	("cognitive computing" or "computer vision").tw,kf.	11,766
34	Image Processing, Computer-Assisted/	150,388
35	Pattern Recognition, Automated/	26,949
36	Image Interpretation, Computer-Assisted/	50,338
37	Diagnosis, Computer-Assisted/	24,914

38	((computer or machine) adj1 (aid* or base* or assist* or support*)).tw,kf.	84,269
39	"CADe".tw,kf.	512
40	"CADx".tw,kf.	345
41	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40	743,294
42	15 and 41	2,734
43	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener).tw,kf.	100
44	(Discovery and Pentax).tw,kf.	2
45	(Argus or EMIS or Endoscopic Multimedia Information System).tw,kf.	1,721
46	45 and 15	2
47	43 or 44 or 46	104
48	42 or 47	2,778
49	exp animals/ not humans/	5,348,122
50	48 not 49	2,727
51	50	2,727
52	limit 51 to yr="2010 -Current"	2,192
53	limit 52 to dt=20240904-20250611	294

Database(s): Ovid MEDLINE(R) ALL 1946 to June 10, 2025.

Abbreviations: EAG, External Assessment Group; SLR, systematic literature review.

Table 47. EAG search strategy for Embase via Ovid – clinical SLR – 04/09/24

#	Searches	Results (04/09/24)
1	colonoscopy/	110,793
2	exp polypectomy/	12,434
3	exp endoscopic polypectomy/	3,187
4	sigmoidoscopy/	14,766
5	rectoscopy/	2,952
6	ileocolonoscopy/	1,635
7	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*).tw,kf.	97,412
8	1 or 2 or 3 or 4 or 5 or 6 or 7	145,407
9	gastrointestinal endoscopy/	42,803
10	endoscop*.tw,kf.	435,863
11	9 or 10	450,740
12	exp large intestine/	213,408

13	sigmoid/	20,917
14	lower gastrointestinal tract/	912
15	exp rectum/	43,520
16	exp anus/	22,970
17	cecum/	22,320
18	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal).tw,kf.	835,980
19	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).tw,kf.	42,805
20	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19	912,945
21	11 and 20	71,477
22	8 or 21	181,653
23	artificial intelligence/	85,709
24	cognitive technology/	7
25	exp machine learning/	508,262
26	deep learning/	63,401
27	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*).tw,kf.	68,904
28	AI.tw,kf.	80,413
29	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning)).tw,kf.	215,958
30	sentiment analysis/	891
31	("Sentiment analysis" or "opinion mining").tw,kf.	1,823
32	exp support vector machine/	47,617
33	(vector adj2 machine).tw,kf.	29,407
34	cognitive computing/	42
35	computer vision/	4,567
36	("cognitive computing" or "computer vision").tw,kf.	10,805
37	natural language processing/	13,790
38	(natural adj2 language* adj2 process*).tw,kf.	12,146
39	large language model/	2,136
40	"large language model".tw,kf.	1,067
41	artificial neural network/	60,059
42	convolutional neural network/	34,202
43	((neural or convolut* or artificial) adj2 network*).tw,kf.	143,046
44	(CNN or CNNs or ANN or ANNs).tw,kf.	99,364
45	"neural net".tw,kf.	795
46	computer analysis/	124,824
47	computer assisted diagnosis/	43,350
48	pattern recognition/	37,615

49	((computer or machine) adj1 (aid* or base* or assist* or support*)).tw,kf.	101,398
50	"CADe".tw,kf.	793
51	"CADx".tw,kf.	445
52	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51	998,314
53	22 and 52	4,659
54	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener).tw,kf.	304
55	(Discovery and Pentax).tw,kf.	7
56	(Argus or EMIS or Endoscopic Multimedia Information System).tw,kf.	2,242
57	56 and 22	14
58	54 or 55 or 57	325
59	53 or 58	4,782
60	exp animals/ not humans/	11,821,428
61	59 not 60	4,128
62	limit 61 to yr="2010 -Current"	3,661

Database(s): Embase 1974 to 2024 September 03.

Abbreviations: EAG, External Assessment Group; SLR, systematic literature review.

Table 48. EAG search strategy for Embase via Ovid – clinical SLR – 11/06/25

#	Searches	Results (11/06/25)
1	colonoscopy/	120,386
2	exp polypectomy/	13,601
3	exp endoscopic polypectomy/	3,296
4	sigmoidoscopy/	15,765
5	rectoscopy/	3,097
6	ileocolonoscopy/	1,869
7	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*).tw,kf.	105,954
8	1 or 2 or 3 or 4 or 5 or 6 or 7	156,564
9	gastrointestinal endoscopy/	44,766
10	endoscop*.tw,kf.	464,716
11	9 or 10	480,133
12	exp large intestine/	223,197
13	sigmoid/	22,016
14	lower gastrointestinal tract/	1,067

15	exp rectum/	45,913
16	exp anus/	24,291
17	cecum/	24,211
18	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal).tw,kf.	885,731
19	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).tw,kf.	44,855
20	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19	965,255
21	11 and 20	77,482
22	8 or 21	195,484
23	artificial intelligence/	108,730
24	cognitive technology/	15
25	exp machine learning/	596,046
26	deep learning/	82,092
27	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*).tw,kf.	91,541
28	AI.tw,kf.	102,010
29	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning)).tw,kf.	262,641
30	sentiment analysis/	1,168
31	("Sentiment analysis" or "opinion mining").tw,kf.	2,122
32	exp support vector machine/	55,073
33	(vector adj2 machine).tw,kf.	32,464
34	cognitive computing/	52
35	computer vision/	6,010
36	("cognitive computing" or "computer vision").tw,kf.	12,514
37	natural language processing/	16,550
38	(natural adj2 language* adj2 process*).tw,kf.	14,243
39	large language model/	5,468
40	"large language model".tw,kf.	2,496
41	artificial neural network/	67,576
42	convolutional neural network/	41,409
43	((neural or convolut* or artificial) adj2 network*).tw,kf.	160,166
44	(CNN or CNNs or ANN or ANNs).tw,kf.	106,197
45	"neural net".tw,kf.	828
46	computer analysis/	125,382
47	computer assisted diagnosis/	42,335
48	pattern recognition/	38,316
49	((computer or machine) adj1 (aid* or base* or assist* or support*)).tw,kf.	107,844
50	"CADe".tw,kf.	1,004

51	"CADx".tw,kf.	528
52	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51	1,120,058
53	22 and 52	5,707
54	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener).tw,kf.	439
55	(Discovery and Pentax).tw,kf.	10
56	(Argus or EMIS or Endoscopic Multimedia Information System).tw,kf.	2,391
57	56 and 22	15
58	54 or 55 or 57	464
59	53 or 58	5,853
60	exp animals/ not humans/	5,928,890
61	59 not 60	5,809
62	limit 61 to yr="2010 -Current"	5,292
63	limit 62 to dc=20240904-20250611	1,147

Database(s): Embase 1974 to 2025 June 10.

Abbreviations: EAG, External Assessment Group; SLR, systematic literature review.

Table 49. EAG search strategy for CENTRAL via Cochrane Library – clinical SLR – 04/09/24

#	Searches	Results (04/09/24)
#1	MeSH descriptor: [Colonoscopy] explode all trees	3065
#2	MeSH descriptor: [Sigmoidoscopy] explode all trees	368
#3	MeSH descriptor: [Proctoscopy] explode all trees	107
#4	(colonoscop* OR polypect* OR sigmoidoscop* OR proctoscop* OR coloscop* OR ileocolonoscop* OR anoscop* OR rectoscop* OR proctosigmoidoscop*)	11450
#5	(#1 OR #2 OR #3 OR #4)	11489
#6	MeSH descriptor: [Endoscopy, Gastrointestinal] this term only	1072
#7	endoscop*	40419
#8	(#6 OR #7)	40419
#9	MeSH descriptor: [Intestine, Large] explode all trees	4361
#10	MeSH descriptor: [Lower Gastrointestinal Tract] this term only	11
#11	(colon OR colons OR colonic OR sigmoid OR sigmoids OR rectum* OR rectal OR colorect* OR anus OR anal OR cecum OR caecum OR cecal OR caecal)	59710
#12	(lower bowel* OR lower intestin* OR lower gastrointestin* OR lower gastro-intestin* OR lower GI OR large bowel* OR large intestin*)	23750
#13	(#9 or #10 or #11 or #12)	77938

#14	(#8 AND #13)	9560
#15	(#5 OR #14)	16802
#16	MeSH descriptor: [Artificial Intelligence] explode all trees	3279
#17	MeSH descriptor: [Machine Learning] explode all trees	1009
#18	MeSH descriptor: [Deep Learning] explode all trees	331
#19	((artificial OR machine* OR comput* OR augment* OR amplif*) NEAR/2 intelligen*)	2573
#20	AI	11382
#21	((machine OR deep OR transfer* OR hierarch* OR computer) NEAR/2 (learn* OR reasoning))	4994
#22	MeSH descriptor: [Sentiment Analysis] this term only	0
#23	"Sentiment analysis" OR "opinion mining"	18
#24	MeSH descriptor: [Support Vector Machine] this term only	63
#25	(vector NEAR/2 machine)	548
#26	"cognitive computing" OR "computer vision"	180
#27	MeSH descriptor: [Natural Language Processing] this term only	73
#28	(natural NEAR/2 language* NEAR/2 process*)	288
#29	"large language model"	24
#30	MeSH descriptor: [Neural Networks, Computer] explode all trees	641
#31	((neural OR convolut* OR artificial) NEAR/2 network*)	2168
#32	(CNN OR CNNs OR ANN OR ANNs)	5234
#33	"neural net"	15
#34	MeSH descriptor: [Diagnosis, Computer-Assisted] this term only	809
#35	MeSH descriptor: [Image Processing, Computer-Assisted] this term only	2373
#36	MeSH descriptor: [Pattern Recognition, Automated] this term only	237
#37	MeSH descriptor: [Image Interpretation, Computer-Assisted] this term only	1080
#38	((computer OR machine) NEXT (aid* OR base* OR assist* OR support*))	26739
#39	"CADe" OR "CADx"	341
#40	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)	50015
#41	(#15 AND #40)	913
#42	(GI Genius OR GIGenius OR ENDO-AID OR ENDOAID OR WISE VISION OR WISEVISION OR CAD-EYE OR CADEYE OR MAGENTIQ OR EndoAngel OR Endo-Angel OR CADDIE OR Endoscreener OR Endo-screener)	347
#43	(Discovery AND Pentax)	5
#44	(Argus OR EMIS OR Endoscopic Multimedia Information System)	133
#45	(#44 AND #15)	2
#46	(#42 OR #43 OR #45)	354
#47	(#41 OR #46)	1125

#48	#47 with Publication Year from 2010 to 2024, in Trials	782

Database(s): Cochrane Library, filtered for trials using "Trials" selection under "Content Type" filter of "limits" panel.

Abbreviations: CENTRAL, Cochrane Central Register of Controlled Trials; EAG, External Assessment Group; SLR, systematic literature review.

Table 50. EAG search strategy for CENTRAL via Cochrane Library – clinical SLR – 11/06/25

#	Searches	Results (11/06/25)
#1	MeSH descriptor: [Colonoscopy] explode all trees	3015
#2	MeSH descriptor: [Sigmoidoscopy] explode all trees	359
#3	MeSH descriptor: [Proctoscopy] explode all trees	96
#4	(colonoscop* OR polypect* OR sigmoidoscop* OR proctoscop* OR coloscop* OR ileocolonoscop* OR anoscop* OR rectoscop* OR proctosigmoidoscop*)	11803
#5	(#1 OR #2 OR #3 OR #4)	11837
#6	MeSH descriptor: [Endoscopy, Gastrointestinal] this term only	1063
#7	endoscop*	41772
#8	(#6 OR #7)	41772
#9	MeSH descriptor: [Intestine, Large] explode all trees	4316
#10	MeSH descriptor: [Lower Gastrointestinal Tract] this term only	11
#11	(colon OR colons OR colonic OR sigmoid OR sigmoids OR rectum* OR rectal OR colorect* OR anus OR anal OR cecum OR caecum OR cecal OR caecal)	61438
#12	(lower bowel* OR lower intestin* OR lower gastrointestin* OR lower gastro-intestin* OR lower GI OR large bowel* OR large intestin*)	24248
#13	(#9 or #10 or #11 or #12)	80027
#14	(#8 AND #13)	9892
#15	(#5 OR #14)	17383
#16	MeSH descriptor: [Artificial Intelligence] explode all trees	3565
#17	MeSH descriptor: [Machine Learning] explode all trees	1156
#18	MeSH descriptor: [Deep Learning] explode all trees	376
#19	((artificial OR machine* OR comput* OR augment* OR amplif*) NEAR/2 intelligen*)	3269
#20	AI	12394
#21	((machine OR deep OR transfer* OR hierarch* OR computer) NEAR/2 (learn* OR reasoning))	5503
#22	MeSH descriptor: [Sentiment Analysis] this term only	0
#23	"Sentiment analysis" OR "opinion mining"	19
#24	MeSH descriptor: [Support Vector Machine] this term only	73
#25	(vector NEAR/2 machine)	586
#26	"cognitive computing" OR "computer vision"	218

#27	MeSH descriptor: [Natural Language Processing] this term only	78
#28	(natural NEAR/2 language* NEAR/2 process*)	322
#29	"large language model"	86
#30	MeSH descriptor: [Neural Networks, Computer] explode all trees	686
#31	((neural OR convolut* OR artificial) NEAR/2 network*)	2246
#32	(CNN OR CNNs OR ANN OR ANNs)	5358
#33	"neural net"	16
#34	MeSH descriptor: [Diagnosis, Computer-Assisted] this term only	815
#35	MeSH descriptor: [Image Processing, Computer-Assisted] this term only	2340
#36	MeSH descriptor: [Pattern Recognition, Automated] this term only	238
#37	MeSH descriptor: [Image Interpretation, Computer-Assisted] this term only	1089
#38	((computer OR machine) NEXT (aid* OR base* OR assist* OR support*))	27105
#39	"CADe" OR "CADx"	384
#40	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)	52131
#41	(#15 AND #40)	994
#42	(GI Genius OR GIGenius OR ENDO-AID OR ENDOAID OR WISE VISION OR WISEVISION OR CAD-EYE OR CADEYE OR MAGENTIQ OR EndoAngel OR Endo-Angel OR CADDIE OR Endoscreener OR Endo-screener)	384
#43	(Discovery AND Pentax)	5
#44	(Argus OR EMIS OR Endoscopic Multimedia Information System)	135
#45	(#44 AND #15)	3
#46	(#42 OR #43 OR #45)	392
#47	(#41 OR #46)	1225
#48	#47 with Publication Year from 2010 to 2025, in Trials	869
#49	#48 with Cochrane Library publication date Between Sep 2024 and Jun 2025	108

Database(s): Cochrane Library, filtered for trials using “Trials” selection under “Content Type” filter of “limits” panel.

Abbreviations: CENTRAL, Cochrane Central Register of Controlled Trials; EAG, External Assessment Group; SLR, systematic literature review.

Table 51. EAG search strategy for CDSR via Cochrane Library – clinical SLR – 04/09/24

#	Searches	Results (04/09/24)
#1	MeSH descriptor: [Colonoscopy] explode all trees	3065
#2	MeSH descriptor: [Sigmoidoscopy] explode all trees	368
#3	MeSH descriptor: [Proctoscopy] explode all trees	107

#4	(colonoscop* OR polypect* OR sigmoidoscop* OR proctoscop* OR coloscop* OR ileocolonoscop* OR anoscop* OR rectoscop* OR proctosigmoidoscop*)	11450
#5	(#1 OR #2 OR #3 OR #4)	11489
#6	MeSH descriptor: [Endoscopy, Gastrointestinal] this term only	1072
#7	endoscop*	40419
#8	(#6 OR #7)	40419
#9	MeSH descriptor: [Intestine, Large] explode all trees	4361
#10	MeSH descriptor: [Lower Gastrointestinal Tract] this term only	11
#11	(colon OR colons OR colonic OR sigmoid OR sigmoids OR rectum* OR rectal OR colorect* OR anus OR anal OR cecum OR caecum OR cecal OR caecal)	59710
#12	(lower bowel* OR lower intestin* OR lower gastrointestin* OR lower gastro-intestin* OR lower GI OR large bowel* OR large intestin*)	23750
#13	(#9 or #10 or #11 or #12)	77938
#14	(#8 AND #13)	9560
#15	(#5 OR #14)	16802
#16	MeSH descriptor: [Artificial Intelligence] explode all trees	3279
#17	MeSH descriptor: [Machine Learning] explode all trees	1009
#18	MeSH descriptor: [Deep Learning] explode all trees	331
#19	((artificial OR machine* OR comput* OR augment* OR amplif*) NEAR/2 intelligen*)	2573
#20	AI	11382
#21	((machine OR deep OR transfer* OR hierarch* OR computer) NEAR/2 (learn* OR reasoning))	4994
#22	MeSH descriptor: [Sentiment Analysis] this term only	0
#23	"Sentiment analysis" OR "opinion mining"	18
#24	MeSH descriptor: [Support Vector Machine] this term only	63
#25	(vector NEAR/2 machine)	548
#26	"cognitive computing" OR "computer vision"	180
#27	MeSH descriptor: [Natural Language Processing] this term only	73
#28	(natural NEAR/2 language* NEAR/2 process*)	288
#29	"large language model"	24
#30	MeSH descriptor: [Neural Networks, Computer] explode all trees	641
#31	((neural OR convolut* OR artificial) NEAR/2 network*)	2168
#32	(CNN OR CNNs OR ANN OR ANNs)	5234
#33	"neural net"	15
#34	MeSH descriptor: [Diagnosis, Computer-Assisted] this term only	809
#35	MeSH descriptor: [Image Processing, Computer-Assisted] this term only	2373
#36	MeSH descriptor: [Pattern Recognition, Automated] this term only	237
#37	MeSH descriptor: [Image Interpretation, Computer-Assisted] this term only	1080
#38	((computer OR machine) NEXT (aid* OR base* OR assist* OR support*))	26739

#39	"CADe" OR "CADx"	341
#40	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)	50015
#41	(#15 AND #40)	913
#42	(GI Genius OR GIGenius OR ENDO-AID OR ENDOAID OR WISE VISION OR WISEVISION OR CAD-EYE OR CADEYE OR MAGENTIQ OR EndoAngel OR Endo-Angel OR CADDIE OR Endoscreener OR Endo-screener)	347
#43	(Discovery AND Pentax)	5
#44	(Argus OR EMIS OR Endoscopic Multimedia Information System)	133
#45	(#44 AND #15)	2
#46	(#42 OR #43 OR #45)	354
#47	(#41 OR #46)	1125
#48	#47 with Cochrane Library publication date Between Jan 2010 and Sep 2024, in Cochrane Reviews	182

Database(s): Cochrane Library, filtered for systematic reviews using “Cochrane Reviews” selection under “Content Type” filter of “limits” panel.

Abbreviations: CDSR, Cochrane Database of Systematic Reviews; EAG, External Assessment Group; SLR, systematic literature review.

Table 52. EAG search strategy for CDSR via Cochrane Library – clinical SLR – 11/06/25

#	Searches	Results (11/06/25)
#1	MeSH descriptor: [Colonoscopy] explode all trees	3015
#2	MeSH descriptor: [Sigmoidoscopy] explode all trees	359
#3	MeSH descriptor: [Proctoscopy] explode all trees	96
#4	(colonoscop* OR polypect* OR sigmoidoscop* OR proctoscop* OR coloscop* OR ileocolonoscop* OR anoscop* OR rectoscop* OR proctosigmoidoscop*)	11803
#5	(#1 OR #2 OR #3 OR #4)	11837
#6	MeSH descriptor: [Endoscopy, Gastrointestinal] this term only	1063
#7	endoscop*	41772
#8	(#6 OR #7)	41772
#9	MeSH descriptor: [Intestine, Large] explode all trees	4316
#10	MeSH descriptor: [Lower Gastrointestinal Tract] this term only	11
#11	(colon OR colons OR colonic OR sigmoid OR sigmoids OR rectum* OR rectal OR colorect* OR anus OR anal OR cecum OR caecum OR cecal OR caecal)	61438
#12	(lower bowel* OR lower intestin* OR lower gastrointestin* OR lower gastro-intestin* OR lower GI OR large bowel* OR large intestin*)	24248
#13	(#9 or #10 or #11 or #12)	80027

#14	(#8 AND #13)	9892
#15	(#5 OR #14)	17383
#16	MeSH descriptor: [Artificial Intelligence] explode all trees	3565
#17	MeSH descriptor: [Machine Learning] explode all trees	1156
#18	MeSH descriptor: [Deep Learning] explode all trees	376
#19	((artificial OR machine* OR comput* OR augment* OR amplif*) NEAR/2 intelligen*)	3269
#20	AI	12394
#21	((machine OR deep OR transfer* OR hierarch* OR computer) NEAR/2 (learn* OR reasoning))	5503
#22	MeSH descriptor: [Sentiment Analysis] this term only	0
#23	"Sentiment analysis" OR "opinion mining"	19
#24	MeSH descriptor: [Support Vector Machine] this term only	73
#25	(vector NEAR/2 machine)	586
#26	"cognitive computing" OR "computer vision"	218
#27	MeSH descriptor: [Natural Language Processing] this term only	78
#28	(natural NEAR/2 language* NEAR/2 process*)	322
#29	"large language model"	86
#30	MeSH descriptor: [Neural Networks, Computer] explode all trees	686
#31	((neural OR convolut* OR artificial) NEAR/2 network*)	2246
#32	(CNN OR CNNs OR ANN OR ANNs)	5358
#33	"neural net"	16
#34	MeSH descriptor: [Diagnosis, Computer-Assisted] this term only	815
#35	MeSH descriptor: [Image Processing, Computer-Assisted] this term only	2340
#36	MeSH descriptor: [Pattern Recognition, Automated] this term only	238
#37	MeSH descriptor: [Image Interpretation, Computer-Assisted] this term only	1089
#38	((computer OR machine) NEXT (aid* OR base* OR assist* OR support*))	27105
#39	"CADe" OR "CADx"	384
#40	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)	52131
#41	(#15 AND #40)	994
#42	(GI Genius OR GIGenius OR ENDO-AID OR ENDOAID OR WISE VISION OR WISEVISION OR CAD-EYE OR CADEYE OR MAGENTIQ OR EndoAngel OR Endo-Angel OR CADDIE OR Endoscreener OR Endo-screener)	384
#43	(Discovery AND Pentax)	5
#44	(Argus OR EMIS OR Endoscopic Multimedia Information System)	135
#45	(#44 AND #15)	3
#46	(#42 OR #43 OR #45)	392
#47	(#41 OR #46)	1225

#48	#47 with Cochrane Library publication date Between Jan 2010 and Jun 2025, in Cochrane Reviews	190
#49	#48 with Cochrane Library publication date Between Sep 2024 and Jun 2025	11

Database(s): Cochrane Library, filtered for systematic reviews using "Cochrane Reviews" selection under "Content Type" filter of "limits" panel.

Abbreviations: CDSR, Cochrane Database of Systematic Reviews; EAG, External Assessment Group; SLR, systematic literature review.

9.2.2 WHO ICTRP search strategy

The EAG's search strategy for WHO ICTRP was (colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop* or endoscop*) AND (AI or artificial or intelligen* or machine or learn* or neural or computer* or CADe or CADx), entered into the title field with recruitment status set as "ALL". For the update performed in June 2025, a date limit of 14/09/24 to 11/06/25 was added to the "date of registration" field.

9.2.3 Clinicaltrials.gov search strategy

For Clinicaltrials.gov, the following search strategy was used:

- Intervention field: colonoscopy OR polypectomy OR sigmoidoscopy OR proctoscopy OR coloscopy OR ileocolonoscopy OR anoscopy OR rectoscopy OR proctosigmoidoscopy OR endoscopy
- Other terms field: AI OR artificial OR intelligence OR intelligent OR machine OR learning OR neural OR computer OR computerised OR computerized OR CADe OR CADx

For the update in June 2025, a date limit of 16/09/24 to 11/06/25 was added to the "results first posted" field.

9.2.4 PROSPERO search strategy

Table 53. EAG search strategy for PROSPERO – clinical SLR – 15/09/24

#	Searches	Results (15/09/24)
1	MeSH DESCRIPTOR colonoscopy	112
2	MeSH DESCRIPTOR sigmoidoscopy	5
3	MeSH DESCRIPTOR proctoscopy	1

4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*)	1038
5	#1 OR #2 OR #3 OR #4	1048
6	MeSH DESCRIPTOR Endoscopy, Gastrointestinal	39
7	endoscop*	5018
8	#6 OR #7	5018
9	MeSH DESCRIPTOR Intestine, large EXPLODE ALL TREES	184
10	MeSH DESCRIPTOR lower gastrointestinal tract	2
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal)	7599
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*)	431
13	#9 OR #10 OR #11 OR #12	7787
14	#8 AND #13	957
15	#5 OR #14	1635
16	MeSH DESCRIPTOR artificial intelligence EXPLODE ALL TREES	477
17	MeSH DESCRIPTOR machine learning EXPLODE ALL TREES	154
18	MeSH DESCRIPTOR deep learning	23
19	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*)	2870
20	AI	4607
21	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning))	3305
22	"sentiment analysis" or "opinion mining"	25
23	MeSH DESCRIPTOR support vector machine	0
24	(vector adj2 machine)	179
25	MeSH DESCRIPTOR neural networks, computer	6
26	((neural or convolut* or artificial) adj2 network)	585
27	(CNN or CNNs or ANN or ANNs)	2488
28	"neural net"	5
29	MeSH DESCRIPTOR natural language processing	8
30	(natural adj2 language adj2 process*)	247
31	"large language model"	33
32	("cognitive computing" or "computer vision")	162
33	MeSH DESCRIPTOR image processing, computer-assisted	16
34	MeSH DESCRIPTOR pattern recognition, automated	1
35	MeSH DESCRIPTOR image interpretation, computer-assisted	4
36	MeSH DESCRIPTOR diagnosis, computer-assisted	9
37	((computer or machine) adj1 (aid* or base* or assist* or support*))	2148
38	"CADe"	68

39	"CADx"	8
40	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #35 OR #34 OR #36 OR #37 OR #38 OR #39	11273
41	#15 AND #40	152
42	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener)	2
43	(Discovery and Pentax)	1
44	(Argus or EMIS or Endoscopic Multimedia Information System)	26
45	#44 AND #15	1
46	#42 OR #43 OR #45	2
47	#41 OR #46	153

Abbreviations: EAG, External Assessment Group; SLR, systematic literature review.

Table 54. EAG search strategy for PROSPERO – clinical SLR – 11/06/25

#	Searches	Results (11/06/25)
1	MeSH DESCRIPTOR colonoscopy	479
2	MeSH DESCRIPTOR sigmoidoscopy	32
3	MeSH DESCRIPTOR proctoscopy	3
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*)	1331
5	#1 OR #2 OR #3 OR #4	1331
6	MeSH DESCRIPTOR Endoscopy, Gastrointestinal	208
7	endoscop*	6269
8	#6 OR #7	6269
9	MeSH DESCRIPTOR Intestine, large EXPLODE ALL TREES	563
10	MeSH DESCRIPTOR lower gastrointestinal tract	2
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal)	9354
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*)	484
13	#9 OR #10 OR #11 OR #12	9571
14	#8 AND #13	1170
15	#5 OR #14	2027
16	MeSH DESCRIPTOR artificial intelligence EXPLODE ALL TREES	4696
17	MeSH DESCRIPTOR machine learning EXPLODE ALL TREES	1701

18	MeSH DESCRIPTOR deep learning	515
19	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*)	4880
20	AI	5287
21	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning))	5087
22	"sentiment analysis" or "opinion mining"	38
23	MeSH DESCRIPTOR support vector machine	42
24	(vector adj2 machine)	224
25	MeSH DESCRIPTOR neural networks, computer	204
26	((neural or convolut* or artificial) adj2 network)	700
27	(CNN or CNNs or ANN or ANNs)	2678
28	"neural net"	4
29	MeSH DESCRIPTOR natural language processing	102
30	(natural adj2 language adj2 process*)	416
31	"large language model"	95
32	("cognitive computing" or "computer vision")	220
33	MeSH DESCRIPTOR image processing, computer-assisted	77
34	MeSH DESCRIPTOR pattern recognition, automated	9
35	MeSH DESCRIPTOR image interpretation, computer-assisted	16
36	MeSH DESCRIPTOR diagnosis, computer-assisted	40
37	((computer or machine) adj1 (aid* or base* or assist* or support*))	2580
38	"CADe"	74
39	"CADx"	12
40	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #35 OR #34 OR #36 OR #37 OR #38 OR #39	14264
41	#15 AND #40	193
42	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener)	5
43	(Discovery and Pentax)	1
44	(Argus or EMIS or Endoscopic Multimedia Information System)	31
45	#44 AND #15	1
46	#42 OR #43 OR #45	5
47	#41 OR #46	195

The 195 records identified were further filtered by adding a date limit from 16/09/24 to 11/06/25 to the “date of registration” field, leaving a total of 54 new records identified in this update from PROSPERO.

Abbreviations: EAG, External Assessment Group; SLR, systematic literature review.

9.2.5 Search strategies for health technology assessment bodies

Different approaches to searching these websites were taken depending on the number of records and the compatibility with certain ways of searching. NICE and HTW websites were searched using "colonoscop* or polypect* or sigmoidoscop* proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop* or endoscop*". The full list of SIGN guidance was reviewed given there were fewer than 50 records, and the term "artificial" was searched on the website of Canada's Drug Agency (with "project line" set to "health technology review") given more complex strings did not appear to function (such as those used to search NICE and HTW websites) and the likelihood that relevant documents would mention AI somewhere in the record. For the update in June 2025, there was no way of restricting or filtering for only new records since the previous searches in NICE, HTW, SIGN or Canada's Drug Agency; instead, all records were retrieved with a focus on those from 2024 onwards, with those from September 2024 onwards reviewed if a month was clearly reported. A more comprehensive strategy based on MeSH and free-text terms for colonoscopy was used for INAHTA, which is presented in Table 55 and Table 56.

Table 55. EAG search strategy for INAHTA database – clinical SLR – 15/09/24

#	Searches	Results (15/09/24)
1	"Colonoscopy"[mh]	46
2	"Sigmoidoscopy"[mh]	9
3	"Proctoscopy"[mh]	1
4	"Endoscopy, Gastrointestinal"[mh]	60
5	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop* or endoscop*)	440
6	((colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop* or endoscop*)) OR ("Endoscopy, Gastrointestinal"[mh]) OR ("Proctoscopy"[mh]) OR ("Sigmoidoscopy"[mh]) OR ("Colonoscopy"[mh])	452

Abbreviations: EAG, External Assessment Group; INAHTA, International Network of Agencies for Health Technology Assessment; SLR, systematic literature review.

Table 56. EAG search strategy for INAHTA database – clinical SLR – 12/06/25

#	Searches	Results (12/06/25)
1	"Colonoscopy"[mh]	46
2	"Sigmoidoscopy"[mh]	9

3	"Proctoscopy"[mh]	1
4	"Endoscopy, Gastrointestinal"[mh]	62
5	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop* or endoscop*)	441
6	((colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop* or endoscop*)) OR ("Endoscopy, Gastrointestinal"[mh]) OR ("Proctoscopy"[mh]) OR ("Sigmoidoscopy"[mh]) OR ("Colonoscopy"[mh])	454

The 454 records above were filtered by year to obtain 21 records between 2024 and 2025. It was not possible to refine results further by exact date to obtain only those that were new since the previous search was run.

Abbreviations: EAG, External Assessment Group; INAHTA, International Network of Agencies for Health Technology Assessment; SLR, systematic literature review.

9.3 Coverage of clinical outcomes in NICE final scope

Table 57. Final scope outcomes and corresponding data prioritised for analysis

Outcomes included in NICE final scope[25]	Outcomes extracted and prioritised for analysis (in main report or DAR supplement)
Measures of ability or accuracy to detect polyps or cancer	**Detection rates** ADR, advanced ADR, non-advanced ADR, SSL DR, significant PDR (adenoma or SSL) and non-neoplastic or hyperplastic polyp DR prioritised for main report. Full details for ADR are included in the main report, while a discussion for each separate intervention and associated figures are included in the DAR supplement for other outcomes listed here. Other outcomes are included in the DAR supplement, including PDR, serrated and advanced serrated lesion DR, serrated neoplasia DR, advanced neoplasia DR, CRC DR and adenocarcinoma DR. **Miss rate outcomes** Narrative summary of AMR prioritised for the main report, with more detail and associated figures presented in the DAR supplement. Other outcomes are included in the DAR supplement, including advanced AMR, PMR, SSL miss rate, sessile serrated adenoma/polyp miss rate, neoplasia miss rate and hyperplastic polyp miss rate. **Per colonoscopy/polypectomy outcomes**

Narrative summary of APC, advanced APC and SSL per colonoscopy prioritised for the main report, with more details and associated figures presented in the DAR supplement.

Other outcomes are included in the DAR supplement, including PPC, hyperplastic, diminutive hyperplastic and non-neoplastic polyps per colonoscopy, inflammatory polyps or normal mucosa per colonoscopy, serrated and advanced serrated lesions per colonoscopy, sessile serrated adenomas/polyps per colonoscopy, traditional serrated adenomas per colonoscopy, neoplastic polyps per colonoscopy, submucosal adenocarcinoma per colonoscopy, advanced or invasive carcinoma per colonoscopy, invasive cancer per colonoscopy, advanced colorectal neoplasias per colonoscopy and advanced lesions (adenomas or serrated lesions) per colonoscopy, missed adenomas per colonoscopy, positive percent agreement (percent of adenomas, sessile serrated adenomas and large >10 mm of hyperplastic polyps of proximal colon), adenoma or advanced adenomas detected per polypectomy (therapeutic ratio) and adenomas per positive patient/per extraction.

Size, location, morphology, histology and visibility of lesions

A narrative summary of ADR and APC separated by size categories has been prioritised for the main report, with more details and associated figures presented in the DAR supplement.

Other outcomes are included in the DAR supplement. This included analyses by size for AMR, missed adenomas per colonoscopy, and detection rates of serrated lesions including SSLs and other serrated lesions.

Some data analysed by location were available for ADR, advanced ADR, APC, advanced APC, AMR, missed adenomas per colonoscopy, and detection rates of serrated lesions including SSLs and other serrated lesions, which were included in the DAR supplement.

Some data for analysis by histology in terms of high-grade or low-grade dysplasia were included in the DAR supplement for ADR, APC and missed adenomas per colonoscopy.

Outcomes broken down by morphology and visibility of lesions on first colonoscopy (for AMR outcomes) were not prioritised for analysis (see Section 3.1.5.1).

Diagnostic accuracy, false positives and false negatives

	A narrative summary of data covering diagnostic accuracy, false positives or false negatives for the CADe aspect of technologies was included in the main report, with more details, tables and figures included in the DAR supplement.
Measures of ability to characterise identified polyps	Narrative results for all polyps and all diminutive polyps (≤5 mm) have been included in the main report, with associated tables included in the DAR supplement. Furthermore, narrative results and tables for other categories (including breakdown by location, other size categories, an analysis of SSLs and an analysis based on patients rather than polyps) are included in the DAR supplement given they were less frequently reported.
Measures related to healthcare resource use (such as time to do a colonoscopy, need for repeat colonoscopy to be done, need for a second observer)	A narrative summary of withdrawal time/inspection time and total procedure time was prioritised for the main report, with more details and associated figures presented in the DAR supplement. Other procedural outcomes (such as insertion time or successful insertion) were not deemed useful for analysis.
Time to colonoscopy and impact on waiting lists	No relevant information identified.
Number of polyp removal procedures	Given there are limited data for this outcome, all data have been included in the main report. This includes data from one study on the total number of biopsy procedures performed and the polypectomy rate on a per-patient and per-polyp basis from another study.
Incidences that the technology does not function	All data reporting information that could be considered to reflect a lack of functioning, such as inability to provide a prediction or an unstable prediction, have been included in the main report.
Impact on decision making	A narrative summary of information that could be considered to reflect impact on decision making have been included in the main report, with further detail, tables and figures presented in the DAR supplement. This included data on the impact on estimated surveillance intervals.
Ease of use/acceptability of the	A narrative summary of data relating to this outcome reported in trials has been included in the main report, with more detail and associated figures presented in the

technologies to healthcare professionals	DAR supplement. This includes quantitative data as well as results of surveys completed by endoscopists.
Morbidity (including outcomes related to the colonoscopy procedure and cancer, such as incidence of post-colonoscopy CRC)	A narrative summary of data potentially related to this outcome have been included in the main report, with more detail and associated figures presented in the DAR supplement. Only morbidity data relating to adverse events were identified.
Mortality	No relevant information identified.
Health-related quality of life (including anxiety)	No relevant information identified.
Acceptability of tests to patients	Information from patient surveys identified from the literature, expert input from a patient representative provided to the EAG regarding the use of AI technologies and general concerns about colonoscopy, and a submission from Bowel Cancer UK are included in Section 3.2.2.1.9 of this report.

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CRC, colorectal cancer; DAR, Diagnostic Assessment Report; DR, detection rate; EAG, External Assessment Group; NICE, National Institute for Health and Care Excellence; PDR, polyp detection rate; PMR, polyp miss rate; PPC, polyps per colonoscopy; SSL, sessile serrated lesion.

9.4 Ongoing clinical trials

Table 58. Ongoing clinical trials

Study name - trial number (anticipated completion date)	Study design and PICO	Link
Argus®		
None identified		
CAD EYE®		
TCTR20240710001 (March 2024)	Parallel RCT FIT-positive CRC screening CAD EYE® vs standard HD-WLE ADR and other detection outcomes	https://www.thaiclinicaltrials.org/show/TCTR20240710001
NCT05542030 (September 2024)	Prospective non-randomised Indication for colonoscopy and undergoing EMR for the treatment of lesions suspicious of high-grade dysplasia and early invasive cancer. EMR followed by CAD EYE® vs without CAD EYE® for detection of remaining malignant tissue and on follow-up Lesion recurrence outcomes	https://clinicaltrials.gov/study/NCT05542030
CADLYII - DRKS00030695 (April 2025)	Parallel RCT Patients with Lynch syndrome undergoing CRC surveillance CAD EYE® vs standard HD-WLE ADR and other detection outcomes, diagnostic accuracy for CADx function	https://drks.de/search/en/trial/DRKS00030695
CADLYNCH - NCT05963191 (October 2025)	Parallel RCT Patients with Lynch syndrome undergoing CRC screening CAD EYE® -assisted detection and optical diagnosis vs standard WL colonoscopy with indigo carmin chromoendoscopy ADR and other detection outcomes, diagnostic accuracy for CADx function	https://clinicaltrials.gov/study/NCT05963191
CADDIE™		
EARTHSCAN - NCT05064124 (May 2025)	Prospective non-randomised Screening, surveillance or symptomatic colonoscopy CADDIE™-assisted polyp detection and characterisation vs colonoscopy without CADDIE™ Diagnostic accuracy and other CADx outcomes	https://clinicaltrials.gov/study/NCT05064124
Discovery™		
NCT05734820 (September 2024)	Prospective non-randomised, crossover Screening colonoscopy	https://clinicaltrials.gov/study/NCT05734820

	Discovery™-assisted colonoscopy first vs standard colonoscopy first ADR and other detection outcomes	
NCT05619614 (October 2024)	Prospective non-randomised Diagnostic, screening or surveillance colonoscopy Discovery™-assisted colonoscopy vs standard colonoscopy Focus on endoscopist gaze time outcomes, unclear if will also capture other outcomes such as detection outcomes	https://clinicaltrials.gov/study/NCT05619614?term=NCT05619614&rank=1
Trial name and number unclear (late 2024) Mentioned in manufacturer submission	Study design unclear Population unclear Colonoscopy with vs without Discovery™ ADR and other detection outcomes	Unclear
NCT04777019 (June 2025)	Prospective non-randomised – application of the technology is *ex vivo* to video recordings Scheduled for a regular or screening colonoscopy Discovery™-assisted colonoscopy (no apparent comparator arm) Accuracy of Discovery™ in detection of polyps (limited details)	https://clinicaltrials.gov/study/NCT04777019?term=NCT04777019&rank=1
ENDO-AID™		
EuroCADe - NCT05943288 (March 2025)	Parallel RCT Colonoscopy for primary CRC screening or post-polypectomy surveillance ENDO-AID™ assisted polyp detection vs standard HD-WLE ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT05943288
NCT06786793 (December 2025)	Parallel RCT Undergoing first outpatient colonoscopy ENDO-AID™ assisted polyp detection vs standard colonoscopy ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT06786793?term=NCT06786793&rank=1
ENDOAID-PRO - NCT06251700 (April 2027)	Longitudinal follow-up of RCT (Lau *et al.* 2024) – single-arm study Screening, surveillance or diagnostic colonoscopy Follow-up of those with ENDO-AID™-assisted colonoscopy Post-colonoscopy outcomes such as CRC	https://clinicaltrials.gov/study/NCT06251700
ENDOANGEL®		
NCT06406062 (December 2025)	Prospective non-randomised Diagnostic, screening or follow-up colonoscopy ENDOANGEL®-assisted colonoscopy vs colonoscopy without ENDOANGEL® ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT06406062

ChiCTR2400091641 (December 2025)	Parallel RCT Undergoing colonoscopy screening or physical examination ENDOANGEL®-assisted colonoscopy vs colonoscopy without ENDOANGEL® (and a third group using Eagle Eye technology) ADR and other detection outcomes	https://www.chictr.org.cn/hvshowproject.html?id=262862&v=1.0
EndoScreener®		
None identified		
Endoscopic Multimedia Information System (EMIS™)		
Trial name and number unclear (late 2024) Mentioned in manufacturer submission	Study design unclear – assessed in regular practice Population unclear Colonoscopy with EMIS™, comparator unclear Outcomes unclear	Unclear
GI Genius™		
AIRCOP - NCT06216405 (January 2024)	Parallel RCT Diagnostic colonoscopy Colonoscopy with vs without GI Genius™ for polyp detection Detection outcomes	https://clinicaltrials.gov/study/NCT06216405
GENIAL-CO - NCT04441580 (April 2024)	Parallel RCT Colonoscopy following positive FIT in context of regional mass screening programme Colonoscopy with vs without GI Genius™ for polyp detection ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT04441580
GENIAL-CO FU - NCT06160466 (May 2024)	Parallel RCT Post-colonoscopy surveillance where prior polyps were identified Colonoscopy with vs without GI Genius™ for polyp detection ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT06160466
NCT05500248 (August 2024)	Parallel RCT Elective colonoscopy GI Genius™-assisted colonoscopy for detection and characterisation, comparing leave *in situ* approach with resection of all polyps and histology ADR and diagnostic accuracy outcomes	https://clinicaltrials.gov/study/NCT05500248
CADeNCE - NCT05888623 (September 2024)	Prospective cohort study Colonoscopy Colonoscopy with and without GI Genius™ ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT05888623
COLODETECT 2 - NCT05594576 (November 2024)	Parallel RCT Colonoscopy following positive FIT, diagnostic colonoscopy or surveillance colonoscopy	https://clinicaltrials.gov/study/NCT05594576

	Colonoscopy with GI Genius™ + ENDOCUFF VISION™, GI Genius™ alone or ENDOCUFF VISION™ alone for polyp detection ADR and other detection outcomes	
NCT05322993 (December 2024)	Non-randomised crossover study Outpatient colonoscopy Colonoscopy with and without GI Genius™ PDR and other detection outcomes	https://clinicaltrials.gov/study/NCT05322993
ODDITY - NCT05391477 (December 2024)	Parallel RCT Colonoscopy for screening following positive FIT or for post-polypectomy surveillance GI Genius™ optical diagnosis vs human optical diagnosis Diagnostic accuracy and other CADx outcomes	https://clinicaltrials.gov/study/NCT05391477
NCT05244278 (January 2025)	Parallel RCT Screening, surveillance and diagnostic colonoscopy Colonoscopy with and without GI Genius™ ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT05244278
NCT06654128 (July 2025)	Tandem RCT Patients with Lynch syndrome GI Genius™-assisted colonoscopy vs standard colonoscopy AMR and other outcomes	https://clinicaltrials.gov/study/NCT06654128?term=NCT06654128&rank=1
NCT05754229 (September 2025)	Single-arm study Colonoscopy following positive FIT, post-polypectomy surveillance or diagnostic colonoscopy Colonoscopy with GI Genius™ for polyp detection and characterisation Diagnostic accuracy outcomes for CADx	https://clinicaltrials.gov/study/NCT05754229
NCT06676930 (September 2026)	Parallel RCT Screening or surveillance colonoscopy GI Genius™-assisted colonoscopy vs standard colonoscopy AMR and other outcomes	https://clinicaltrials.gov/study/NCT06676930?term=NCT06676930&rank=1
NCT06173258 (October 2026)	Parallel RCT Primary CRC screening, colonoscopy following positive FIT or post-polypectomy surveillance GI Genius™-supported colonoscopy with water exchange vs water exchange only ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT06173258
NCT06799793 (December 2026)	Parallel RCT Screening colonoscopy in those with positive FIT GI Genius™-assisted colonoscopy vs standard colonoscopy ADR and other outcomes	https://clinicaltrials.gov/study/NCT06799793?term=NCT06799793&rank=1
MAGENTIQ-COLO™		
NCT06568523 (August 2025)	Single-arm trial	https://clinicaltrials.gov/study/NCT06568523?t

	Non-iFOBT screening or surveillance colonoscopy Colonoscopy with use of MAGENTIQ-COLO™ for optical diagnosis Diagnostic accuracy and other CADx outcomes	erm=NCT06568523&rank=1
Mixed trials		
NCT06077435 (June 2025)	Parallel RCT Elective colonoscopy Colonoscopy with CAD EYE®, ENDO-AID™ or GI Genius™ vs colonoscopy without AI ADR and other detection outcomes, CADx outcomes	https://clinicaltrials.gov/study/NCT06077435
NCT06173258 (October 2026)	Parallel RCT Colonoscopy for primary screening, post-polypectomy surveillance or following positive FIT Colonoscopy with CAD EYE®, ENDO-AID™ or another AI system not covered in this review with water exchange compared to water exchange only ADR and other detection outcomes	https://clinicaltrials.gov/study/NCT06173258
jRCT1032230396 (December 2026)	Parallel RCT Colonoscopy (no further details) Colonoscopy with vs without AI technologies (including CAD EYE®, ENDO-AID™ and WISE VISION®) for polyp detection ADR and other detection outcomes	https://jrct.niph.go.jp/latest-detail/jRCT1032230396
NCT06041945 (September 2027)	Parallel RCT Colonoscopy for specific indications (no further details) Colonoscopy with different AI technologies (CAD EYE®, GI Genius™ and WISE VISION®) – compare CADe, CADe/CADx and CADe/CADx with leave *in situ* approach CADe and CADx outcomes	https://clinicaltrials.gov/study/NCT06041945?term=NCT06041945&rank=1

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; AMR, adenoma miss rate; BCSP, Bowel Cancer Screening Programme; CADx, computer-aided characterisation; CRC, colorectal cancer; EMIS™; Endoscopic Multimedia Information System; EMR, endoscopic mucosal resection; FIT, faecal immunochemical test; iFOBT, immunochemical faecal occult blood test; HD-WLE, high-definition white-light endoscopy; PDR, polyp detection rate; PICO, population intervention comparator outcome; RCT, randomised controlled trial.

9.5 Economic evaluation literature review: search strategies

The details of the key search strategies used for electronic databases in the economic evaluation literature review are given in the tables below.

9.5.1 MEDLINE via Ovid – 2 September 2024

Table 59. EAG search strategy for Medline via Ovid – economic review

#	Searches	Results (02/09/2024)
1	Colonoscopy/	32,642
2	Sigmoidoscopy/	4,921
3	Proctoscopy/	2,135
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*).tw,kf.	49,482
5	1 or 2 or 3 or 4	63,983
6	Endoscopy, Gastrointestinal/	21,809
7	endoscop*.tw,kf.	267,767
8	6 or 7	273,161
9	exp intestine, large/	151,942
10	lower gastrointestinal tract/	205
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal).tw,kf.	586,548
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).tw,kf.	32,070
13	9 or 10 or 11 or 12	641,245
14	8 and 13	33,906
15	5 or 14	82,332
16	exp Artificial Intelligence/	206,765
17	exp Machine Learning/	74,585
18	Deep Learning/	22,141
19	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*).tw,kf.	59,199
20	AI.tw,kf.	60,564
21	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning)).tw,kf.	186,045
22	Sentiment Analysis/	213
23	("sentiment analysis" or "opinion mining").tw,kf.	2,061
24	Support Vector Machine/	10,806
25	(vector adj2 machine).tw,kf.	24,475
26	neural networks, computer/	54,691
27	((neural or convolut* or artificial) adj2 network).tw,kf.	84,968
28	(CNN or CNNs or ANN or ANNs).tw,kf.	40,982
29	"neural net".tw,kf.	629
30	Natural Language Processing/	7,090
31	(natural adj2 language adj2 process*).tw,kf.	10,426
32	"large language model".tw,kf.	1,027
33	("cognitive computing" or "computer vision").tw,kf.	10,103

34	Image Processing, Computer-Assisted/	144,802
35	Pattern Recognition, Automated/	26,690
36	Image Interpretation, Computer-Assisted/	48,647
37	Diagnosis, Computer-Assisted/	24,501
38	((computer or machine) adj1 (aid* or base* or assist* or support*)).tw,kf.	80,373
39	"CADe".tw,kf.	450
40	"CADx".tw,kf.	304
41	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40	666,493
42	15 and 41	2,443
43	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener).tw,kf.	92
44	(Discovery and Pentax).tw,kf.	2
45	(Argus or EMIS or Endoscopic Multimedia Information System).tw,kf.	1,621
46	45 and 22	0
47	43 or 44 or 46	94
48	42 or 47	2,484
49	Economics/	27,539
50	exp "Costs and Cost Analysis"/	272,759
51	Economics, Nursing/	4,013
52	Economics, Medical/	9,289
53	Economics, Pharmaceutical/	3,146
54	exp Economics, Hospital/	25,953
55	Economics, Dental/	1,922
56	exp "Fees and Charges"/	31,501
57	exp Budgets/	14,249
58	budget*.ti,ab,kf.	38,594
59	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	300,818
60	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	415,849
61	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	231,069
62	(value adj2 (money or monetary)).ti,ab,kf.	3,256
63	exp models, economic/	16,489
64	economic model*.ab,kf.	4,533

65	markov chains/	16,397
66	markov.ti,ab,kf.	31,368
67	monte carlo method/	33,238
68	monte carlo.ti,ab,kf.	64,161
69	exp Decision Theory/	13,806
70	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	44,633
71	or/49-70	964,579
72	48 and 71	111
Database: Ovid MEDLINE(R) ALL 1946 to August 29, 2024. Search run on 2 September 2024.		

9.5.2 *Embase via Ovid – 2 September 2024*

Table 60. EAG search strategy for Embase via Ovid – economic review

#	Searches	Results (02/09/2024)
1	colonoscopy/	110,761
2	exp polypectomy/	12,429
3	exp endoscopic polypectomy/	3,185
4	sigmoidoscopy/	14,763
5	rectoscopy/	2,952
6	ileocolonoscopy/	1,634
7	(colonoscop* or polypect* or sigmoidoscop* proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*).tw,kf.	92,399
8	1 or 2 or 3 or 4 or 5 or 6 or 7	144,103
9	gastrointestinal endoscopy/	42,785
10	endoscop*.tw,kf.	435,633
11	9 or 10	450,509
12	exp large intestine/	213,228
13	sigmoid/	20,894
14	lower gastrointestinal tract/	911
15	exp rectum/	43,444
16	exp anus/	22,958
17	cecum/	22,293
18	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal).tw,kf.	835,280
19	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).tw,kf.	42,772
20	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19	912,208

21	11 and 20	71,443
22	8 or 21	180,478
23	artificial intelligence/	85,351
24	cognitive technology/	7
25	exp machine learning/	506,911
26	deep learning/	63,059
27	((artificial or machine* or comput* or augment* or amplif*) adj2 intelligen*).tw,kf.	68,524
28	AI.tw,kf.	80,068
29	((machine or deep or transfer* or hierarch* or computer) adj2 (learn* or reasoning)).tw,kf.	215,191
30	sentiment analysis/	880
31	("Sentiment analysis" or "opinion mining").tw,kf.	1,811
32	exp support vector machine/	47,539
33	(vector adj2 machine).tw,kf.	29,350
34	cognitive computing/	42
35	computer vision/	4,551
36	("cognitive computing" or "computer vision").tw,kf.	10,786
37	natural language processing/	13,745
38	(natural adj2 language* adj2 process*).tw,kf.	12,105
39	large language model/	2,072
40	"large language model".tw,kf.	1,037
41	artificial neural network/	59,997
42	convolutional neural network/	34,111
43	((neural or convolut* or artificial) adj2 network*).tw,kf.	142,777
44	(CNN or CNNs or ANN or ANNs).tw,kf.	99,270
45	"neural net".tw,kf.	792
46	computer analysis/	124,820
47	computer assisted diagnosis/	43,341
48	pattern recognition/	37,605
49	((computer or machine) adj1 (aid* or base* or assist* or support*)).tw,kf.	101,328
50	"CADe".tw,kf.	791
51	"CADx".tw,kf.	444
52	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51	996,523
53	22 and 52	4,641
54	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener).tw,kf.	304
55	(Discovery and Pentax).tw,kf.	7

56	(Argus or EMIS or Endoscopic Multimedia Information System).tw,kf.	2,240
57	56 and 22	14
58	54 or 55 or 57	325
59	53 or 58	4,764
60	Economics/	246,487
61	Cost/	64,949
62	exp Health Economics/	1,091,179
63	Budget/	35,096
64	budget*.ti,ab,kf.	50,999
65	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	370,042
66	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	580,314
67	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	317,451
68	(value adj2 (money or monetary)).ti,ab,kf.	4,388
69	Statistical Model/	178,912
70	exp economic model/	4,393
71	economic model*.ab,kf.	6,796
72	Probability/	158,108
73	markov.ti,ab,kf.	41,282
74	monte carlo method/	54,690
75	monte carlo.ti,ab,kf.	67,922
76	Decision Theory/	1,888
77	Decision Tree/	25,682
78	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	59,599
79	or/60-78	2,144,383
80	59 and 79	774
Database: Ovid Embase 1946 to August 30, 2024. Search run on 2 September 2024.		

9.5.3 NHS EED via CRD – 3 September 2024

Table 61. EAG search strategy for NHS EED via CRD – economic review

#	Searches	Results (03/09/2024)
1	MeSH DESCRIPTOR colonoscopy IN NHSEED	140

2	MeSH DESCRIPTOR sigmoidoscopy IN NHSEED	37
3	MeSH DESCRIPTOR proctoscopy IN NHSEED	3
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*) IN NHSEED	241
5	#1 OR #2 OR #3 OR #4	241
6	MeSH DESCRIPTOR endoscopy, gastrointestinal IN NHSEED	60
7	(endoscop*) IN NHSEED	762
8	#6 OR #7	762
9	MeSH DESCRIPTOR intestine, large EXPLODE ALL TREES IN NHSEED	60
10	MeSH DESCRIPTOR lower gastrointestinal tract IN NHSEED	1
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal) IN NHSEED	709
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*) IN NHSEED	27
13	#9 OR #10 OR #11 OR #12	725
14	#8 AND #13	97
15	#5 OR #14	282
16	MeSH DESCRIPTOR artificial intelligence EXPLODE ALL TREES IN NHSEED	100
17	MeSH DESCRIPTOR machine learning EXPLODE ALL TREES IN NHSEED	0
18	MeSH DESCRIPTOR Deep Learning IN NHSEED	0
19	((artificial or machine* or comput* or augment* or amplif*) NEAR intelligen*) IN NHSEED	0
20	(AI) IN NHSEED	66
21	((machine or deep or transfer* or hierarch* or computer) NEAR (learn* or reasoning)) IN NHSEED	1
22	((sentiment analysis) or (opinion mining)) IN NHSEED	0
23	MeSH DESCRIPTOR support vector machine IN NHSEED	0
24	(vector NEAR machine) IN NHSEED	0
25	MeSH DESCRIPTOR neural networks, computer IN NHSEED	0
26	((neural or convolut* or artificial) NEAR network) IN NHSEED	4
27	(CNN or CNNs or ANN or ANNs) IN NHSEED	190
28	(neural net) IN NHSEED	1
29	MeSH DESCRIPTOR natural language processing IN NHSEED	1
30	(natural NEAR language NEAR process*) IN NHSEED	1
31	(large language model) IN NHSEED	0
32	((cognitive computing) OR (computer vision)) IN NHSEED	0
33	MeSH DESCRIPTOR image processing, computer-assisted IN NHSEED	17

34	MeSH DESCRIPTOR pattern recognition, automated IN NHSEED	0
35	MeSH DESCRIPTOR image interpretation, computer-assisted IN NHSEED	3
36	MeSH DESCRIPTOR diagnosis, computer-assisted IN NHSEED	11
37	((computer OR machine) NEAR (aid* or base* or assist* or support*)) IN NHSEED	248
38	(CADe) IN NHSEED	3
39	(CADx) IN NHSEED	0
40	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39	589
41	#15 AND #40	20
42	(GI Genius or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener) IN NHSEED	0
43	(Discovery AND Pentax) IN NHSEED	0
44	(Argus or EMIS or Endoscopic Multimedia Information System) IN NHSEED	1
45	#22 AND #44	0
46	#42 OR #43 OR #45	0
47	#41 OR #46	20
Database: NHS EED via CRD. Search run on 3 September 2024.		

9.5.4 INAHTA – 4 September 2024

Table 62. EAG search strategy for INAHTA – economic review

#	Searches	Results (04/09/2024)
1	"Colonoscopy"[mh]	46
2	"Sigmoidoscopy"[mh]	9
3	"Proctoscopy"[mh]	1
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*)[keywords]	3
5	#1 OR #2 OR #3 OR #4	50
6	"Endoscopy Gastrointestinal"[mh]	60
7	(endoscop*)[keywords]	9
8	#6 OR #7	65
9	"Intestine Large"[mhe]	55

10	"Lower Gastrointestinal Tract"[mh]	1
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal)[keywords]	49
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*).)[keywords]	54
13	#9 OR #10 OR #11 OR #12	157
14	#13 AND #18	5
15	#5 OR #14	53
16	"Artificial Intelligence"[mhe]	121
17	"Machine Learning"[mhe]	4
18	"Deep Learning"[mh]	0
19	("artificial intelligence"~2)[keywords]	8
20	(AI)[keywords]	0
21	("machine learning"~2)[keywords]	0
22	"Sentiment Analysis"[mh]	0
23	("sentiment analysis" or "opinion mining")[keywords]	0
24	"Support Vector Machine"[mh]	0
25	("vector machine"~2)[keywords]	0
26	"Neural Networks Computer"[mh]	0
27	("neural network"~2)[keywords]	0
28	(CNN or CNNs or ANN or ANNs)[keywords]	0
29	("neural net")[keywords]	0
30	"Natural Language Processing"[mh]	0
31	("large language model")[keywords]	0
32	("cognitive computing" or "computer vision")[keywords]	0
33	"Image Processing Computer-Assisted"[mh]	37
34	"Pattern Recognition Automated"[mh]	1
35	"Image Interpretation Computer-Assisted"[mh]	36
36	"Diagnosis, Computer-Assisted"[mh]	43
37	(CADe)[keywords]	0
38	(CADx)[keywords]	0

39	#38 OR #37 OR #36 OR #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16	209
40	#39 AND #15	50
41	("GI Genius" or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener)[keywords]	2
42	(Discovery AND Pentax)[keywords]	0
43	(Argus OR EMIS or "Endoscopic Multimedia Information System")[keywords]	0
44	#43 AND #22	0
45	#41 OR #42 OR #44	2
46	#40 OR #45	52
Database: INAHTA. Search run on 4 September 2024.		

9.5.5 Cochrane library – 5 September 2024

Table 63. EAG search strategy for Cochrane library – economic review

#	Searches	Results (05/09/2024)
1	MeSH descriptor: [Colonoscopy] this term only	2784
2	MeSH descriptor: [Sigmoidoscopy] this term only	368
3	MeSH descriptor: [Proctoscopy] this term only	64
4	(colonoscop* or polypect* or sigmoidoscop* or proctoscop* or coloscop* or ileocolonoscop* or anoscop* or rectoscop* or proctosigmoidoscop*):kw (Word variations have been searched)	6595
5	#1 or #2 or #3 or #4	6595
6	MeSH descriptor: [Endoscopy, Gastrointestinal] this term only	1072
7	(endoscop*):kw	14853
8	#6 OR #7	14853
9	MeSH descriptor: [Intestine, Large] explode all trees	4361
10	MeSH descriptor: [Lower Gastrointestinal Tract] this term only	11
11	(colon or colons or colonic or sigmoid or sigmoids or rectum* or rectal or colorect* or anus or anal or cecum or caecum or cecal or caecal):kw	34579
12	(lower bowel* or lower intestin* or lower gastrointestin* or lower gastro-intestin* or lower GI or large bowel* or large intestin*):kw	971
13	#9 OR #10 OR #11 OR #12	35336
14	#8 AND #13	2168
15	#5 OR #14	7634
16	MeSH descriptor: [Artificial Intelligence] this term only	664

17	MeSH descriptor: [Machine Learning] this term only	622
18	MeSH descriptor: [Deep Learning] this term only	331
19	(artificial NEAR intelligence):kw	1437
20	(AI):kw	597
21	(machine NEAR learning):kw	1914
22	MeSH descriptor: [Sentiment Analysis] this term only	0
23	(vector NEAR machine):kw	417
24	MeSH descriptor: [Neural Networks, Computer] this term only	352
25	(neural NEAR network):kw	756
26	MeSH descriptor: [Natural Language Processing] this term only	73
27	("large language model"):kw	9
28	("cognitive computing" or "computer vision"):kw	47
29	MeSH descriptor: [Image Processing, Computer-Assisted] this term only	2373
30	MeSH descriptor: [Pattern Recognition, Automated] this term only	237
31	MeSH descriptor: [Image Interpretation, Computer-Assisted] this term only	1080
32	MeSH descriptor: [Diagnosis, Computer-Assisted] this term only	809
33	(CADe):kw	0
34	(CADx):kw	0
35	("sentiment analysis" OR "opinion mining"):kw	3
36	MeSH descriptor: [Support Vector Machine] this term only	63
37	(CNN or CNNs or ANN or ANNs):kw	2
38	("neural net"):kw	0
39	182-#38	8958
40	#15 AND #39	191
41	("GI Genius" or GIGenius or ENDO-AID or ENDOAID or WISE VISION or WISEVISION or CAD-EYE or CADEYE or MAGENTIQ or EndoAngel or Endo-Angel or CADDIE or Endoscreener or Endo-screener):kw	1
42	(Discovery AND Pentax):kw	0
43	(Argus OR EMIS or "Endoscopic Multimedia Information System"):kw	0
44	#43 AND #22	0
45	#41 OR #42 Or #44	1
46	#40 OR #45	192
47	MeSH descriptor: [Economics] this term only	59
48	MeSH descriptor: [Costs and Cost Analysis] explode all trees	16658
49	MeSH descriptor: [Economics, Nursing] this term only	14
50	MeSH descriptor: [Economics, Medical] this term only	35
51	MeSH descriptor: [Economics, Pharmaceutical] this term only	139
52	MeSH descriptor: [Economics, Hospital] explode all trees	930

53	MeSH descriptor: [Economics, Dental] this term only	2
54	MeSH descriptor: [Fees and Charges] this term only	69
55	MeSH descriptor: [Budgets] explode all trees	66
56	(budget*):kw	536
57	(cost* NEXT (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)):kw	23600
58	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or (pharmaco NEXT economic*) or expenditure or expenditures or expense or expenses or financial or finance or finances or financed):kw	41037
59	(value NEAR(money OR monetary)):kw	3
60	MeSH descriptor: [Models, Economic] explode all trees	682
61	("economic model"):kw	129
62	MeSH descriptor: [Markov Chains] this term only	586
63	("markov"):kw	1076
64	MeSH descriptor: [Monte Carlo Method] this term only	395
65	("monte carlo"):kw	821
66	MeSH descriptor: [Decision Theory] explode all trees	339
67	(decision NEAR (tree* or analy* or model*)):kw	2380
68	{OR #47-#67}	43689
69	#46 AND #68	5

Database: Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews via Cochrane Library. Search run on 5 September 2024

9.6 Economic evaluation literature review: further details of included studies

Further details of the studies included in the economic SLR (see Section 0) are given in the table below.

Table 64. Economic evaluation SLR: further study details

Study	Health states (if relevant)	Natural history inputs	Cost inputs	HRQoL inputs	Key results
Areia *et al.* 2022[147]	• Colorectal neoplasia; • Low-risk adenoma; • High-risk adenomas; • Localised CRC; • Regional CRC; • Distant CRC; • CRC-related death; • Non-CRC-related death.	Transition probabilities were calibrated against data from the SEER and GLOBOCAN databases.[183, 184]	**AI costs:** The cost for AI technology was calculated based on the average cost available in October 2020. **Other costs:** Costs for procedures, monitoring and CRC treatment were informed by 2018 CMS reimbursement rates.[185]	Utility values were aligned with a previous HRQoL study (Ness *et al.* 1999).[186]	**Incremental LYG:** Not reported **Incremental QALYs:** 0.014 **Incremental cost:** USD –94.00 **Cost-utility:** Colonoscopy with CADe dominant
Barkun *et al.* 2023[151]	• Small adenomas (undiagnosed/diagnosed); • Medium adenomas (undiagnosed/diagnosed); • Large adenomas (undiagnosed/diagnosed); • CRC stage I (undiagnosed/diagnosed\post-treatment); • CRC stage II (undiagnosed/diagnosed/post-treatment);	Transition probabilities were informed by a survival analysis for CRC (Gilard-Pioc *et al.* 2015) and a previous economic evaluation of CRC screening programmes (Coretti *et al.* 2020).[187, 188]	**AI costs:** The cost for AI technology was calculated based on a monthly subscription cost provided by the manufacturer. **Other costs:** Costs for procedures, monitoring and CRC treatment were sourced from Canada-specific cost databases and existing economic analyses.[189-194]	Utility values were aligned with an existing economic model for CRC screening (Coretti *et al.* 2020); utilities for healthy/post-CRC patients were not reported.[188]	**Incremental LYG:** 0.019 **Incremental QALYs:** 0.005 **Incremental cost:** CAD –$13.85 **Cost-utility:** Colonoscopy with CADe dominant

	• CRC stage III (undiagnosed/diagnosed/post-treatment); • Endoscopic polypectomy (tunnel state) • CRC surgery (tunnel state) • Death				
Chin *et al.* 2023[145]	Health states were not used.	Natural history inputs were not required, as only the outcomes of the initial colonoscopy were considered.	**AI costs:** Details of how the cost for GI Genius™ technology was derived were not given. **Other costs:** Procedure revenue was derived based on Singapore Ministry of Health Table of Surgical Procedure codes.	HRQoL was not modelled.	**Net budget impact:** USD $24,000/year; colonoscopy with CADe leads to increased revenue.
Hassan *et al.* 2023[153]	The same health states as Barkun *et al.* 2023 were used (see above).	Natural history inputs were the same as those used in Barkun *et al.* 2023 (see above).	**AI costs:** Cost for AI technology per procedure was calculated assuming three years of software upgrades and support, with 1,500 colonoscopies assumed per year; no source was given for the input cost. **Other costs:** Costs for procedures were based on outpatient tariffs and national diagnosis-related groups tariffs.	Utility inputs for patients with adenomas or CRC were the same as those used in Barkun *et al.* 2023 (see above). Utilities for healthy patients were aligned with general population utility values for Italy.[195]	**Incremental LYG:** 0.02373 **Incremental QALYs:** 0.027 **Incremental cost: –** €14.34 **Cost-utility:** Colonoscopy with CADe dominant

HTW 2024[43]	Health states were not used.	Progression probabilities to HRA and CRC due to missed polyps, and long-term payoffs for each decision tree branch, were sourced from an existing model for CRC screening (MiMiC-Bowel); a similar approach was used in the NICE appraisal for CRC screening using FIT (DG56).[33, 159]	**AI costs:** AI technology costs were estimated from NHS Supply Chain 2024 data, and costs provided by AI technology manufacturers (based on GI Genius™, ENDO-AID™ and Discovery™); frequency of usage was based on data from National Endoscopy Programme. **Other costs:** Other costs were aligned with DG56 or NHS reference costs 2021/22.[33]	Utility values were not directly considered, as long-term QALY payoffs were sourced directly from the MiMiC-Bowel model.[6] Disutilities for complications of colonoscopy were not applied.	**Incremental LYG:** Not reported **Incremental QALYs:** 0.001 **Incremental cost:** £3.00 **Cost-utility:** Colonoscopy with CADe results in increased costs and QALYs. ICER: £4,197/QALY.
Mori *et al.* 2020[146]	Health states were not used.	**Natural history:** Natural history inputs were not required, as only the outcomes of the initial colonoscopy were considered.	**AI costs:** The AI technology cost was only applied in the Japanese context, since EndoBRAIN was unavailable outside Japan at the time of writing. **Other costs:** For the analysis for England, procedure costs were derived from NHS reference costs.	HRQoL was not modelled.	*Results for the UK perspective are presented* **Incremental cost per colonoscopy:** USD $52 **Incremental cost per year:** USD –$12,360,348 **Cost-consequence/ budget impact:** Colonoscopy with CADx results in overall savings, both on the per-patient level and for the whole patient population over a year.
Sekiguchi *et al.* 2023[155]	• Normal epithelium; • Non-advanced polyp (1-4mm);	Transition probabilities were informed by previous	**AI costs:** Rather than considering a single cost	The sources informing utility	**Incremental QALYs:** 0.00094

	• Advanced polyp (5-9mm); • CRC (Duke's stage A); • CRC (Duke's stage B); • CRC (Duke's stage C); • CRC (Duke's stage D); • CRC death; • Non-CRC death.	economic models exploring CRC screening and surveillance in the Japanese population (Sekiguchi *et al.* 2016, Sekiguchi *et al.* 2019).[196, 197]	for the AI technologies, a range of costs was considered. **Other costs:** Procedure costs were sourced from Japanese national reimbursement tables.	values used in the model were not reported.	**Incremental costs:** For AI costs ranging between JPY 1,000-7,000, incremental costs ranged from JPY 746.60-5,443.40. **Cost-utility:** For AI costs ranging between JPY 1,000-7,000, AI led to increased QALYs and increased costs, with ICERs ranging from JPY 796,328-5,806,263/QALY.
Thiruvengadam *et al.* 2023[157]	• Normal colon; • <5mm adenoma; • 5-9mm adenoma; • Advanced adenoma; • Local CRC (with/without symptoms); • Regional CRC (with/without symptoms); • Metastatic CRC (with/without symptoms); • Post-treatment local CRC; • Post-treatment regional CRC; • Death.	Age-specific transition probabilities were developed by calibrating to 1990-1994 SEER data and published polyp prevalence data from the same period.[183] General population mortality was aligned with 2018 CDC USA Life Tables.[198]	**AI costs:** AI costs were informed by expert opinion. **Other costs:** Procedure and CRC care costs were based on 2020 Medicare estimated national average costs obtained from CMS, for patients aged 65+.[199-201] For patients younger than 65, costs were informed by a study of commercial costs for colonoscopy patients aged 50-64 based on the Truven MarketScan Database (Ladabaum *et al.* 2014).[202]	Utility values for localised, regional and distant CRC were obtained from an existing HRQoL study (Ramsey *et al.* 2000).[203] It is unclear what utility values were used for other health states. It is unclear whether disutilities for AEs were applied.	**Incremental QALYs:** 0.01 **Incremental costs:** USD –$143 **Cost-utility:** Colonoscopy with CADe dominant

Thiruvengadam *et al.* 2024[126]	The model used was identical to the model presented in Thiruvengadam *et al.* 2023 (see above).	**T**he same inputs were used as in Thiruvengadam *et al.* 2023 (see above).	**T**he same inputs were used as in Thiruvengadam *et al.* 2023 (see above).	**T**he same inputs were used as in Thiruvengadam *et al.* 2023 (see above).	**Incremental QALYs:** 0.01 **Incremental costs:** USD $203 **Cost-utility:** Colonoscopy with CADe led to increased costs and QALYs, with an ICER of USD $29,300/QALY.

Abbreviations: AE, adverse event; AI, artificial intelligence; CAD, Canadian dollars; CADe, computer-aided detection; CADx, computer-aided diagnosis; CDC, Centers for Disease Control and Prevention; CMS, Centers for Medicare & Medicaid Services; CRC, colorectal cancer; FIT, faecal immunochemical test; HRA, high-risk adenoma; HRQoL, health-related quality of life; HTW, Health Technology Wales; ICER, incremental cost-effectiveness ratio; JPY, Japanese Yen; LYG, life years gained; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year; SEER, Surveillance, Epidemiology and End Results; SLR, systematic literature review; UK, United Kingdom; USA, United States of America; USD, United States dollars.

9.7 Economic evaluation literature review: quality assessment

The quality of the studies included in the economic SLR was assessed using the Drummond checklist,[148] with results presented in Table 65 below.

Please note that one of the studies included in the SLR (Thiruvengadam *et al.* 2024) reports results for alternative efficacy inputs for the same model described in Thiruvengadam *et al.* 2023; no further details on the modelling methodology used. Therefore, Thiruvengadam *et al.* 2024 was not separately assessed for quality.

Table 65. Economic evaluation study quality

Checklist Item	Areia *et al.* 2022	Chin et al.2023	Barkun *et al.* 2023	Hassan *et al.* 2023	HTW 2024	Mori *et al.* 2020	Sekiguchi *et al.* 2023	Thiruvengadam *et al.* 2023
Study design								
1. The research question is stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. The economic importance of the research question is stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. The viewpoint(s) of the analysis are clearly stated and justified.	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4. The rationale for choosing alternative programmes or interventions compared is stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. The alternatives being compared are clearly described.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6. The form of economic evaluation used is stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. The choice of form of economic evaluation is justified in relation to the questions addressed.	No	No	Yes	No	No	No	No	No
Data collection								

8. The source(s) of effectiveness estimates used are stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. Details of the design and results of effectiveness study are given (if based on a single study).	No	Yes	No	Yes	N/A	Yes	No	Yes
10. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies).	No	N/A	No	No	Yes	N/A	No	No
11. The primary outcome measure(s) for the economic evaluation are clearly stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
12. Methods to value benefits are stated.	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
13. Details of the subjects from whom valuations were obtained were given.	N/A	N/A	N/A	N/A	N/A	N/A	No	N/A
14. Productivity changes (if included) are reported separately.	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A
15. The relevance of productivity changes to the study question is discussed.	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A
16. Quantities of resource use are reported separately from their unit costs.	No	Yes	No	No	N/A	N/A	No	No
17. Methods for the estimation of quantities and unit costs are described.	No	No	No	No	Yes	Yes	No	Yes
18. Currency and price data are recorded.	No	No	Yes	Yes	Yes	Yes	Yes	Yes
19. Details of currency of price adjustments for inflation or currency conversion are given.	No	No	No	Yes	Yes	N/A	No	N/A
20. Details of any model used are given.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
21. The choice of model used and the key parameters on which it is based are justified.	No	No	No	No	No	Yes	No	Yes

Analysis and interpretation of results								
22. Time horizon of costs and benefits is stated.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
23. The discount rate(s) is stated.	Yes	N/A	Yes	Yes	Yes	N/A	Yes	Yes
24. The choice of discount rate(s) is justified.	Yes	N/A	Yes	Yes	Yes	N/A	No	Yes
25. An explanation is given if costs and benefits are not discounted.	N/A	N/A	N/A	N/A	N/A	No	N/A	N/A
26. Details of statistical tests and confidence intervals are given for stochastic data.	N/A	Yes	N/A	N/A	N/A	Yes	No	Yes
27. The approach to sensitivity analysis is given.	Yes	N/A	Yes	Yes	Yes	N/A	Yes	Yes
28. The choice of variables for sensitivity analysis is justified.	No	N/A	No	No	Yes	N/A	No	No
29. The ranges over which the variables are varied are justified.	No	N/A	No	No	No	N/A	No	No
30. Relevant alternatives are compared.	Yes	No	Yes	Yes	Yes	No	Yes	Yes
31. Incremental analysis is reported.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
32. Major outcomes are presented in a disaggregated as well as aggregated form.	No	Yes	No	No	No	Yes	No	Yes
33. The answer to the study question is given.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
34. Conclusions follow from the data reported.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
35. Conclusions are accompanied by the appropriate caveats.	Yes	No	Yes	Yes	Yes	No	Yes	Yes

Abbreviations: HTW, Health Technology Wales; N/A, not applicable.

9.8 Economic evaluation model: details of subgroup analyses

Subgroup analyses based on population subgroups were performed for technologies for which an ADR RR could be identified. These subgroup analyses were performed as follows:

- Inputs for the prevalence of each true disease state were informed by data from Turvill *et al.* 2021 for the screening and symptomatic/diagnostic subgroups, as the patient population in Turvill *et al.* 2021 was more closely aligned with these subgroups (input values are given in Table 25 in Section 4.2.1.5);[163]
- Inputs for the prevalence of each true disease state were informed by data from Crispin *et al.* 2013 for the Lynch syndrome surveillance and overall surveillance subgroups, as the patient population in Crispin *et al.* 2013 was more closely aligned with these subgroups (input values are given in Table 25 in Section 4.2.1.5);[164]
- ADR RR input values were selected from trials identified in the clinical SLR or meta-analyses, based on the relevance of the patient population in the trial to the subgroup of interest. It should be noted that Scholer *et al.* 2024 and Gong *et al.* 2020 studies are considered to be at a higher risk of bias and were excluded from the EAG's primary meta-analyses,[2, 75] but have been used to inform the symptomatic/diagnostic subgroup given no other data for CAD EYE® were available for this subgroup;
- Inputs for long-term cost, LYG and QALY payoffs were aligned with screening payoffs for the screening and symptomatic/diagnostic subgroups, and surveillance payoffs for the surveillance and Lynch syndrome subgroups.

A summary of the subgroup analyses carried out, and the relevant ADR RR inputs used to parametrise these scenarios, is given in Table 66.

Table 66. ADR RR inputs for subgroup analyses.

Subgroup	Technology	ADR RR (95% CI)	Source
Screening	CAD EYE®	1.14 (1.07 to 1.21)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
	ENDO-AID™	1.20 (0.89 to 1.63)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
	EndoScreener®	1.16 (0.87 to 1.53)	Glissen Brown *et al.* 2022, whole study[112]

	GI Genius™	1.29 (1.13 to 1.47)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
Symptomatic/diagnostic	CAD EYE®	1.04 (0.76 to 1.41)	Scholer *et al.* 2024, whole study[2]
	Discovery™	1.20 (0.79 to 1.83)	Maas *et al.* 2024a, diagnostic subgroup[104]
	ENDO-AID™	1.28 (1.04 to 1.56)	Lau *et al.* 2024, diagnostic subgroup[107]
	EndoScreener®	1.26 (1.13 to 1.40)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
	GI Genius™	1.32 (1.08 to 1.60)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
Lynch syndrome surveillance	CAD EYE®	1.38 (0.75 to 2.54)	Huneburg *et al.* 2023, whole study[89]
	GI Genius™	0.89 (0.69 to 1.16)	Ortiz *et al.* 2024, whole study[121]
Surveillance	CAD EYE®	1.18 (1.00 to 1.38)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
	Discovery™	1.01 (0.74 to 1.39)	Maas *et al.* 2024a, surveillance subgroup[104]
	ENDO-AID™	1.32 (1.08 to 1.62)	Lau *et al.* 2024, surveillance subgroup[107]
	GI Genius™	1.08 (0.99 to 1.19)	Meta-analysis (see Sections 1.19 and 1.20 of the DAR supplement)
	MAGENTIQ-COLO™	1.23 (0.95 to 1.59)	Maas *et al.* 2024b, surveillance subgroup[136]

Abbreviations: ADR, adenoma detection rate; RR, risk ratio.

9.9 Economic evaluation model: long-term outcomes

As discussed in the main body of this report, the long-term outcomes applied to the decision tree branches for AA and CRC were derived from the MiMiC-Bowel model, an existing economic model which uses a simulation approach to estimate long-term outcomes for patients undergoing screening and surveillance for CRC and related conditions. The input values used in the economic

model in this evaluation were derived from the values used in DG10083, an ongoing evaluation of the PillCam COLON2 technology, which used a similar overall modelling methodology.[159]

This appendix gives a broad overview of the methodology used in the MiMiC-Bowel model, and describes how the input values for long-term outcomes used in this evaluation were generated. The scope of this overview is limited to aspects of the MiMiC-Bowel model that the EAG considers to be directly relevant to the current appraisal. However, directions to more detailed accounts of relevant methodology (for example, original publications or previous NICE appraisals) are also given.

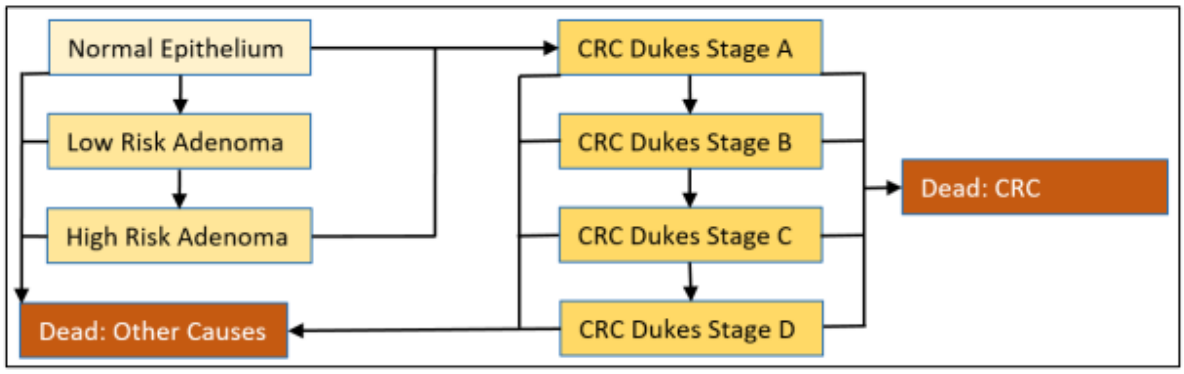
9.9.1 Description of the MiMiC-Bowel model

The MiMiC-Bowel model is an individual patient simulation model developed in R. The model was developed with a UK NHS and PSS perspective, with costs encompassing diagnostic tests for CRC and adenomas (including removal of adenomas), treatment and monitoring for CRC, and palliative care. Health benefits were captured via LYG and total QALYs.

The model functions by generating a representative patient population by Monte Carlo sampling of relevant patient characteristics (namely, baseline age, CRC/adenoma status, and risk factors for CRC). Each generated patient is then simulated moving through a set of health states corresponding to a healthy epithelium, low- or high-risk adenoma, and CRC by Dukes stage. Transitions between health states are modelled on a cyclical basis, with a default cycle length of one year. Transition probabilities are informed by a patient's current health state, age, and several underlying risk factors (including BMI, ethnicity, and family history).

The health states, along with potential transitions, are shown in Figure 19.

Figure 19. Health state transitions in the MiMiC-Bowel model (reproduced from Figure 1, Thomas et *al.* 2020)[6]



At each cycle, patients have an associated probability of undergoing screening or surveillance based on their current health state, as well as other patient characteristics (e.g. age or previous screening results). The model includes functionalities to capture flexible sigmoidoscopy (FS), faecal immunochemical test (FIT), colonoscopy and computerised tomography colonography (CTC). These processes are modelled using decision trees capturing the potential outcomes of the screening or surveillance procedure (e.g. detection and removal of adenomas, or failure to detect adenomas, following a colonoscopy). The outcomes of the screening or surveillance procedures may update the patient's health state (e.g. if a patient with high-risk adenoma undergoes a successful colonoscopy, they may return to the normal epithelium health state).

For each cycle, outcomes including costs and QALYs are calculated. The patient is modelled for the rest of their natural lifetime before progressing to the next patient, with discounting applied at 3.5% per year for costs and QALYs. Total outcomes are then averaged over the patient population.

The individual patient simulation structure of the model allows screening and surveillance procedures to be integrated into the underlying Markov health state structure, and permits tracking of patient history (in particular, future surveillance following positive screening results), without the use of cumbersome tunnel states.

The model was parametrised using values appropriate to the UK context; these were generally derived from existing sources, although transition probabilities between health states were derived by calibrating parameter values to existing data sets capturing the incidence and prevalence of CRC.

Full details of the modelling methodology used in the MiMiC-Bowel model are given in a technical document by the developers of the model.[6] Further details of the calibration process and subsequent cross-validation of the model are provided in a separate discussion paper.[162]

9.9.2 Derivation of long-term payoffs

The long-term payoffs for each branch in the decision tree in the economic model for the current evaluation were derived from the values used in DG10083.[159] In particular, for each potential outcome of the initial decision tree, the long-term QALYs and LYG were aligned with DG10083, while costs were inflated from cost year 2022/2023 to 2023/2024, using the 2023/2024 provisional inflation rate for the NHSCII pay and prices index (4.31%).[174] Costs and QALYs were derived assuming discounting by 3.5% per year, while LYG was not discounted, as this was considered to give more meaningful results.

A summary of the methodologies used to derive the long-term payoffs in DG10083 is given in Table 67; further details are given in the following sub-sections.

Table 67. Summary of sources for long-term outcomes

Decision tree outcome	Source for long-term outcomes	
	Screening population	Surveillance population
No pathology	QALYs and LYG aligned with general population; no further costs assumed (details given in Section 9.9.2.1).	
LRA	QALYs and LYG aligned with general population; no further costs assumed (details given in Section 9.9.2.1).	Analysis of MiMiC-Bowel model (details given in Section 9.9.2.2).
LRA (delayed diagnosis)	As for LRA, but with additional QALY and LYG decrement, and additional costs for delayed diagnosis (details given in Section 9.9.2.3).	Analysis of MiMiC-Bowel model (details given in Section 9.9.2.2).
AA	QALYs and LYG aligned with general population; no further costs assumed (details given in Section 9.9.2.1).	Analysis of MiMiC-Bowel model (details given in Section 9.9.2.2).
AA (delayed diagnosis)	Analysis of MiMiC-Bowel model (details given in Section 9.9.2.2).	
IBD	LYG aligned with general population; QALYs and costs aligned for patients with UC and CD (details given in Section 9.9.2.4).	
IBD (delayed diagnosis)	As for IBD, with additional QALY decrement and costs for increased risk of complications due to delayed diagnosis (details given in Section 9.9.2.4).	
CRC	Analysis of MiMiC-Bowel model (details given in Section 9.9.2.2).	
CRC (delayed diagnosis)	Analysis of MiMiC-Bowel model (details given in Section 9.9.2.2).	

Abbreviations: AA, advanced adenoma; CRC, colorectal cancer; IBD, inflammatory bowel disease; LRA, low-risk adenoma; LYG, life years gained; QALY, quality-adjusted life year.

9.9.2.1 General population QALYs and LYG

General population LYG was informed by the 2017-2019 Office for National Statistics (ONS) life tables for England, while general population QALYs were informed by general population utility values sourced from Hernández Alava *et al.* 2022.[160, 161] These values were used for all patients with no pathology at baseline, and for patients with LRA and AA diagnosed without delay, as it would be expected that these patients would not have a long-term difference in health outcomes compared to the general population.

9.9.2.2 Long-term outcomes derived from the MiMiC-Bowel model

To derive long-term outcomes for patients with LRA, AA and CRC, the MiMiC-Bowel model with initial patient characteristics adjusted to align with the relevant branch. For patients diagnosed

without delay, it was assumed that patients with LRA and AA would be treated immediately, and were therefore assigned to the healthy epithelium health state at baseline, but with a requirement for follow-up surveillance. For patients with CRC, patients were assumed to be split equally between the Dukes Stage A and Stage B health states at baseline. Different outcomes were generated for the screening and surveillance populations, due to differing follow-up requirements.

To derive long-term outcomes for patients with LRA, AA and CRC with a delayed diagnosis, it was assumed that patients with LRA and AA would initially occupy the corresponding health state in the MiMiC-Bowel model, while patients with CRC were assumed to be split equally between the Dukes Stage A and Stage B health states. The transition probabilities from the MiMiC-Bowel model were then used to derive the expected distribution of patients at the time of correct (delayed) diagnosis, assuming a delay of 78 weeks (1.5 years), informed by clinical expert opinion; the delay was assumed to be the same regardless of the patient's true underlying condition. Using this updated initial distribution of patients between health states, the MiMiC-Bowel model was then run as if a correct diagnosis had been made and appropriate treatments received.

The same methodology was used to generate delayed diagnosis penalties in DG56; a more detailed account of the methodology used to derive the delayed diagnosis payoffs is given in Appendix 12 of the EAG report for DG56.[33]

9.9.2.3 Long-term outcomes for patients with LRA (delayed diagnosis)

Long-term outcomes for patients with a delayed diagnosis of LRA in the screening population were not available from the MiMiC-Bowel model. Therefore, the long-term outcomes for this population were calculated by applying cost, survival and QALY penalties for delayed diagnosis to the long-term outcomes for the general population (which were themselves used to calculate long-term outcomes for patients diagnosed with LRA without delay). The penalties were calculated by assuming that the ratio of the delayed diagnosis penalties of LRA to AA in the screening population was the same as in the surveillance population. The outcomes for delayed diagnosis for LRA in the screening population were therefore calculated as follows:

$$O_d(LRA, screening) = O(LRA, screening) - [O\ (AA, screening) - O_d(AA, screening)] \times \frac{O(LRA\ , surveillance) - O_d(LRA, surveillance)}{O(AA, surveillance) - O_d(AA, surveillance)}$$

Where O is the outcome of interest for patients diagnosed without delay, and O_d is the same outcome for patients diagnosed with delay.

9.9.2.4 Long-term payoffs for patients with IBD

Long-term payoffs for patients with IBD were calculated using the approach used in DG56. Patients with IBD diagnosed with no delay were assumed to enter a simple state transition model with only 'alive' and 'dead' health states. Movement between health states was parametrised using general population mortality. It was assumed that 40% of patients have Crohn's disease (CD) and 60% of patients have ulcerative colitis (UC), informed by a population-based cohort study of the incidence and prevalence of IBD in UK primary care (Pasvol *et al.* 2020).[204] Patients accrued costs and utilities appropriate for these conditions while in the 'alive' health state.

Informed by a UK costing study of IBD (Ghosh *et al.* 2015), at any given time, 50% of patients with UC were assumed to be in remission, 40% were assumed to be in mild-moderate relapse, and 10% were assumed to be in severe relapse.[205] Similarly, at any given time, 50% of patients with CD were assumed to be in remission and 50% were assumed to be in relapse.[205] Utility values for patients with IBD were derived from TA856 (Upadacitinib for treating moderately to severely active ulcerative colitis) and TA342 (Vedolizumab for treating moderately to severely active ulcerative colitis), with an overall weighted utility value applied in the state transition model based on the proportion of patients with UC and CD described above, as well as the proportion of patients with each level of disease severity.[206, 207] Costs per year were derived from Ghosh *et al.* 2015, uplifted to the appropriate cost year using the NHSCII pay and prices index; similarly to utility values, an overall weighted cost per year was derived based on the split of patients between UC and CD, and the proportion of patients with each level of disease severity.[174, 205]

Long-term payoffs for patients with IBD diagnosed with a delay were calculated in the same way; however, a multiplier was applied to the utility value in the first two cycles (i.e. assuming diagnosis and treatment occur two years after the initial misdiagnosis) to reflect the higher probability of complications associated with IBD prior to diagnosis and treatment. This multiplier was derived from a study of EQ-5D scores in patients with IBD (Stark *et al.* 2009).[208]

A more detailed account of the methodology used to derive the long-term IBD outcomes is given in the EAG report for DG56.[33]

9.10 Economic evaluation model: implementation of scenario analyses exploring alternative polyp management strategies

The base case of the economic model assumed a resect-all polyp management strategy, in line with current UK clinical practice; however, alternative approaches, including 'diagnose-and-leave' and 'resect-and-discard' strategies have also been proposed. These strategies were explored in scenario analyses as follows:

- Both strategies were modelled comparing conventional colonoscopy without AI technologies with each AI with a CADe component. In this analysis, the diagnostic effectiveness inputs (sensitivity and specificity) were assumed to be the same between the intervention and comparator, since in both cases diagnosis would be performed by the endoscopist, but the overall outcomes differed due to the variation in the number of polyps detected. The EAG notes that a key input value could not be identified for the EMIS™ technology to implement these scenarios (i.e., mean difference in APC for colonoscopy with EMIS™ compared with colonoscopy without EMIS™); to facilitate these scenarios, a value of 0 was assumed for this input, but these analyses should be considered to be exploratory.
- Both strategies were modelled by comparing conventional colonoscopy without AI technologies with each AI with a CADx component. These analyses were carried out for technologies with available CADx efficacy data (CAD EYE® and GI Genius™; Discovery™ was excluded from the analysis since only CADx technology for patients with ulcerative colitis was available, and MAGENTIQ-COLO™ was excluded as no CADx data for MAGENTIQ-COLO™ were identified). For these analyses, it was assumed that the CADe functionality of the AI technologies would be used alongside the CADx functionality. The EAG considers these analyses to be exploratory in nature, given the limited availability of trial data (see Section 3.2.2.1.2 of this report, and Section 1.13 of the DAR supplement for further details).

Descriptions of how these analyses were implemented in the model are given in the following sections.

9.10.1 Diagnose-and-leave

To apply this scenario, it was assumed that patients correctly diagnosed with no underlying pathology would not undergo a therapeutic colonoscopy, thereby reducing the associated costs. The proportion of patients with no underlying pathology to whom this was relevant was determined by multiplying the non-neoplastic detection rate of the technology by the probability that all polyps were correctly diagnosed as non-adenomatous.

One scenario was considered in which all polyps diagnosed as non-neoplastic were left *in situ,* regardless of the level of confidence in the diagnosis. In this case, the probability of all polyps being correctly diagnosed was calculated as follows:

$$Probability\ (correct\ diagnosis, all\ adenomas) = specificity^{PPC}$$

Here, PPC refers to the polyps identified per colonoscopy for the relevant technology, and specificity refers to the probability that a non-adenomatous polyp is correctly diagnosed as such.

The EAG notes that diagnoses made both by endoscopists and CADx vary in their associated level of confidence (e.g., diagnoses of polyps with clearly defined morphology are more likely to be considered high-confidence). Therefore, where data were available, a separate scenario was also considered, in which only polyps with a diagnosis that was considered to be high-confidence were left *in situ*. In this case, the probability that all polyps were correctly diagnosed as non-adenomatous with high confidence was calculated as follows:

$$\begin{aligned} &Probability\ (correct\ diagnosis, all\ adenomas) \\ &\qquad = [probability\ (correct\ diagnosis\ for\ one\ adenoma)]^{APC} \\ &= [1 - probability(incorrect\ diagnosis\ for\ one\ adenoma)]^{APC} \\ &= [1 - probability\ (high\ confidence) \times (1 - specificity)]^{APC} \end{aligned}$$

Here, probability (high confidence) refers to the probability that an individual polyp is diagnosed with high confidence, and specificity refers to the probability that a non-adenomatous polyp is correctly diagnosed as such given that the diagnosis was considered high-confidence.

However, a proportion of patients with LRA or AA present and detected may have adenomas missed due to incorrect diagnosis. The proportion of patients with a correct diagnosis (i.e., no adenomas missed) was calculated as follows:

$$Probability\ (correct\ diagnosis, all\ adenomas) = (sensitivity)^{APC}$$

Here, sensitivity refers to the probability that an adenomatous polyp is correctly diagnosed as such. In the second scenario in which only polyps diagnosed with high confidence were left *in situ*, the proportion of patients with a correct diagnosis was calculated as follows:

$$Probability\ (correct\ diagnosis, all\ adenomas) = [1 - probability\ (high\ confidence) \times (1 - sensitivity|high\ confidence)]^{APC}$$

Here, sensitivity|high confidence refers to the probability that an adenomatous polyp is correctly diagnosed as such given that the diagnosis was considered high-confidence.

No data were identified for sensitivity and specificity for advanced or low-risk polyps alone; therefore, the same sensitivity and specificity were assumed for LRA and AA disease states. Likewise, the proportion of low-confidence diagnoses was not generally reported separately for hyperplastic polyps, LRA and AA, so it was assumed that this proportion would be the same across disease states.

For the comparator and interventions without a CADx element, inputs were informed by analyses of VCE technology effectiveness carried out as part of the NICE diagnostic assessment of VCE technologies as an adjunct to colonoscopy (DG28).[39] The EAG considers that this approach is reasonable, since clinical experts at the scoping workshop for this project stated that VCE technologies would be commonly used for diagnostic purposes in UK clinical practice. PPC and APC for AI technologies were informed by applying the APC IRR informed by the clinical SLR and meta-analyses (Section 3.2.2.1.1.8) to the baseline PPC or APC of the comparator technology. For modelling CADx functionalities, inputs were informed by a relevant trial identified in the clinical SLR (Section 1.13 of the DAR supplement); data for the adjunct use of AI technologies alongside colonoscopy were prioritised over autonomous AI classification.

Full details of the parameter values used to parametrise this scenario are given in Table 68 below.

9.10.2 Resect-and-discard

This scenario was implemented in order to align as far as possible with the strategy which is currently being rolled out in the BCSP. To apply this scenario, it was assumed that a proportion of histopathological testing costs for patients with underlying LRA or AA with adenomas detected and diagnosed would be avoided, corresponding to the proportion of polyps diagnosed with high confidence. This is a slight simplification of the BCSP strategy, which recommends that resect-and-discard is only applied to polyps which are diminutive (≤5 mm), since the EAG were unable to identify data on the proportion of polyps which meet this definition.

Polyps not diagnosed with high confidence were assumed to incur histopathological testing costs. Since the NHS reference costs for colonoscopy include the costs related to histopathological testing, the expected therapeutic colonoscopy cost for each technology in this scenario was therefore reduced by the histopathological testing cost multiplied by the expected number of histopathological tests avoided due to high-confidence diagnoses of diminutive polyps.

The expected number of histopathological tests avoided was calculated by multiplying the PPC by the proportion of polyps diagnosed with high confidence for a given technology.

Therefore, the overall histopathological testing costs avoided were calculated as follows:

$$Histopathology\ costs\ avoided = PPC \times probability\ (high\ confidence) \times cost\ per\ histopathological\ test$$

This cost avoided was applied to all patients expected to undergo a therapeutic colonoscopy (i.e. patients with no pathology undergoing unnecessary polyp removal, and patients with LRA or AA pathology).

Of patients diagnosed with high confidence, it was assumed that a proportion of patients would be diagnosed incorrectly; for this scenario, it was assumed that misdiagnosis would result in an adenoma being miscategorised as non-adenomatous. However, since the adenoma would be removed, these patients would not incur the downstream cost and QALY penalties for delayed diagnosis.

All input values required for this scenario are given in Table 68.

9.10.3 Input values

The input values required for the polyp management scenarios described are given in Table 68 below. For accuracy inputs for CADx technologies, data based on trials in which the technology was used as an adjunct to standard colonoscopy were prioritised.

For the Argus® technology only the mean APC was reported; therefore, in the economic model, confidence intervals were derived assuming a standard error of 10% of the mean value, in line with other model inputs for which SEs or confidence intervals were not available.

Table 68. Input values for alternative polyp management scenarios

Input	Technology	Value (95% CI, where available)	Source
PPC (no underlying pathology)	Colonoscopy without CADx	1.4	Raju *et al.* 2013, total non-neoplastic polyps/total patients with polyps.[209]
APC	Colonoscopy without CADx	LRA: 1.9 (1.7 to 2.1) AA: 4.2 (2.2 to 6.2)	Raju *et al.* 2013, APC (LRA: for all patients positive for precancerous lesions, AA: for patients with advanced adenomas).[209]
APC mean difference compared with colonoscopy without CADx	Argus®	0.107	Strapko *et al.* 2023 (reported in the instructions for use document for the Argus® technology)[67]
	CAD EYE®	0.24 (0.16 to 0.31)	Clinical SLR and meta-analysis (Section 3.2.2.1.1.8).
	Discovery™	0.00 (-0.19 to 0.19)	Maas *et al.* 2024a[104]
	EMIS™	0.00	Assumption
	ENDO-AID™	0.45 (0.39 to 0.52)	Clinical SLR and meta-analyses (Section 3.2.2.1.1.8).
	EndoScreener®	0.29 (-0.18 to 0.76)	Glissen Brown *et al.* 2022[112]
	GI Genius™	0.23 (0.17 to 0.30)	Clinical SLR and meta-analyses (Section 3.2.2.1.1.8).
	MAGENTIQ-COLO™	0.19 (0.04 to 0.34)	Maas *et al.* 2024b[136]

Sensitivity, all diagnoses	Colonoscopy without CADx	0.88 (0.83 to 0.92)	DG28, NBI effectiveness (p 124, Technology Assessment Report).[39]
	CAD EYE®	*0.943 (0.911 to 0.967)*	*Sato et al. 2024*[97]
	GI Genius™	*0.800 (0.737 to 0.853)*	*Hassan et al. 2022.*[132]
Specificity, all diagnoses	Colonoscopy without CADx	0.81 (0.75 to 0.85)	DG28, NBI effectiveness (p 124, Technology Assessment Report).[39]
	CAD EYE®	*0.713 (0.600 to 0.808)*	*Sato et al. 2024*[97]
	GI Genius™	*0.931 (0.898 to 0.956)*	*Hassan et al. 2022.*[132]
Proportion diagnoses which are not high-confidence	Colonoscopy without CADx	0.214 (0.21 to 0.22)	DG28, NBI effectiveness (p 160, Technology Assessment Report).[39]
	CAD EYE®	0.077 (0.057 to 0.102)	*Rondonotti et al. 2023.*[96]
	GI Genius™	0.078 (0.054 to 0.010)	*Hassan et al. 2022 (note, 95% CI derived from mean value and sample size using normal approximation).*[132]
Sensitivity, high-confidence diagnoses	Colonoscopy without CADx	0.91 (0.85 to 0.95)	DG28, NBI effectiveness (p 124, Technology Assessment Report).[39]
	CAD EYE®	0.886 (0.837 to 0.914)	*Rondonotti et al. 2023.*[96]
	GI Genius™	0.820 (0.751 to 0.876)	*Hassan et al. 2022.*[132]
Specificity, high-confidence diagnoses	Colonoscopy without CADx	0.82 (0.76 to 0.87)	DG28, NBI effectiveness (p 124, Technology Assessment Report).[39]
	CAD EYE®	0.881 (0.839 to 0.914)	*Rondonotti et al. 2023.*[96]
	GI Genius™	0.944 (0.912 to 0.967)	*Hassan et al. 2022.*[132]
Cost for histopathological testing	All technologies	£8.00	NHS reference costs (2023/24), DAPS02 – Histopathology and histology[171]

Footnotes: input values in *italics* were used only for exploratory analyses.

Abbreviations: AA, advanced adenoma; APC, adenomas per colonoscopy; CADx, computer-aided diagnosis; CI, confidence interval; CSR, clinical study report; IRR, incidence rate ratio; LRA, low-risk adenoma; NBI, narrow band imaging; PPC, polyps per colonoscopy; SLR, systematic literature review.

9.11 Economic evaluation model: external validation

The model was validated by comparing key results to existing cost-effectiveness analyses of AI technologies identified in the SLR (see Section 0 for further details). In general, only the total and

incremental QALYs and LYG could be meaningfully compared, as the majority of existing studies were conducted in countries other than the UK. However, a comparison of costs is also conducted with the HTW 2024 appraisal, which was conducted in a UK context.

A summary of the results compared for colonoscopy without AI is given in Table 69. A summary of incremental results for AI technologies in this study compared to other existing studies is given in Table 70. In general, the total LYG and QALYs for patients undergoing colonoscopy without AI were slightly smaller in this study than results reported in other studies; this variation is likely attributable to the varying contexts of these studies (including the age at baseline, which is likely to vary between studies due to the differing country contexts). Similarly, the incremental LYG and QALYs for colonoscopy with AI compared to colonoscopy without AI for this study were generally smaller than results noted in other studies, although the incremental QALY results were in the same order of magnitude as the Barkun *et al.* 2023 and HTW 2024 analyses, and considerably larger than the results for Sekiguchi *et al.* 2023. [43, 151, 155] Since the range of results across different analyses was so wide, the EAG considers that the results of this study are not incoherent with the existing literature. Similarly, the incremental costs for this study were generally negative, compared to the one identified existing study, which reported an incremental cost (the HTW 2024 appraisal); however, this is not a major concern since the absolute differences in cost were extremely small in all cases. Furthermore, the HTW 2024 appraisal was based on a nonspecific CADe technology with costing for the technology based on assumptions, and so a slightly different incremental cost result is to be expected.[43]

Table 69. Comparison of results: colonoscopy without AI

Study	Total LYG (undiscounted)	Total QALYs
This study	14.061	10.981
Areia *et al.* 2022[147]	31.443	19.410
Barkun *et al.* 2023[151]	19.125*	17.113
Sekiguchi *et al.* 2023[155]	NR	20.40883
Thiruvengadam *et al.* 2023[157]	NR	21.72
Thiruvengadam *et al.* 2024[126]	NR	21.74

Footnotes: *Discounted results

Abbreviations: LYG, life years gained; NR, not reported; QALY, quality-adjusted life year.

Table 70. Comparison of results: colonoscopy with AI vs colonoscopy without AI

Study	Intervention	Incremental LYG (undiscounted)	Incremental QALYs	Incremental cost
This study	Argus®	0.003	0.004	-£43.81
	CAD EYE®	0.006	0.005	-£61.80
	Discovery™	0.000	0.001	£8.70
	EMIS™	0.002	0.002	-£12.96
	ENDO-AID™	0.002	0.004	-£73.23
	EndoScreener®	0.007	0.006	-£89.10
	GI Genius™	0.004	0.002	-£45.16
	MAGENTIQ-COLO™	0.007	0.006	-£90.26
Areia *et al.* 2022[147]	Nonspecific CADe	0.265	0.014	N/A
Barkun *et al.* 2023[151]	GI Genius™	0.019*	0.005	N/A
Hassan *et al.* 2023[153]	GI Genius™	0.02373*	0.027	N/A
HTW 2024[43]	Nonspecific CADe	NR	0.001	£3.00
Sekiguchi *et al.* 2023[155]	Nonspecific CADe	NR	0.00094	N/A
Thiruvengadam *et al.* 2023[157]	Nonspecific CADe	NR	0.01	N/A
Thiruvengadam *et al.* 2024[126]	GI Genius™	NR	0.01	N/A

Footnotes: *Discounted results

Abbreviations: CADe, computer-aided detection; LYG, life years gained; N/A, not applicable; NR, not reported; QALY, quality-adjusted life year.

Total costs, QALYs and LYG for the colonoscopy-only arm were also compared against the results of DG10083. The results of this comparison are shown in Table 71. The results of this study are relatively closely aligned with the results reported in DG10083, with the outcomes for the base case of study generally lying between the results for the symptomatic and surveillance populations in DG10083; this is as expected, given that the base case in this study used a mixture of symptomatic and surveillance populations.[159]

Table 71. Comparison of results for colonoscopy without AI with DG10083

Study	Total LYG (undiscounted)	Total QALYs	Total costs
This study	14.06	10.981	£3,172

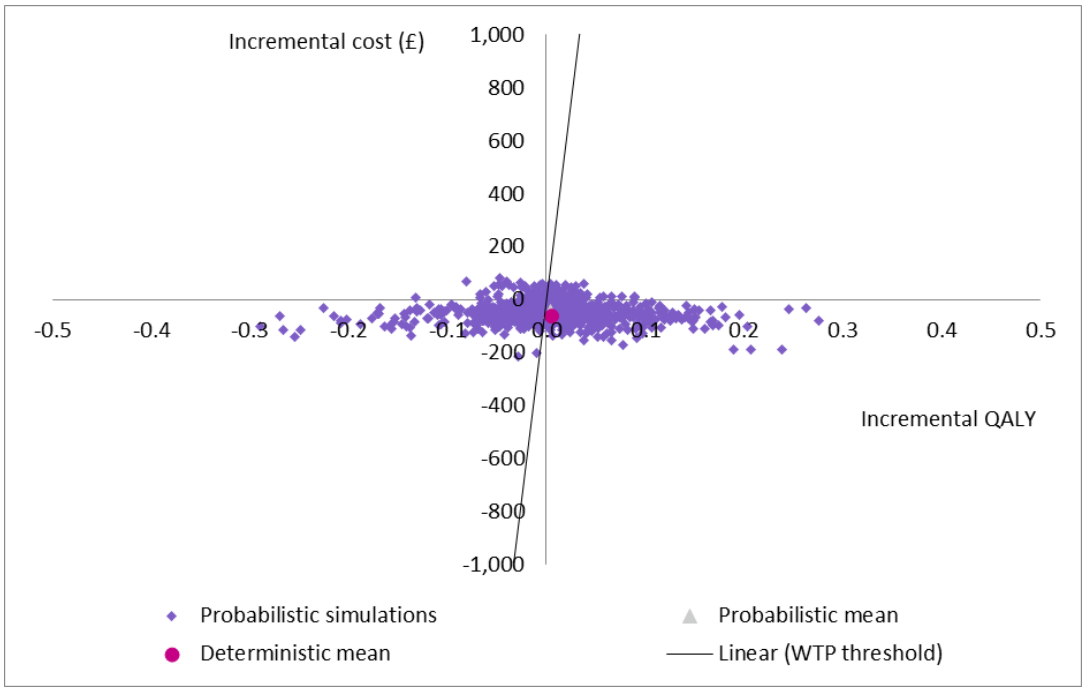
DG10083(symptomatic patients, FIT 10-100µg/g, COL-eligible) [159]	14.52	11.352	£5,090
DG10083(symptomatic patients, FIT <10µg/g, COL-eligible) [159]	14.60	11.469	£2,283
DG10083(surveillance population, COL-eligible) [159]	14.01	10.888	£2,028

Abbreviations: LYG, life years gained; QALY, quality-adjusted life year.

9.12 Economic evaluation model: additional results

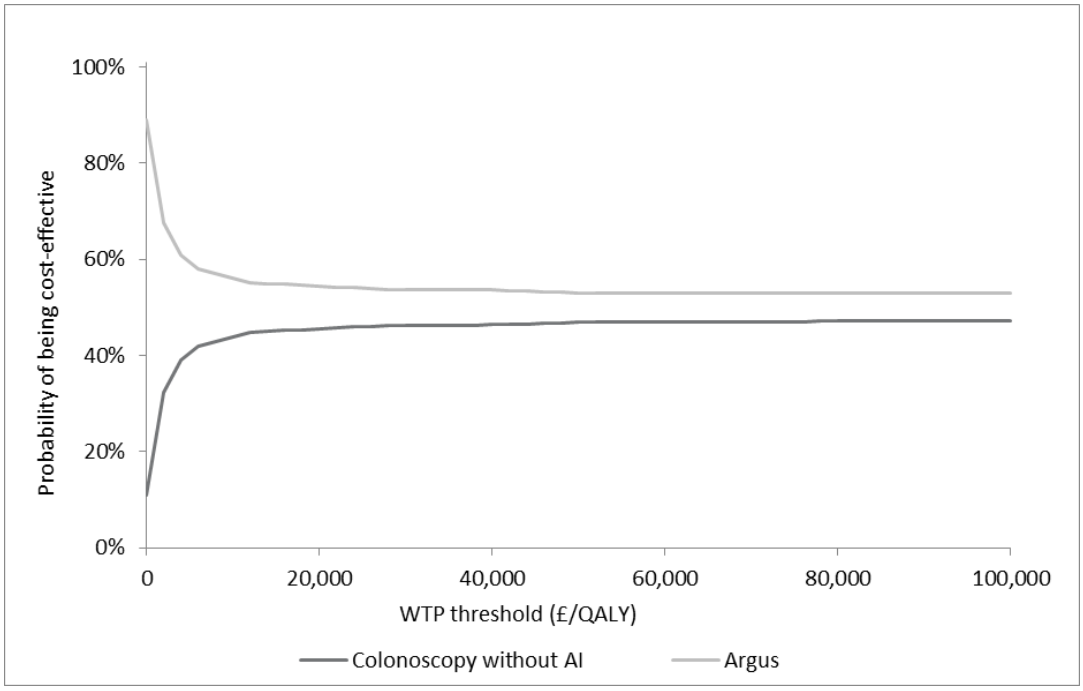
9.12.1 Additional probabilistic analysis results

Figure 20. Argus® vs colonoscopy without AI cost-effectiveness plane



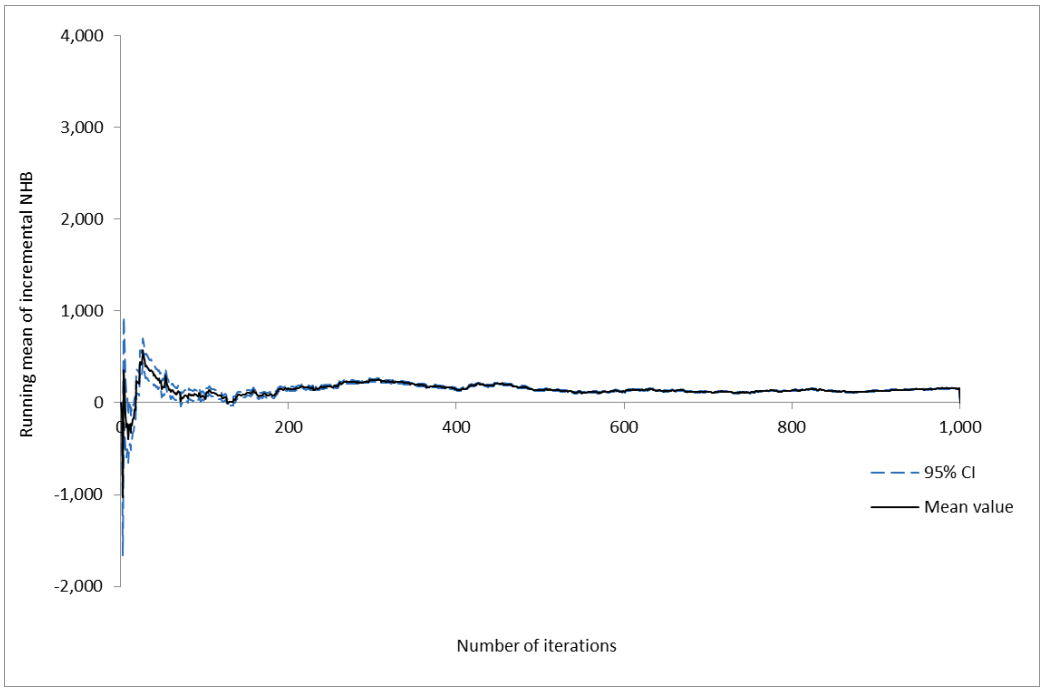
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 21. Argus® vs colonoscopy without AI CEAC



Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 22. Argus® vs colonoscopy without AI incremental NHB convergence plot

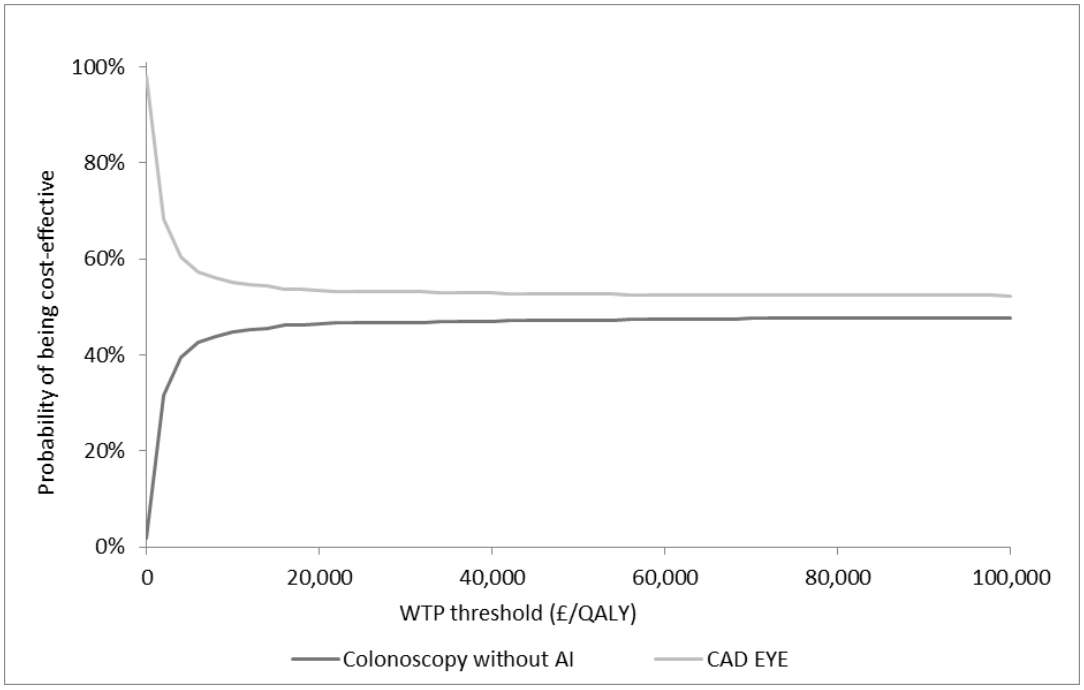


Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 23. CAD EYE® vs colonoscopy without AI cost-effectiveness plane

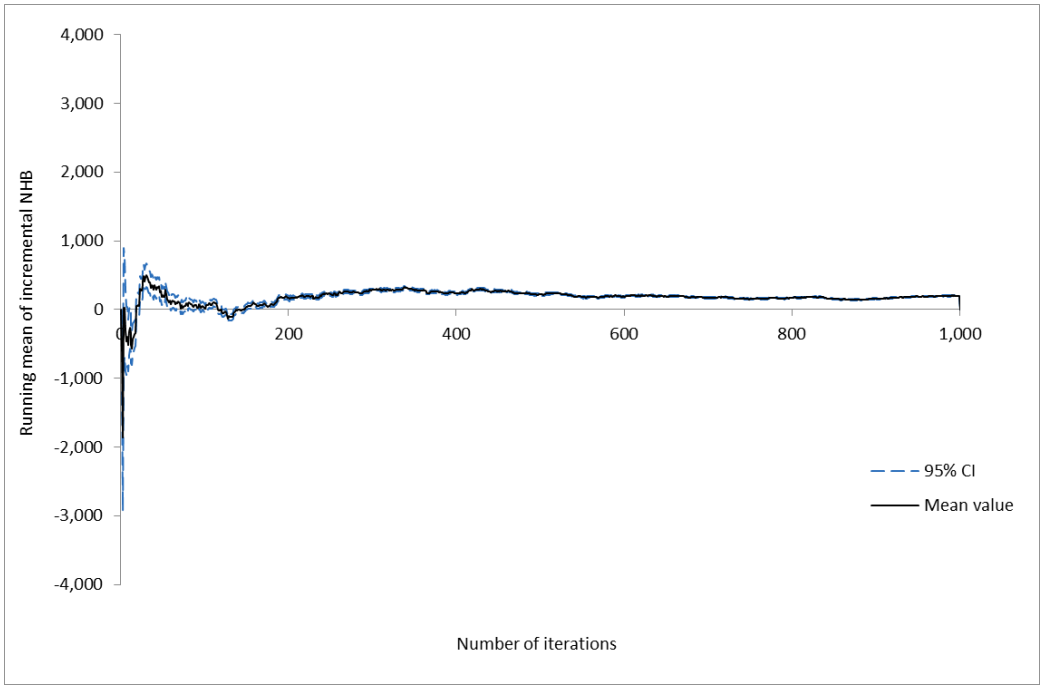
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 24. CAD EYE® vs colonoscopy without AI CEAC



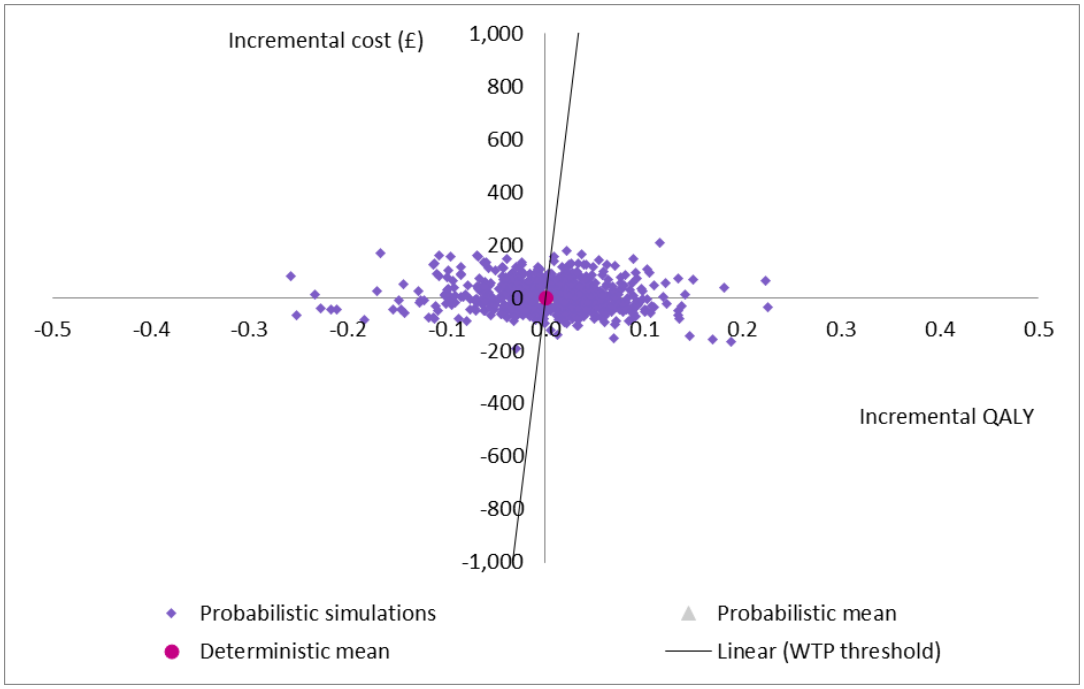
Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 25. CAD EYE® vs colonoscopy without AI incremental NHB convergence plot



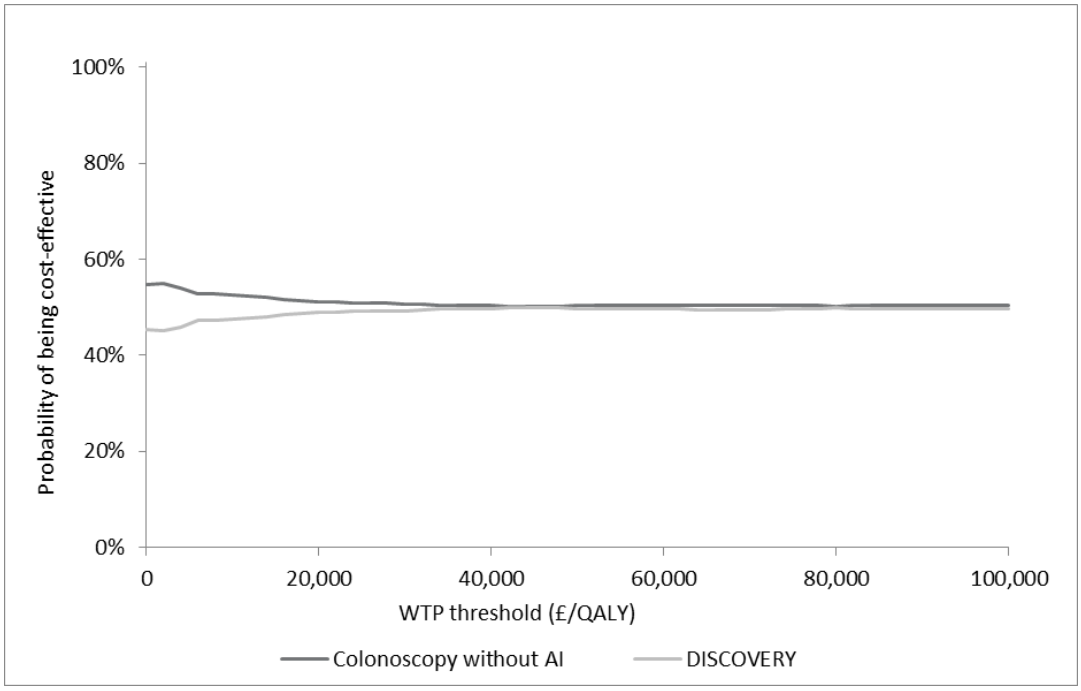
Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 26. Discovery™ vs colonoscopy without AI cost-effectiveness plane



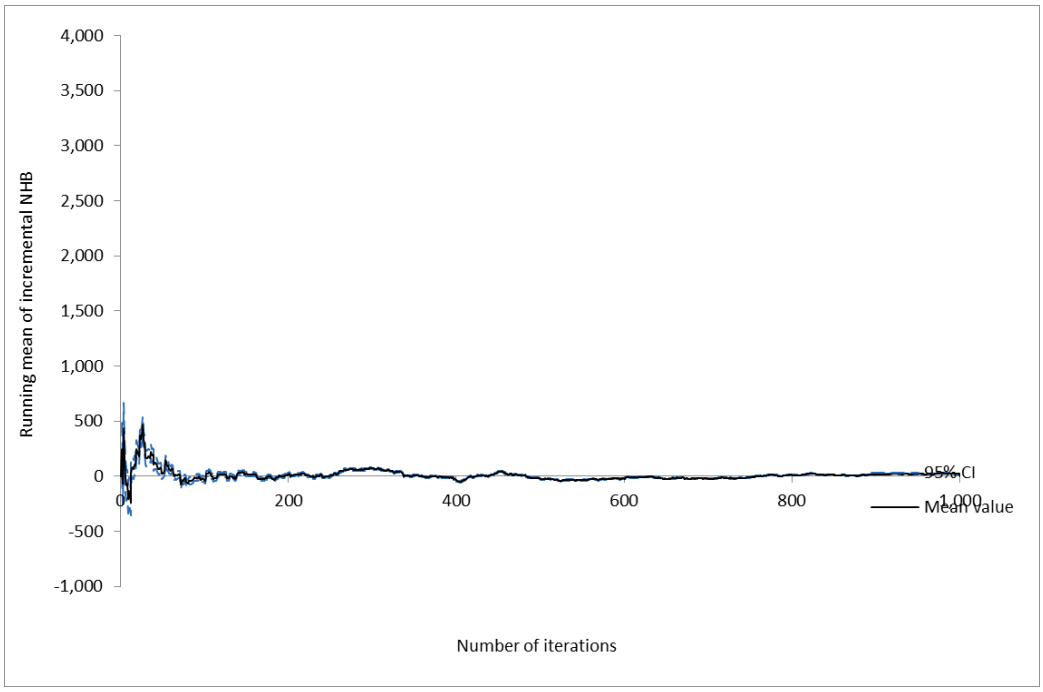
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 27. Discovery™ vs colonoscopy without AI CEAC



Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 28. Discovery™ vs colonoscopy without AI incremental NHB convergence plot

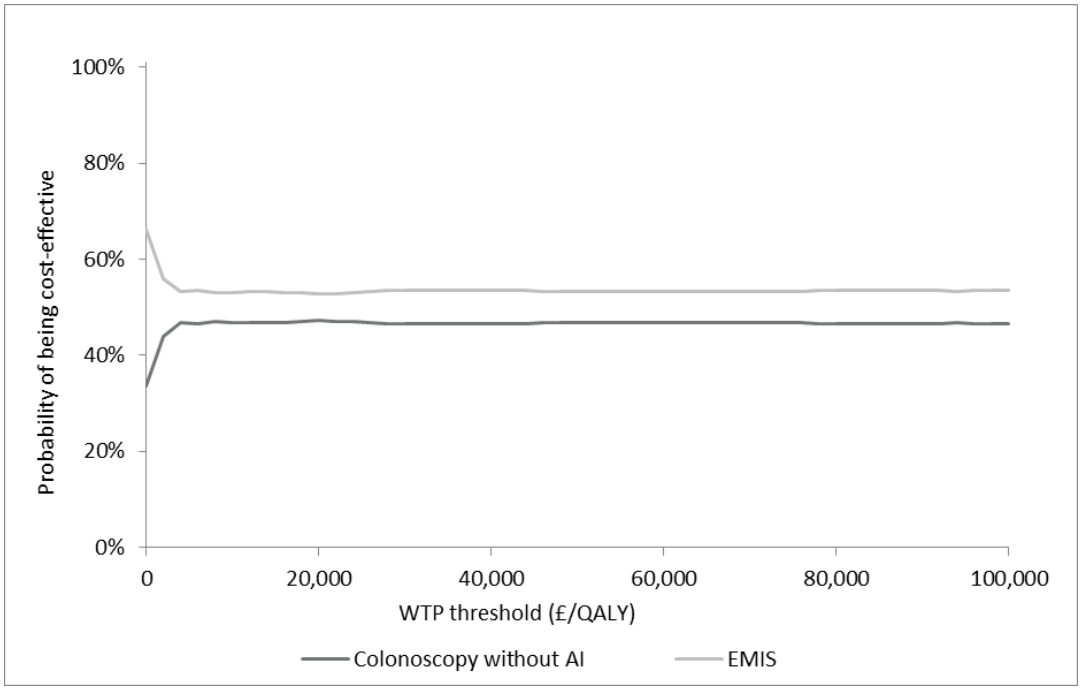


Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 29.EMIS™ vs colonoscopy without AI cost-effectiveness plane

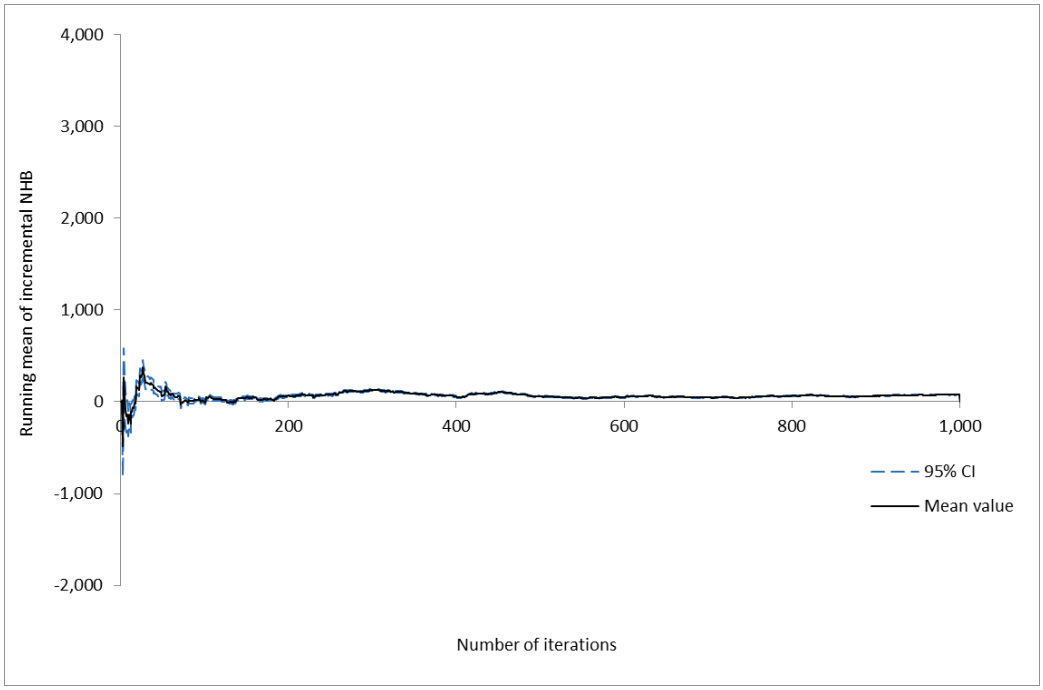
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 30. EMIS™ vs colonoscopy without AI CEAC



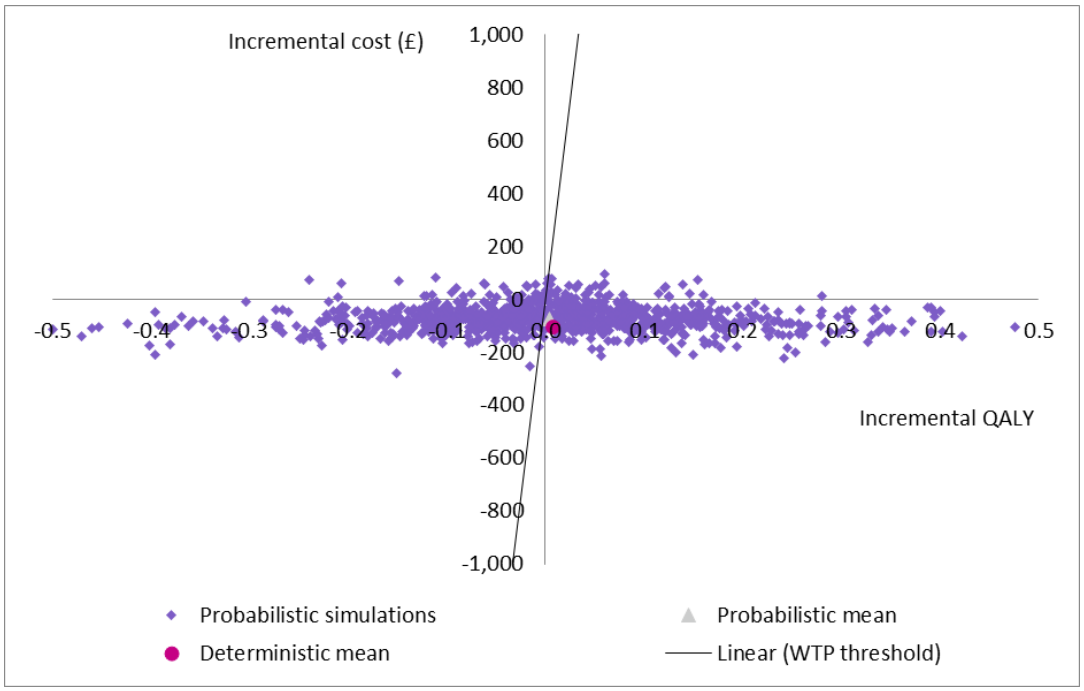
Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 31. EMIS™ vs colonoscopy without AI incremental NHB convergence plot



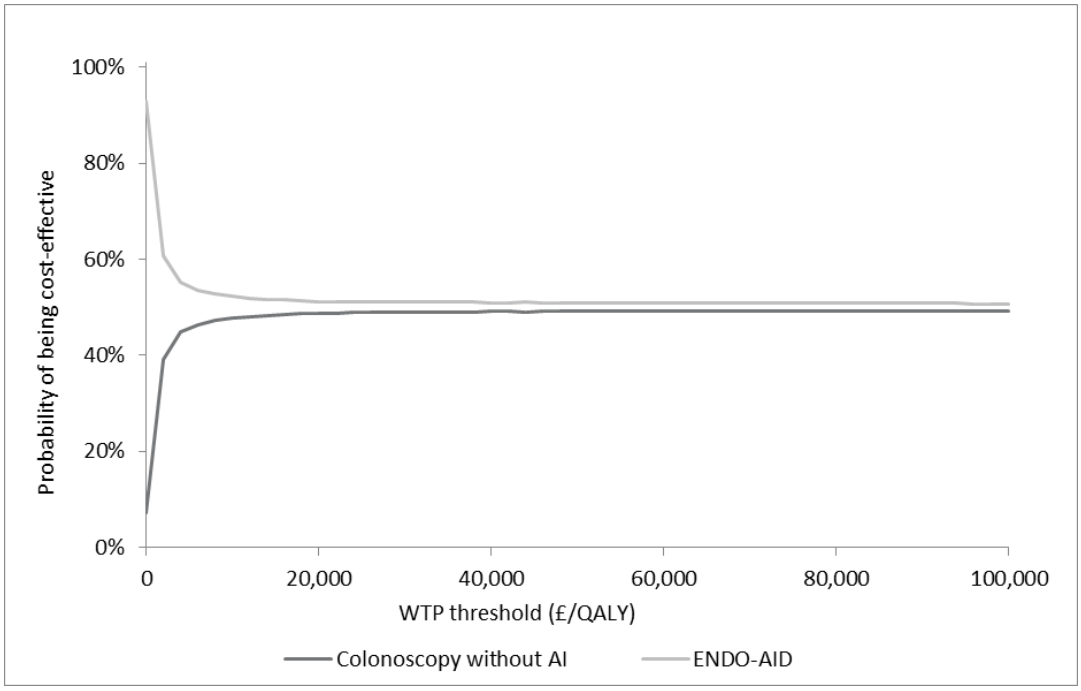
Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 32. ENDO-AID™ vs colonoscopy without AI cost-effectiveness plane



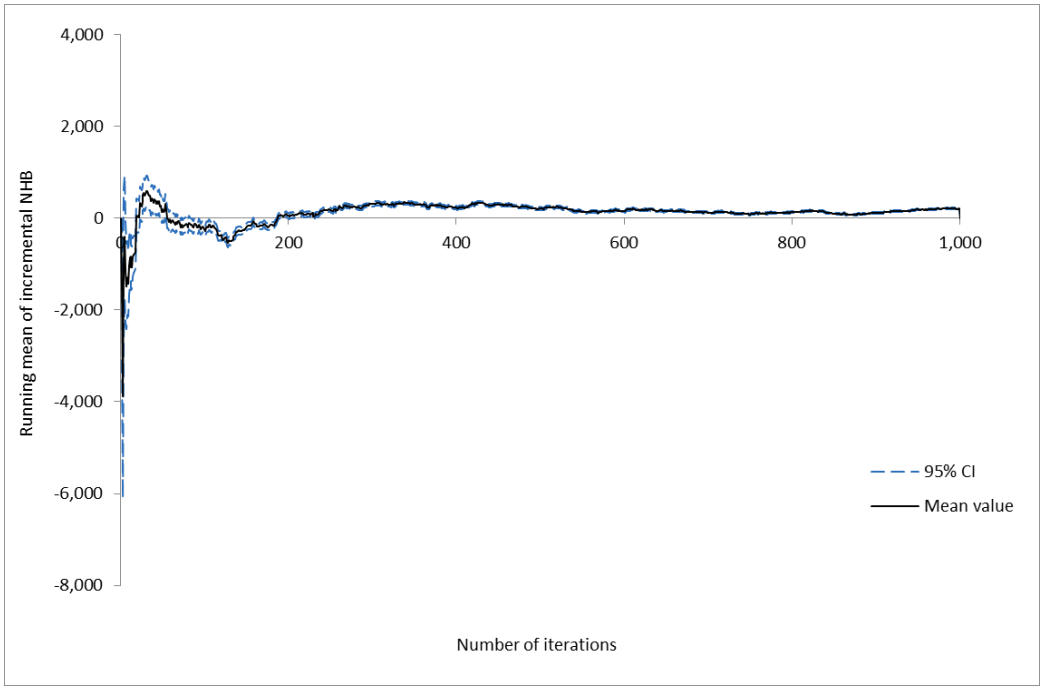
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 33. ENDO-AID™ vs colonoscopy without AI CEAC



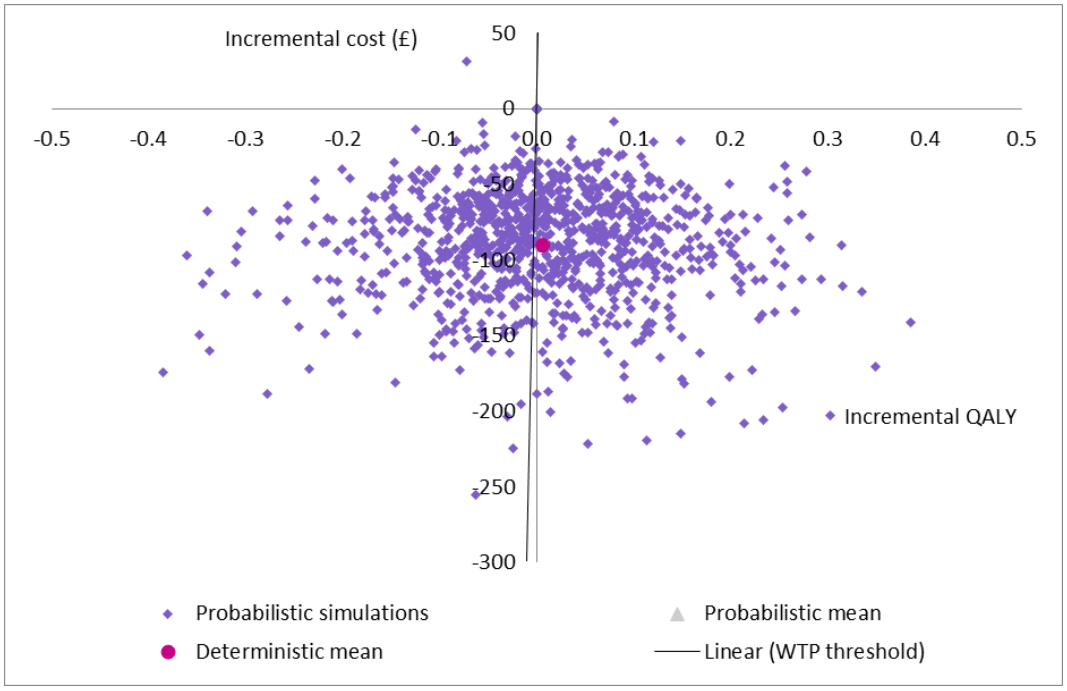
Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 34. ENDO-AID™ vs colonoscopy without AI incremental NHB convergence plot



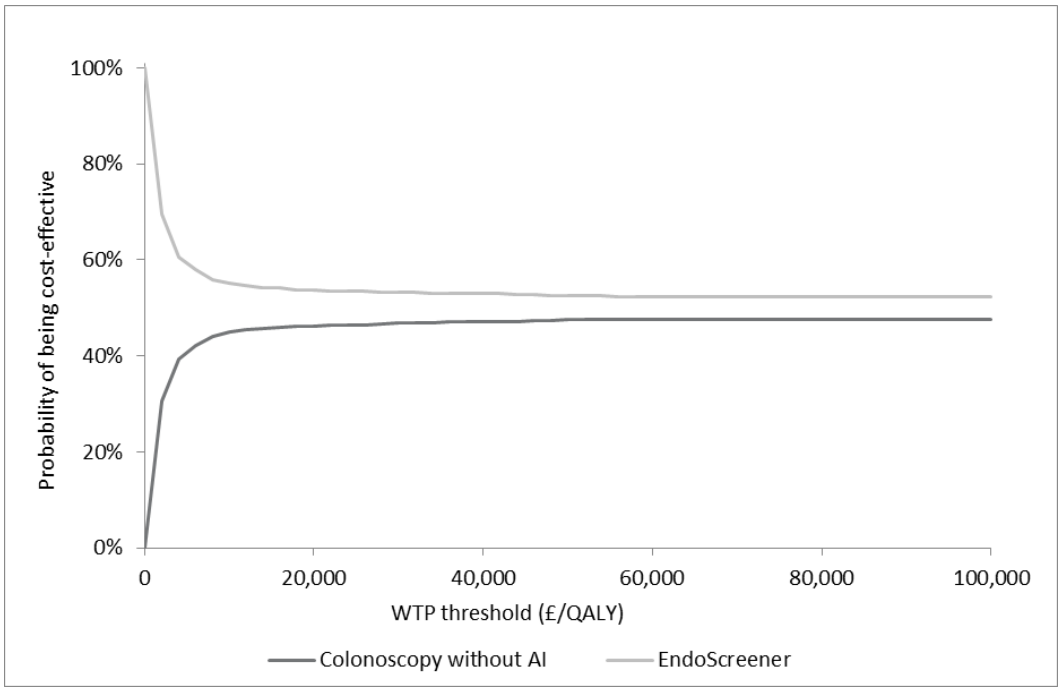
Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 35. EndoScreener® vs colonoscopy without AI cost-effectiveness plane



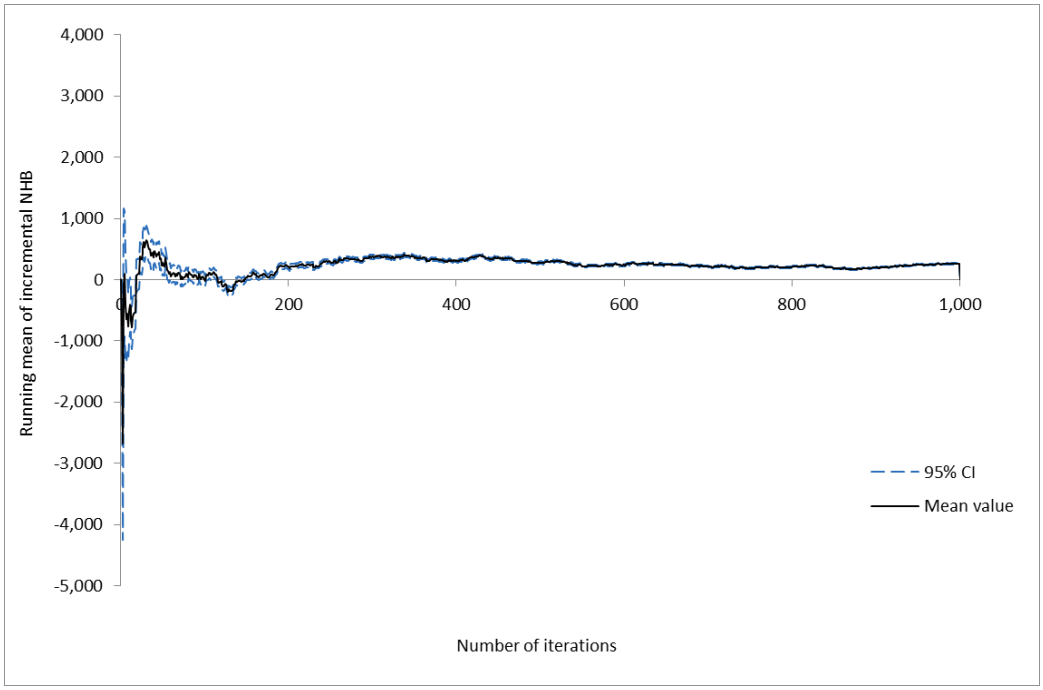
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 36. EndoScreener® vs colonoscopy without AI CEAC



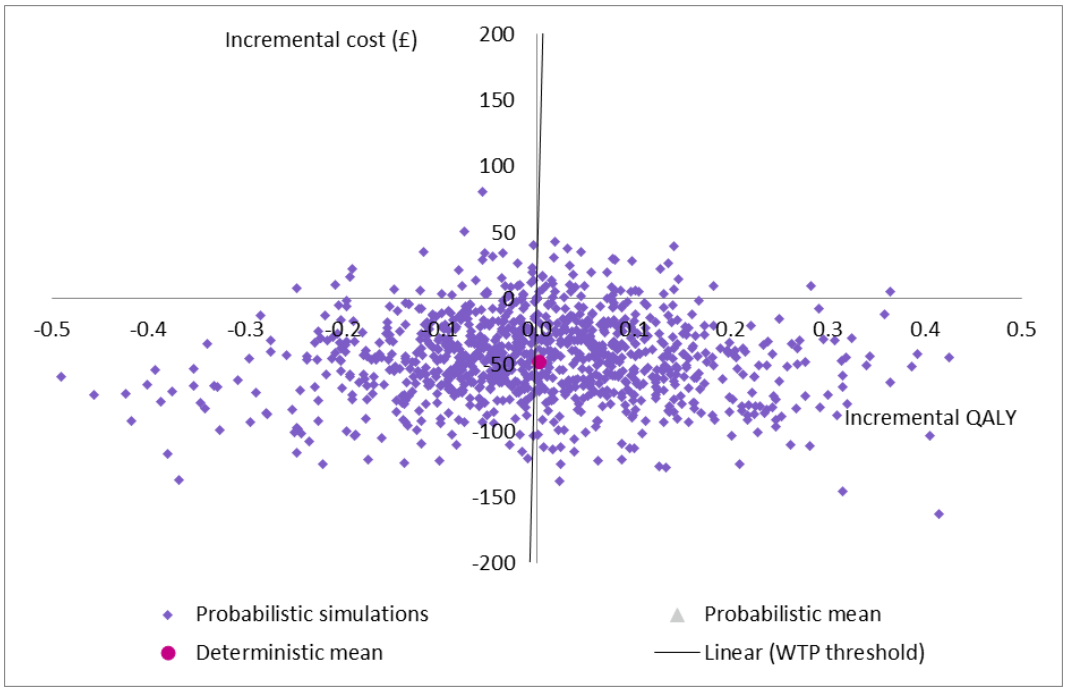
Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 37. EndoScreener® vs colonoscopy without AI incremental NHB convergence plot



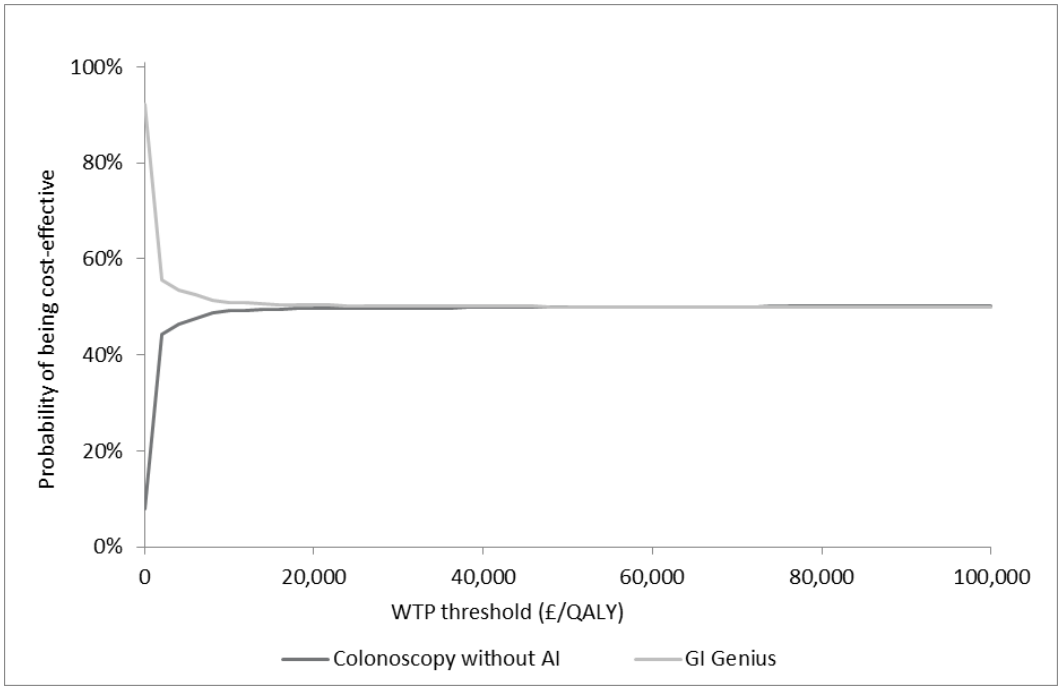
Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 38. GI Genius™ vs colonoscopy without AI cost-effectiveness plane



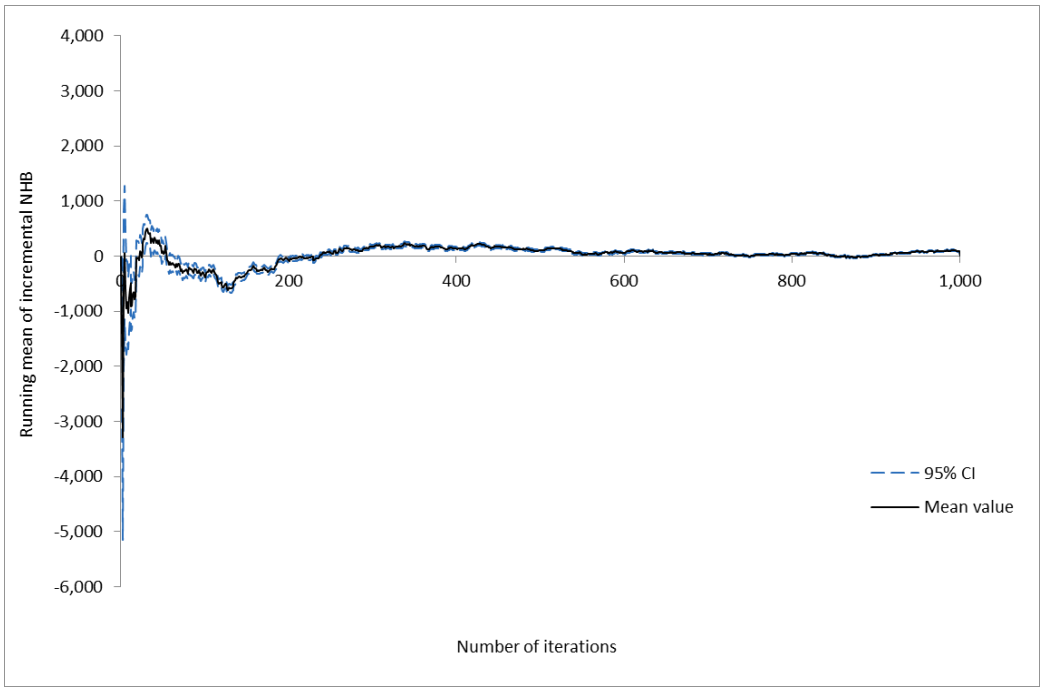
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 39. GI Genius™ vs colonoscopy without AI CEAC



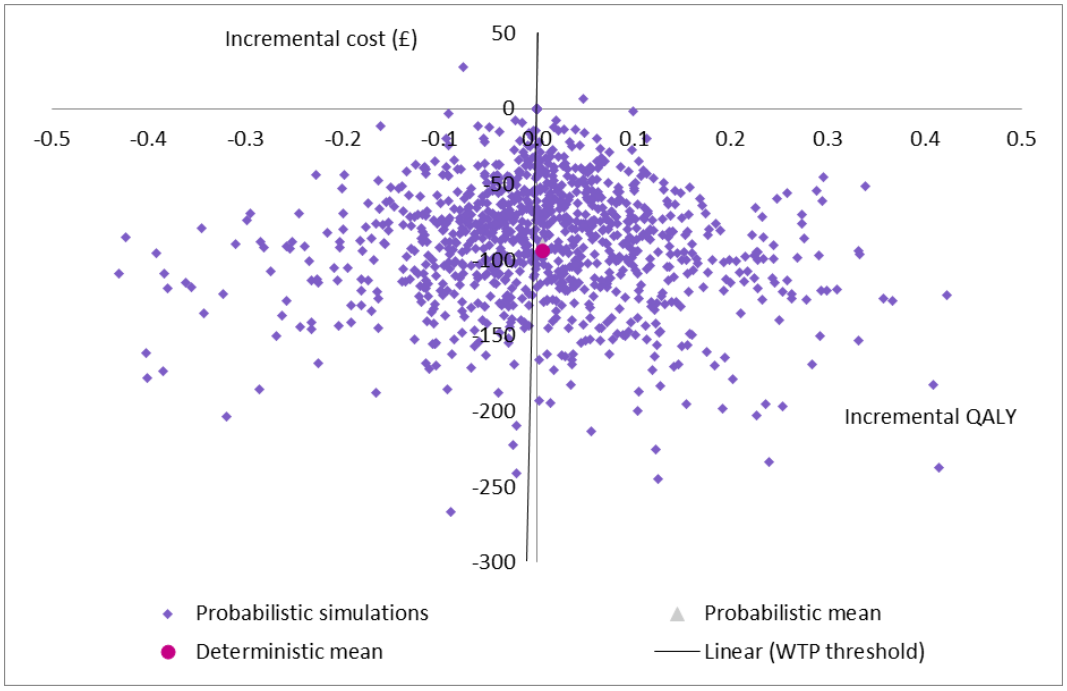
Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 40. GI Genius™ vs colonoscopy without AI incremental NHB convergence plot



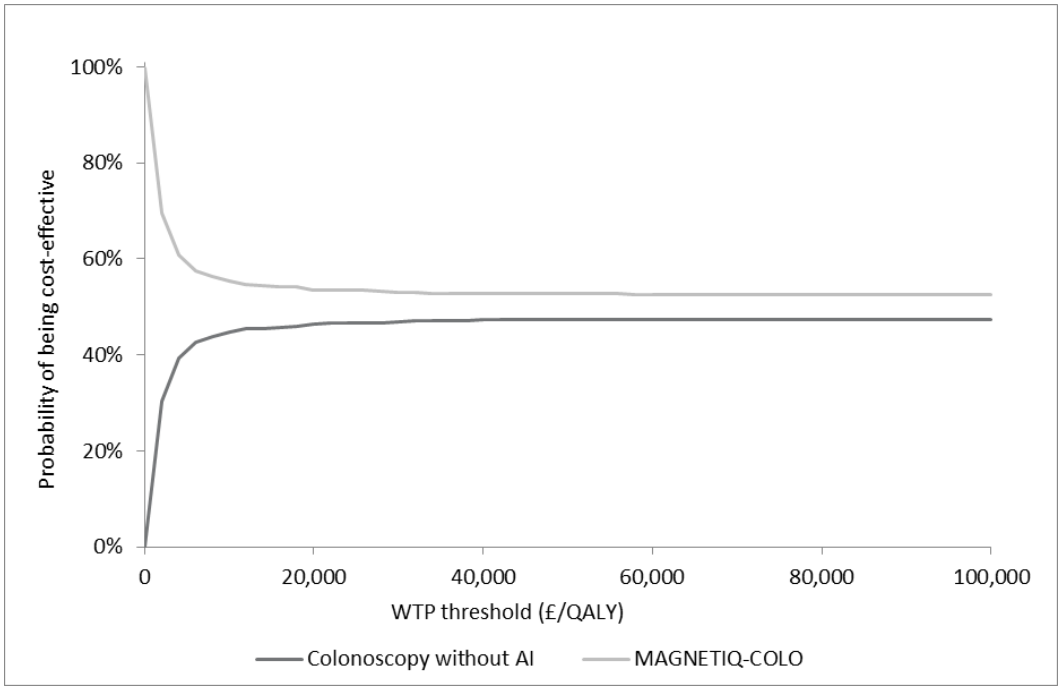
Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 41. MAGENTIQ-COLO™ vs colonoscopy without AI cost-effectiveness plane



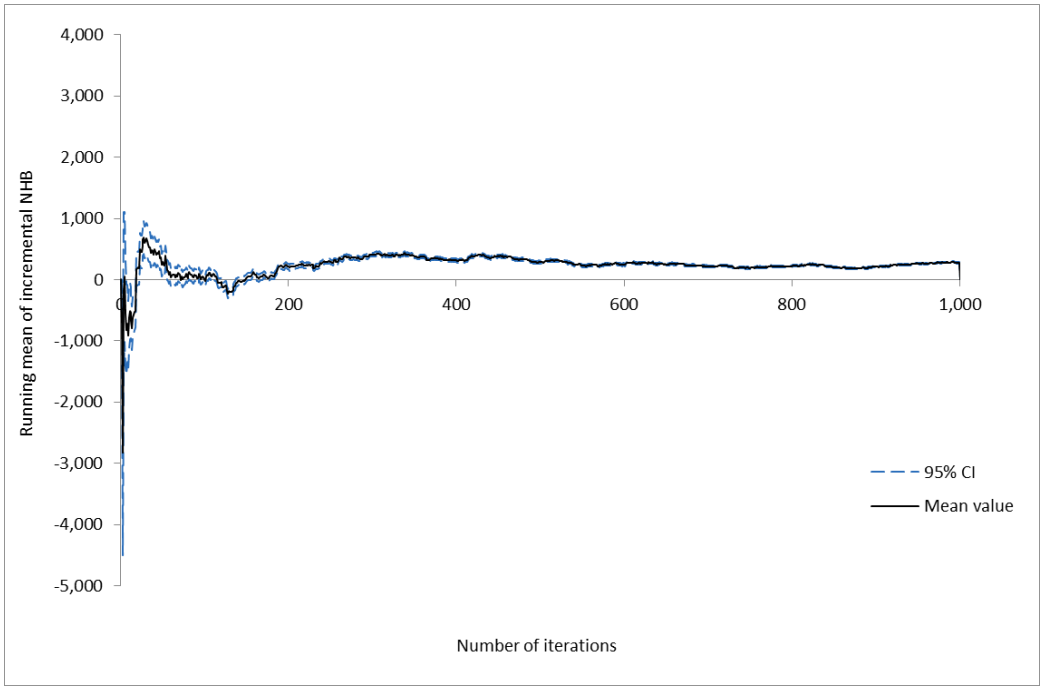
Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 42. MAGENTIQ-COLO™ vs colonoscopy without AI CEAC



Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

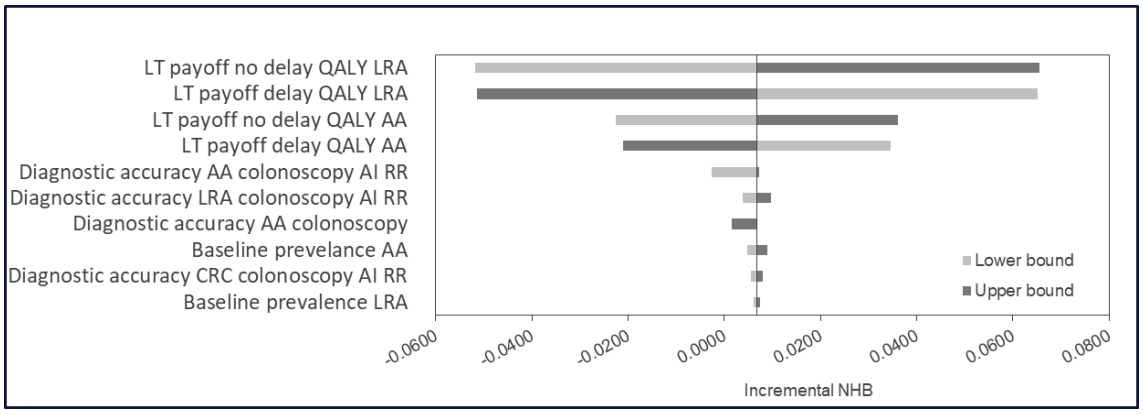
Figure 43. MAGENTIQ-COLO™ vs colonoscopy without AI incremental NHB convergence plot



Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

9.12.2 Additional DSA results

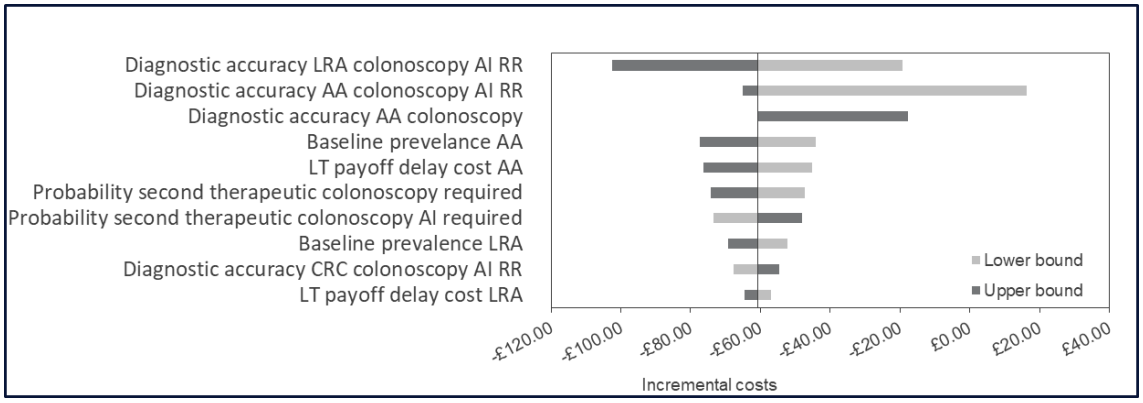
Figure 44. Argus® vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

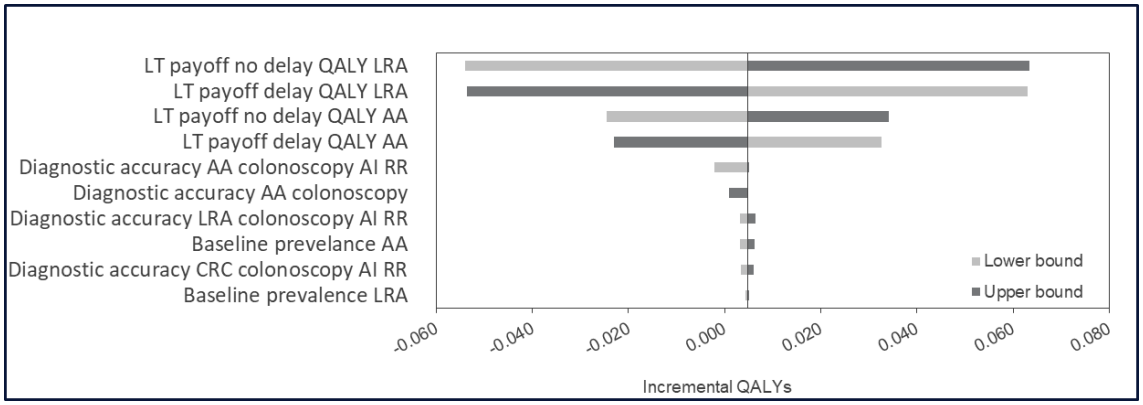
Figure 45. Argus® vs colonoscopy without AI incremental costs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; RR, risk ratio.

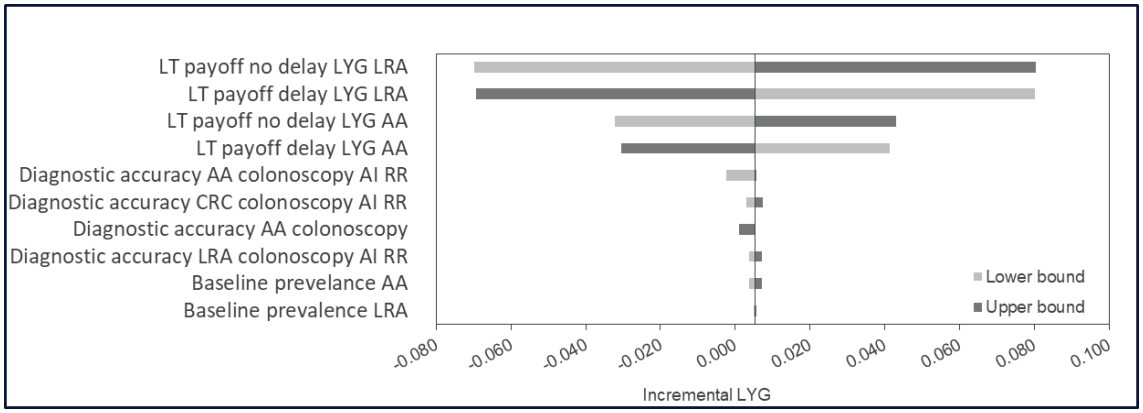
Figure 46. Argus® vs colonoscopy without AI incremental QALYs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

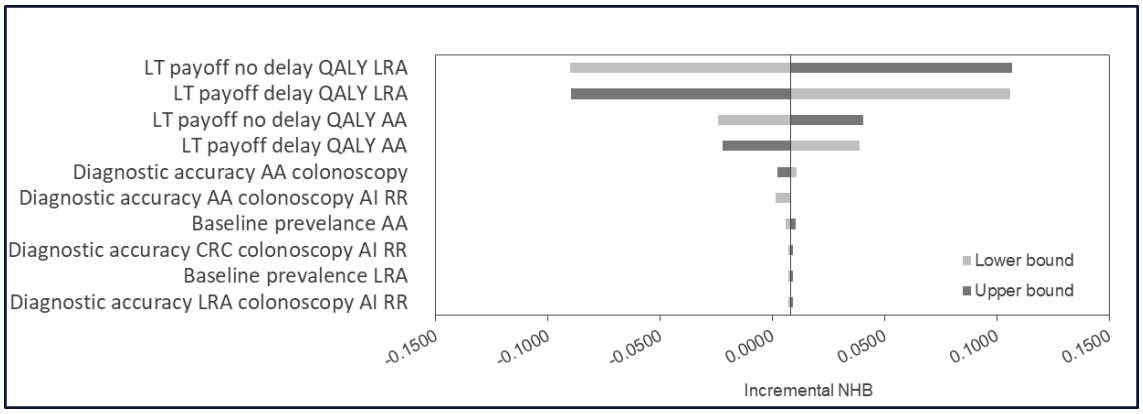
Figure 47. Argus® vs colonoscopy without AI incremental LYG tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

Figure 48. CAD EYE® vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; NSBP, no significant bowel pathology; QALY, quality-adjusted life year; RR, risk ratio.

Figure 49. CAD EYE® vs colonoscopy without AI incremental costs tornado plot

Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NSBP, no specific bowel pathology; RR, risk ratio.

Figure 50. CAD EYE® vs colonoscopy without AI incremental QALYs tornado plot

Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

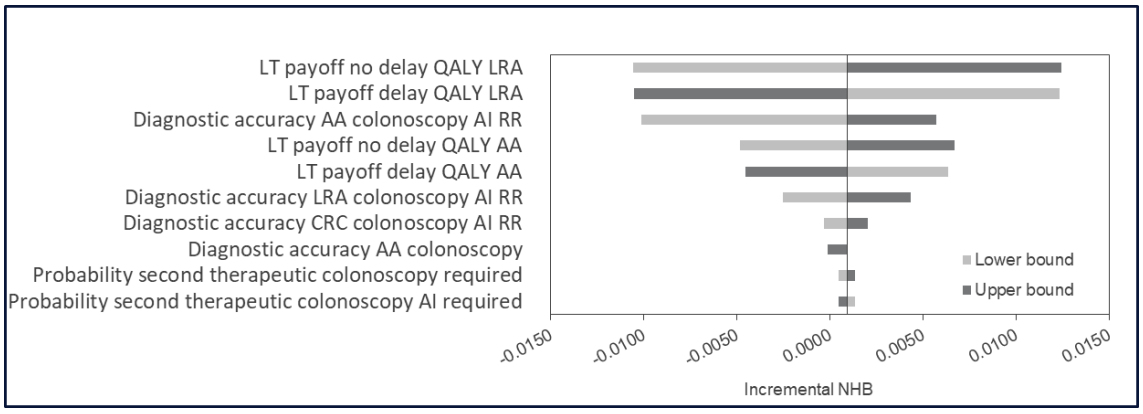
Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

Figure 51. CAD EYE® vs colonoscopy without AI incremental LYG tornado plot

Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

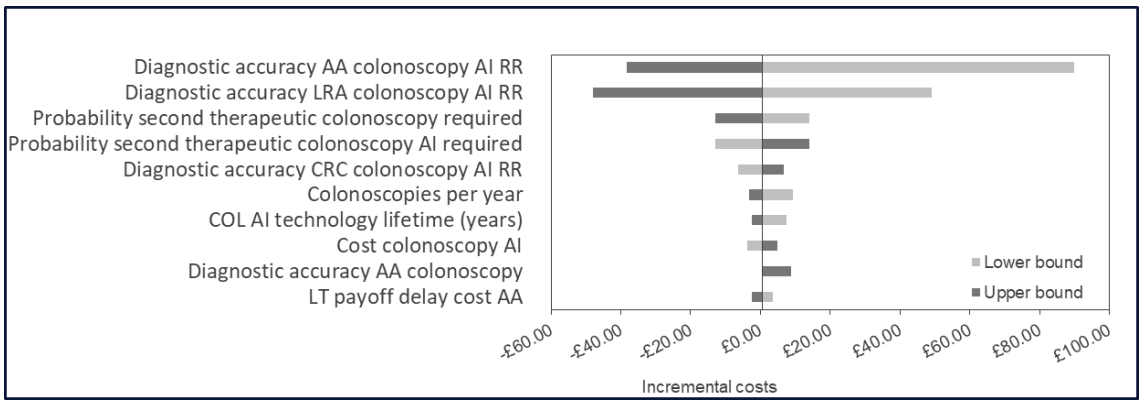
Figure 52. Discovery™ vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

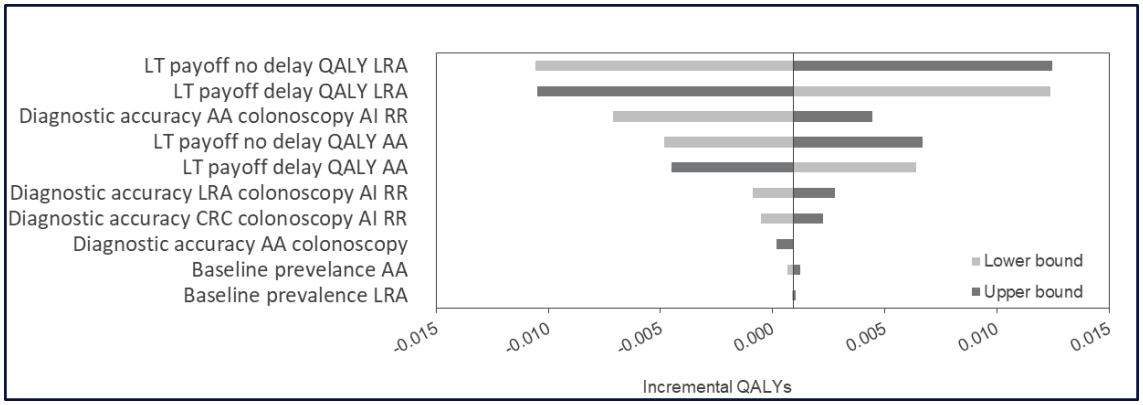
Figure 53. Discovery™ vs colonoscopy without AI incremental costs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NSBP, no specific bowel pathology; RR, risk ratio.

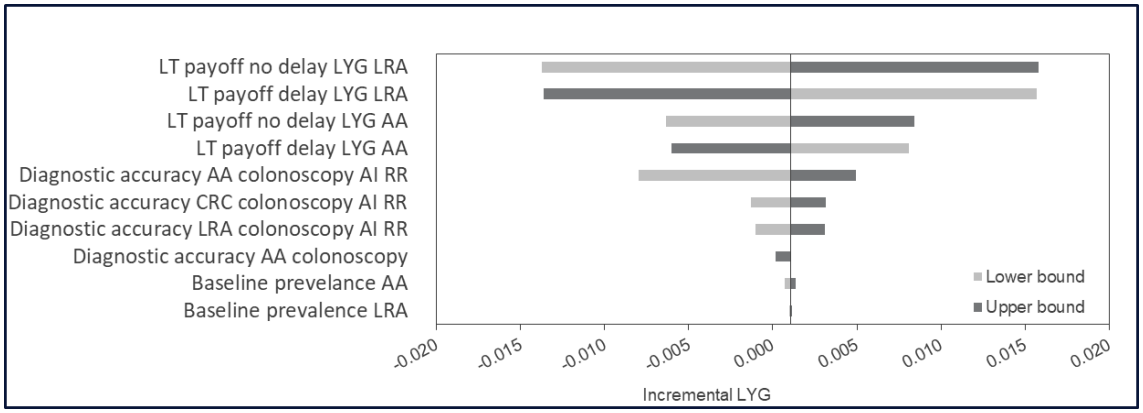
Figure 54. Discovery™ vs colonoscopy without AI incremental QALYs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

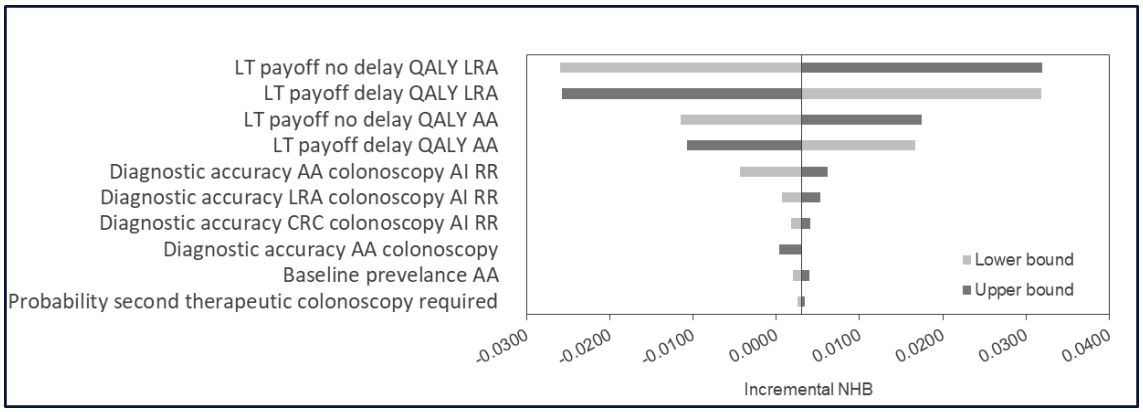
Figure 55. Discovery™ vs colonoscopy without AI incremental LYG tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

Figure 56. EMIS™ vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

Figure 57. EMIS™ vs colonoscopy without AI incremental costs tornado plot

Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; RR, risk ratio.

Figure 58. EMIS™ vs colonoscopy without AI incremental QALYs tornado plot

Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

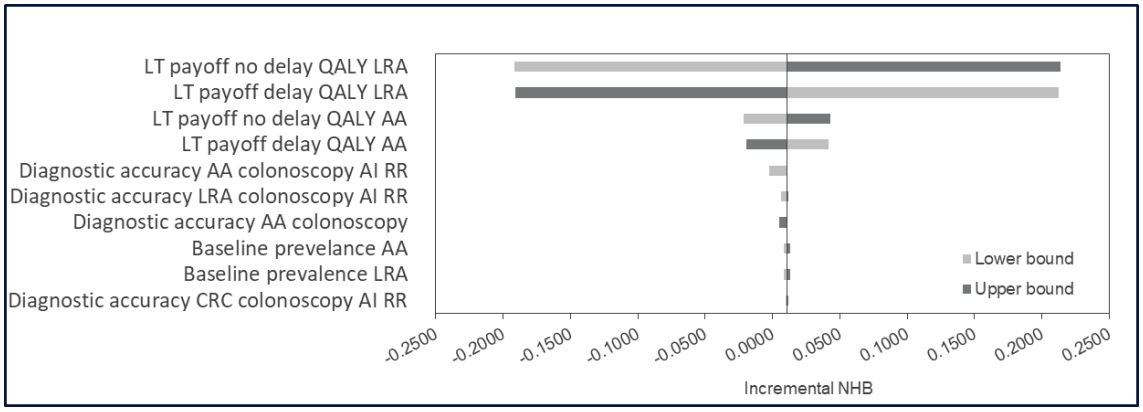
Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

Figure 59. EMIS™ vs colonoscopy without AI incremental LYG tornado plot

Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

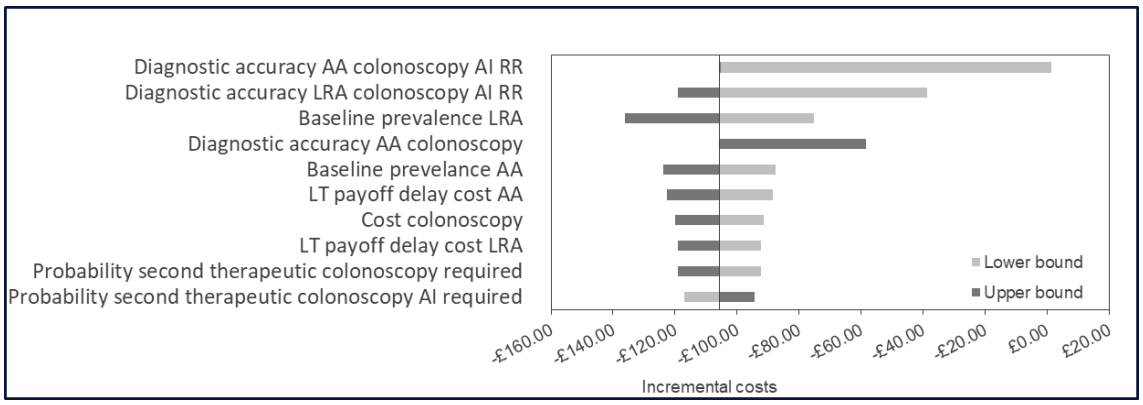
Figure 60. ENDO-AID™ vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

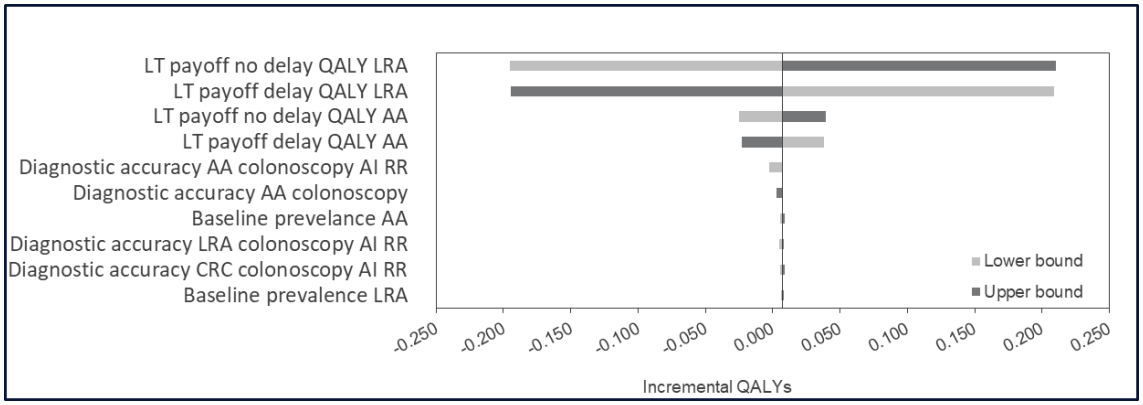
Figure 61. ENDO-AID™ vs colonoscopy without AI incremental costs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NSBP, no specific bowel pathology; RR, risk ratio.

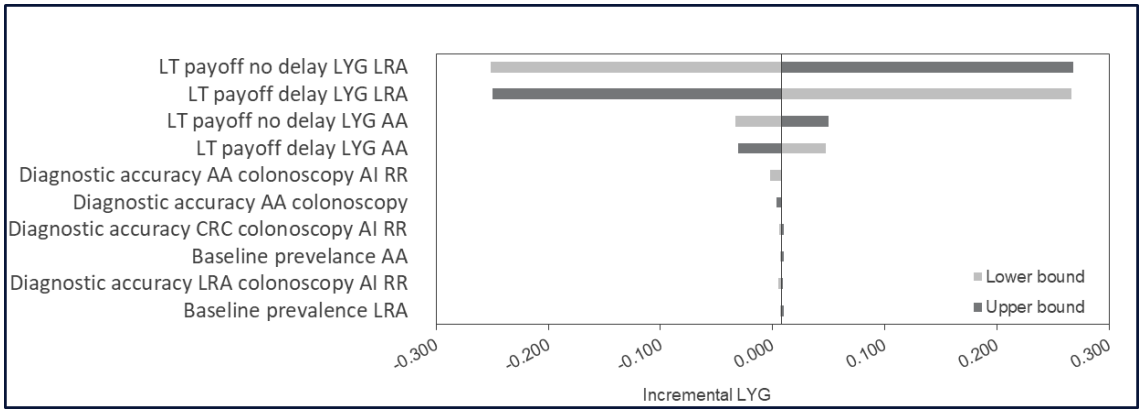
Figure 62. ENDO-AID™ vs colonoscopy without AI incremental QALYs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

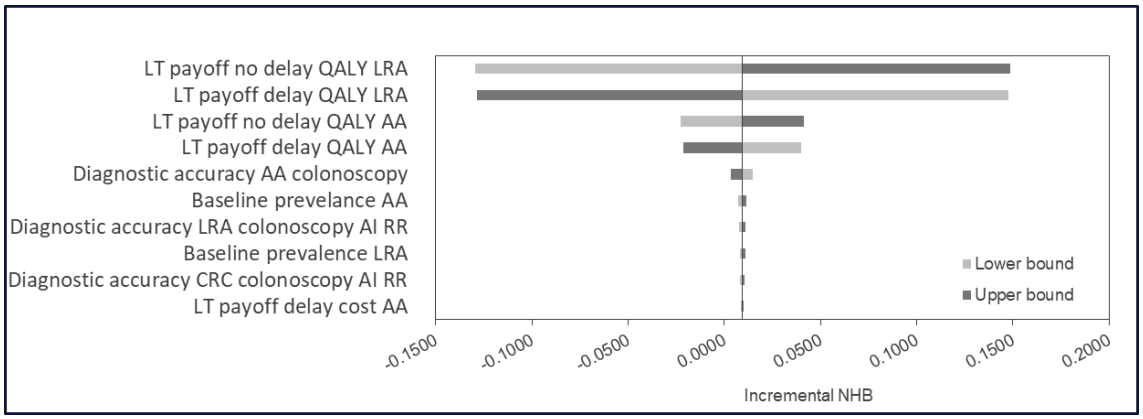
Figure 63. ENDO-AID™ vs colonoscopy without AI incremental LYG tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

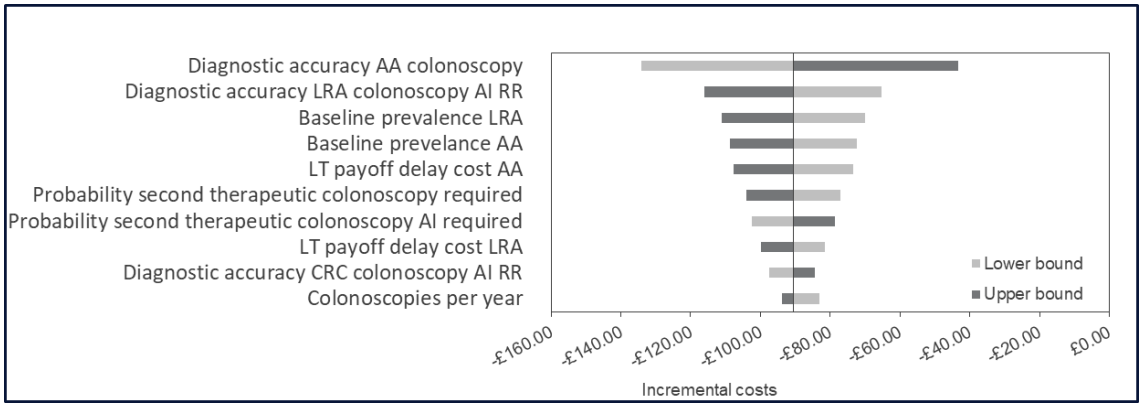
Figure 64. EndoScreener® vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

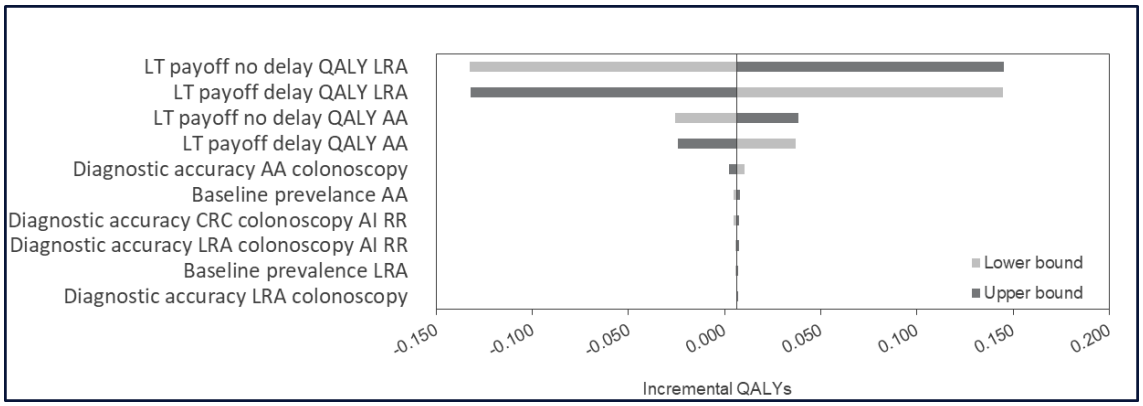
Figure 65. EndoScreener® vs colonoscopy without AI incremental costs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; RR, risk ratio.

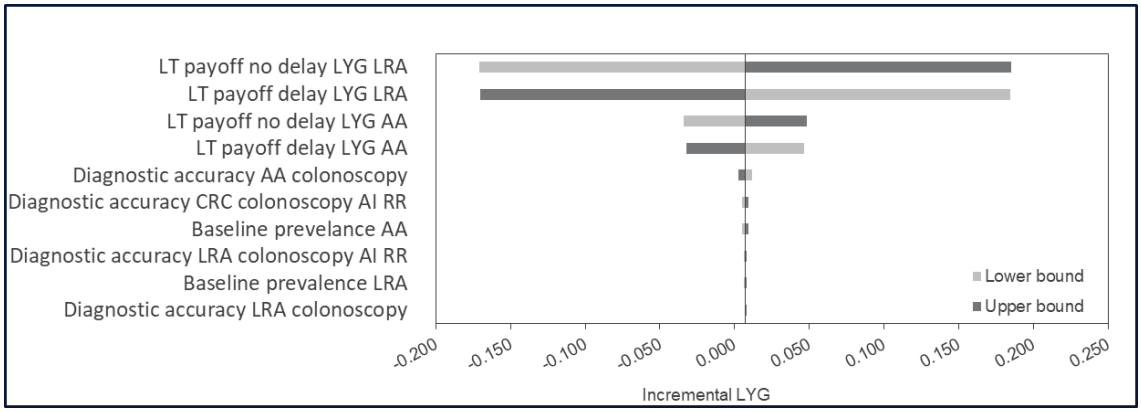
Figure 66. EndoScreener® vs colonoscopy without AI incremental QALYs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

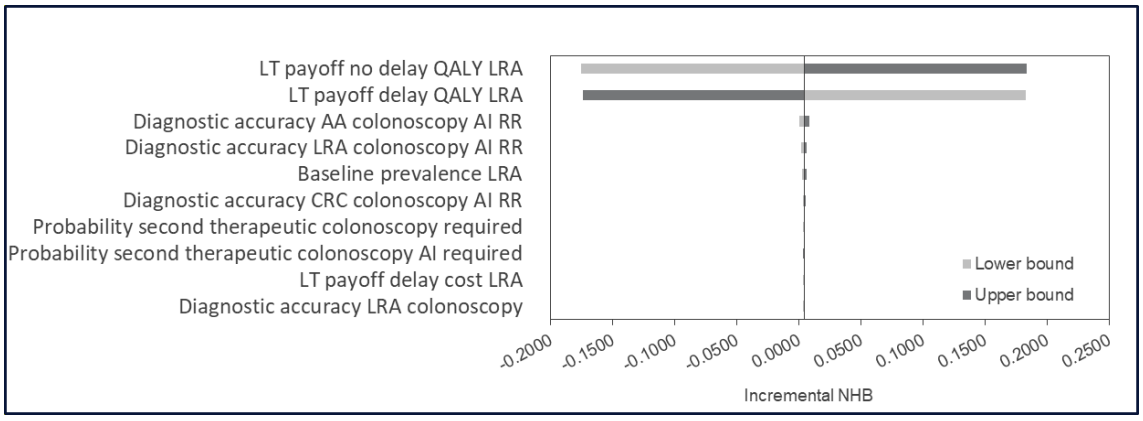
Figure 67. EndoScreener® vs colonoscopy without AI incremental LYG tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

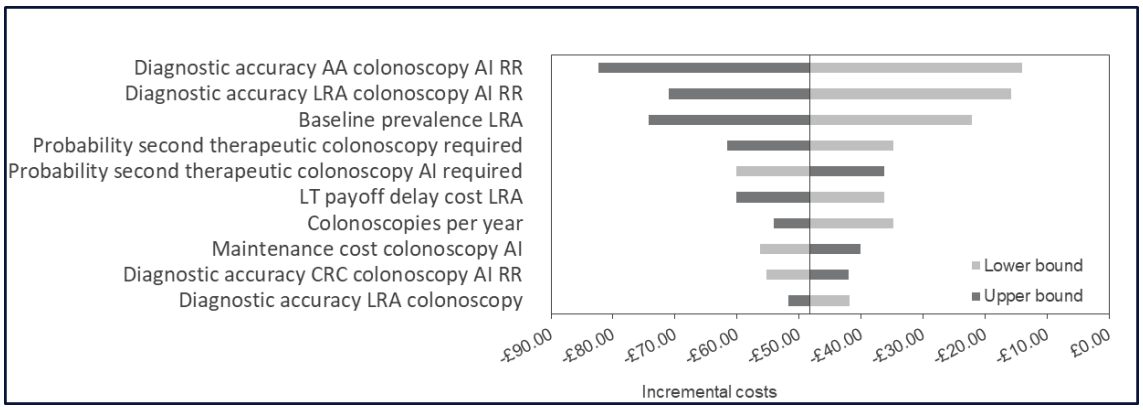
Figure 68. GI Genius™ vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; NSBP, no significant bowel pathology; QALY, quality-adjusted life year; RR, risk ratio.

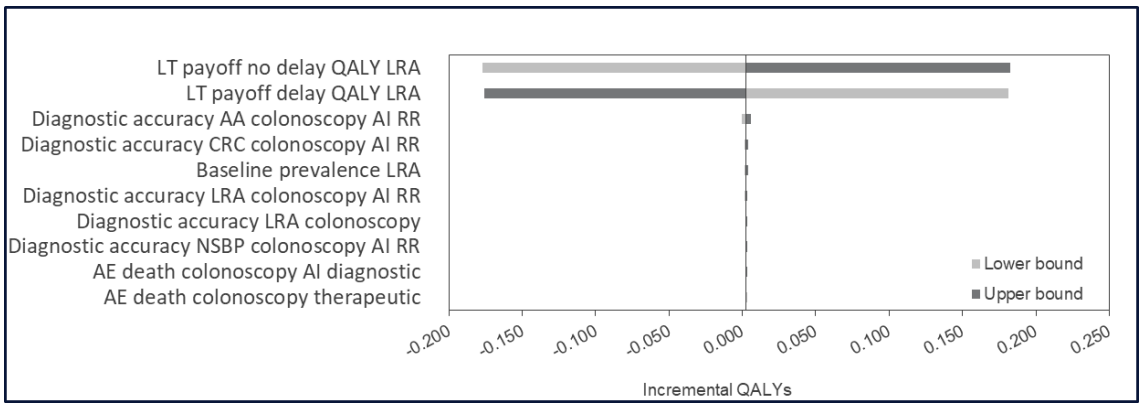
Figure 69. GI Genius™ vs colonoscopy without AI incremental costs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NSBP, no specific bowel pathology; RR, risk ratio.

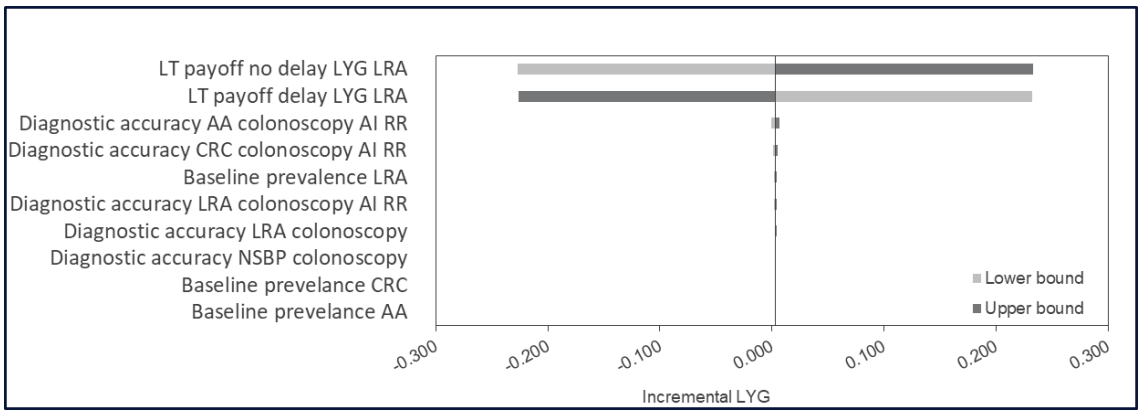
Figure 70. GI Genius™ vs colonoscopy without AI incremental QALYs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AE, adverse event; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

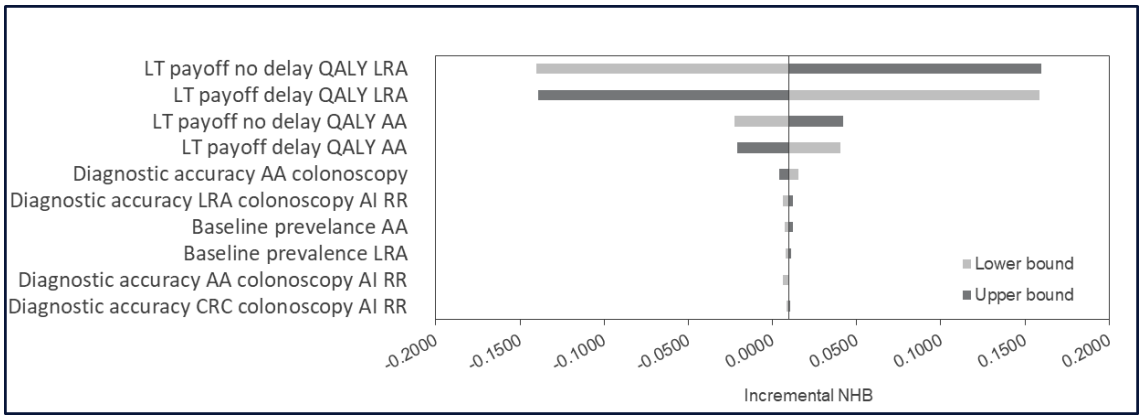
Figure 71. GI Genius™ vs colonoscopy without AI incremental LYG tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; LT, long-term; RR, risk ratio.

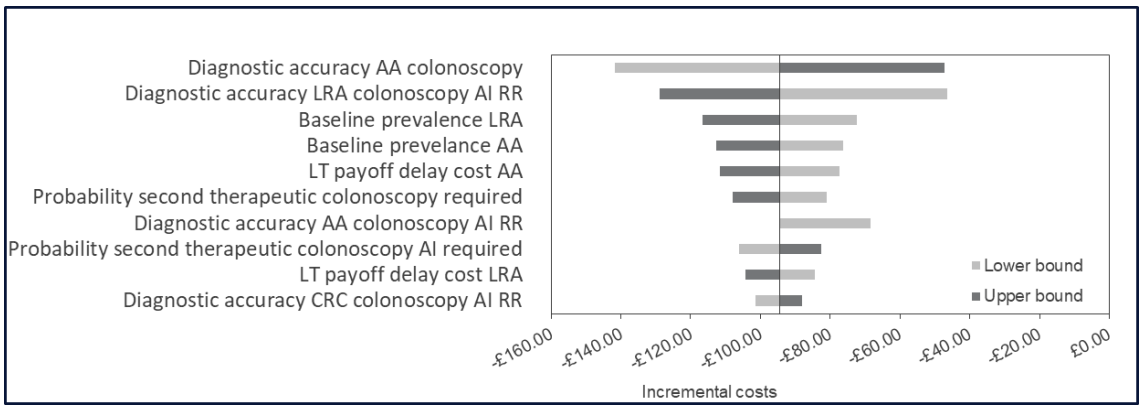
Figure 72. MAGENTIQ-COLO™ vs colonoscopy without AI incremental NHB tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

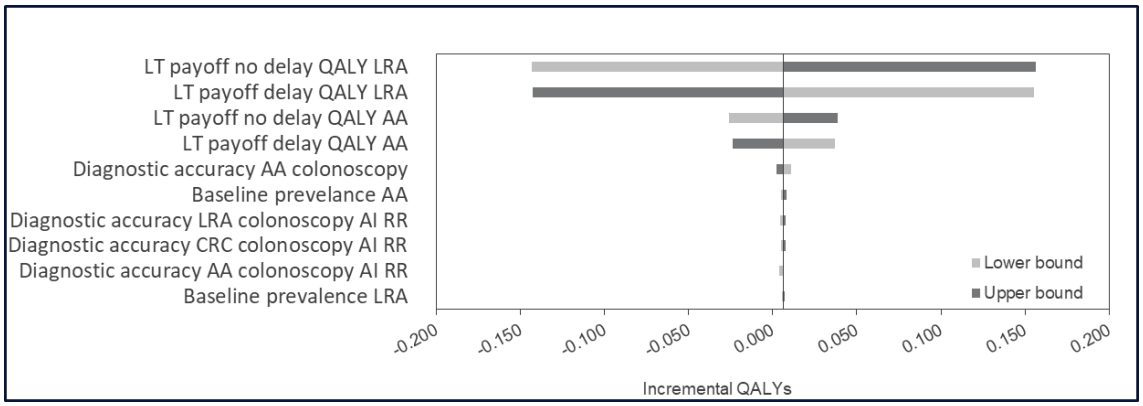
Figure 73. MAGENTIQ-COLO™ vs colonoscopy without AI incremental costs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; LRA, low-risk adenoma; LT, long-term; RR, risk ratio.

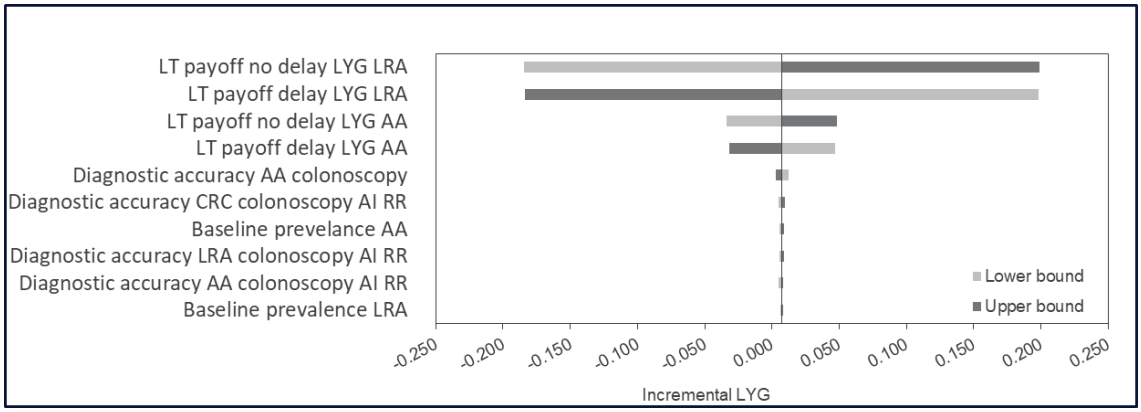
Figure 74. MAGENTIQ-COLO™ vs colonoscopy without AI incremental QALYs tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; QALY, quality-adjusted life year; RR, risk ratio.

Figure 75. MAGENTIQ-COLO™ vs colonoscopy without AI incremental LYG tornado plot



Footnote: the lower and upper bound used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; RR, risk ratio.

9.12.3 Additional scenario analysis results

Table 72. Scenario analysis results: ICER vs colonoscopy without AI

Scenario	ICER vs colonoscopy without AI (£/QALY)							
	Argus®	CAD EYE®	Discovery™	EMIS™	ENDO-AID™	EndoScreener®	GI Genius™	MAGENTIQ-COLO™
Base case	Dominant	Dominant	£8,669.76	Dominant	Dominant	Dominant	Dominant	Dominant
1a. Diagnose-and-leave polyp management strategy	Dominant	Dominant	£13,107.11	*Dominant**	Dominant	Dominant	Dominant	Dominant
1b. Diagnose-and-leave (high confidence) polyp management strategy	Dominant	Dominant	£10,923.05	*Dominant**	Dominant	Dominant	Dominant	Dominant
2. Resect-and-discard polyp management strategy	Dominant	Dominant	Dominated	*Dominant**	Dominant	Dominant	Dominant	Dominant
*3a. Diagnose-and-leave polyp management strategy with CADx**	*N/A*	*Dominant*	*N/A*	*N/A*	*N/A*	*N/A*	*Dominated*	*N/A*
*3b. Diagnose-and-leave (high confidence) polyp management strategy with CADx**	*N/A*	*Dominated*	*N/A*	*N/A*	*N/A*	*N/A*	*Dominated*	*N/A*
*4. Resect-and-discard polyp management strategy with CADx**	*N/A*	*Dominant*	*N/A*	*N/A*	*N/A*	*N/A*	*Dominant*	*N/A*
5. Alternative values for sensitivity of detection for colonoscopy without AI	Dominant	Dominant	£3,602.94	Dominant	Dominant	Dominant	Dominant	Dominant
6. CADe sensitivity of interventions calculated using AMR	N/A	£30,353.52 (SW quadrant)	N/A	N/A	N/A	Dominant	Dominant	Dominated

7. CADe sensitivity of interventions calculated using APC	Dominant	£41,128.85 (SW quadrant)	Dominant	N/A	Dominant	Dominant	Dominant	Dominant
8a. Alternative rate of CRC detection: 100% for all technologies	Dominant	Dominant	£9,233.93	Dominant	Dominant	Dominant	Dominant	Dominant
8b. Alternative rate of CRC detection: 90% for all technologies	Dominant	Dominant	£9,540.33	Dominant	Dominant	Dominant	Dominant	Dominant
8c. Alternative rate of CRC detection: informed by ADR RR	Dominant	Dominant	£15,773.13	Dominant	Dominant	Dominant	Dominant	Dominant
9a. Alternative rate of IBD detection: 100% for all technologies	Dominant	Dominant	£8,394.51	Dominant	Dominant	Dominant	Dominant	Dominant
9b. Alternative rate of IBD detection: 80% for all technologies	Dominant	Dominant	£9,337.45	Dominant	Dominant	Dominant	Dominant	Dominant
10. Alternative values for sensitivity of detection for AA for missing values	Dominant	N/A	£18,966.27	£2,725.00	N/A	Dominant	N/A	Dominant
11. Alternative approach to parametrising unnecessary polyp removal for missing values	Dominant	N/A	£8,213.63	Dominant	Dominant	Dominant	N/A	Dominant
12. Alternative costing for failed initial colonoscopies: 0% of diagnostic colonoscopy cost	Dominant	Dominant	£8,369.01	Dominant	Dominant	Dominant	Dominant	Dominant

13a. Alternative proportion of patients receiving secondary therapeutic colonoscopies: 0%	Dominant	Dominant	£8,606.66	Dominant	Dominant	Dominant	Dominant	Dominant
13b. Alternative proportion of patients receiving secondary therapeutic colonoscopies: 50%	Dominant	Dominant	£8,963.83	Dominant	Dominant	Dominant	Dominant	Dominant
13c. Alternative proportion of patients receiving secondary therapeutic colonoscopies: informed by ADR RR	Dominant	Dominant	£12,084.14	Dominant	Dominant	Dominant	Dominant	Dominant
14a. Alternative expected lifetime of AI technologies: three years	Dominant	Dominant	£6,140.75	N/A	Dominant	N/A	N/A	N/A
14b. Alternative expected lifetime of AI technologies: five years	Dominant	Dominant	£1,683.21	N/A	Dominant	N/A	N/A	N/A
14c. Alternative expected lifetime of AI technologies: 10 years	Dominant	Dominant	£548.54	N/A	Dominant	N/A	N/A	N/A
15. AE costs removed for patients who die	Dominant	Dominant	£10,299.12	Dominant	Dominant	Dominant	Dominant	Dominant

Footnote: *These analyses should be considered to be exploratory

Abbreviations: ADR, adenoma detection rate; AE, adverse event; AI, artificial intelligence; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; IBD, inflammatory bowel disease; ICER, incremental cost-effectiveness ratio; N/A, not applicable; QALY, quality-adjusted life year; SW, south-west (quadrant of the cost-effectiveness plane).

BMJ TAG

Artificial intelligence software to help detect and characterise colorectal polyps [GID-DG10118]

Diagnostics Assessment Report Supplement

September 2025

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Produced by:	BMJ Technology Assessment Group (BMJ TAG)
Authors:	Steve Edwards, Director of Health Technology Assessment, BMJ-TAG, London Nicole Downes, Senior Clinical Evidence Analyst, BMJ-TAG, London Sophie Ip, Senior Health Economist, BMJ-TAG, London Victoria Wakefield, Principal Clinical Evidence Analyst, BMJ-TAG, London Clare Dadswell, Clinical Evidence Manager, BMJ-TAG, London Isaac Mackenzie, Health Economist, BMJ-TAG, London Tracey Jhita, Health Economics Manager, BMJ-TAG, London
Correspondence to:	Steve Edwards, BMJ TAG, BMJ Group, 5th Floor, 90 Whitfield Street, London W1T 4EZ, UK.
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This review has been registered on PROSPERO under registration number CRD42024586541.

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List of Abbreviations

ADR	Adenoma detection rate
AE	Adverse event
AI	Artificial intelligence
AMR	Adenoma miss rate
APC	Adenomas per colonoscopy
ASA	American Society of Anesthesiologists
ASGE	American Society for Gastrointestinal Endoscopy
BBPS	Boston Bowel Preparation Scale
BCSP	Bowel Cancer Screening Programme
BLI	Blue-light imaging
BSG	British Society of Gastroenterology
CADe	Computer-aided detection
CADx	Computer-aided characterisation
CI	Confidence interval
CRC	Colorectal cancer
CSR	Clinical study report
CT	Computed tomography
CV	Cardiovascular
DCE	Dye-based chromoendoscopy
DDW	Digestive Disease Week
DR	Detection rate
DRSP	Diminutive rectosigmoid polyp
EAG	External Assessment Group
EMIS™	Endoscopic Multimedia Information System
EPCAM	Epithelial cell adhesion molecule gene
ESGE	European Society of Gastrointestinal Endoscopy
FAP	Familial adenomatous polyposis
FAS	Full analysis set
FIT	Faecal immunochemical test
FOBT	Faecal occult blood test
GE/GI	Gastrointestinal
HD	High-definition
HNPCC	Hereditary nonpolyposis colorectal cancer
IBD	Inflammatory bowel disease
iFOBT	Immunochemical faecal occult blood test
INR	International normalised ratio
IQR	Interquartile range

IRR	Incidence rate ratio
ITT	Intention to treat
IV	Inverse variance
JNET	Japan Narrow Band Imaging Expert Team
LCI	Linked-colour imaging
LS	Lynch syndrome
MD	Mean difference
M-H	Mantel-Haenszel
mITT	Modified intention to treat
MLH1	mutL homolog 1
MMR	Mismatch repair
MSH2	mutS homolog 2
MSH6	mutS homolog 6
NA	Not applicable
NAIAD	Nationwide study of Artificial Intelligence in Adenoma Detection
NBI	Narrow-band imaging
NHS	National Health Service
NICE	National Institute for Health and Care Excellence OR NBI International Colorectal Endoscopic criteria
NPV	Negative predictive value
NR	Not reported
NRS	Non-randomised study
OD	Optical diagnosis
OR	Odds ratio
PDR	Polyp detection rate
PIVI	Preservation and Incorporation of Valuable Endoscopic Innovation
PMR	Polyp miss rate
PMS2	PMS1 homolog 2, mismatch repair system component
PPC	Polyps per colonoscopy
PPV	Positive predictive value
RCT	Randomised controlled trial
RoB	Risk of bias
RR	Risk ratio
SD	Standard deviation
SE	Standard error
SLR	Systematic literature review
SQ	Signalling question
SSL	Sessile serrated lesion

UC	Ulcerative colitis
UEG	United European Gastroenterology
USMSTF	US Multi-society Task Force on Colorectal Cancer
VCE	Virtual chromoendoscopy
WASP	Workgroup Serrated Polyps and Polyposis
WHO	World Health Organization
WLE	White-light endoscopy
WLI	White-light imaging

1 Additional information for outcomes in main report

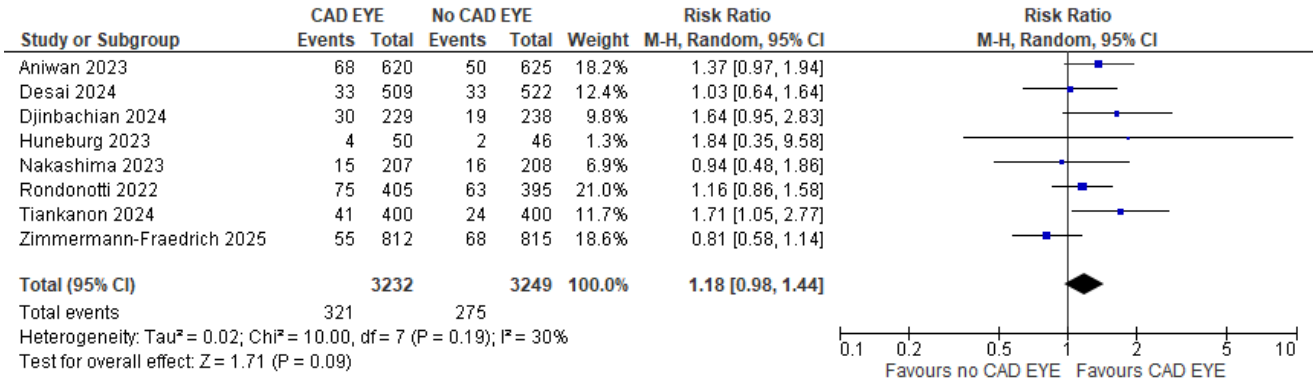
This section includes a more detailed breakdown of results per intervention for outcomes other than adenoma detection rate (ADR) included in the main report, including forest plots showing results of individual studies and meta-analyses.

1.1 Advanced adenoma detection rate

CAD EYE®

Eight randomised controlled trials (RCTs) reporting advanced ADR for this technology compared to standard colonoscopy were meta-analysed.[3, 4, 6-11] Colonoscopy indications and endoscopist experience were similar to those described for ADR. Results suggest a higher (not statistically significant; p-value 0.09) advanced ADR with CAD EYE® (Figure 1). There is notable variation between point estimates and an I^2 value of 30% suggesting some statistical heterogeneity.

Figure 1. Advanced ADR in CAD EYE® studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

CADDIE™

[redacted]

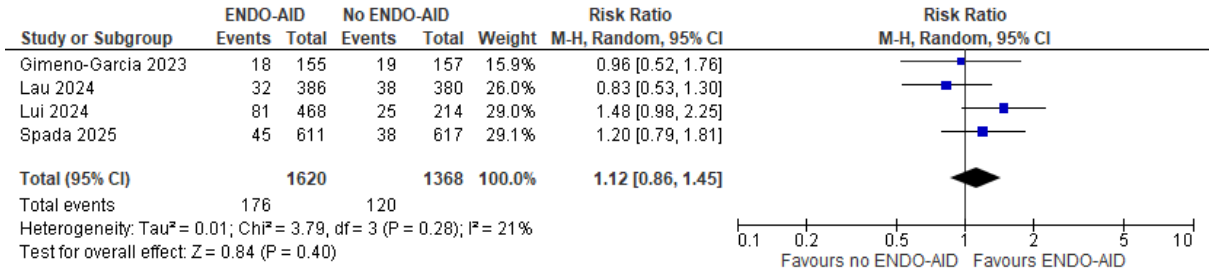
Figure 2. Advanced ADR in CADDIE™ studies

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

ENDO-AID™

Four RCTs reporting advanced ADR for this technology compared to standard colonoscopy were meta-analysed.[13-16] Colonoscopy indications and endoscopist experience were similar to those described for ADR. Results suggest a slightly higher advanced ADR with ENDO-AID™ (Figure 3) but this was not statistically significant (p-value 0.40). There is visible variation in point estimates with some evidence of statistical heterogeneity based on the I^2 value of 21%.

Figure 3. Advanced ADR in ENDO-AID™ studies



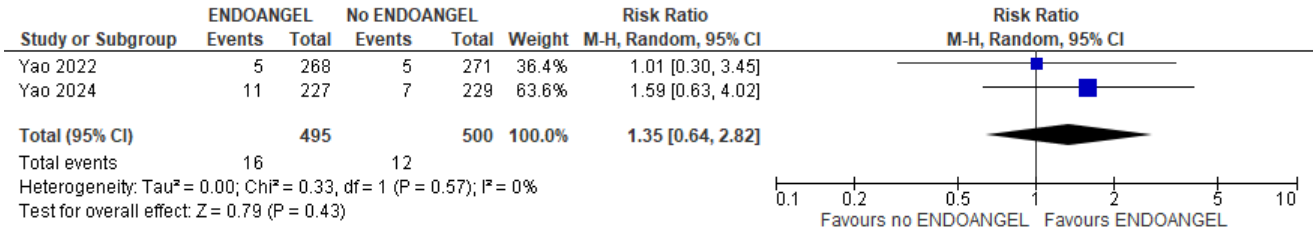
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

ENDOANGEL®

Two RCTs reporting advanced ADR for this technology compared to standard colonoscopy were meta-analysed.[17, 18] Colonoscopy indications and endoscopist experience were similar to those described for ADR. Results suggest a higher advanced ADR with ENDOANGEL® (

Figure 4) but this was not statistically significant (p-value 0.43). There is notable variation between the point estimates of the two studies, despite statistical heterogeneity not being indicated based on the I^2 value.

Figure 4. Advanced ADR in ENDOANGEL® studies

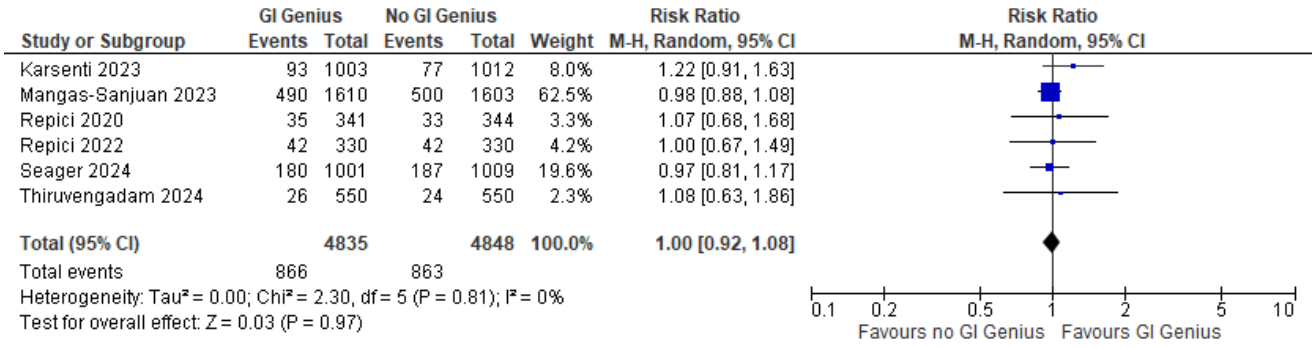


Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

GI Genius™ (Medtronic)

Six RCTs reporting advanced ADR for this technology compared to standard colonoscopy were meta-analysed.[19-24] Colonoscopy indications and endoscopist experience were similar to those described for ADR, but none of the studies covered a Lynch syndrome population specifically. Results suggest no difference in advanced ADR between GI Genius™-assisted and standard colonoscopy, with a risk ratio of 1.00 and no statistically significant difference (p-value 0.97; Figure 5). There is notable variation between studies based on point estimates, despite no evidence of statistical heterogeneity based on the I^2 value. The EAG considers results from the non-randomised Nationwide study of Artificial Intelligence in Adenoma Detection (NAIAD trial; diagnostic colonoscopy population) [redacted] (see Section 3.2.2.1.10 of the main report).[25]

Figure 5. Advanced ADR in GI Genius™ studies



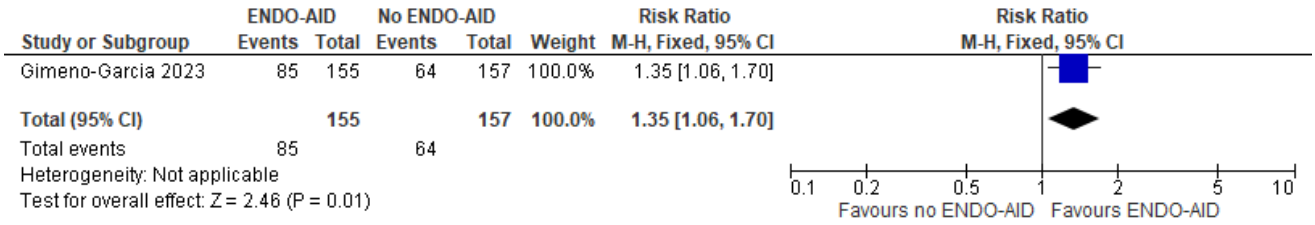
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

1.2 Non-advanced adenoma detection rate

ENDO-AID™

A single RCT reporting non-advanced ADR for this technology compared to standard colonoscopy was included.[13] The population included average-risk population screening, post-polypectomy surveillance, familial colorectal cancer (CRC) screening and colonoscopy due to symptoms or suspicion of CRC. Any endoscopist with at least 2000 prior colonoscopies could be included. Results suggest a higher (statistically significant; p-value 0.01) non-advanced ADR with ENDO-AID™ (Figure 6).

Figure 6. Non-advanced ADR in ENDO-AID™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

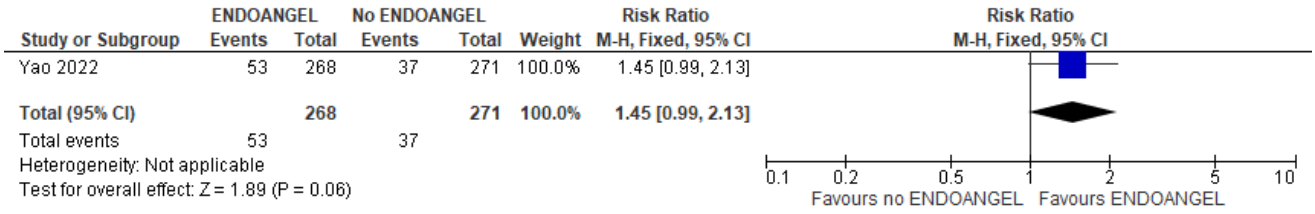
ENDOANGEL®

A single RCT reporting non-advanced ADR for this technology compared to standard colonoscopy was included.[17] The population included symptomatic, post-polypectomy surveillance and

symptomatic colonoscopies. Endoscopist included had to have performed at least 2000 prior colonoscopies. Results suggest a higher non-advanced ADR with ENDOANGEL® (

Figure 7) but this was not statistically significant (p-value 0.06).

Figure 7. Non-advanced ADR in ENDOANGEL® studies

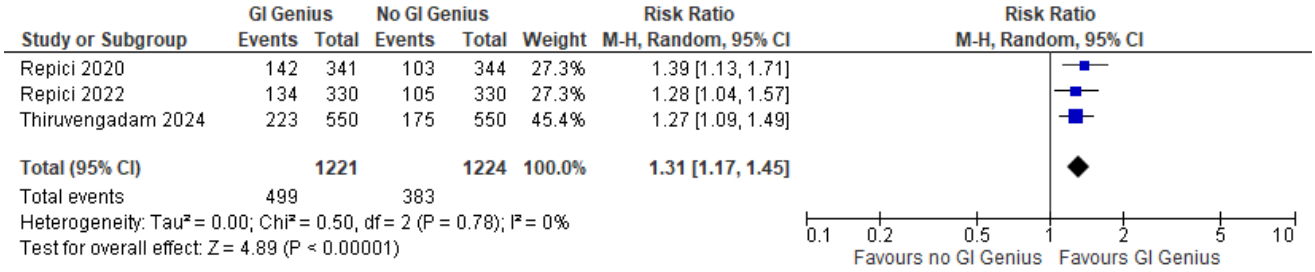


Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

GI Genius™

Three RCTs reporting non-advanced ADR for this technology compared to standard colonoscopy were meta-analysed.[21, 22, 24] Colonoscopy indications and endoscopist experience were similar to those described for ADR, but none of the studies covered a Lynch syndrome population specifically and there was not a study focusing specifically on a national screening programme. Results suggest a higher non-advanced ADR with GI Genius™, which was statistically significant (p-value <0.00001; Figure 8). Results appear to be similar across studies, with no evidence of statistical heterogeneity based on the I^2 value. The EAG considers results from the non-randomised NAIAD trial (diagnostic colonoscopy population) [redacted] (see Section 3.2.2.1.10 of the main report).

Figure 8. Non-advanced ADR in GI Genius™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

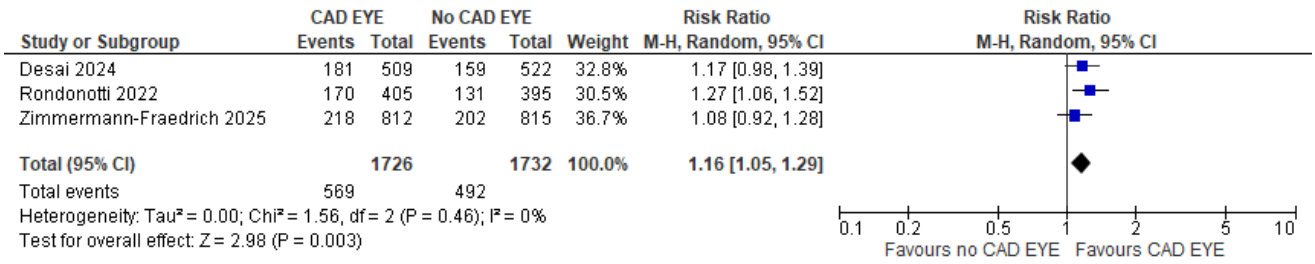
1.3 Adenoma detection rate separated by size

CAD EYE®

Four RCTs reported ADR broken down by size in some form.[6, 7, 9, 11] Two broke this down into three size categories (≤5 mm or <5 mm, 6-9 mm or ≥5 to 9 mm, and ≥10 mm), one only reported size-based ADR for adenomas <5 mm and the other split sizes into <10 mm and ≥10 mm. This led to one single-study analysis comparing CAD EYE® against standard colonoscopy (for ADR of <10 mm)), and three meta-analyses of two (for ADR of 6-9 mm or ≥5 to 9 mm) or three (for ADR of ≤5 mm or <5 mm and ≥10 mm) studies. Populations covered by each study varied but included screening (general and following a positive faecal immunochemical test [FIT]), screening or surveillance colonoscopy (with a surveillance interval of at least three years) and screening or diagnostic colonoscopy. Endoscopist experience varied, with two requiring a certain number of procedures (for example, at least 1000 prior colonoscopies or at least 300 per year) and a baseline ADR of at least 25%, one requiring experienced colonoscopists with no definition provided and the remaining study had no such requirements.

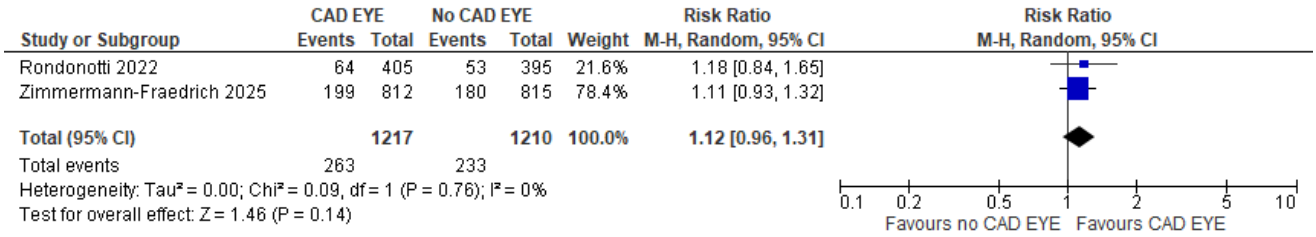
Results suggest a higher ADR with CAD EYE® across all size categories based on point estimates, although results for the ≤5 or <5 mm analysis are significant and others are not. These results suggest a possible trend towards the impact of CAD EYE® being greater for smaller polyps, but the External Assessment Group (EAG) notes there is not a huge difference in the risk ratios generated and considerable overlap in terms of 95% confidence intervals (CIs) across analyses for different size categories, there are fewer events observed for the larger size category and there are only a few studies on which to base any conclusions (Figure 9 to Figure 12). Therefore, the EAG considers evidence for a differential impact depending on adenoma size to be limited.

Figure 9. ADR by size (≤5 mm or <5 mm) in CAD EYE® studies



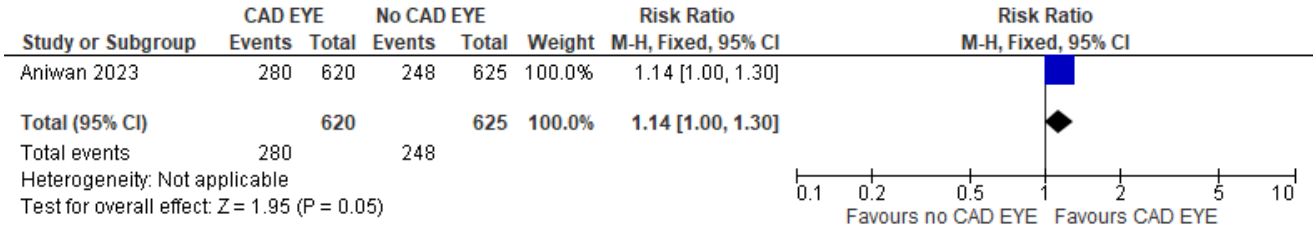
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 10. ADR by size (6-9 mm) in CAD EYE® studies



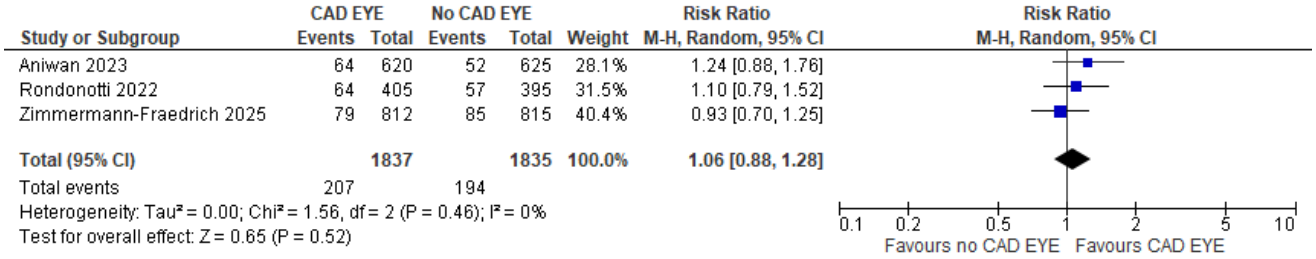
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 11. ADR by size (<10 mm) in CAD EYE® studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 12. ADR by size (≥10 mm) in CAD EYE® studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

CADDIE™

[redacted]

[redacted]

Figure 13. ADR by size (≤5 mm) in CADDIE™ studies

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 14. ADR by size (6-9 mm) in CADDIE™ studies

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 15. ADR by size (≥10 mm) in CADDIE™ studies

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

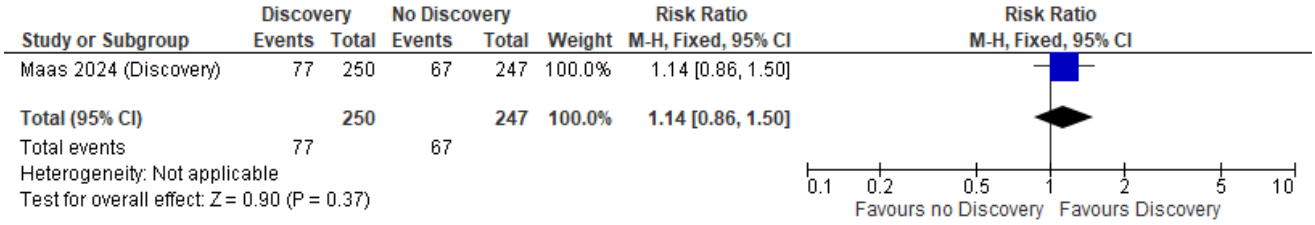
Discovery™

The RCT identified for Discovery™ (non-immunochemical faecal occult blood test [iFOBT] screening, surveillance or diagnostic colonoscopy, with endoscopists having >2000 prior colonoscopies) reported ADR separately for three separate size categories.[26] None of the analyses indicate

statistically significant benefits of Discovery™ (p-values 0.37, 0.17 and 0.97) and while there are differences in point estimates between size categories, these do not appear to follow any particular pattern, as it moves from a benefit of Discovery™ for ≤5 mm to a benefit of standard colonoscopy in the 6-9 mm category, to no difference for ≥10 mm (

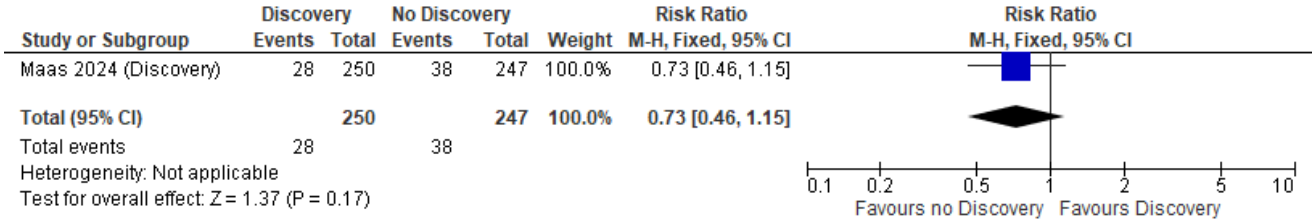
Figure 16 to Figure 18). The EAG does not consider there to be sufficient data on which to base conclusions about differences in ADR between size categories, particularly given event rates drop with increases in the size category.

Figure 16. ADR by size (≤5 mm) in Discovery™ studies



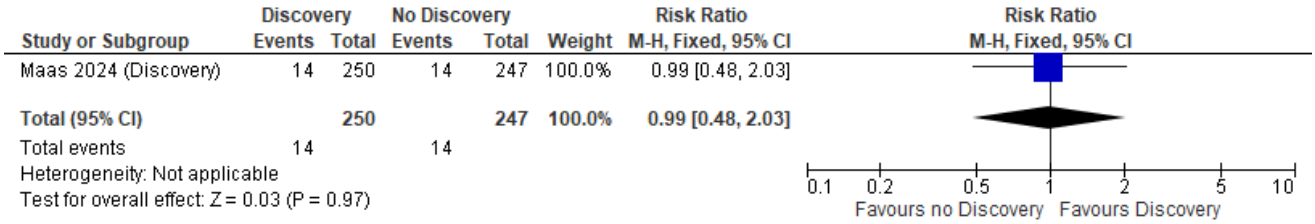
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 17. ADR by size (6-9 mm) in Discovery™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 18. ADR by size (≥10 mm) in Discovery™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

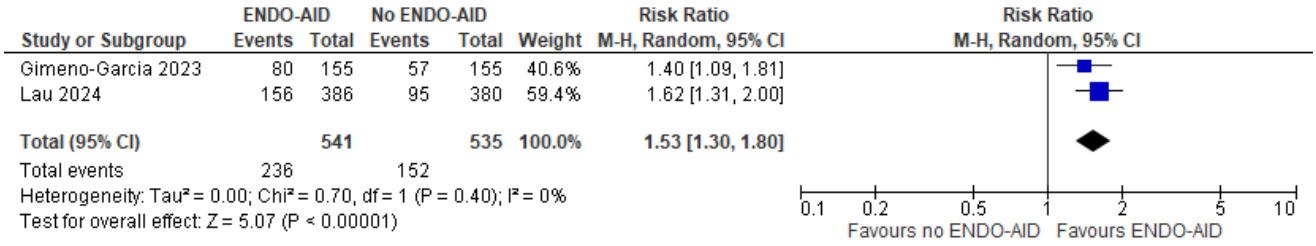
ENDO-AID™

Two of the four ENDO-AID™ RCTs reported data split by size categories,[13, 14] splitting into categories of ≤5 or <5 mm, 5-10 mm or 6-9 mm and >10 mm or ≥10 mm, which were combined into three meta-analyses. These studies covered broad populations of screening, diagnostic or surveillance colonoscopies, with endoscopist experience differing (>2000 prior colonoscopies required in one and the other being performed by trainees under supervision).

Results across these size categories suggest a trend for the benefit of ENDO-AID™ on ADR reducing the larger the size category; analyses for the two smaller size categories have a point estimate suggesting increased ADR with ENDO-AID™ and are statistically significant (p-values <0.00001 and 0.03), whereas the point estimate suggests the opposite for the >10 or ≥10 mm category, although this is not statistically significant (p-value 0.52; Figure 19 to

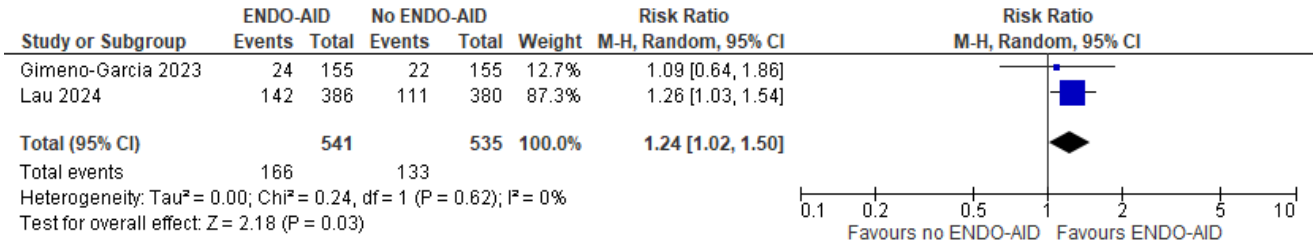
Figure 21). While this trend is noted, the EAG does not consider the data to be strong enough to base a firm conclusion on, as there is obvious heterogeneity between the two studies for the >10 or ≥10 mm analysis (point estimates in opposing directions, I^2 value 67%) and the number of events is substantially reduced compared to the other size categories.

Figure 19. ADR by size (<5 or ≤5 mm) in ENDO-AID™ studies



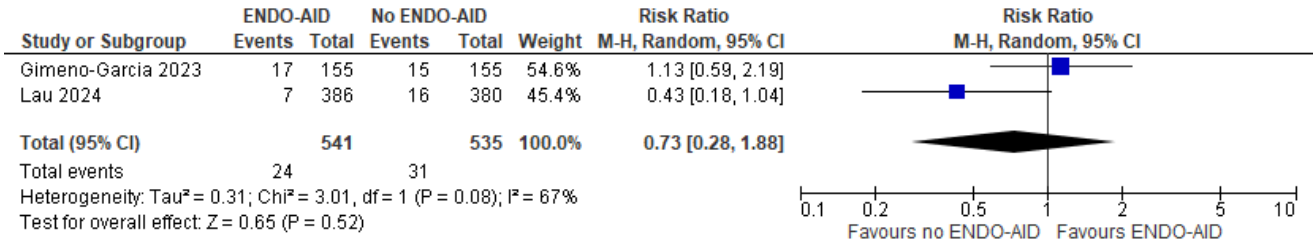
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 20. ADR by size (5-10 or 6-9 mm) in ENDO-AID™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 21. ADR by size (>10 or ≥10 mm) in ENDO-AID™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

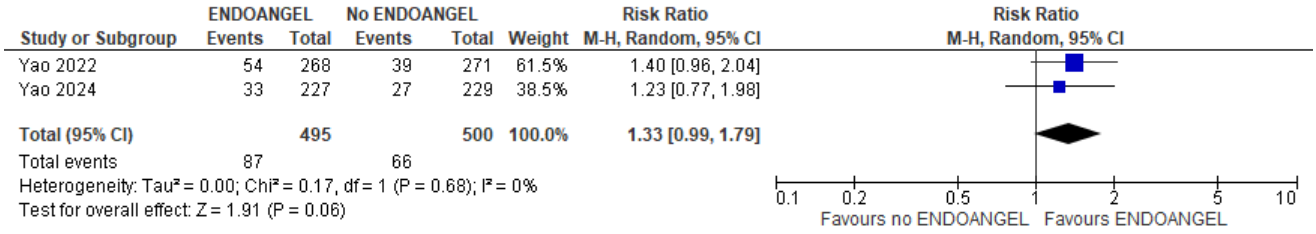
ENDOANGEL®

Three of the four RCTs for ENDOANGEL® reported ADR for different size categories,[17, 18, 27] with data from two analysed when one study (Gong *et al.* 2020) considered to be at a higher risk of bias was excluded from the primary analysis.[27] Both studies covered screening, symptomatic and surveillance colonoscopies but endoscopist experience varied; one covered more experienced endoscopists (requirement for at least 2000 prior colonoscopies), while the other was performed by novices supported by experts with at least 5000 prior colonoscopies where required for aspects other than polyp detection.

Results do not suggest a trend in any particular direction, with all three size categories appearing to have an improved ADR with ENDOANGEL®, which was not statistically significant in any analysis (p-values 0.06, 0.10 and 0.60). Point estimates suggest that the impact was larger in the 6-9 mm analysis, but the point estimate for ≥10 mm adenomas was similar to that for ≤5 mm adenomas (

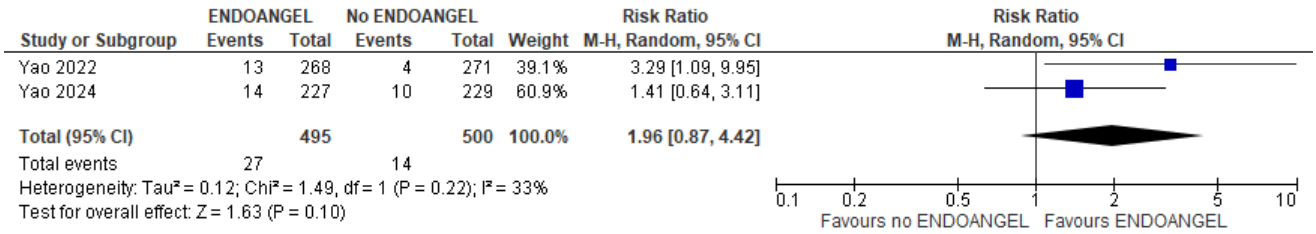
Figure 22 to Figure 24). The EAG does not consider there to be strong evidence of a differential impact of ENDOANGEL® across adenoma size categories. There is some evidence of heterogeneity in two of the analyses based on the I^2 value and/or point estimates. As noted for other interventions, reduced events in the larger size categories limits the ability to draw conclusions.

Figure 22. ADR by size (≤5 mm) in ENDOANGEL® studies



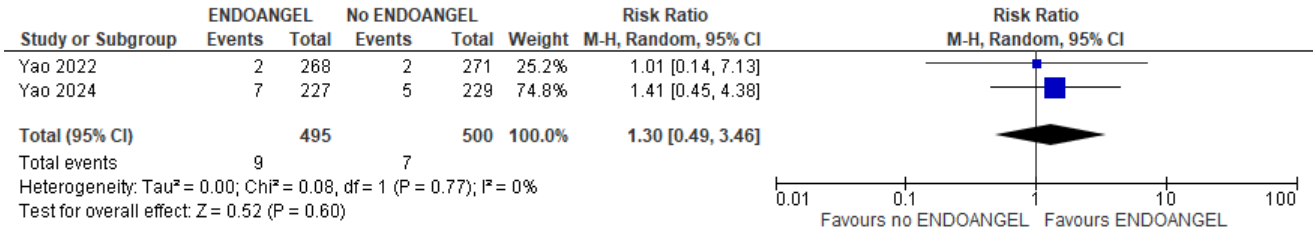
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 23. ADR by size (6-9 mm) in ENDOANGEL® studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 24. ADR by size (≥10 mm) in ENDOANGEL® studies



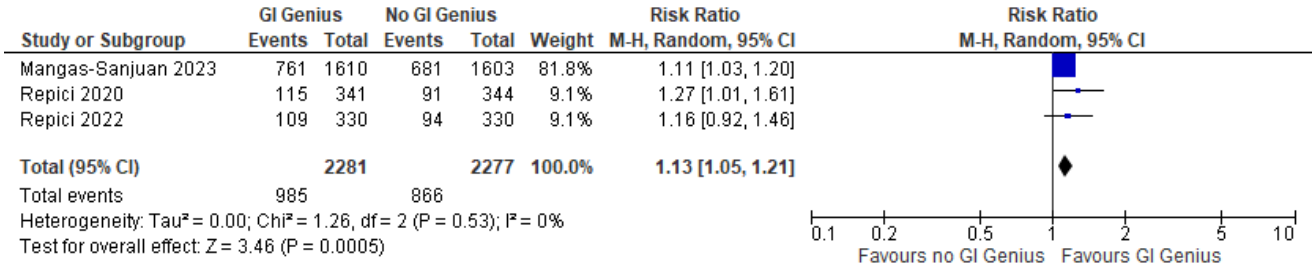
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

GI Genius™

Four RCTs for GI Genius™ reported ADR for different size categories,[20-22, 28] with one study (Engelke *et al.* 2023) considered to be at a higher risk of bias excluded from the primary analysis.[28] All three studies analysed reported it broken down for three separate categories (≤5 mm, 6-9 mm and ≥10 mm). One also reported a combined <10 mm category. Overall, studies covered screening, symptomatic and surveillance colonoscopies; two were mixed populations, varying slightly in each, but one was specific to those having CRC screening or presenting after a positive FIT. Endoscopist experience also varied; one was in non-expert endoscopists (defined as <2000 prior colonoscopies) and two were specifically endoscopists within a screening programme.

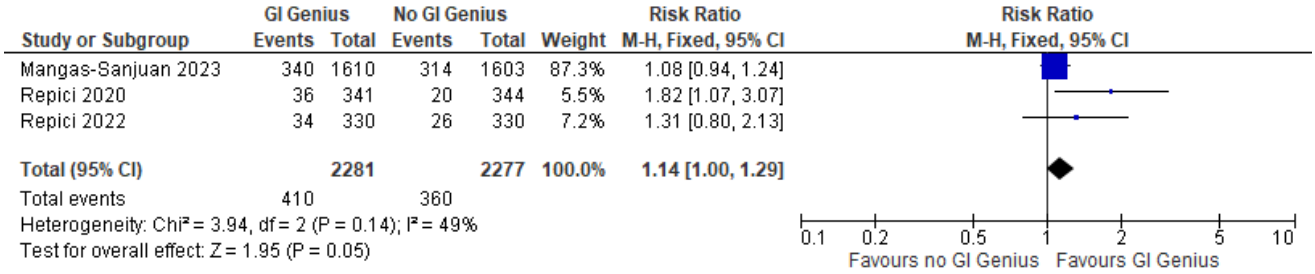
Results suggest that the impact of GI Genius™ may be larger for ≤5 mm and 6-9 mm (or <10 mm) categories based on point estimates, although a statistically significant impact was only identified for the ≤5 mm size category (p-values 0.0005, 0.05, 0.07 and 0.49; Figure 25 to Figure 28). However, the EAG considers the evidence for a differential impact between size categories to be limited, particularly with reducing events as the size grouping increases. There is some evidence of heterogeneity within all analyses other than the ≤5 mm analysis based on point estimates and/or statistical heterogeneity based on the I^2 value.

Figure 25. ADR by size (≤5 mm) in GI Genius™ studies



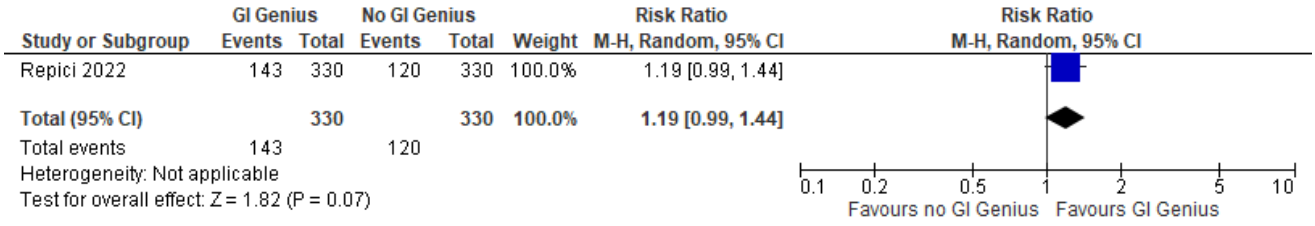
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 26. ADR by size (6-9 mm) in GI Genius™ studies



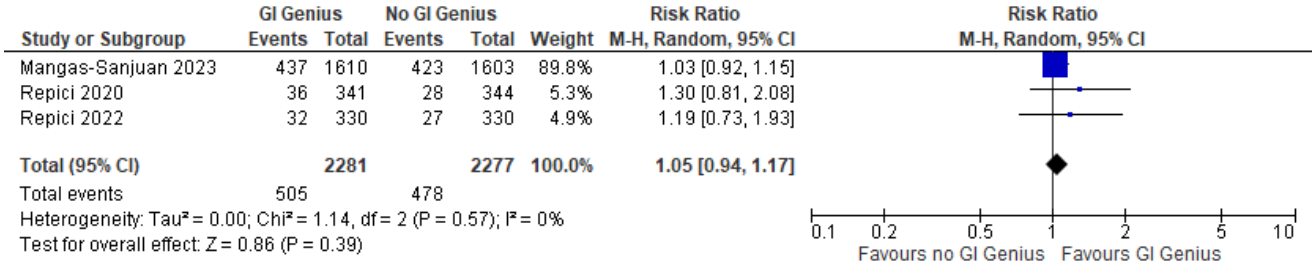
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 27. ADR by size (<10 mm) in GI Genius™ studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 28. ADR by size (≥10 mm) in GI Genius™ studies



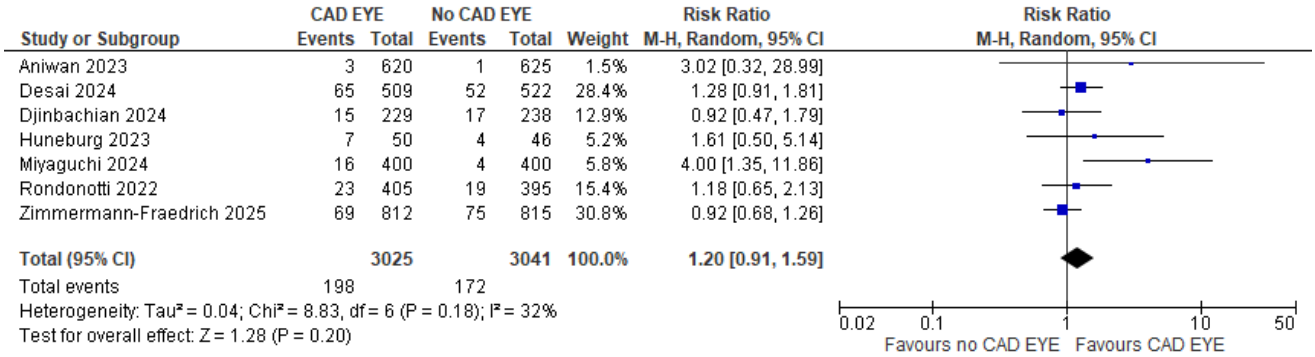
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

1.4 Sessile serrated lesion detection rate

CAD EYE®

Eight RCTs reporting sessile serrated lesion (SSL) detection rate for this technology compared to standard colonoscopy were identified,[2, 6-11, 29] with one study (Scholer *et al.* 2024) at a higher risk of bias excluded from the primary meta-analysis.[2] Colonoscopy indications and endoscopist experience were similar to those described for ADR. Results suggest a higher (not statistically significant; p-value 0.20) SSL detection rate with CAD EYE® (Figure 29). There is some indication of heterogeneity based on visible differences between point estimate and some statistical heterogeneity with an I^2 value of 32%.

Figure 29. SSL DR in CAD EYE® studies



Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

CADDIE™

[redacted]

Figure 30).

Figure 30. SSL DR in CADDIE™ studies

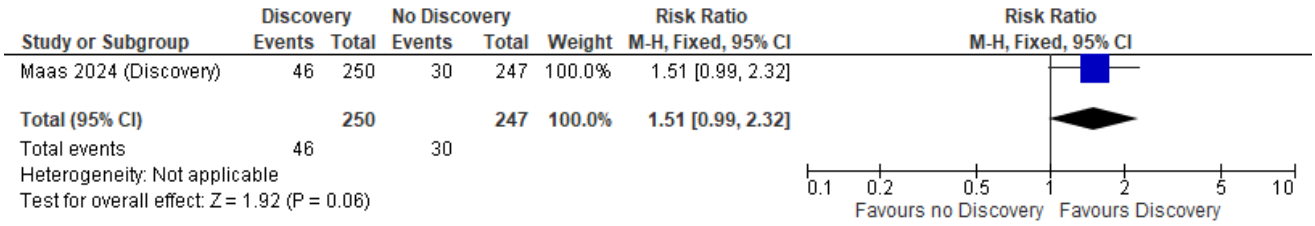
[redacted]

Abbreviations: CI, confidence interval; CSR, clinical study report; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

Discovery™

A single RCT reporting SSL detection rate for this technology compared to standard colonoscopy was identified.[26] The population was those scheduled for non-iFOBT screening, surveillance or diagnosis colonoscopy and endoscopists included had performed at least 2000 prior colonoscopies. Results suggest a higher SSL detection rate with Discovery™ compared to standard colonoscopy but this was not statistically significant (p-value 0.06; Figure 31).

Figure 31. SSL DR in Discovery™ studies



Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

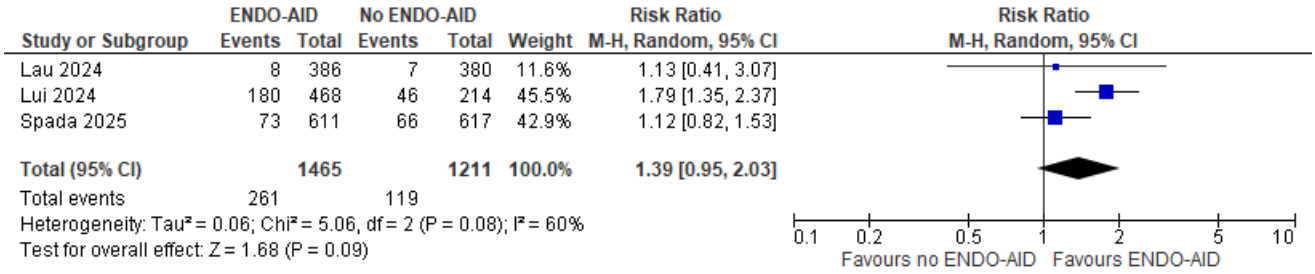
ENDO-AID™

Three RCTs reporting SSL detection rate for this technology compared to standard colonoscopy were meta-analysed.[14-16] Populations were similar, with two covering screening, surveillance and symptomatic colonoscopies and the other only covering screening and surveillance colonoscopy. Endoscopist experience varied; one did not appear to have any criteria for inclusion, one included endoscopists with >2000 colonoscopy procedures and the other was specifically trainee

endoscopists with supervisors present. Results suggest a higher (not statistically significant; p-value 0.09) SSL detection rate with ENDO-AID™ (

Figure 32). There is evidence of substantial statistical heterogeneity based on the I^2 value of 60% and visual differences in point estimates.

Figure 32. SSL DR in ENDO-AID™ studies

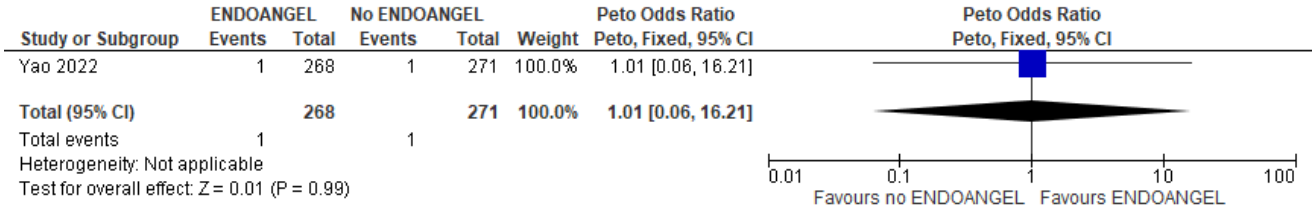


Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

ENDOANGEL®

Only one of the four RCTs for ENDOANGEL® reported SSL detection rate compared to standard colonoscopy.[17] The population in this study included screening, post-polypectomy surveillance and colonoscopy for gastrointestinal symptoms. Endoscopists required >2000 colonoscopies to participate. Results suggest no difference between trial arms, although this was based on only a single event in both arms (Figure 33).

Figure 33. SSL DR in ENDOANGEL® studies



Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

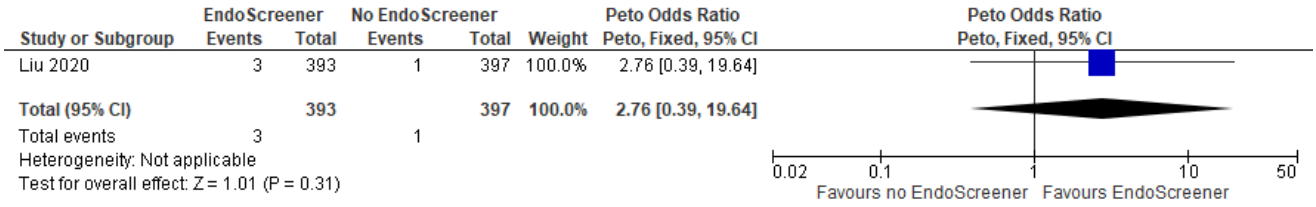
EndoScreener®

Only a single RCT for this technology reported SSL detection rate.[30] Any colonoscopy indication appeared to be included, with no requirements for endoscopist experience described. Results

suggest a higher SSL detection rate with EndoScreener® but this was not statistically significant and was based on a difference of only two events between trial arms (p-value 0.31;

Figure 34).

Figure 34. SSL DR in EndoScreener® studies



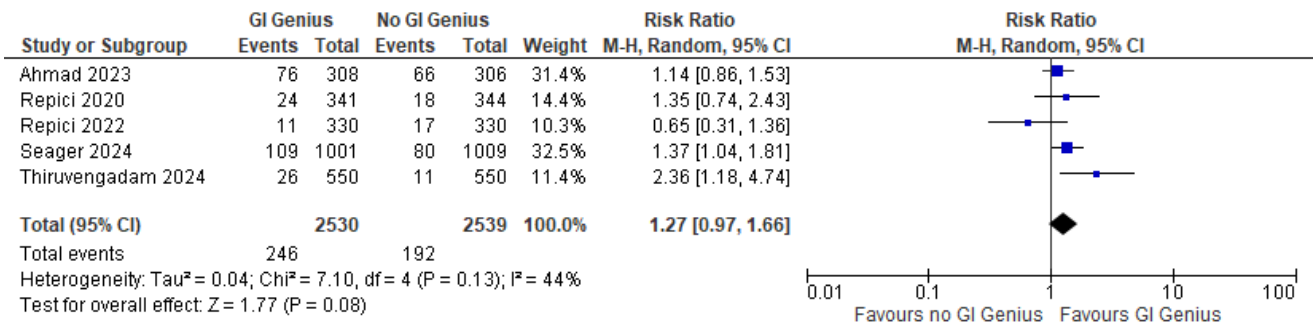
Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

GI Genius™

Six RCTs reporting SSL detection rate for this technology compared to standard colonoscopy were identified,[1, 2, 21-24] with one study (Scholer *et al.* 2024) at a higher risk of bias excluded from the primary meta-analysis.[2] Colonoscopy indications and endoscopist experience were similar to those described for ADR, but none of the studies covered a Lynch syndrome population specifically. Results suggest a higher SSL detection rate with GI Genius™ but this was not statistically significant (p-value 0.08;

Figure 35). There is notable variation between studies based on point estimates and evidence of statistical heterogeneity based on the I^2 value of 44%. The EAG considers results from the non-randomised NAIAD trial (diagnostic colonoscopy population) [redacted] (see Section 3.2.2.1.10 of the main report).

Figure 35. SSL DR in GI Genius™ studies

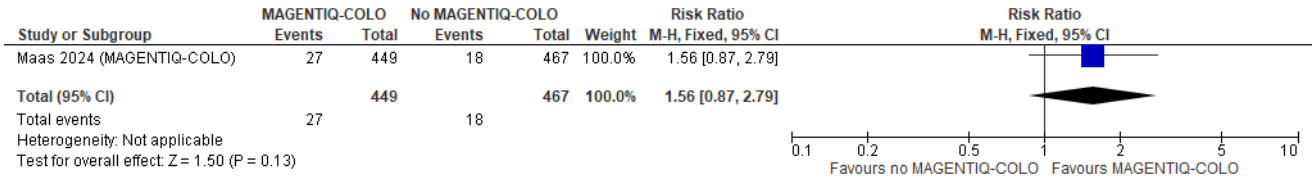


Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

MAGENTIQ-COLO™ (MAGENTIQ-EYE)

A single RCT reporting SSL detection rate for this technology compared to standard colonoscopy was identified.[31] The population was non-iFOBT screening or surveillance colonoscopies (within the last three years for surveillance colonoscopies) and endoscopists had an ADR between 25 and 40%. Results suggest a higher SSL detection rate with MAGENTIQ-COLO™ compared to standard colonoscopy, which was not statistically significant (p-value 0.13; Figure 36).

Figure 36. SSL DR in MAGENTIQ-COLO™ studies



Abbreviations: CI, confidence interval; DR, detection rate; M-H, Mantel-Haenszel; SSL, sessile serrated lesion.

1.5 Significant polyp detection rate

Forest plots relating to data CADDIE™, Endoscopic Multimedia Information System (EMIS™) and GI Genius™, for significant polyp detection rate or similar, in Section 3.2.2.1.1.6 of the main report are presented below in Figure 37 to Figure 39, respectively. These data were from one study for each intervention.[1, 12, 32]

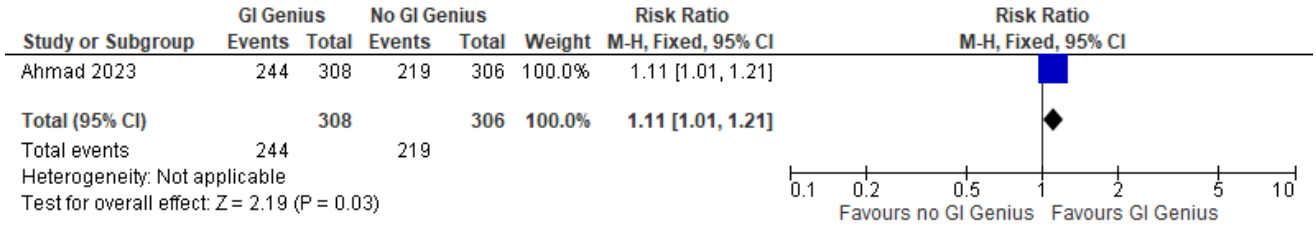
Figure 37. Neoplastic detection rate in CADDIE™ studies

Abbreviations: CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 38. ADR (including adenomatous, sessile and tubulovillous polyps) in EMIS™ studies

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; EMIS™, Endoscopic Multimedia Information System; M-H, Mantel-Haenszel.

Figure 39. Significant polyp detection rate in GI Genius™ studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

1.6 Adenoma miss rate

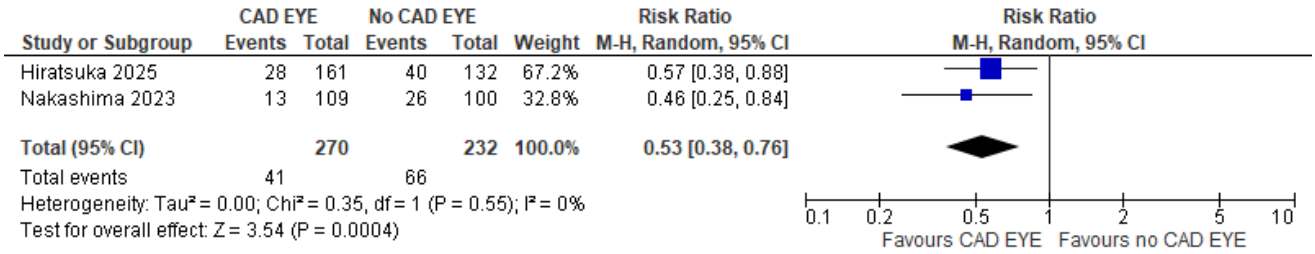
CAD EYE®

Three RCTs reported adenoma miss rate (AMR) for CAD EYE® on a per lesion basis,[3, 33, 34] covering primary endoscopic screening for CRC, screening following a positive FIT test of occult blood, patients with colorectal neoplasia undergoing endoscopic resection or for surveillance following colonic polypectomy, with specific inclusions varying between the three studies and one simply reporting indications as screening, surveillance and symptomatic patients. Endoscopist experience was board-certified endoscopists in one, trainees in another (with a tandem procedure performed by experts with >5000 prior colonoscopies) and experts and non-experts (≥10 vs <10 years' experience) in the remaining study.

The way in which AMR was calculated in these studies differed slightly; Nakashima *et al.* 2023 and Hiratsuka *et al.* 2025 calculated it as number of adenomas in the second colonoscopy divided by the total number across first and second colonoscopies, while Yamaguchi *et al.* 2024 calculated it by

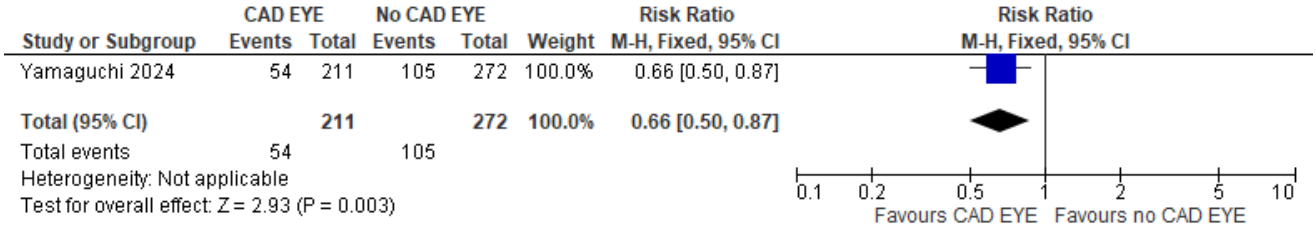
dividing the number of adenomas identified only by experts (number by experts minus number by trainees) by the total number identified by experts.[3, 33, 34] Therefore, it was not considered appropriate to pool data from Yamaguchi *et al.* 2024 with the other two studies for this outcome. Results indicate a statistically significant benefit of CAD EYE® in terms of AMR in both analyses (based on the fact that 95% CIs in both analyses do not cross the line of null effect), with fewer missed lesions compared to standard colonoscopy (Figure 40 and Figure 41).

Figure 40. AMR in CAD EYE® studies – per lesion – total adenomas on both colonoscopies as denominator



Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 41. AMR in CAD EYE® studies – per lesion – total adenomas on colonoscopy performed by expert as denominator



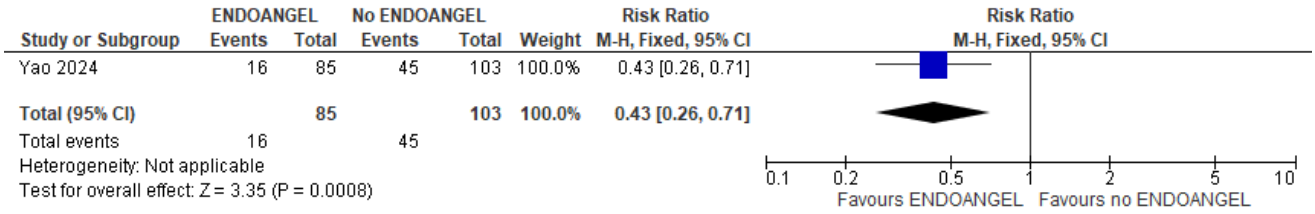
Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

ENDOANGEL®

One RCT reported AMR for ENDOANGEL® on a per lesion basis,[18] covering diagnostic, screening or surveillance colonoscopy. Endoscopist experience was novices, with insertion performed by experts with >5000 prior colonoscopies. Results indicate a statistically significant benefit of ENDOANGEL® in terms of AMR (p-value 0.0008), with fewer missed lesions compared to standard colonoscopy (

Figure 42).

Figure 42. AMR in ENDOANGEL® studies – per lesion

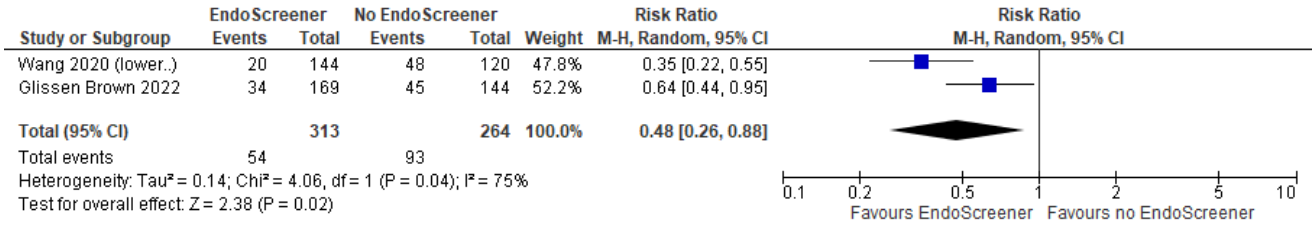


Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

EndoScreener®

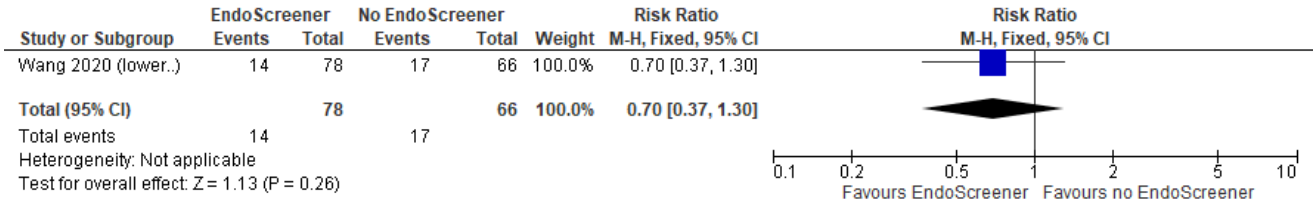
Two RCTs reported AMR for EndoScreener® on a per lesion basis,[35, 36] with one also reporting it on a per-patient basis.[36] The studies covered screening or surveillance colonoscopy, or diagnostic, screening or surveillance colonoscopy (prior polypectomy). Endoscopist were described as experienced endoscopists from division of gastroenterology in one study and in the other were described as having a high baseline ADR. Results indicate a statistically significant benefit of EndoScreener® in terms of per lesion AMR (p-value 0.02), with fewer missed lesions compared to standard colonoscopy. Some evidence of substantial statistical heterogeneity was present based on an I^2 value of 75% and visible differences in point estimates (Figure 43). For the per-patient analysis, the point estimate also suggested a benefit of EndoScreener®, but this was not statistically significant (p-value 0.26; Figure 44).

Figure 43. AMR in EndoScreener® studies – per lesion



Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 44. AMR in EndoScreener® studies – per-patient

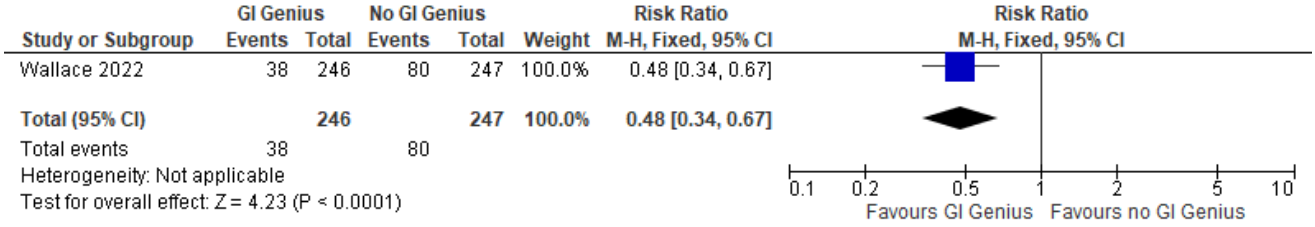


Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

GI Genius™

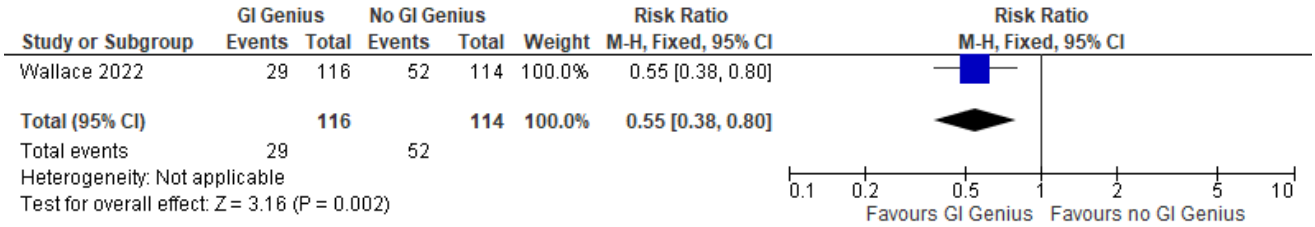
One RCT reported AMR for GI Genius™ on a per lesion and per-patient basis.[37] The population was those ≥45 years undergoing screening or surveillance colonoscopy for CRC and to participate, endoscopists required a baseline ADR between 20 and 40% and at least 1000 prior colonoscopies. Results indicate a statistically significant benefit of GI Genius™ for both outcomes (p-values <0.0001 and 0.002), with fewer missed lesions compared to standard colonoscopy and fewer patients with at least one missed adenoma or carcinoma (Figure 45 and Figure 46).

Figure 45. AMR in GI Genius™ studies – per lesion



Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 46. AMR in GI Genius™ studies – per-patient

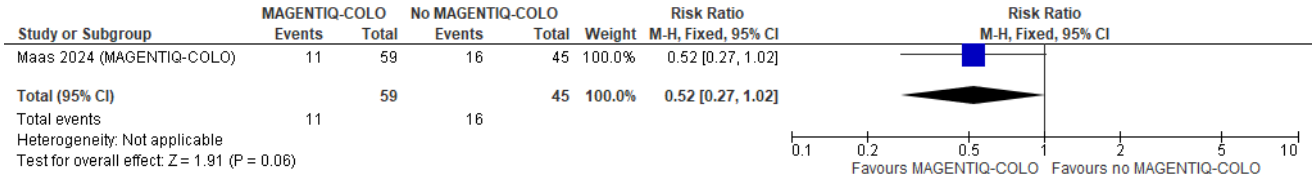


Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

MAGENTIQ-COLO™

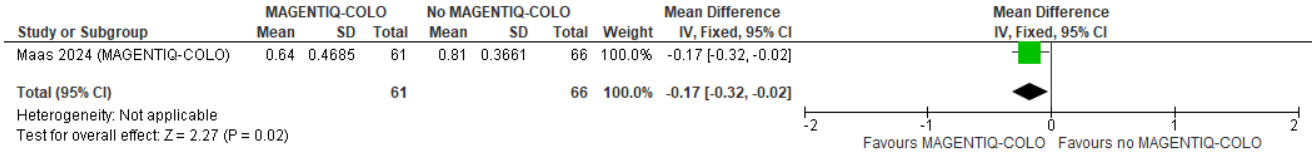
A single RCT reporting AMR for this technology compared to standard colonoscopy on a per lesion basis and as a mean AMR per-patient was identified.[31] The population was non-iFOBT screening or surveillance colonoscopies (within the last three years for surveillance colonoscopies) and endoscopists had an ADR between 25 and 40%. Only the tandem arms within this RCT were used to calculate these outcomes. Results suggest benefit of MAGENTIQ-COLO™ compared to standard colonoscopy, with fewer missed lesions and a lower mean per-patient AMR (Figure 47 and Figure 48).

Figure 47. AMR in MAGENTIQ-COLO™ studies – per lesion



Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 48. AMR in MAGENTIQ-COLO™ studies – mean per-patient AMR



Abbreviations: AMR, adenoma miss rate; CI, confidence interval; M-H, Mantel-Haenszel.

1.7 Adenomas per colonoscopy

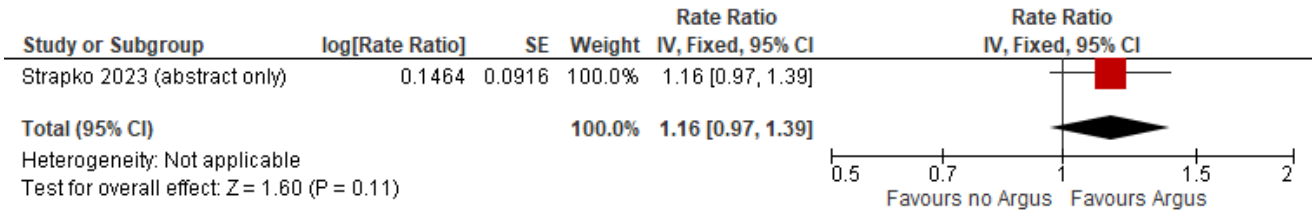
Argus®

A single abstract, with some limited additional information in the instructions for use manual provided by the manufacturer, covering Argus® reported data for adenomas per colonoscopy (APC) that could be analysed.[38, 39] Formal analysis using a forest plot was possible as an incidence rate ratio (IRR), but not as a mean difference as only mean values with no measure of variation were reported. Colonoscopy indications were as described for the ADR outcome, with endoscopist experience not reported.

Results for mean values only suggest a higher APC in the Argus®-assisted colonoscopy group (0.782 vs 675, p-value not reported). When analysed as an IRR, results indicate increased APC with Argus®, but no statistically significant difference is noted (p-value 0.11;

Figure 49).

Figure 49. APC in Argus® studies – IRR



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

CAD EYE®

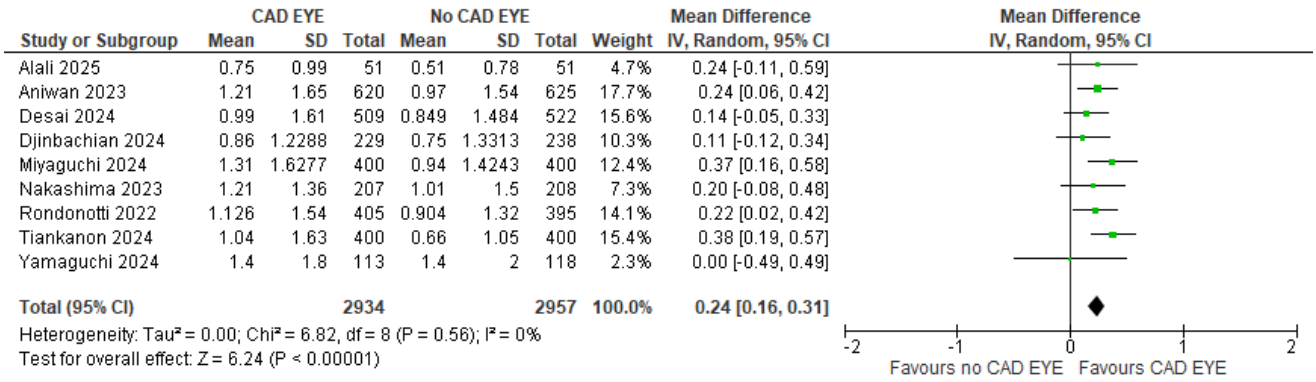
Twelve RCTs covering CAD EYE® reported data for APC that could be analysed,[3, 4, 6-11, 29, 33, 34, 40] including nine as mean and standard deviation (SD) and twelve where data could be used to calculate an IRR. Colonoscopy indications and endoscopist experience were similar to those described for ADR.

Results indicate statistically significant benefits of CAD EYE®, with increased APC when reported as mean difference as well as IRR (p-value <0.00001 for both;

Figure 50 and

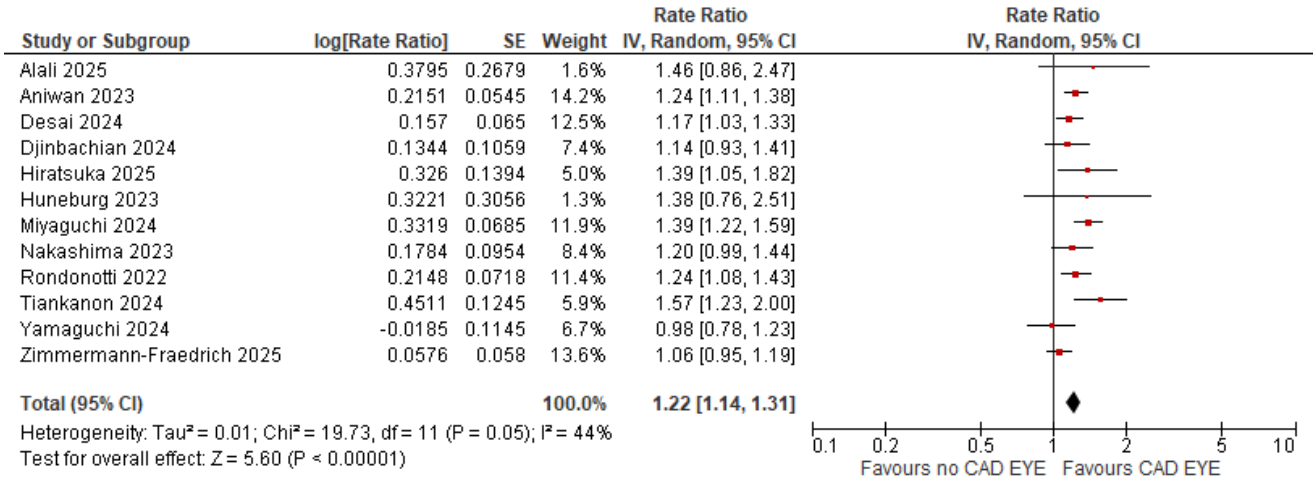
Figure 51). There was some evidence of statistical heterogeneity in the IRR analysis (I^2 value of 44%) and some evidence of heterogeneity based on visual differences in point estimates for the analysis as a continuous outcome.

Figure 50. APC in CAD EYE® studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 51. APC in CAD EYE® studies – IRR



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

CADDIE™

[redacted]

Figure 52. APC in CADDIE™ studies – mean and SD

[redacted]

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

Figure 53. APC in CADDIE™ studies – IRR

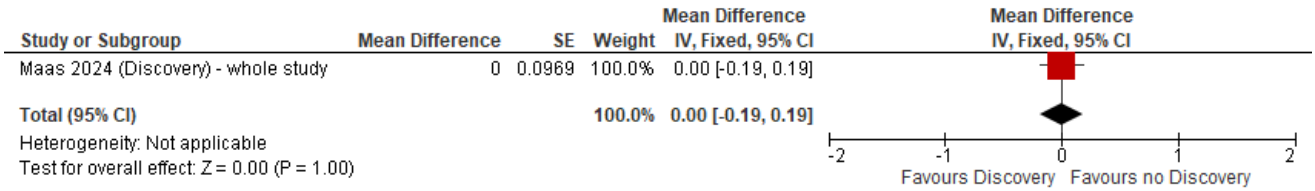
[redacted]

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

Discovery™

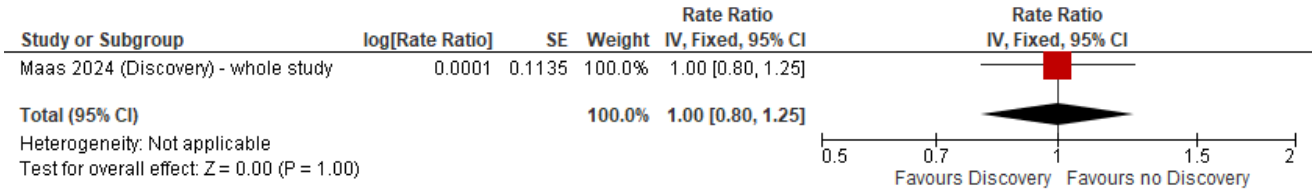
A single RCT reporting APC for this technology compared to standard colonoscopy was identified, with data analysed as a mean difference and as an IRR.[26] Colonoscopy indications and endoscopist experience are as described for ADR. Results suggest no difference in APC in either analysis with Discovery™ compared to standard colonoscopy (Figure 54 and Figure 55).

Figure 54. APC in Discovery™ studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation; SE, standard error.

Figure 55. APC in Discovery™ studies – IRR



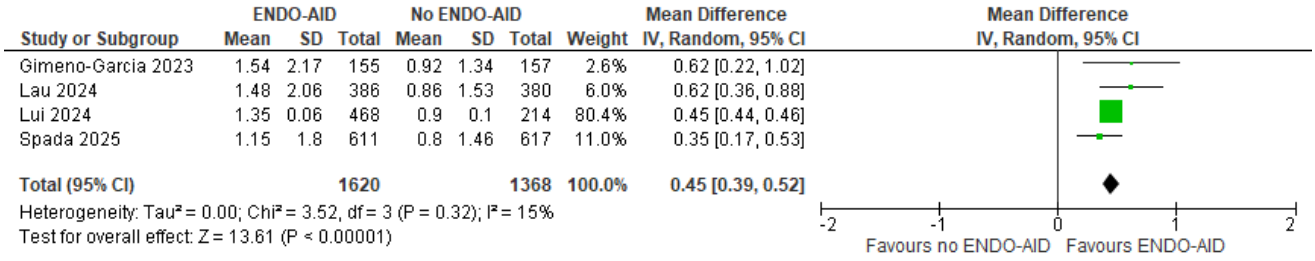
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

ENDO-AID™

Five RCTs covering ENDO-AID™ reported data for APC that could be analysed, including four as mean and SD and five when analysed as an IRR.[13-16, 42] For the IRR analysis, data from one study considered to be at a higher risk of bias (Vilkoite *et al.* 2023) was excluded from the primary analysis.[42] Colonoscopy indications and endoscopist experience are as described for ADR. Results indicate

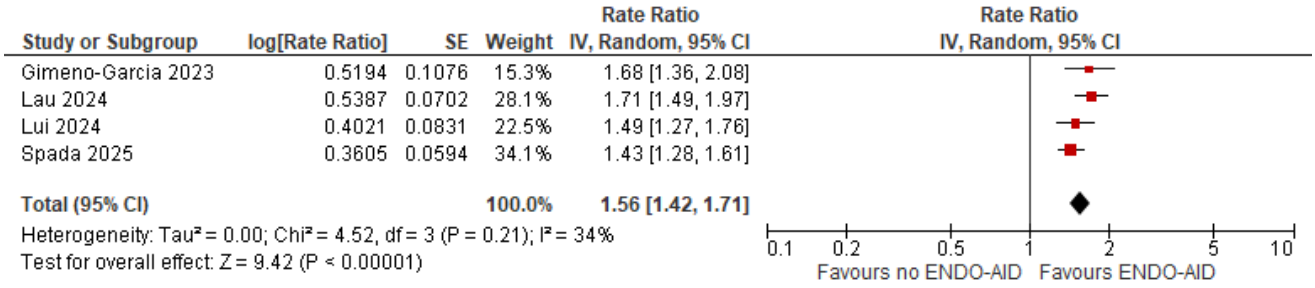
statistically significant benefits of ENDO-AID™, with increased APC when reported as mean difference as well as IRR (p-value <0.00001 for both; Figure 56 and Figure 57). There was some evidence of statistical heterogeneity in these analyses, particularly for the IRR analysis (I^2 values 15% and 34%), but all studies were consistent with a statistically significant increase in APC with ENDO-AID™.

Figure 56. APC in ENDO-AID™ studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 57. APC in ENDO-AID™ studies – IRR



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

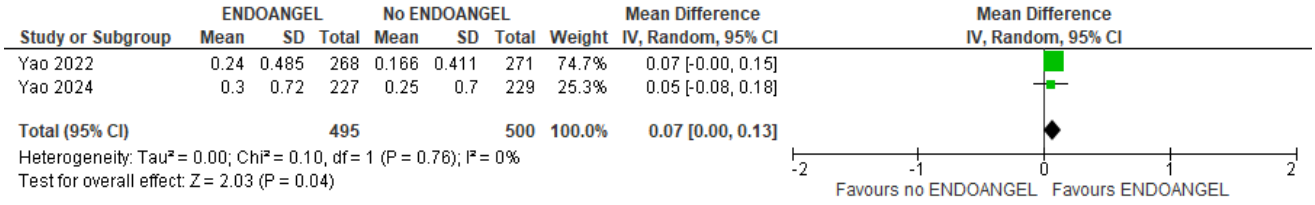
ENDOANGEL®

Three RCTs covering ENDOANGEL® reported data for APC that could be analysed, as mean and SD and as an IRR,[17, 18, 27] with data from one study considered to be at a high risk of bias (Gong *et al.* 2020) excluded from the primary analyses.[27] Colonoscopy indications and endoscopist experience are as described for ADR. Results indicate statistically significant benefits of ENDOANGEL®, with increased APC when reported as mean difference (p-value 0.04); a similar result was observed for the IRR analysis but this did not reach statistical significance (p-value 0.05;

Figure 58 and

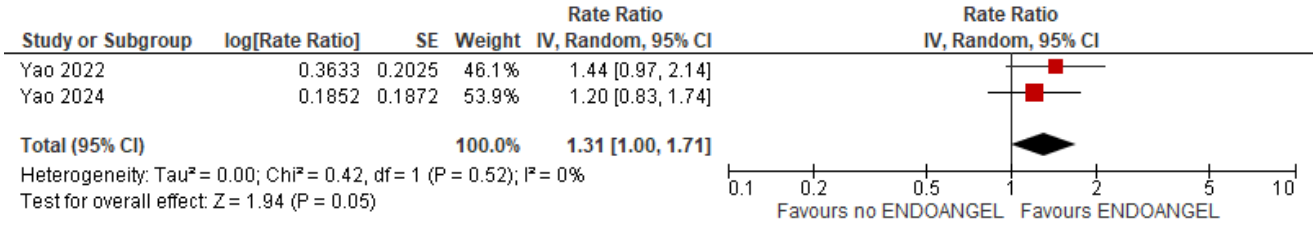
Figure 59). There was no strong evidence of statistical heterogeneity in either analysis.

Figure 58. APC in ENDOANGEL® studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 59. APC in ENDOANGEL® studies – IRR

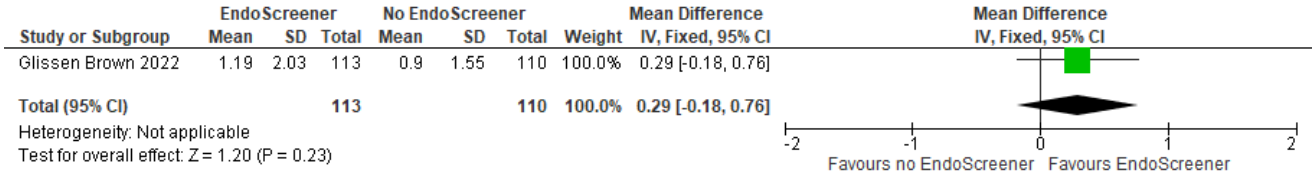


Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

EndoScreener®

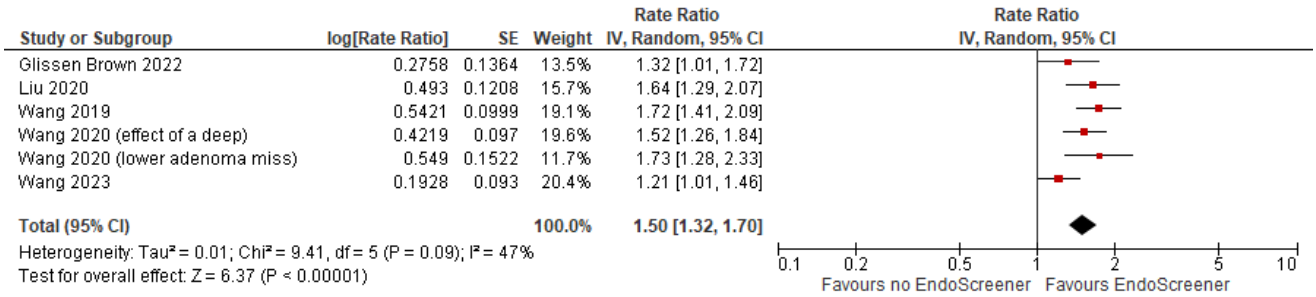
Only one RCT covering EndoScreener® reported data for APC that could be analysed as mean and SD,[35] with data for analysis as an IRR available for all six RCTs.[30, 35, 36, 43-45] Colonoscopy indications and endoscopist experience are as described for ADR. Results indicate benefits of ENDOANGEL®, with increased APC when reported as mean difference as well as IRR based on point estimates. This was not statistically significant when analysed as a mean and SD from a single study (p-value 0.23) but the results for IRR from all six studies was statistically significant (p-value <0.0001; Figure 60 and Figure 61). There was some evidence of statistical heterogeneity in the IRR analysis based on an I^2 value of 47%.

Figure 60. APC in EndoScreener® studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 61. APC in EndoScreener® studies – IRR

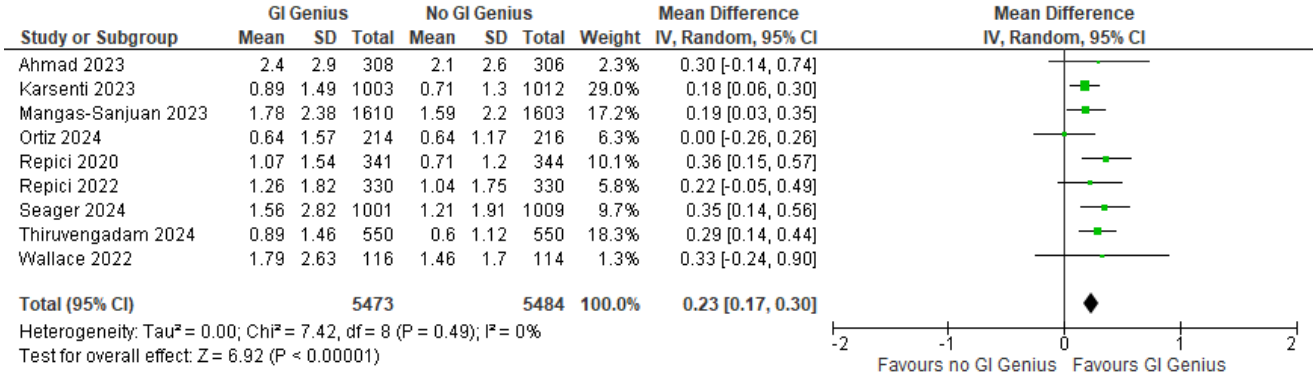


Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

GI Genius™

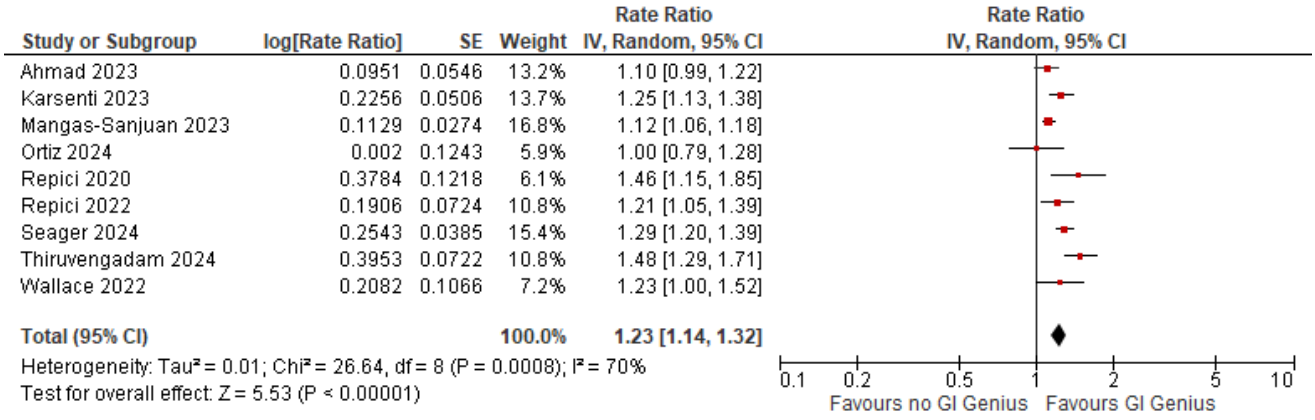
Eleven RCTs covering GI Genius™ reported data for APC, with nine reporting data that could be analysed as mean and SD and all eleven having data for analysis as an IRR.[1, 19-24, 28, 37, 46, 47] For the IRR analysis, two studies considered to be at a higher risk of bias (Engelke *et al.* 2023 and Lagstrom *et al.* 2025) were excluded from the primary analysis.[28, 47] Colonoscopy indications and endoscopist experience are similar to that described for ADR. Results indicate statistically significant benefits of GI Genius™ compared to standard colonoscopy, with increased APC when reported as a mean difference or as an IRR (p-value <0.00001 for both; Figure 62 and Figure 63). There was evidence of substantial statistical heterogeneity in the IRR analysis based on an I^2 value of 70% and some heterogeneity based on visible differences in point estimates for the mean and SD analysis. For APC reported as a mean difference, the EAG considers results from the non-randomised NAIAD trial (diagnostic colonoscopy population) [redacted] (see Section 3.2.2.1.10 of the main report).

Figure 62. APC in GI Genius™ studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SD, standard deviation.

Figure 63. APC in GI Genius™ studies – IRR



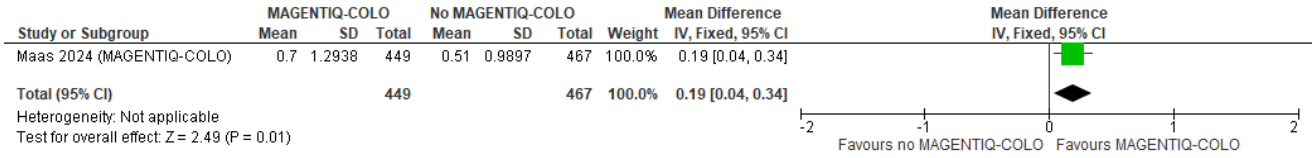
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

MAGENTIQ-COLO™

A single RCT reporting APC for this technology compared to standard colonoscopy was identified and analysed as a mean and SD and as an IRR.[31] Colonoscopy indications and endoscopist experience are as described for ADR. Results suggest a statistically significant benefit of MAGENTIQ-COLO™ compared to standard colonoscopy, with a higher APC when analysed as a mean difference or an IRR (p-values 0.01 and 0.0003, respectively;

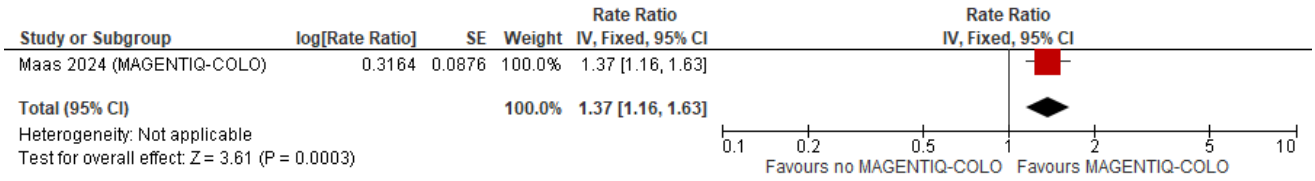
Figure 64 and Figure 65).

Figure 64. APC in MAGENTIQ-COLO™ studies – mean and SD



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 65. APC in MAGENTIQ-COLO™ studies – IRR



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

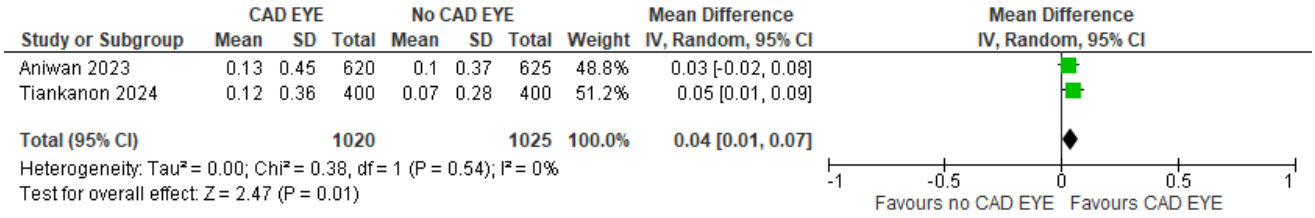
1.8 Advanced adenomas per colonoscopy

CAD EYE®

Two RCTs reporting advanced APC for this technology compared to standard colonoscopy were meta-analysed.[4, 6] Populations included in studies were the same, covering those aged 50 to 75 years undergoing routine screening colonoscopy or screening following a positive FIT. Endoscopist experience differed; one did not appear to have any requirements but the other required an ADR of ≥35%. Results suggest a higher (statistically significant; p-value 0.01) advanced APC with CAD EYE® (

Figure 66), with a mean difference of 0.04 advanced APC. There does not appear to be any evidence of heterogeneity in this analysis. Furthermore, one study reported advanced adenomas per positive patient, in a screening (age cut-off 50 years for men and 55 years for women) and diagnostic (polyp follow-up and symptom evaluation) population, with experienced examiners (not defined) performing procedures. Data were only available as median values, with an identical median of 1.0 (IQR 1.0 to 1.0) reported in both groups.[11]

Figure 66. Advanced APC in CAD EYE® studies



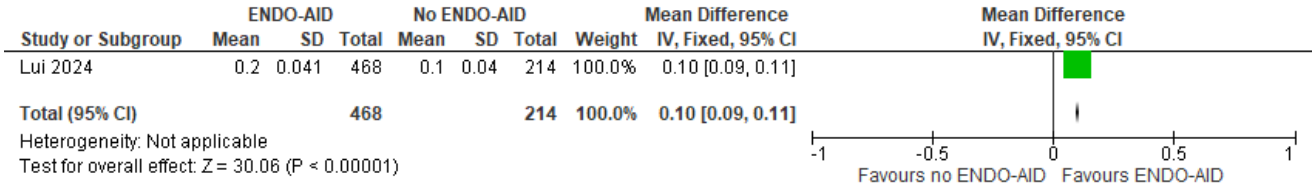
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

ENDO-AID™

One RCT reporting advanced APC for this technology compared to standard colonoscopy was identified.[15] The population included people ≥40 years undergoing elective colonoscopy for screening, surveillance or diagnostic workup. There did not appear to be any requirements for

inclusion of endoscopists. Results suggest a higher (statistically significant; p-value <0.00001) advanced APC with ENDO-AID™ (Figure 67), with a mean difference of 0.10 advanced APC.

Figure 67. Advanced APC in ENDO-AID™ studies

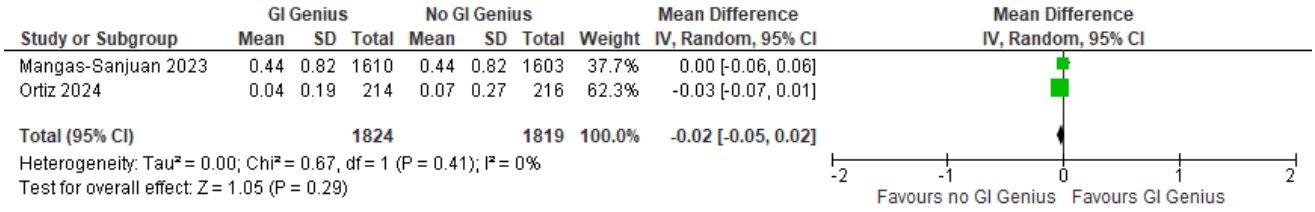


Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

GI Genius™

Two RCTs reporting advanced APC were meta-analysed for the GI Genius™ intervention.[20, 46] One study included a population covering a screening population after a positive FIT test and the other was specifically patients with Lynch syndrome undergoing surveillance. No requirements were mentioned for endoscopists in the screening study but they are likely to have been sufficiently qualified to participate in the screening programme, and the other study included endoscopists with an ADR of at least 20% or more for screening colonoscopy and 35% or more for colonoscopy following FIT, at least 2000 prior colonoscopies and training in optical diagnosis and chromoendoscopy techniques. Results suggest a slightly lower number of advanced APC with GI Genius™ compared to standard colonoscopy, although this was not statistically significant.

Figure 68. Advanced APC in GI Genius™ studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

1.9 Adenomas per colonoscopy separated by size

CAD EYE®

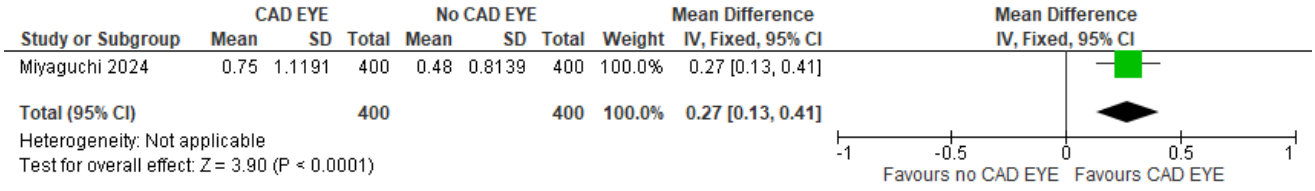
Two RCTs reported APC broken down by size in some form.[9, 29] One separated APC into three size categories (≤5 mm, 6-9 mm and ≥10 mm) and the other split sizes into <10 mm and ≥10 mm. This led to three single-study analyses comparing CAD EYE® against standard colonoscopy (≤5 mm, 6-9 mm

and <10 mm analyses) and one meta-analysis of two studies (≥10 mm). One study covered those ≥20 years undergoing colonoscopy due to positive FIT, abdominal symptoms or for follow-up of colon polyps and the other covered those aged 50 to 74 years undergoing colonoscopy as part of CRC screening programme following positive FIT. Endoscopist experience varied, with one requiring qualification for participation in a FIT-based screening programme and a baseline ADR of at least 25%, and the other with no such requirements.

Results in

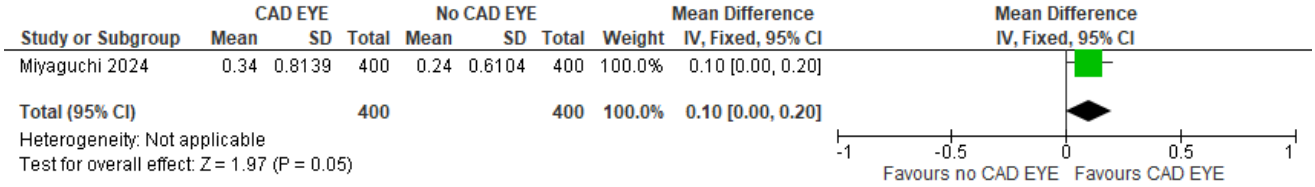
Figure 69 to Figure 72 suggest a higher APC with CAD EYE® across all size categories based on point estimates, although results for the ≤5 mm and <10 mm analyses are significant and others are not. On review of results across size categories, differences trend towards being less for the larger size categories, but the EAG does not consider there to be robust evidence to support this currently.

Figure 69. APC by size (≤5 mm) in CAD EYE® studies



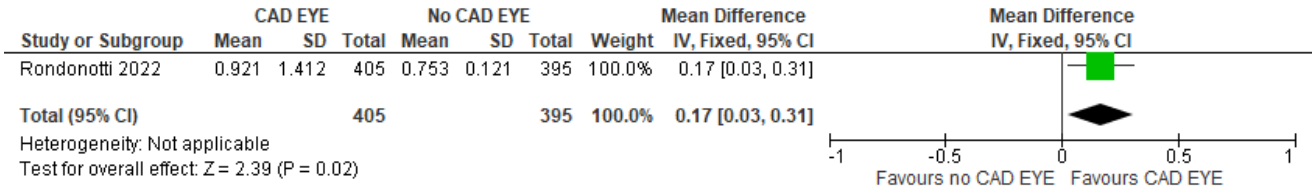
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 70. APC by size (6-9 mm) in CAD EYE® studies



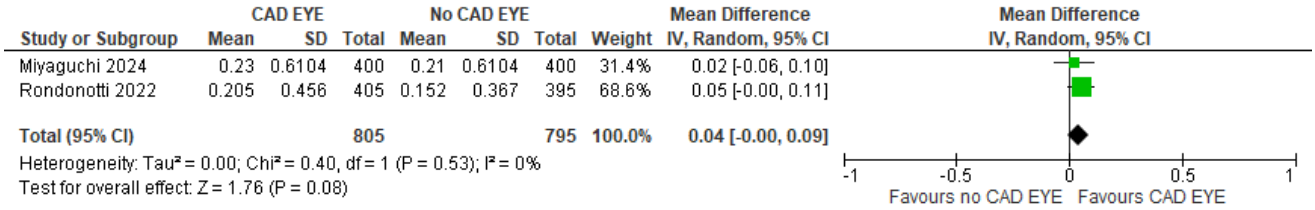
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 71. APC by size (<10 mm) in CAD EYE® studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 72. APC by size (≥10 mm) in CAD EYE® studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

CADDIE™

[redacted]

[redacted]

Figure 73. APC by size (≤5 mm) in CADDIE™ studies

[redacted]

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

Figure 74. APC by size (6-9 mm) in CADDIE™ studies

[redacted]

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

Figure 75. APC by size (≥10 mm) in CADDIE™ studies

[redacted]

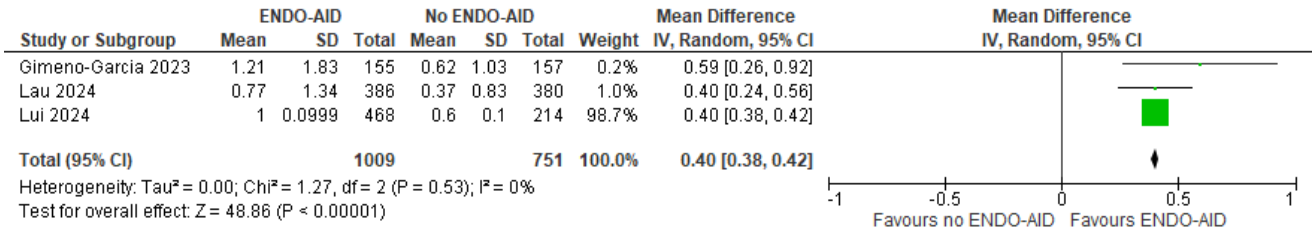
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

ENDO-AID™

Three of the four ENDO-AID™ RCTs reported data split by size categories, splitting into categories of ≤5 or <5 mm, 5-9 mm, 5-10 mm or 6-9 mm, and >10 mm or ≥10 mm, which were combined into three meta-analyses.[13-15] Colonoscopy indications and endoscopist experience are similar to that described for ADR.

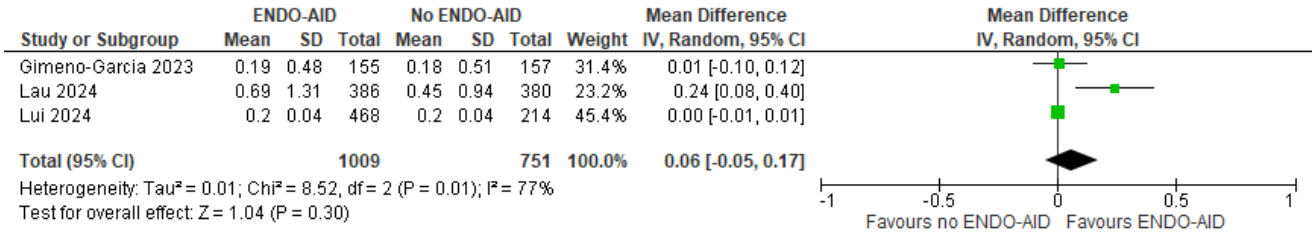
Results across these size categories suggest a trend for the benefit of ENDO-AID™ on APC reducing the larger the size category; the point estimate of all analyses suggest increased APC, with statistically significant differences for only the smallest size category (p-values <0.00001, 0.30 and 0.52, respectively; Figure 76 to Figure 78). While this trend is noted, the EAG does not consider the evidence for this to be strong and there is notable heterogeneity for two of the three analyses.

Figure 76. APC by size (<5 or ≤5 mm) in ENDO-AID™ studies



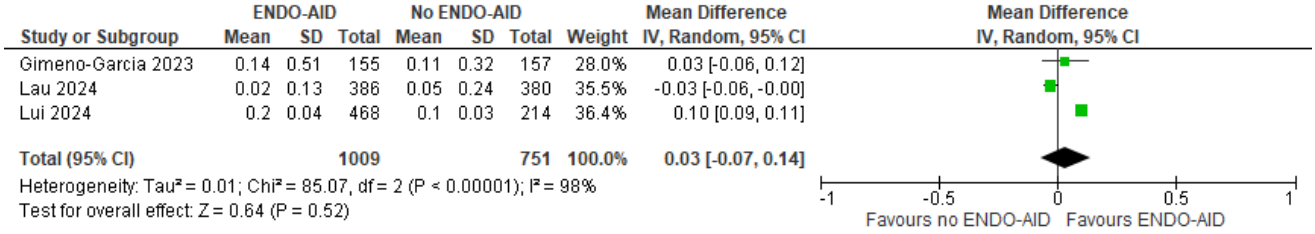
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 77. APC by size (5-9 or 5-10 or 6-9 mm) in ENDO-AID™ studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 78. APC by size (>10 or ≥10 mm) in ENDO-AID™ studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

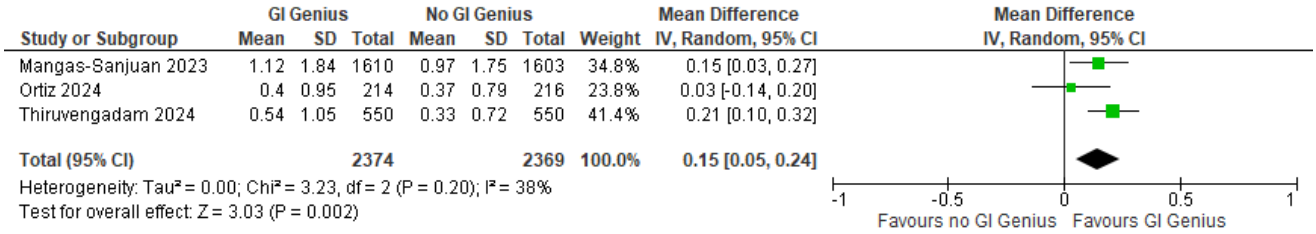
GI Genius™

Five RCTs for GI Genius™ reported APC for different size categories;[20-22, 24, 46] three reported it broken down for three separate categories (≤5 or <5 mm, 5-9 mm or 6-9 mm and ≥10 mm), while the other two reported categories of <10 mm and ≥10 mm. Colonoscopy indications and endoscopist experience are similar to that described for ADR.

Results suggest that the impact of GI Genius™ on APC may be greater for smaller size categories, particularly when comparing the <10 and ≥10 mm analyses. Point estimates for three of the four analyses suggest an increased APC with GI Genius™, with only the ≤5 mm or <5 mm and <10 mm analyses being statistically significant (p-values 0.002, 0.28, 0.0005 and 0.91, respectively; Figure 79 to

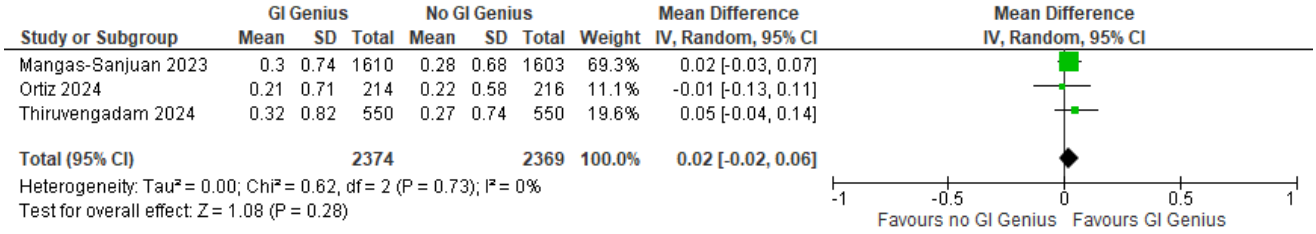
Figure 82). However, the EAG considers the evidence for a differential impact between size categories to be limited, particularly as the results for the 5-9 mm or 6-9 mm category reported by some trials does not appear to align with results for ≤5 mm or <5 mm and <10 mm analyses). There is some evidence of statistical heterogeneity within the ≤5 or <5 mm analysis based on the I^2 value of 38%.

Figure 79. APC by size (≤5 mm or <5 mm) in GI Genius™ studies



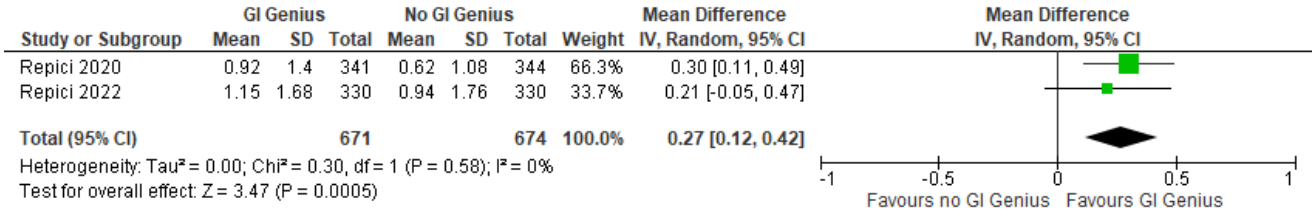
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 80. APC by size (5-9 mm or 6-9 mm) in GI Genius™ studies



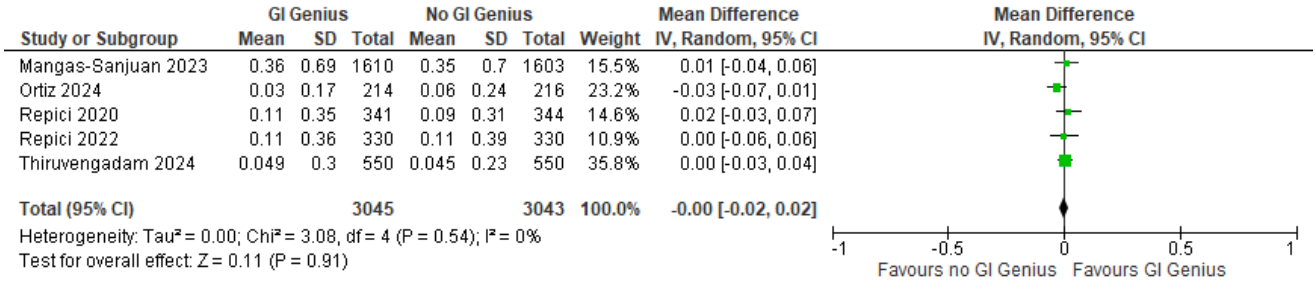
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 81. APC by size (<10 mm) in GI Genius™ studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 82. APC by size (≥10 mm) in GI Genius™ studies



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

MAGENTIQ-COLO™

Only a single study reported APC by size for MAGENTIQ-COLO™,[31] as means and p-values only. Results indicate that the technology had a similar impact on adenomas classed as being ≤5 or 6-9 mm, increasing APC within these categories compared to standard colonoscopy, with results being statistically significant (p-values 0.035 and 0.036). However, a similar effect was not observed within the ≥10 mm category, with mean values very similar (a difference of 0.01 only) and a non-significant p-value reported (0.83). The numbers analysed in each analysis are unclear, but the EAG notes that it is possible that similar issues described above for other technologies regarding smaller sample sizes for the larger size category apply to this study. Therefore, the EAG considers this evidence should not be used to draw strong conclusions from in terms of any differential effects of artificial intelligence (AI) across different size categories.

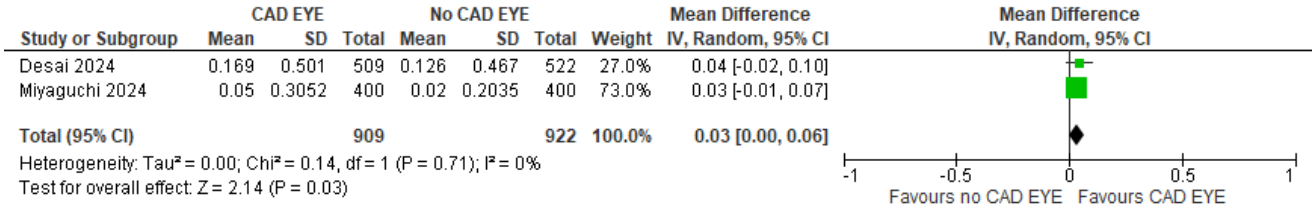
1.10 Sessile serrated lesions per colonoscopy

CAD EYE®

Two RCTs reporting SSL per colonoscopy for this technology compared to standard colonoscopy were meta-analysed.[7, 29] One study included those aged ≥45 years undergoing screening or surveillance colonoscopy for a history of polyps (surveillance interval ≥3 years) and the other those ≥20 years undergoing colonoscopy due to positive FIT, abdominal symptoms or for follow-up of colon polyps in studies. Endoscopist experience differed between the two studies; one had no apparent requirements and the other required at least 1000 prior colonoscopies with a baseline ADR between 25 and 40%. Results suggest a higher (statistically significant; p-value 0.03) SSL per colonoscopy with CAD EYE® (

Figure 83), with no indication of statistical heterogeneity.

Figure 83. SSL per colonoscopy in CAD EYE® studies



Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation; SSL, sessile serrated lesion.

CADDIE™

[redacted]

Figure 84. SSL per colonoscopy in CADDIE™ studies

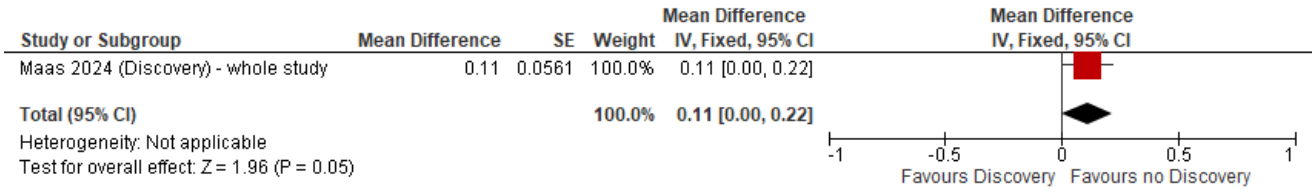
[redacted]

Abbreviations: CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation; SSL, sessile serrated lesion.

Discovery™

A single RCT reporting SSL per colonoscopy for this technology compared to standard colonoscopy was identified.[26] Colonoscopy indications and endoscopist experience are as described for ADR. Results suggest an increased SSL per colonoscopy with Discovery™ compared to standard colonoscopy based on the point estimate, although this was not statistically significant (p-value 0.05; Figure 85).

Figure 85. SSL per colonoscopy in Discovery™ studies

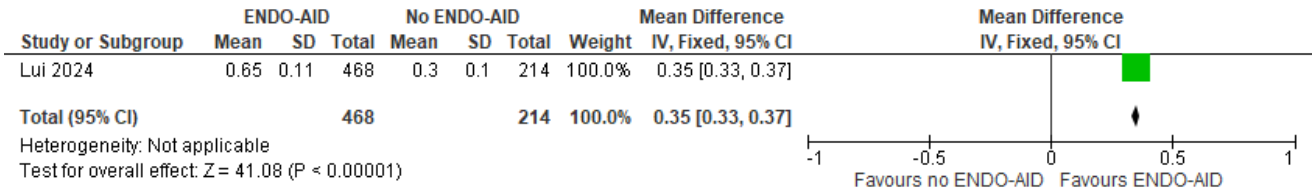


Abbreviations: CI, confidence interval; IV, inverse variance; SE, standard error; SSL, sessile serrated lesion.

ENDO-AID™

A single RCT reporting SSL per colonoscopy for this technology compared to standard colonoscopy was identified.[15] The population was those ≥40 years undergoing elective colonoscopy for screening, surveillance or diagnostic workup and no requirements for endoscopists were reported. Results suggest an increased SSL per colonoscopy with ENDO-AID™ compared to standard colonoscopy, which is a statistically significant difference (p-value <0.00001; Figure 86).

Figure 86. SSL per colonoscopy in ENDO-AID™ studies

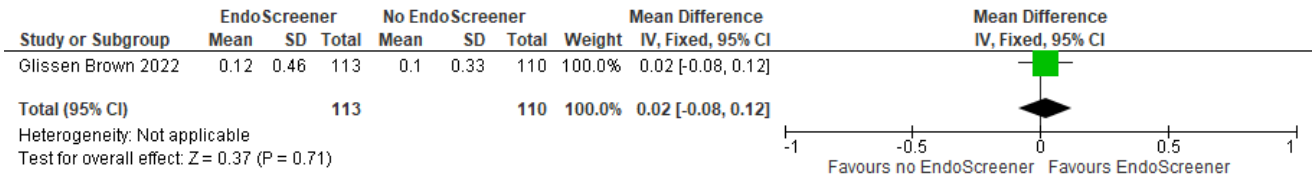


Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation; SSL, sessile serrated lesion.

EndoScreener®

A single RCT reporting SSL per colonoscopy for this technology compared to standard colonoscopy was identified.[35] The population was those ≥22 years undergoing colonoscopy for CRC screening or surveillance and endoscopists included were said to have a high baseline ADR. Results suggest a slightly increased SSL per colonoscopy with EndoScreener® compared to standard colonoscopy, although this was not statistically significant (p-value 0.71; Figure 87).

Figure 87. SSL per colonoscopy in EndoScreener® studies



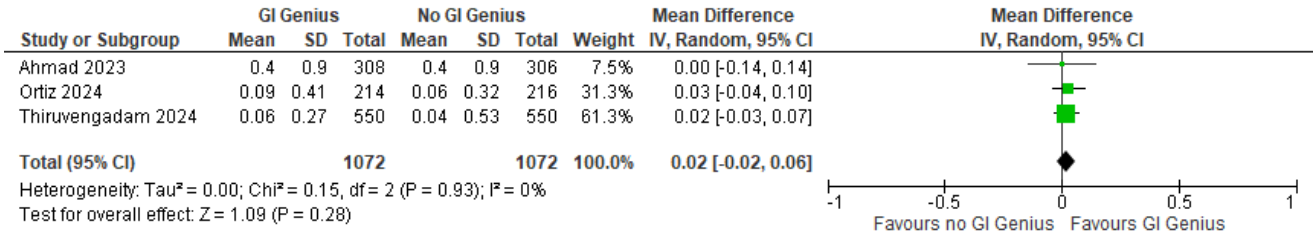
Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation; SSL, sessile serrated lesion.

GI Genius™

Three RCTs reporting SSL per colonoscopy for this technology compared to standard colonoscopy were meta-analysed.[1, 24, 46] One study included those aged 60 to 74 years with positive FIT test within the National Health Service (NHS) Bowel Cancer Screening Programme (BCSP), established history of adenomas attending for surveillance colonoscopy within BCSP or >55 years referred for colonoscopy due to large/multiple adenomas during screening flexible sigmoidoscopy, one was specific to Lynch syndrome patients having surveillance colonoscopy and the other appeared to include any colonoscopy indication. Endoscopist experience also differed between the studies; two required at least 1000 or 2000 prior colonoscopies with a baseline ADR of at least 20 or 25% and the other included endoscopists working as part of the NHS BCSP.

Results suggest a slightly higher SSL per colonoscopy with GI Genius™ (Figure 88), although this was not statistically significant (p-value 0.28). There is no indication of heterogeneity in this analysis.

Figure 88. SSL per colonoscopy in GI Genius™ studies



Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation; SSL, sessile serrated lesion.

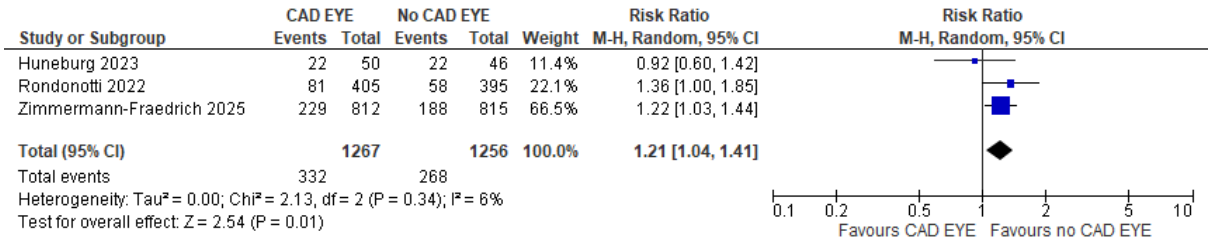
1.11 Non-neoplastic and hyperplastic polyp detection rate

CAD EYE®

Three RCTs reported either non-neoplastic or hyperplastic polyp detection rate for this technology compared to standard colonoscopy and were meta-analysed.[8, 9, 11] One was specific to those with Lynch syndrome undergoing surveillance, one was specifically individuals with a positive FIT and the other was a mix of screening and diagnostic colonoscopy (polyp follow-up and symptoms). Endoscopist experience differed between the two studies; for one, requirements were at least 1000 colonoscopies (with at least 300 in Lynch syndrome), one described endoscopists as experienced with no further details and the other required screening credentials to be met, including an ADR of at least 25%. Results are notably different in one study compared to the other two studies; the study in Lynch syndrome suggests a very small difference between arms with a slightly increased detection

rate in the standard colonoscopy group, while the other two suggest that CAD EYE® increases the detection rate for these polyps. Overall, a statistically significant difference suggesting increased detection of these lesions with CAD EYE® is suggested by the meta-analysis, with heterogeneity noted based visual differences in point estimates and based on an I^2 value of 6% (Figure 89).

Figure 89. Non-neoplastic/hyperplastic polyp detection rate in CAD EYE® studies

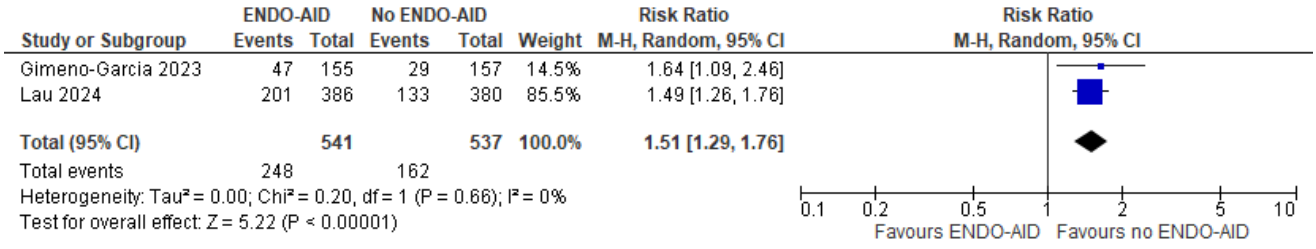


Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

ENDO-AID™

Two studies reported non-neoplastic detection or resection rates for ENDO-AID™ compared to standard colonoscopy.[13, 14] Both studies had broad populations, including screening, diagnostic and surveillance colonoscopies, but they different with regards to endoscopist experience; one only included endoscopists with at least 2000 prior colonoscopies while the other was specifically endoscopists in training. Results show a statistically significant increase in detection rates of these polyps with AI, with no obvious heterogeneity between the results of the two studies noted (Figure 90).

Figure 90. Non-neoplastic resection/detection rate in ENDO-AID™ studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

ENDOANGEL®

One study reporting non-precancerous polyp detection rate for ENDOANGEL® compared to standard colonoscopy was identified.[17] The study included a broad colonoscopy population, with endoscopists required to have performed at least 2000 prior colonoscopies. Results indicate statistically significant

increase in the detection rate of these polyps with ENDOANGEL® compared to standard colonoscopy (

Figure 91).

Figure 91. Non-precancerous polyp detection rate in ENDOANGEL® studies

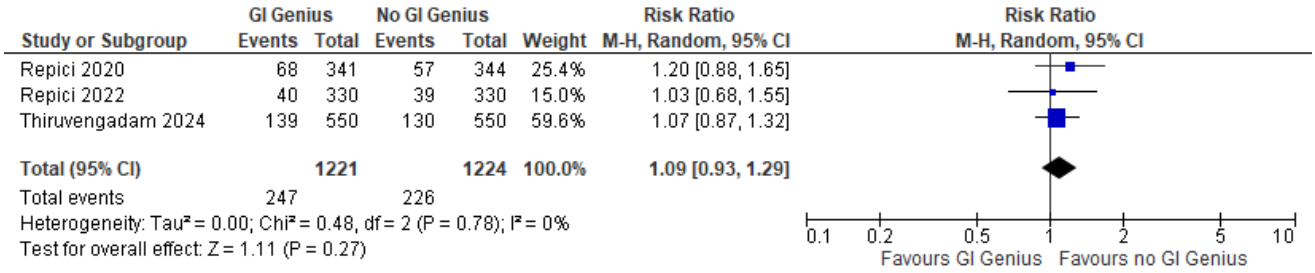
Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

GI Genius™

Three RCTs reporting non-neoplastic polyp detection rate for this technology compared to standard colonoscopy were meta-analysed.[21, 22, 24] All three included screening, diagnostic and surveillance colonoscopies, with endoscopist experience differing slightly between studies. One study required at least 1000 prior colonoscopies and a baseline ADR of 25%, another required at least 2000 prior colonoscopies and the other only included endoscopists with fewer than 2000 prior colonoscopies. Results suggest slightly higher detection of these polyps with GI Genius™, although this was not statistically significant (Figure 92).

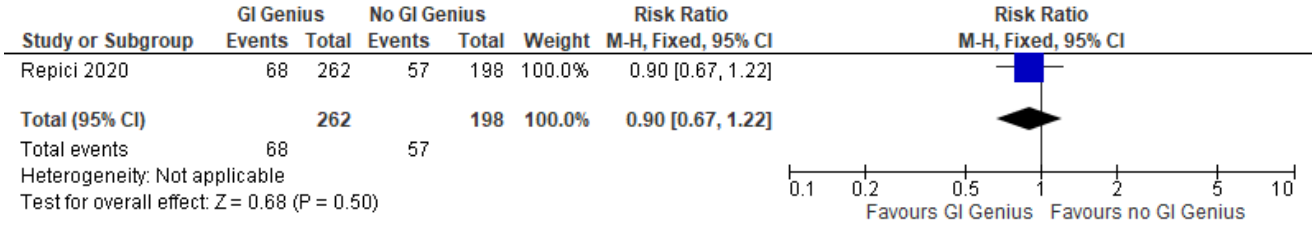
Furthermore, two studies reported non-neoplastic resection rate, although one of these (Lagstrom *et al.* 2025) was excluded from the main analysis given it was considered to be at high risk of bias.[21, 47] The study that was included in the analysis defined non-neoplastic resection rate as the proportion of patients with no adenomas or SSLs confirmed on histology that had at least one resection.[21] The study, in a broad colonoscopy population with procedures performed by endoscopists with at least 2000 prior colonoscopies, reported that this occurred less often in the GI Genius™ group, but the difference was not statistically significant (Figure 93).

Figure 92. Non-neoplastic polyp detection rate in GI Genius™ studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

Figure 93. Non-neoplastic polyp resection rate in GI Genius™ studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

1.12 Detection-based diagnostic accuracy data

1.12.1 Narrative discussion

CAD EYE®

For CAD EYE®, one study reported limited diagnostic accuracy data for autonomous CAD EYE®'s ability to detect polyps in n=56 patients undergoing colonoscopy.[48] This paper reported very limited details on the methodology and it is unclear what the reference standard for this calculation was, meaning it should be considered to be at a high risk of bias. Data are further limited given they are for autonomous use rather than adjunct. Results for this outcome are presented in Table 1; they indicate a good sensitivity of 97.0% and a fairly good specificity of 84.0%, with an accuracy of 93.0%.

A separate study reported other diagnostic accuracy data, including the positive predictive value (PPV) of a polyp identified with CAD EYE®-assisted colonoscopy or standard colonoscopy being confirmed as an adenoma on histology and the true histology rate, which refers to the percentage of all identified polyps that were confirmed on histology to be either an adenoma, an SSL or a large (>10 mm) hyperplastic polyps of the proximal colon.[7] The results in Table 2 show slightly better

outcomes for CAD EYE®-assisted colonoscopy, but these were only assessed as non-inferiority analyses.

CADDIE™ (Odin Vision)

[redacted]

Figure 94. False positive rate in CADDIE™ studies

Abbreviations: CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Discovery™

Two studies for Discovery™ reported some type of diagnostic accuracy data, including one reporting on the sensitivity of autonomous Discovery™ for detecting suspicious lesions and one reporting false positives with the system.[26, 49] The study reporting sensitivity for detecting suspicious lesions was specifically in those with ulcerative colitis undergoing surveillance colonoscopy, and it was compared to detection with virtual chromoendoscopy-assisted colonoscopy as part of a non-randomised study.[49] Very limited information on methods was provided, including no details of the reference standard used to calculate sensitivity. However, results and information that were available are summarised in Table 3, with sensitivity values being higher for the Discovery™ assessment. These data are considered to be at a high risk of bias given the lack of details provided, as well as the fact it is for autonomous Discovery™ detection rather than as an adjunct.

The second study was an RCT reporting on the number of false positives with Discovery™,[26] with false positives defined as an unsuspected area highlighted by the computer-aided detection (CADe) system for longer than three seconds, as judged by the endoscopist. The mean number of false positives per colonoscopy was 4.1 (SD 6.1), with the median reported as 2.0 (interquartile range [IQR] 0.0 to 5.0).

ENDO-AID™

One RCT for ENDO-AID™ reported on the false positive signal rate for ENDO-AID™ when used to assist colonoscopies, which was defined as incorrect alerts from computer artifacts due to various reasons lasting for at least two seconds, as reported by operators. In 386 procedures, a false positive rate of 23.83% was reported, with a mean of 1.085 false positives per colonoscopy.[14]

ENDOANGEL®

For ENDOANGEL®, one study reported diagnostic accuracy data in the form of sensitivity and/or specificity for polyp detection on a per-polyp and per-patient basis,[50] and another reported the number of false positives when ENDOANGEL® was used in colonoscopies.[17] For the sensitivity/specificity data, the reference standard used was expert video review of colonoscopies for polyp detection and the study was considered to be at a high risk of bias.[50] Results in Table 4 show that ENDOANGEL® appears to improve sensitivity for the per-polyp and per-patient analyses, which was shown to be statistically significant for the per-polyp analysis (p-value <0.001; statistical significance not reported for per-patient, difference appears less prominent). Specificity was reported for the per-patient analysis and was not different between assessments with and without ENDOANGEL®.

The study reporting on false positives with ENDOANGEL®, where a false positive is defined as an area with no polyp verified by the operators but being consistently labelled as containing a polyp by the system for more than one second, reported the number of these for CADe when used alone or with a computer-aided quality improvement system than monitors withdrawal speed.[17] The latter was not considered relevant for this assessment and has not been extracted for other outcomes, but given false positives are only reported as a combined single group, these data are covered here. The study reported a total of 54 false positives with ENDOANGEL® across a total of 566 colonoscopies.

EndoScreener®

All six RCTs identified for EndoScreener® reported on the number of false detections and false negatives with the EndoScreener® system.[30, 35, 36, 43-45] In all studies, a consistent false detection by EndoScreener® was defined as a detected area that was continuously tracked by the system but deemed by the endoscopist not to be a polyp. For one study, they defined consistent as detection for at least two seconds. Definitions of false negatives or missed lesions varied slightly between studies, with definitions including:

- Considered to be polyps detected by the operating endoscopist and confirmed by histology but that did not result in an alert by EndoScreener®;
- Lesions not detected or detected for less than two seconds by EndoScreener® and deemed by the endoscopist to be consistent with a polyp;
- Verified by the endoscopist as a polyp but not reported by EndoScreener® in any frame.

For all studies (see Table 5), the number of false positives observed was fairly low and for most studies the number of false positives per colonoscopy was much lower than one (generally around 0.1), with the exception of one study with a per colonoscopy estimate of 0.95. Only one study provided comparative data for false positives as the comparator arm involved observers which could be considered similar to the role of EndoScreener® in these studies; the results from this study indicated fewer false positives per colonoscopy compared to when human observers were involved, which was statistically significant (p-value <0.001). For missed polyps, five studies reported than none of the polyps identified by endoscopists were missed by the CADe system, while the remaining study reported a low miss rate of 3/315 polyps detected by endoscopists. While these results are limited in terms of their use and robustness, they indicate that EndoScreener® may not create a large burden in terms of false positive indications and does not appear to miss many polyps detected by endoscopists during colonoscopy.

GI Genius™

For GI Genius™, one study reports false positives associated with the system in terms of detection based on endoscopist review (as well as false positives for polyps according to histology),[46] one abstract reports the sensitivity of GI Genius™ for polyp identification in patients with Lynch syndrome,[51] and another study reports on false positives based on histology of those resected.[37]

For the study reporting on false positives with GI Genius™ according to endoscopist review,[46] a false positive was defined as areas signalled as lesions by GI Genius™ during the colonoscopy procedure

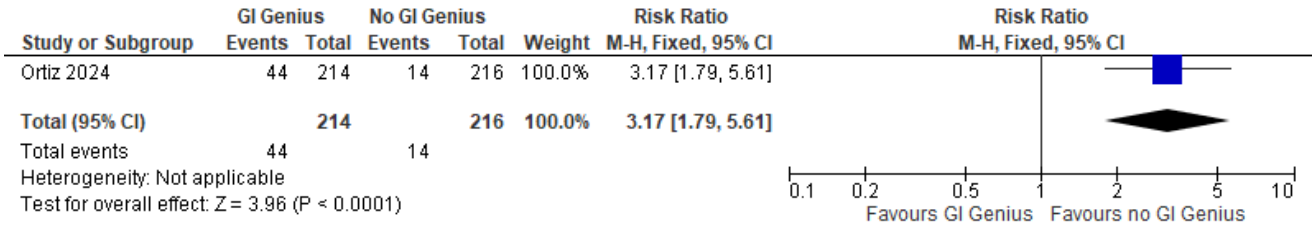
for two or more seconds in an adequate condition for inspection (i.e. well-centred image, without significant bubbles or debris on the area) and that were considered not polyps by the endoscopist with a high-confidence of optical diagnosis. It reported that 77 colonoscopies (out of 214) had at least one false positive alert (36.0%). This study also reported on false positives for polyps according to histology, with false positives in this case defined as lesions resected by the endoscopist and confirmed on histology to be clinically non-significant (normal mucosa, subtle hyperplastic changes or inflammatory changes). Results for the proportion of patients with at least one false positive based on histology, and the mean number of false positives based on histology per colonoscopy, suggested increased false positives with GI Genius™ compared to standard colonoscopy based on point estimates, with both analyses being statistically significant (p-values <0.0001 and 0.003, respectively;

Figure 95 and Figure 96).

A second study reported a similar outcome of false positives based on histology, but reported it as a per-polyp analysis rather than per-patient.[37] The results of this analysis did not align with those previously discussed, as the point estimate suggested a benefit of GI Genius™ in reducing false positives, but this was not statistically significant (p-value 0.67; Figure 97). This study also reported false negative rate, defined as the proportion of patients that had a negative first colonoscopy that had at least one adenoma or carcinoma at their second examination. Results in Figure 98 indicate that the incidence of this was statistically significantly reduced with GI Genius™ (p-value 0.02).

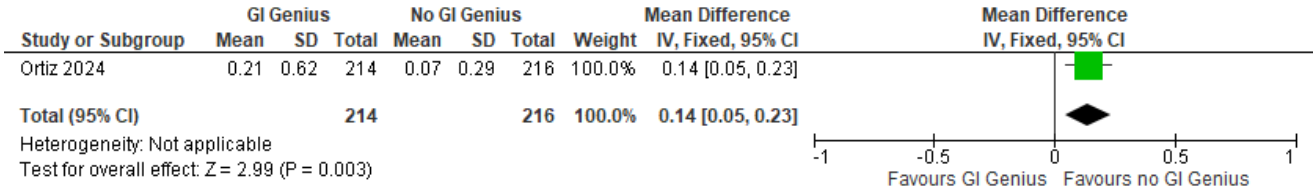
For the abstract covering the Lynch syndrome population,[51] results for sensitivity of GI Genius™ for identification of polyps, where expert endoscopists using high-definition (HD) white-light colonoscopy is used as the reference standard, are presented in Table 6 below. It is unclear if these data reflect adjunct or autonomous GI Genius™ use. It reports a sensitivity of 68.4% for polyp detection, with limited other data available in terms of results and methods. It also reports that at least one false positive was identified in 86.0% of colonoscopies. Data in this table are considered to be at a high risk of bias.

Figure 95. False positive rate in GI Genius™ studies – histology (per-patient)



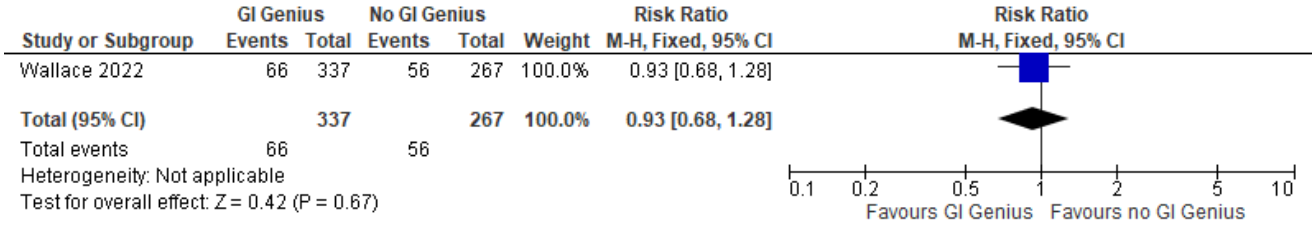
Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

Figure 96. False positive rate in GI Genius™ studies – histology (mean per colonoscopy)



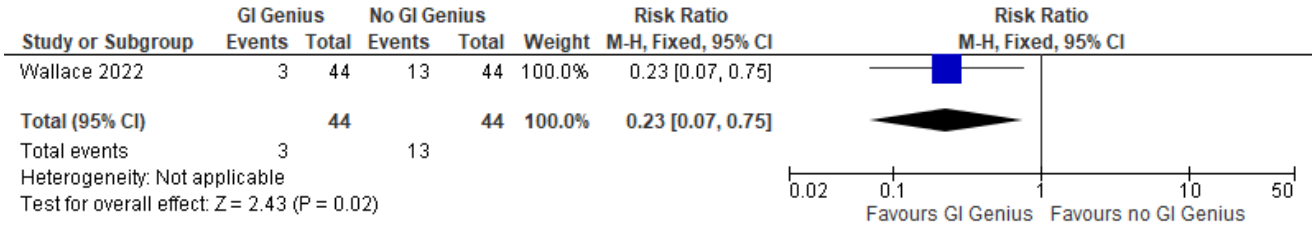
Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 97. False positive rate in GI Genius™ studies – histology (per-polyp)



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

Figure 98. False negative rate in GI Genius™ studies – per-patient



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

1.12.2 Results tables

Table 1. Diagnostic accuracy data for autonomous CAD EYE® colorectal polyp detection

Study	Population	Details of index test	Reference standard	Target condition	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Zavyalov 2024[48]	Patients (n=56) undergoing colonoscopy with CAD EYE® (no further details)	Autonomous CAD EYE® (not adjunct)	Unclear for detection	Detection of colorectal polyps Unclear number of lesions assessed	97.0% (NR)	84.0% (NR)	93.0%	Very limited information on methods and difficult to interpret. Autonomous AI not adjunct

Abbreviations: AI, artificial intelligence; CI, confidence interval; NR, not reported.

Table 2. PPV for adenomas and true histology rate for CAD EYE®-assisted and standard colonoscopy

Study (outcome)	CAD EYE®-assisted		Without CAD EYE®		Comparison between arms	Comments
	Result	Number analysed	Result	Number analysed		
Desai 2024 (PPV of a polyp being an adenoma)[7]	PPV 48.6%	509 procedures	PPV 54.0%	522 procedures	Effect estimates: Delta with boot-strapped 95% CI: -5.4% (-9.56 to -1.48%) Less than the 10% non-inferiority threshold established, p-value for non-inferiority <0.001	Calculated by dividing all adenomas identified by all of the polyps removed.
Desai 2024 (True histology rate)[7]	True histology rate 57.0%	509 procedures	True histology rate 62.3%	522 procedures	Effect estimates: Delta with boot-strapped 95% CI: -5.3% (-10.3 to -2.06%)	Defined as total number of histologically confirmed adenomas (adenoma, villous adenoma and high-grade dysplasia), SSL (sessile serrated, traditional serrated adenoma and serrated lesion with cytological

					Less than the 10% non-inferiority threshold established, p-value not reported	dysplasia) and large >10 mm hyperplastic polyps of the proximal colon (transverse colon, hepatic flexure, ascending colon and caecum) resected in relation to all polyps resected.

Abbreviations: CI, confidence interval; PPV, positive predictive value; SSL, sessile serrated lesion.

Table 3. Diagnostic accuracy data for autonomous Discovery™ detection of suspicious lesions

Study	Population	Details of index test	Reference standard	Target condition	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Lopez-Serrano 2024[49]	Patients with ulcerative colitis at risk of CRC (n=52) undergoing surveillance colonoscopy	Autonomous Discovery™ (not adjunct) vs VCE-assisted colonoscopy	Unclear for detection	Detection of suspicious lesions 61 suspicious lesions identified	93.4% (86.6 to 100.0%) vs 86.9% (77.0 to 96.1%)	NR	NR	Very limited information on methods and difficult to interpret. Autonomous AI not adjunct 8 lesions said to be exclusively detected by Discovery™, 4 exclusively detected by virtual chromoendoscopy 57/61 suspicious lesions detected vs 53/61 detected for Discovery™ vs VCE-assisted colonoscopy

Abbreviations: AI, artificial intelligence; CI, confidence interval; CRC, colorectal cancer; NR, not reported; VCE, virtual chromoendoscopy.

Table 4. Diagnostic accuracy data for ENDOANGEL®-assisted detection of polyps – per-polyp and per-patient analyses

Study	Population	Details of index test	Reference standard	Target condition	Sensitivity (95% CI)	Specificity (95% CI)	Comments
Zhang 2023[50]	Screening or diagnostic colonoscopy, no breakdown provided. N=1293 colonoscopies included	Endoscopists detecting polyps using CADe function	Raw videos from each examination reviewed by an independent evaluation group - two experts with colonoscopy experience >5 years and total volume >3000 colonoscopies independently reviewed all raw videos and labelled whether examination was positive (polyp detected) or negative (no polyp detected). In case of disagreement, a third expert with colonoscopy experience >8 years and total volume of >5000 colonoscopies would perform the final diagnosis.	Polyp detection – polyp level	AI: 84.97% (95% CI: 82.76 to 87.17%) No AI: 72.07% (95% CI: 69.43 to 74.71%)	NR	Difference in sensitivity of 12.89% (95% CI: 9.46 to 16.33%) between groups p-value <0.001 1011 and 1110 polyps on reference standard in AI and no AI groups, respectively.
				Polyp detection – patient level (those with at least one polyp)	AI: 89.89% (95% CI: 86.85 to 92.94%) No AI: 82.02% (95% CI: 78.28 to 85.76%)	AI: 100.0% (95% CI: 98.63 to 100.00%) No AI: 100.0% (95% CI: 98.50 to 100.00%)	376 and 406 patients with polyps on reference standard in AI and no AI groups, respectively

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CI, confidence interval; NR, not reported.

Table 5. False detections and missed lesions with and without EndoScreener®

Study (outcome)	EndoScreener®-assisted Result (number analysed)	Without EndoScreener® Result (number analysed)	Comments
Wang 2020 - lower adenoma miss… (false detections and missed lesions)[36]	There were 67 consistent false detections in the CADe colonoscopy. None were missed by the CADe system among all detected polyps by the endoscopists in the CADe colonoscopy (369 procedures [CADe used as first or second procedure combined])	NA	Consistent false detection: area continuously tracked by the system but not deemed a polyp by endoscopist.
Wang 2019 (false positives and false negatives)[43]	A total of 39 false positives were recorded in the EndoScreener® group, leading to an average of 0.075 false alarms per colonoscopy. Of all detected polyps in the EndoScreener® group, none were missed by the software (522 procedures)	NA	False alarm: lesion continuously tracked by system but not deemed a polyp by endoscopist.
Liu 2020 (false detections and missed polyps)[30]	A total of 29 false detections were recorded in the EndoScreener® group, leading to an average of 0.074 false alarms per colonoscopy. 0 (0%) polyps missed by CADe system.165 polyps, including 73 adenomas and one SSL (0.19 adenomas and 0.42 polyps per-patient), detected by CADe system prior to endoscopists (393 procedures)	NA	Consistent false detection: lesion continuously traced by system but not deemed a polyp by endoscopist.
Wang 2023 (false detections and missed polyps)[45]	A total of 122 false detections were recorded in the EndoScreener® group, leading to an average of 0.19 false alarms per colonoscopy. 0 (0%) polyps missed by CADe system p-value <0.001 between interventions for false detections (636 procedures)	A total of 191 false detections were recorded in the observed-assisted (no EndoScreener®) group, leading to an average of 0.31 false alarms per colonoscopy NA for missed polyps (625 procedures false detections)	False detection: consistent tracking of object by system but not deemed a polyp by endoscopist for CADe-assisted. For observer-assisted, lesions flagged by observer but not deemed a polyp by endoscopist. Missed polyp: identified by endoscopist but no alert from system.

Glissen Brown 2022 (false positive and negative rates)[35]	107 false detections with CADe when performed first – per colonoscopy value of 0.95 False negative rate of all CADe procedures (whether performed first or second) of 3/315 polyps detected (0.95%) (113 procedures false detections, 213 procedures false negative rate)	96 false detections with CADe when performed second – per colonoscopy value of 0.87 false negative rate reported in previous column for combined CADe procedures (110 procedures false detections)	False positives: lesions detected for ≥2 seconds by software but not deemed a polyp by endoscopist. False negatives: considered a polyp by endoscopist but not detected or detected for <2 seconds by software.
Wang 2020 – effect of a deep… (false detections, missed polyps and lesions detected ahead of endoscopists)[44]	48 false detections in the CADe group – per colonoscopy value of 0.1 (as determined by endoscopist during procedure) Two additional false detections found after biopsy results – findings consistent with healthy colon mucosa No polyps detected in the CADe group were missed by the CADe system Following lesions detected by CADe but initially missed by endoscopists: • 159 polyps (0.33 per-patient); • 81 adenomas (0.17 per-patient); • 5 sessile serrated adenomas/polyps (0.01 per-patient) (484 procedures)	NA	Consistent false detections: area traced consistently by system but not deemed a polyp by endoscopist. Missed detection: polyp detected by endoscopist and histology but no alert by CADe system.
Abbreviations: CADe, computer-aided detection; NA, not applicable; SSL, sessile serrated lesion.			

Table 6. Diagnostic accuracy data for GI Genius™-assisted detection of polyps

Study	Population	Details of index test	Reference standard	Target condition	Sensitivity (95% CI)	Specificity (95% CI)	Comments
Pinto 2022 (abstract only)[51]	Patients with Lynch Syndrome undergoing screening colonoscopies	Polyps identified with assistance of GI Genius™	Expert endoscopist using high-definition white-light colonoscopy	Identification of polyps	68.4% (63.8 to 72.0%)	NR	False positive identified in 31 (86.0%) colonoscopies Abstract only. Limited description of methods e.g. whether reference standard is suitable Unclear if used as assisted colonoscopy or AI alone

Abbreviations: AI, artificial intelligence; CI, confidence interval; NR, not reported.

1.13 Measures of ability to characterise identified polyps – results tables from main report and other analyses

Results tables for the computer-aided characterisation (CADx) assessments for all polyps and all diminutive polyps, discussed in Section 3.2.2.1.2 of the main report, are presented here in Section 1.13.1. In addition, the use of CADx for categorisation of various other subgroups of polyps is reported across the included studies. These are summarised below in Section 1.13.2, with respective tables also presented in Section 1.13.3.

1.13.1 All polyps and all diminutive polyp analyses – results tables

1.13.1.1 All polyps – CAD EYE® as adjunct technology

Table 7. Diagnostic accuracy data for adjunct CAD EYE® optical diagnosis – neoplastic vs hyperplastic

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Cassinotti 2023 (endoscopic surveillance of patients with ulcerative colitis) – 133 lesions assessed[52]					
Outcome: classification of any polyps (no details on classification categories, i.e. neoplastic vs hyperplastic)					
CAD EYE®-assisted optical diagnosis with BLI and LCI (no further details)	Histology	83% (95% CI NR)	65% (95% CI NR)	68% (95% CI NR)	• Possible adjunct use of CAD EYE® – although criteria used in conjunction with unclear • No details of whether only high confidence diagnoses included or how SSLs treated in the analysis. • CAD EYE® "not inferior" to conventional Kudo and NICE classifications, but Kudo-IBD had higher
Endoscopist optical diagnosis alone (no further details) Optical diagnosis performed using conventional Kudo, NICE and Kudo-IBD classifications	Histology	• Conventional Kudo: 67% • NICE: 72% • Kudo-IBD: 89% (95% CI NR)	• Conventional Kudo: 71% • NICE: 68% • Kudo-IBD: 83% (95% CI NR)	• Conventional Kudo: 71% • NICE: 68% • Kudo-IBD: 84% (95% CI NR)	

					sensitivity, and statistically significantly higher specificity and accuracy (p-value <0.05). • NPV values were 96.0% for CAD EYE®-assisted optical diagnosis, 93.0% for endoscopist optical diagnosis with conventional Kudo classification and 94.0% for endoscopist optical diagnosis with NICE classification (NR for endoscopist optical diagnosis with Kudo-IBD classification). 95% CIs were not reported.
Sato 2024 (positive FIT, symptoms, screening colonoscopy or where colonoscopy otherwise required) – 380 lesions assessed[53]					
Outcome: classification of any polyps (neoplastic or hyperplastic categories)					
CAD EYE®-assisted optical diagnosis	Histology	94.3% (95% CI, 91.1 to 96.7%)	71.3% (95% CI, 60.0 to 80.8%)	89.5% (95% CI, 85.9 to 92.4%)	• SSLs considered to be hyperplastic in line with AI which is not able to

Unclear but assume based on combination of endoscopist diagnoses on WLI, magnified and non-magnified BLI with AI diagnoses on magnified and non-magnified BLI WLI based on endoscopist experience, non-magnified BLI based on NBI International Colorectal Endoscopic classification and magnified BLI based on JNET criteria					determine these lesions. • Excludes polyps considered by endoscopists to be whitish diminutive polyps or rectosigmoid, invasive cancer and submucosal tumours. • Does not appear to limit to high-confidence diagnoses. • NPV values were 77.0% (95% CI, 67.4 to 84.5%) for CAD EYE®-assisted optical diagnosis, and 64.7% (95% CI, 55.9 to 72.6%), 72.7% (95% CI, 63.3 to 91.2%) and 76.4% (95% CI, 66.6 to 84.0%) for endoscopist optical diagnosis using WLI, non-magnified BLI and magnified BLI, respectively.
Endoscopist optical diagnosis alone Reported separately when using WLI, non-magnified BLI and magnified BLI WLI based on endoscopist experience, non-magnified BLI based on NBI International Colorectal Endoscopic classification and magnified BLI based on JNET criteria	Histology	**WLI** 90.0% (95% CI, 86.0 to 93.2%) **Non-magnified BLI** 93.0% (95% CI, 89.5 to 95.6%) **Magnified BLI** 94.3% (95% CI, 91.1 to 96.7%)	**WLI** 68.8% (95% CI, 57.4 to 78.7%) **Non-magnified BLI** 70.0% (95% CI, 58.7 to 79.7%) **Magnified BLI** 68.8% (95% CI, 57.4 to 78.7%)	**WLI** 85.5% (95% CI, 81.6 to 88.9%) **Non-magnified BLI** 88.2% (95% CI, 84.5 to 91.2%) **Magnified BLI** 88.9% (95% CI, 85.4 to 91.9%)	

Abbreviations: AI, artificial intelligence; BLI, blue-light imaging; CI, confidence interval; FIT, faecal immunochemical test; IBD, inflammatory bowel disease; JNET, Japan Narrow Band Imaging Expert Team; LCI, linked-colour imaging; NBI, narrow-band imaging; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; NR, not reported; SSL, sessile serrated lesion; WLI, white-light imaging.

1.13.1.2 All polyps – CAD EYE® as autonomous technology

Table 8. Diagnostic accuracy data for autonomous CAD EYE® optical diagnosis – neoplastic vs hyperplastic

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of any colorectal polyps into neoplastic vs hyperplastic					
Picardo 2023 (abstract only; consecutive IBD patients undergoing surveillance) – 61 polyps assessed[54]					
Autonomous CAD EYE® (not adjunct) Neoplastic vs hyperplastic Optical diagnosis based on CAD EYE®	Resected lesions, histopathology; Non-resected pseudopolyps, IBD expert consensus	**Resected/non-resected lesions:** 78.6% (NR) **Resected lesions only:** 78.6%	**Resected/non-resected lesions:** 97.9% (NR) **Resected lesions only:** 100.0%	**Resected/non-resected lesions:** NR **Resected lesions only:** 88.0%	• Autonomous use of CAD EYE®; • Still images of non-resected pseudopolyps (maximum of five per-patient) were included if verified as inflammatory pseudopolyps by two IBD experts; • No mention of how SSLs categorised; • Does not appear to limit only to high confidence diagnoses. • NPV values not reported and not possible to calculate from data available.
Endoscopist optical diagnosis alone (no details provided) Unclear which criteria used for optical diagnosis	Resected lesions, histopathology; Non-resected pseudopolyps, IBD expert consensus	**Resected/non-resected lesions:** NR **Resected lesions only:** 71.4%	**Resected/non-resected lesions:** NR **Resected lesions only:** 100.0%	**Resected/non-resected lesions:** NR **Resected lesions only:** 78.6%	

Abbreviations: CI, confidence interval; IBD, inflammatory bowel disease; NPV, negative predictive value; SSL, sessile serrated lesion; NR, not reported.

1.13.1.3 All polyps - CADDIE™ as adjunct technology

Table 9. Diagnostic accuracy data for CADDIE™-assisted optical diagnosis – adenoma vs non-adenoma

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
[redacted]					
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; EAG, External Assessment Group; NPV, negative predictive value; RCT, randomised controlled trial; SSL, sessile serrated lesion; WHO, World Health Organization.

1.13.1.4 All polyps - Discovery™ as adjunct technology

Table 10. Diagnostic accuracy data for Discovery™-assisted optical diagnosis – dysplasia vs non-dysplasia

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of any polyps into dysplasia vs non-dysplasia					
Lopez-Serrano 2024 (surveillance colonoscopy in consecutive ulcerative colitis patients at risk of CRC) – 48 resected polyps assessed[49]					
Discovery™-assisted optical diagnosis Paris and Kudo pit pattern classification (alongside Discovery™) used for optical diagnosis	Histology based on Vienna criteria	90.0% (71.0 to 100.0%)	5.0% (0.0 to 12.0%)	22.9% (NR)	• Categorised into dysplasia (low-grade dysplasia, high-grade dysplasia, invasive carcinoma and sessile serrated adenomas with dysplasia) or non-dysplasia (hyperplastic polyps, sessile serrated polyps without dysplasia, post-inflammatory polyps, scarring tissue and other nonspecific non-neoplastic mucosal changes); • Does not appear to limit only to high confidence diagnoses. • Unclear whether used technology as intended, as no CADx function for Discovery™ outlined in manufacturer submission. • NPV values were 67.0% (95% CI, 54.0 to 100.0%) and 83.0% (95% CI, 54.0 to 100.0%), respectively, for Discovery™-assisted optical diagnosis and virtual chromoendoscopy-assisted colonoscopy, respectively.
Virtual chromoendoscopy-assisted colonoscopy Paris and Kudo pit pattern classification used for optical diagnosis	Histology based on Vienna criteria	90.0% (71.0 to 100.0%)	13.0% (2.0 to 24.0%)	29.2% (NR)	

Abbreviations: CI, confidence interval; CRC, colorectal cancer; NPV, negative predictive value; NR, not reported.

1.13.1.5 All polyps – GI Genius™ as adjunct technology

Table 11. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis – adenoma vs non-adenoma

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of colorectal polyps of any size into adenomatous or non-adenomatous					
Hassan 2022 (colonoscopy for primary CRC screening, post-polypectomy surveillance, positive FIT test or for symptoms/signs) – 544 polyps assessed[55]					
GI Genius™-assisted optical diagnosis Adenomatous vs non-adenomatous Unclear which criteria used for optical diagnosis alongside GI Genius™ Expert endoscopists included (>2000 screening colonoscopies, trained in optical diagnosis and prior studies on polyp characterisation with BLI)	Histopathology	80% (73.7 to 85.3%)	93.1% (89.8 to 95.6%)	88.1% (85.0 to 90.7%)	• SSLs considered to be non-adenomatous in the analysis; • High and low confidence diagnoses included; • Does not appear to have excluded those where AI could not make a prediction. • NPV value was 88.2% (95% CI, 84.3 to 91.4%).

Abbreviations: AI, artificial intelligence; BLI, blue-light imaging; CI, confidence interval; CRC, colorectal cancer; FIT, faecal immunochemical test; NPV, negative predictive value; SSL, sessile serrated lesion.

1.13.1.6 All diminutive polyps – CAD EYE® as adjunct technology

Table 12. Diagnostic accuracy data for CAD EYE®-assisted optical diagnosis in diminutive polyps – adenoma, hyperplastic and serrated histologies

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of diminutive (≤5 mm) polyps of any location into adenoma, hyperplastic and serrated histologies					
Djinbachian 2024 (colonoscopy for screening, surveillance or diagnostic purposes) – 179 polyps assessed[5]					
CAD EYE®-assisted optical diagnosis (all prior experience with optical diagnosis, experience varied) Unclear which criteria used for optical diagnosis	Histopathology	83.6% (75.4 to 90.0%)	63.8% (51.3 to 75.0%)	72.1% (95% CI, 65.5 to 78.6%)	• Main analysis does not limit to high-confidence diagnoses only; • The main analysis also allows for the classification of SSLs as its own group; • Analysed all polyps ≤5 mm that were resected and retrieved for histopathology, were not normal mucosa/inflammatory polyps and where optical diagnosis was performed. • NPV value was 71.0% (95% CI, 58.1 to 81.8%).
Outcome: classification of diminutive (≤5 mm) polyps of any location that underwent a resect-and-discard or diagnose-and-leave strategy into adenomatous or non-adenomatous categories					
Taghiakbari 2025 (outpatient colonoscopy – no further details) – 138 polyps assessed[56]					
CAD EYE®-assisted optical diagnosis Unclear which criteria used for optical diagnosis	Video review by 3 expert endoscopists (as polyps not sent for histology in this study)	89.9% (95% CI, 81.0 to 95.5%)	89.8% (95% CI, 79.2 to 96.2%)	89.9% (95% CI, 83.6 to 94.3%)	• Analysis limited to high-confidence diagnoses; • SSLs or suspected SSLs not captured as these were supposed to be sent for histology; • Reference standard less than ideal as video review by experts rather than histology; • Analysed those polyps that were not sent for histology but where resect-and-discard or diagnose-and-leave approaches were implemented. • NPV value was 86.9% (95% CI, 77.4 to 92.8%).
Outcome: classification of diminutive (≤5 mm) polyps of any location that underwent a diagnose-and-leave strategy into adenomatous or non-adenomatous categories					
Taghiakbari 2025 (outpatient colonoscopy – no further details) – 40 polyps assessed[56]					

CAD EYE®-assisted optical diagnosis Unclear which criteria used for optical diagnosis	Video review by 3 expert endoscopists (as polyps not sent for histology in this study)	25.0% (95% CI, 0.63 to 80.6%)	100.0% (95% CI, 90.3 to 100.0%)	92.5% (95% CI, 79.6 to 98.4%)	• Analysis limited to high-confidence diagnoses; • SSLs or suspected SSLs not captured as these were supposed to be sent for histology; • Reference standard less than ideal as video review by experts rather than histology; • Analysed those polyps that were not sent for histology but where diagnose-and-leave approach was implemented. • NPV value was 92.3% (95% CI, 87.2 to 95.5%).
Outcome: classification of diminutive (≤5 mm) polyps of any location that underwent a resect-and-discard strategy into adenomatous or non-adenomatous categories					
Taghiakbari 2025 (outpatient colonoscopy – no further details) – 98 polyps assessed[56]					
CAD EYE®-assisted optical diagnosis Unclear which criteria used for optical diagnosis	Video review by 3 expert endoscopists (as polyps not sent for histology in this study)	93.3% (95% CI, 85.1 to 97.8%)	73.9% (95% CI, 51.6 to 89.8%)	88.8% (95% CI, 80.8 to 94.3%)	• Analysis limited to high-confidence diagnoses; • SSLs or suspected SSLs not captured as these were supposed to be sent for histology; • Reference standard less than ideal as video review by experts rather than histology; • Analysed those polyps that were not sent for histology but where resect-and-discard approach was implemented. • NPV value was 77.3% (95% CI, 58.5 to 89.1%).
Abbreviations: CI, confidence interval; NPV, negative predictive value; SSL, sessile serrated lesion.					

1.13.1.7 All diminutive polyps – CADDIE™ as adjunct technology

Table 13. Diagnostic accuracy data for CADDIE™-assisted optical diagnosis in diminutive polyps – adenoma vs non-adenoma

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
[redacted]					
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; EAG, External Assessment Group; NPV, negative predictive value; RCT, randomised controlled trial; SSL, sessile serrated lesion; WHO, World Health Organization.

1.13.1.8 All diminutive polyps – GI Genius™ as adjunct technology

Table 14. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis in diminutive polyps – adenomatous vs non-adenomatous

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of diminutive (≤5 mm) colorectal polyps into adenomatous or non-adenomatous					
Hassan 2022 (colonoscopy for primary CRC screening, post-polypectomy surveillance, positive FIT test or for symptoms/signs) – 476 polyps assessed[55]					

GI Genius™-assisted optical diagnosis Adenomatous vs non-adenomatous Unclear which criteria used for optical diagnosis alongside GI Genius™ Expert endoscopists included (>2000 screening colonoscopies, trained in optical diagnosis and prior studies on polyp characterisation with BLI)	Histopathology	78.6% (71.7% to 84.5%)	94.0% (90.7% to 96.4%)	88.4% (85.2% to 91.1%)	• SSLs considered to be non-adenomatous in the analysis; • High and low confidence diagnoses included; • Does not appear to have excluded those where AI could not make a prediction. • NPV value was 88.4% (95% CI, 84.4 to 91.7%).
Rondonotti 2024 (colonoscopy for screening, symptoms or post-polypectomy surveillance with at least one diminutive colorectal polyp) – 376 polyps assessed[57]					
GI Genius™-assisted optical diagnosis Adenomatous vs non-adenomatous Unclear which criteria used for optical diagnosis alongside GI Genius™ Experts and non-experts included (experts had training, prior studies of optical diagnosis, auditing and monitoring and performed on regular basis according to ESGE criteria)	Histopathology	94.8% (91.1 to 97.1%)	58.9% (49.7 to 67.5%)	83.0% (78.8 to 86.6%)	• SSLs considered to be non-adenomatous in the analysis; • Only high confidence diagnoses included in analysis; • Does not appear to have excluded those where AI could not make a prediction. • NPV value was 84.9% (95% CI, 75.2 to 91.4%).

Abbreviations: AI, artificial intelligence; BLI, blue-light imaging; CI, confidence interval; CRC, colorectal cancer; ESGE, European Society of Gastrointestinal Endoscopy; FIT, faecal immunochemical test; NPV, negative predictive value; SSL, sessile serrated lesion.

1.13.2 Additional polyp category analyses – narrative discussion

Diminutive (≤5 mm) polyps divided into rectosigmoid and non-rectosigmoid based on location

CAD EYE®

Two studies for CAD EYE® assess the ability of CAD EYE® as an adjunct to endoscopist judgement in categorising diminutive rectosigmoid polyps (one categorising into adenoma, hyperplastic or serrated histologies, and the other into adenomatous vs non-adenomatous) and one assesses its ability to categorise diminutive non-rectosigmoid polyps (adenomatous vs non-adenomatous).[5, 58] Results are presented in Table 15.

For the rectosigmoid analyses, one suggested no major differences in any of the diagnostic accuracy measures compared to endoscopist optical diagnosis alone when high confidence diagnoses were considered (limited data for low confidence analyses were provided but negative predictive value (NPV) and accuracy were substantially lower for the CAD EYE®-assisted assessment),[58] while the other only reported results for the AI-supported arm and included any confidence diagnoses.[5] In the latter, sensitivity results were higher (100.0% vs 88.6%) and specificity was lower (71.4% vs 88.1%) compared to the other study. The study including any confidence diagnoses may be more appropriate given it includes more data and it allows separate classification of SSLs rather than combining as non-adenomatous, but it does not provide comparative data and the number of polyps analysed is unclear.

Limited data for the non-rectosigmoid analysis is reported, but specificity and NPV appear to be substantially lower for the CAD EYE®-assisted assessment when compared with the same results for the rectosigmoid analysis from this study when high confidence diagnoses only are included, with a similar accuracy measure reported.[58] No data for the comparator assessment of endoscopist optical diagnosis alone were reported.

CADDIE™

[redacted]

GI Genius™

One study for GI Genius™ assesses the ability GI Genius™ as an adjunct to endoscopist judgement in categorising diminutive rectosigmoid polyps into adenomatous or non-adenomatous polyps.[55] SSLs were included as non-adenomatous and only high confidence diagnoses were included. An autonomous AI arm was not prioritised for extraction given the adjunct assessment is the most relevant to this review. Results indicate a sensitivity value with GI Genius™ of 81.2% and a high specificity of 98.0%, resulting in a fairly high overall accuracy of 96.1%. Results are presented in Table 17.

Similarly, a second study reported the negative predictive value for GI Genius™-assisted optical diagnosis in diminutive rectosigmoid polyps, indicating the correct classification of non-adenomatous histology in this group of polyps.[59] The study involved trainee endoscopists that could be supported by an expert during polypectomies, and any elective colonoscopies could be included. For 223 diminutive rectosigmoid polyps analysed, a NPV of 90.3% (95% CI, 85.0 to 94.0%) was reported. This was noted in the paper to meet the requirements for the diagnose-and-leave strategy based on the Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) 2 threshold (≥90%). This study included an expert optical diagnosis alone and autonomous GI Genius™ assessment, but these were not extracted as experts only reviewed videos and adjunct data for GI Genius™ has been prioritised where available in this report over autonomous data. It is unclear how

SSLs were treated in the analysis, but analyses do not appear to have limited to high-confidence diagnoses only. Results are presented in Table 17.

One study using GI Genius™ autonomously reports data for diminutive non-rectosigmoid polyps, including any confidence diagnoses and classifying SSLs as adenomatous in the analysis.[60] When compared to endoscopist optical diagnosis alone, sensitivity was fairly similar but specificity was higher, leading to a slightly higher overall accuracy on GI Genius™. Of note, results where "no prediction" was returned by the AI system were excluded from the analyses, which may be a concern given this response from the AI system is a possibility in clinical practice. Although not presented here as adjunct data are available for this outcome with GI Genius™, results were similar but less positive for GI Genius™ in diminutive rectosigmoid polyps (specificity and overall accuracy were higher with endoscopist judgement), although fewer polyps were analysed in this analysis. Results are presented in Table 18.

Diminutive (≤5 mm) polyps divided into proximal and distal location

One study for GI Genius™ assesses the ability GI Genius™ as an adjunct to endoscopist judgement in categorising diminutive polyps when separated by a distal and proximal location into adenomatous or non-adenomatous polyps.[57] These analyses include SSLs as non-adenomatous and are limited to high confidence diagnoses only. Only the adjunct assessment was extracted, with the only comparative data being autonomous GI Genius™ use and not prioritised for inclusion in this review. Results suggest lower sensitivity with GI Genius™ in the diminutive distal polyps compared to diminutive proximal polyps, with the opposite observed for specificity. Overall accuracy was higher in the proximal polyps compared to distal polyps. Results are presented in Table 19.

Any polyps divided into left- and right-sided location

One study assessing autonomous CAD EYE® categorisation explored the functionality separated in left-and right-sided polyps of any size, with comparisons against endoscopist optical diagnosis alone and not limiting to high confidence diagnoses.[61] SSLs, polypoid mucosa, inflammatory polyps and juvenile polyps were excluded from the analysis. Results suggest a lower sensitivity but higher specificity compared to endoscopists alone in the right-sided analysis (statistically significant; p-value <0.05), with similar observed for the left-sided analysis, although comments about statistical significance for the latter are not given. Overall accuracy is slightly higher but fairly similar in CAD

EYE®-assisted and endoscopist optical diagnosis alone, with the difference slightly larger for the right-sided analysis. Results are presented in Table 20.

Polyps ≤10 mm or any sized polyps divided into rectosigmoidal (distal) and proximal location

One study reports the NPV for GI Genius™-assisted optical diagnosis in any sized rectosigmoid polyps, with the Japan Narrow Band Imaging Expert Team (JNET) 1 classification used to define hyperplastic polyps on optical diagnosis.[59] The study involved trainee endoscopists that could be supported by an expert during polypectomies, and any elective colonoscopies could be included. For 252 rectosigmoid polyps analysed, a NPV of 90.1% (95% CI, 85.0 to 94.0%) was reported. This study included an expert optical diagnosis alone and autonomous GI Genius™ assessment, but these were not extracted as experts only reviewed videos and adjunct data for GI Genius™ has been prioritised where available in this report over autonomous data. It is unclear how SSLs were treated in the analysis, but analyses do not appear to have limited to high-confidence diagnoses only. Results are presented in Table 21.

One study using GI Genius™ autonomously reports data for colorectal polyps ≤10 mm when separated into rectosigmoidal (distal) and proximal location, including any confidence diagnoses and classifying SSLs as adenomatous in the analysis.[60] For distal polyps, when compared to endoscopist optical diagnosis alone, sensitivity was identical but a lower specificity was observed with GI Genius™, leading to a higher overall accuracy for endoscopist optical diagnosis alone. For polyps ≤10 mm classified as having a proximal location, sensitivity with GI Genius™ was lower but a much higher specificity was observed, leading to a higher overall accuracy with GI Genius™. Of note, results where “no prediction” was returned by the AI system were excluded from the analyses, which may be a concern given this response from the AI system is a possibility in clinical practice. Results are presented in Table 22.

Furthermore, a second study using GI Genius™ autonomously reports data for any polyps separated into colon and rectosigmoid locations, with classification of these polyps into adenomatous or non-adenomatous polyps.[62] It is unclear how SSLs were treated in the analysis but there is no mention of any restriction to high-confidence diagnoses only. However, the analyses did exclude polyps where GI Genius™ returned “no prediction”. There was no comparator assessment reported in the paper. Results indicate sensitivities of 90.1% and 87.3% for those within the colon and those within the

rectosigmoid, respectively, with no 95% CI reported. For sensitivity, corresponding values of 54.2% and 64.9% were obtained and overall accuracy values were 83.7% and 77.4%, respectively. Results are presented in Table 22.

Any rectosigmoid polyps divided into different size categories

One study reported on GI Genius™-assisted optical diagnosis in rectosigmoid polyps of specific size categories.[59] While only NPV and PPV were directly reported, sufficient data on true positives, true negatives, false positives and false negatives were available for the EAG to calculate sensitivity, specificity and overall accuracy values. The study involved trainee endoscopists that could be supported by an expert during polypectomies, and any elective colonoscopies could be included. This study included an expert optical diagnosis alone and autonomous GI Genius™ assessment, but these were not extracted as experts only reviewed videos and adjunct data for GI Genius™ has been prioritised where available in this report over autonomous data. It is unclear how SSLs were treated in the analysis, but analyses do not appear to have limited to high-confidence diagnoses only. In terms of ability to classify into adenomatous and non-adenomatous polyps accurately, sensitivity and specificity vary noticeably across three categories of 1 to 2 mm (106 polyps), 3 to 5 mm (117 polyps) and 6 to 30 mm (23 polyps), with the latter category being particularly limited given the small number of polyps analysed. Sensitivity values were 27.27%, 65.52% and 94.12%, specificity values were 95.79%, 84.09% and 50.0% and overall accuracy values were 88.68%, 79.49% and 82.61% in the three groups, respectively. Results are presented in Table 23.

Any polyps divided into other size categories

CAD EYE®

Results from a single study for autonomous CAD EYE® categorisation indicate higher sensitivity for CAD EYE® categorisation as well as endoscopist optical diagnosis alone when applied to large polyps (≥10 mm) compared to small polyps (6-9 mm).[61] Specificity results were also higher for the CAD EYE® categorisation in large polyps, but much lower for the endoscopist optical diagnosis alone, suggesting CAD EYE® categorisation may improve specificity compared to endoscopist optical diagnosis alone in large polyps; however, the EAG expresses caution in this result given only 45 large polyps were assessed. There appeared to be a worse sensitivity with CAD EYE® categorisation compared to endoscopist assessment in small polyps (statistically significant; p-value <0.05), but

results were identical in the large polyp assessment for sensitivity. A better specificity for CAD EYE® categorisation was observed for small polyps when compared with endoscopist assessment but this was not reported to be statistically significant. Results are presented in Table 24.

GI Genius™

One study using GI Genius™ autonomously reports data for colorectal polyps when separated into ≤10 mm and 6-10 mm categories, including any confidence diagnoses and classifying SSLs as adenomatous in the analysis[60]. When compared to endoscopist optical diagnosis alone, sensitivity was fairly similar but slightly lower with GI Genius™ when polyps ≤10 mm were considered, with the opposite observed for specificity; overall accuracy were very similar between the two assessments. For 6-10 mm polyps specifically, similar was observed, but the difference in specificity was larger meaning that overall accuracy was slightly higher with GI Genius™. Of note, results where "no prediction" was returned by the AI system were excluded from the analyses, which may be a concern given this response from the AI system is a possibility in clinical practice. Although not presented here as adjunct data are available for this outcome with GI Genius™, results were not too dissimilar to the results for polyps ≤5 mm assessed in this study (sensitivity and specificity, and overall accuracy, were very similar between the two assessments). Results are presented in Table 25.

Specific polyp types including hyperplastic and adenomatous polyps

One study reported on GI Genius™-assisted optical diagnosis in specific groups of polyps based on their categorisation using NBI International Colorectal Endoscopic (NICE) or JNET criteria, including for NICE 1 (hyperplastic on NICE classification), NICE 2 (adenomatous on NICE classification) and JNET2a (adenomas with low-grade dysplasia on JNET classification), reporting full diagnostic accuracy data for two of these groups.[59] The study involved trainee endoscopists that could be supported by an expert during polypectomies, and any elective colonoscopies could be included. This study included an expert optical diagnosis alone and autonomous GI Genius™ assessment, but these were not extracted as experts only reviewed videos and adjunct data for GI Genius™ has been prioritised where available in this report over autonomous data. It is unclear how SSLs were treated in the analysis, but analyses do not appear to have limited to high-confidence diagnoses only. Results indicate sensitivity values of 84.9% and 63.2% for NICE 1 and NICE 2 analyses, but this was not reported for JNET2a. Corresponding specificity values for NICE 1 and NICE 2 analyses were 63.3%

and 83.0%, respectively. Overall accuracy values for NICE 1, NICE 2 and JNET2a analyses were similar, with values of 73.5%, 73.8% and 72.0%, respectively. Results are presented in Table 26.

Classification of patients having at least one neoplastic lesion

Results from a single study for autonomous CAD EYE® categorisation reported the ability to correctly classify patients into having at least one neoplastic lesion or not.[61] Results indicated a worse sensitivity (statistically significant; p-value 0.027) but better specificity for CAD EYE® categorisation (not statistically significant; p-value 0.125) compared to endoscopist optical diagnosis, and a slightly lower overall accuracy of CAD EYE® categorisation (not statistically significant; p-value 0.189). Results are presented in Table 27.

Classification of SSLs into adenomatous or non-adenomatous

One study using GI Genius™ autonomously reports limited data for the ability of GI Genius™ to classify SSLs as adenomatous, which was the preferred way of analysing these in this study.[60] Only 7 SSLs were identified in this study, but it reports that AI and endoscopists both classified 3/7 SSLs as adenomas.

1.13.3 Additional polyp category analyses – results tables

1.13.3.1 Diminutive (≤5 mm) polyps divided into rectosigmoid and non-rectosigmoid based on location

Table 15. Diagnostic accuracy data for CAD EYE®-assisted optical diagnosis in diminutive polyps separated by rectosigmoid and non-rectosigmoid location

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of diminutive (≤5 mm) rectosigmoid polyps into adenoma, hyperplastic and serrated histologies					
Djinbachian 2024 (colonoscopy for screening, surveillance or diagnostic purposes) – unclear number of polyps assessed[5]					
CAD EYE®-assisted optical diagnosis (all prior experience with optical diagnosis, experience varied) Unclear which criteria used for optical diagnosis	Histopathology	100.0% (83.9 to 100.0)	71.4% (55.4 to 84.3)	NR	• Main analysis does not limit to high-confidence diagnoses; • Main analysis allows for the classification of SSLs as own group; • Analysed all rectosigmoid polyps ≤5 mm that were resected and retrieved for histopathology, were not normal mucosa/inflammatory polyps and where optical diagnosis was performed. • NPV value was 100.0% (95% CI, 90.7 to 100.0%).
Outcome: classification of diminutive (≤5 mm) rectosigmoid polyps into adenomatous vs non-adenomatous					
Rondonotti 2023 (aged 18-85 years undergoing outpatient colonoscopy – no further details) – 550 (CAD EYE®) or 540 (endoscopist) polyps assessed **High-confidence endoscopist diagnoses only[58]**					
CAD EYE®-assisted optical diagnosis (expert and non-expert endoscopists) Optical diagnosis based on CAD EYE® and BASIC criteria	Histopathology using Vienna classification	88.6% (83.7 to 91.4%)	88.1% (83.9 to 91.4%)	88.4% (85.3 to 90.9%)	• Non-adenomatous on histology included hyperplastic polyps, SSLs, inflammatory polyps or normal mucosal samples; • Only analysed diminutive rectosigmoid polyps that could be retrieved and where high-confidence optical diagnosis could be made by the endoscopist. • NPV values were 91.0% (95% CI, 87.1 to 93.9%) and 90.9% (95% CI, 86.8 to 93.7%) for CAD EYE®-assisted optical diagnosis and endoscopist optical diagnosis, respectively.
Endoscopist optical diagnosis only (expert and non-expert endoscopists) Optical diagnosis based on BASIC criteria	Histopathology using Vienna classification	88.6 % (83.6 to 92.2%)	88.8% (84.5 to 91.9%)	88.7% (85.7 to 91.2%)	

Rondonotti 2023 (aged 18-85 years undergoing outpatient colonoscopy – no further details) – unclear number of polyps assessed **Low-confidence endoscopist diagnoses only[58]**					
CAD EYE®-assisted optical diagnosis Optical diagnosis based on CAD EYE® and BASIC criteria	Histopathology using Vienna classification	NR	NR	50.0% (45.3% to 74.9%)	• Non-adenomatous on histology included hyperplastic polyps, SSLs, inflammatory polyps or normal mucosal samples; • Only analysed diminutive rectosigmoid polyps that could be retrieved and where low-confidence optical diagnosis was made by the endoscopist; • No data reported for endoscopist optical diagnosis only assessment. • NPV value was 70.6% (95% CI, 44.0 to 87.1%).
Outcome: classification of diminutive (≤5 mm) non-rectosigmoid polyps into adenomatous vs non-adenomatous					
Rondonotti 2023 (aged 18-85 years undergoing outpatient colonoscopy – no further details) – unclear number of polyps assessed **High-confidence endoscopist diagnoses only[58]**					
CAD EYE®-assisted optical diagnosis Optical diagnosis based on CAD EYE® and BASIC criteria	Histopathology using Vienna classification	NR	66.7% (53.5% to 69.6%)	87.0% (86.0% to 92.9%)	• Non-adenomatous on histology included hyperplastic polyps, SSLs, inflammatory polyps or normal mucosal samples; • Only analysed diminutive non-rectosigmoid polyps that could be retrieved and where high-confidence optical diagnosis could be made by the endoscopist; • Non-rectosigmoid polyps defined as those proximal to the rectosigmoid tract; • No data reported for endoscopist optical diagnosis only assessment. • NPV value was 72.4 % (95% CI, 58.8 to 82.9%).

Abbreviations: CI, confidence interval; NPV, negative predictive value; NR, not reported; SSL, sessile serrated lesion.

Table 16. Diagnostic accuracy data for CADDIE™-assisted optical diagnosis in diminutive rectosigmoid polyps – adenoma vs non-adenoma

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
[redacted]					
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; NPV, negative predictive value; RCT, randomised controlled trial; SSL, sessile serrated lesion; WHO, World Health Organization.

Table 17. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis in diminutive rectosigmoid polyps

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of diminutive (≤5 mm) rectosigmoid colorectal polyps into adenomatous or non-adenomatous					
Hassan 2022 (colonoscopy for primary CRC screening, post-polypectomy surveillance, positive FIT test or for symptoms/signs) – 279 polyps assessed[55]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Unclear which criteria used for optical diagnosis alongside GI Genius™ Expert endoscopists included (>2000 screening colonoscopies, trained in optical diagnosis and prior studies on polyp characterisation with BLI)	Histopathology	81. 2% (63.5 to 82.8%)	98.0% (95.3 to 99.3%)	96.1% (93.1 to 98%)	• SSLs considered to be non-adenomatous in the analysis; • Only high confidence diagnoses included in analysis; • Does not appear to have excluded those where AI could not make a prediction. • NPV value was 97.6% (95% CI, 94.8 to 99.1%).

Outcome: correct classification of non-adenomatous histology in diminutive rectosigmoid polyps					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – 223 polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	NR	NR	NR	• Only NPV reported: 90.3% (95% CI, 85.0 to 94.0%); • Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses; • PIVI 2 requirement for diagnose-and-leave strategy states that non-neoplastic DRSPs can be left without resection and requires NPV of at least 90% for adenomatous histology.

Abbreviations: AI, artificial intelligence; BLI, blue-light imaging; CI, confidence interval; CRC, colorectal cancer; DRSPs, diminutive rectosigmoid polyps; FIT, faecal immunochemical test; JNET, Japan Narrow Band Imaging Expert Team; NBI, narrow-band imaging; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; NR, not reported; PIVI 2, Preservation and Incorporation of Valuable Endoscopic Innovations – diagnose-and-leave strategy; SSL, sessile serrated lesion.

Table 18. Diagnostic accuracy data for autonomous GI Genius™ optical diagnosis in diminutive non-rectosigmoid polyps

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of diminutive (≤5 mm) non-rectosigmoid colorectal polyps into adenomatous or non-adenomatous					
Baumer 2023 (colonoscopies for 14 different indications, including screening, surveillance, various symptoms, etc.) – 103 polyps assessed[60]					
Autonomous GI Genius™ (not adjunct) – adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	87.2% (77.7 to 93.7%)	64.0% (42.5 to 82.0%)	81.6% (72.7 to 88.5%)	• Autonomous use of GI Genius™; • SSLs considered to be adenomatous in the analysis; • Any confidence diagnoses included; • Excluded where an AI result of "no prediction" was made. • NPV values were 61.5% (95% CI, 45.5 to 75.4%) and 60.0% (95% CI, 40.9 to 76.5%) for autonomous GI Genius™ and endoscopist optical diagnosis, respectively.
Endoscopist diagnosis alone - adenomatous vs non-adenomatous (<5, 5-10 or >10 years of experience) NICE and WASP classifications used	Histopathology	89.7% (80.8 to 95.5%)	48.0% (27.8 to 68.7%)	79.6% (70.5 to 86.9%)	

Abbreviations: AI, artificial intelligence; CI, confidence interval; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; SSL, sessile serrated lesion; WASP, Workgroup Serrated Polyps and Polyposis.

1.13.3.2 Diminutive (≤5 mm) polyps divided into proximal and distal location

Table 19. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis in diminutive distal and proximal polyps

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of diminutive (≤5 mm) distal colorectal polyps into adenomatous or non-adenomatous					
Rondonotti 2024 (colonoscopy for screening, symptoms or post-polypectomy surveillance with at least one diminutive colorectal polyp) – 163 polyps assessed[57]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Unclear which criteria used for optical diagnosis alongside GI Genius™ Experts and non-experts included (experts had training, prior studies of optical diagnosis, auditing and monitoring and performed on regular basis according to ESGE criteria)	Histopathology	91.4% (83.3 to 95.9%)	64.3% (51.9 to 75.1%)	79.8% (72.8 to 85.6%)	• SSLs considered to be non-adenomatous in the analysis; • Only high confidence diagnoses included in analysis; • Does not appear to have excluded those where AI could not make a prediction. • NPV value was 84.9% (95% CI, 71.9 to 92.8%).

Outcome: classification of diminutive (≤5 mm) proximal colorectal polyps into adenomatous or non-adenomatous					
Rondonotti 2024 (colonoscopy for screening, symptoms or post-polypectomy surveillance with at least one diminutive colorectal polyp) – 213 polyps assessed[57]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Unclear which criteria used for optical diagnosis alongside GI Genius™ Experts and non-experts included (experts had training, prior studies of optical diagnosis, auditing and monitoring and performed on regular basis according to ESGE criteria)	Histopathology	96.9% (92.4 to 98.8%)	51.9% (38.0 to 65.5%)	85.5% (80.0 to 89.9%)	• SSLs considered to be non-adenomatous in the analysis; • Only high confidence diagnoses included in analysis; • Does not appear to have excluded those where AI could not make a prediction. • NPV value was 84.8% (95% CI, 80.0 to 89.9%).
Abbreviations: AI, artificial intelligence; CI, confidence interval; ESGE, European Society of Gastrointestinal Endoscopy; NPV, negative predictive value; SSL, sessile serrated lesion.					

1.13.3.3 Any polyps divided into left- and right-sided location

Table 20. Diagnostic accuracy data for autonomous CAD EYE® optical diagnosis in left- and right-sided polyps of any size

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of any right-sided colorectal polyps into neoplastic vs hyperplastic					
Li 2023 (colonoscopy for clinical signs and symptoms, polyp surveillance or screening for CRC) – 571 polyps assessed[61]					
Autonomous CAD EYE® (not adjunct) - neoplastic vs hyperplastic	Histopathology	62.0% (56.9 to 66.9%)	84.9% (79.0 to 89.6%)	69.7% (65.8 to 73.4%)	

Optical diagnosis based on CAD EYE®		p-value <0.05 vs endoscopists	p-value <0.05 vs endoscopists	p-value <0.05 vs endoscopists	• Autonomous use of CAD EYE®; • Neoplastic lesions refer to all polyps that are not hyperplastic and include adenomatous lesions which may be tubular or villous in nature, and with low-grade or high-grade dysplasia; • SSLs/sessile serrated polyps excluded from analysis. Polypoid mucosa, inflammatory polyps and juvenile polyps also excluded from analysis; • Does not appear to limit only to high confidence diagnoses. • NPV values were 53.1% (95% CI, 47.3 to 58.8%) and 57.7% (95% CI, 51.5 to 63.8%) for autonomous CAD EYE® and endoscopist optical diagnosis, respectively.
Endoscopist optical diagnosis alone (credentialed endoscopists that had undergone 3-year training programme in optical diagnosis) Optical diagnosis based on NICE and JNET classifications	Histopathology	70.4% (65.6 to 75.0%)	79.7% (73.3 to 85.1%)	73.6% (69.7 to 77.1%)	
Outcome: classification of any left-sided colorectal polyps into neoplastic vs hyperplastic					
Li 2023 (colonoscopy for clinical signs and symptoms, polyp surveillance or screening for CRC) – 90 polyps assessed[61]					
Autonomous CAD EYE® (not adjunct) - neoplastic vs hyperplastic Optical diagnosis based on CAD EYE®	Histopathology	58.6% (38.9 to 76.5%)	95.1% (86.3 to 99.0%)	83.3% (74.0 to 90.4%)	

Endoscopist optical diagnosis alone (credentialed endoscopists that had undergone 3-year training programme in optical diagnosis) Optical diagnosis based on NICE and JNET classifications	Histopathology	69.0% (49.2 to 84.7%)	93.4% (84.1 to 98.2%)	85.6% (76.6 to 92.1%)	• Autonomous use of CAD EYE®; • Neoplastic lesions refer to all polyps that are not hyperplastic and include adenomatous lesions which may be tubular or villous in nature, and with low-grade or high-grade dysplasia; • SSLs/sessile serrated polyps excluded from analysis. Polypoid mucosa, inflammatory polyps and juvenile polyps also excluded from analysis; • Does not appear to limit only to high confidence diagnoses. • NPV values were 82.9% (95% CI, 72.0 to 90.8%) and 86.4% (95% CI, 75.7 to 93.6%) for autonomous CAD EYE® and endoscopist optical diagnosis, respectively.

Abbreviations: CI, confidence interval; CRC, colorectal cancer; JNET, Japan Narrow Band Imaging Expert Team; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; SSL, sessile serrated lesion.

1.13.3.4 Polyps ≤10 mm or any sized polyps divided into rectosigmoidal (distal) and proximal location

Table 21. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis in any sized rectosigmoid polyps

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: correct classification of non-adenomatous histology in any size rectosigmoid polyps – JNET1 (hyperplastic polyps)					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – 252 polyps[59]					

GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	NR	NR	NR	• Only NPV reported: 90.1% (95% CI, 85.0 to 94.0%) • Those considered on optical diagnosis to be JNET1 used to calculate the NPV; • Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses; • PIVI 2 requirement for diagnose-and-leave states that non-neoplastic DRSPs can be left without resection and requires NPV of at least 90% for adenomatous histology.

Abbreviations: CI, confidence interval; DRSPs, diminutive rectosigmoid polyps; JNET, Japan Narrow Band Imaging Expert Team; NBI, narrow-band imaging; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; NR, not reported; PIVI 2, Preservation and Incorporation of Valuable Endoscopic Innovations – diagnose-and-leave strategy; SSL, sessile serrated lesion.

Table 22. Diagnostic accuracy data for autonomous GI Genius™ optical diagnosis in distal (rectosigmoid) and proximal polyps ≤10 mm

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of rectosigmoidal (distal) colorectal polyps ≤10 mm into adenomatous or non-adenomatous					
Baumer 2023 (colonoscopies for 14 different indications, including screening, surveillance, various symptoms, etc.) – 79 polyps assessed[60]					
Autonomous GI Genius™ (not adjunct) - adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	85.0% (62.1 to 96.8%)	79.7% (67.2% to 89.0%)	81.0% (70.6 to 89.0%)	

Endoscopist diagnosis alone - adenomatous vs non-adenomatous (<5, 5-10 or >10 years of experience) NICE and WASP classifications used	Histopathology	85.0% (62.1 to 96.8%)	86.4% (75.0 to 94.0%)	86.1% (76.5% to 92.8%)	• Autonomous GI Genius™ use; • SSLs considered to be adenomatous in the analysis; • Any confidence diagnoses included; • Excluded where an AI result of "no prediction" was made. • NPV values were 94.0% (95% CI, 84.6 to 97.8%) and 94.4% (95% CI, 85.6 to 98.0%) for autonomous GI Genius™ and endoscopist optical diagnosis, respectively.
Outcome: classification of proximal colorectal polyps ≤10 mm into adenomatous or non-adenomatous					
Baumer 2023 (colonoscopies for 14 different indications, including screening, surveillance, various symptoms, etc.) – 183 polyps assessed[60]					
Autonomous GI Genius™ (not adjunct) - adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	90.3% (84.3 to 94.6%)	68.4% (51.4 to 82.5%)	85.8% (79.9 to 91.0%)	

Endoscopist diagnosis alone - adenomatous vs non-adenomatous (<5, 5-10 or >10 years of experience) NICE and WASP classifications used	Histopathology	93.1% (87.7 to 96.6%)	42.1% (26.3 to 59.2%)	82.5% (76.2 to 87.7%)	• Autonomous GI Genius™ use; • SSLs considered to be adenomatous in the analysis; • Any confidence diagnoses included; • Excluded where an AI result of “no prediction” was made. • NPV values were 65.0% (95% CI, 51.9 to 76.2%) and 61.5% (95% CI, 44.2 to 76.4%) for autonomous GI Genius™ and endoscopist optical diagnosis, respectively.

Outcome: classification of any polyps within the colon into adenomatous or non-adenomatous					
Koh 2024 (colonoscopies by accredited trainees and specialists in endoscopy unit) – 404 polyps[62]					
Autonomous GI Genius™ (not adjunct) - adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	90.1% (95% CI, 86.4 to 93.1%)	53.5% (95% CI, 41.3 to 65.5%)	83.7% (95% CI, 79.7 to 87.1%)	• Autonomous GI Genius™ use; • Unclear how SSLs treated in the analysis; • No mention of any restriction to high-confidence diagnoses; • Excludes polyps where no prediction was returned by GI Genius™. • Specificity value corrected slightly compared to that reported in the paper. 95% CI values calculated by EAG. • NPV value was 53.5% (95% CI, 43.8 to 63.0%). Corrected compared to paper.

Outcome: classification of any polyps within the rectosigmoid into adenomatous or non-adenomatous					
Koh 2024 (colonoscopies by accredited trainees and specialists in endoscopy unit) – 211 polyps[62]					
Autonomous GI Genius™ (not adjunct) - adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	87.3% (95% CI, 79.9 to 92.7%)	64.5% (95% CI, 53.9 to 74.2%)	77.3% (95% CI, 71.0 to 82.7%)	• Autonomous GI Genius™ use; • Unclear how SSLs treated in the analysis; • No mention of any restriction to high-confidence diagnoses; • Excludes polyps where no prediction was returned by GI Genius™. • Specificity and accuracy values corrected slightly compared to that reported in the paper. 95% CI values calculated by EAG. • NPV value was 80.0% (95% CI, 70.9 to 86.8%). Corrected compared to paper.

Abbreviations: AI, artificial intelligence; CI, confidence interval; EAG, External Assessment Group; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; NR, not reported; SSL, sessile serrated lesion; WASP, Workgroup Serrated Polyps and Polyposis.

1.13.3.5 Any rectosigmoid polyps divided into different size categories

Table 23. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis rectosigmoid polyps of different sizes

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of rectosigmoid colorectal polyps sized 1 to 2 mm into adenomatous or non-adenomatous					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – 106 polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	Calculated as: 27.27% (95% CI, 6.02 to 60.97%)	Calculated as: 95.79% (95% CI, 89.57 to 98.84%)	Calculated as: 88.68% (95% CI, 81.06 to 94.01%)	• Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses. • NPV value was 91.9% (95% CI, 85.0 to 96.0%).
Outcome: classification of rectosigmoid colorectal polyps sized 3 to 5 mm into adenomatous or non-adenomatous					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – 117 polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts	Histopathology	Calculated as: 65.52% (95% CI, 45.67 to 82.06%)	Calculated as: 84.09% (95% CI, 74.75 to 91.02%)	Calculated as: 79.49% (95% CI, 71.03 to 86.39%)	• Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses. • NPV value was 88.1% (95% CI, 79.0 to 94.0%).

(>2000 colonoscopies) able to support with polypectomies					
Outcome: classification of rectosigmoid colorectal polyps sized 6 to 30 mm into adenomatous or non-adenomatous					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – 23 polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	Calculated as: 94.12% (95% CI, 71.31 to 99.85%)	Calculated as: 50.0% (95% CI, 11.81 to 88.19%)	Calculated as: 82.61% (95% CI, 61.22 to 95.05%)	• Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses. • NPV value was 75.0% (95% CI, 19.0 to 99.0%).
Abbreviations: CI, confidence interval; JNET, Japan Narrow Band Imaging Expert Team; NBI, narrow-band imaging; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; SSL, sessile serrated lesion.					

1.13.3.6 Any polyps divided into other size categories

Table 24. Diagnostic accuracy data for autonomous CAD EYE® optical diagnosis in small and large polyps

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of small (6-9 mm) colorectal polyps into neoplastic vs hyperplastic					
Li 2023 (colonoscopy for clinical signs and symptoms, polyp surveillance or screening for CRC) – 109 polyps assessed[61]					
Autonomous CAD EYE® (not adjunct) - neoplastic vs hyperplastic Optical diagnosis based on CAD EYE®	Histopathology	72.7% (62.2 to 81.7%) p-value <0.05 vs endoscopists	66.7% (43.0 to 85.4%)	71.6% (62.1 to 79.8%)	• Autonomous use of CAD EYE®; • Neoplastic lesions refer to all polyps that are not hyperplastic and include adenomatous lesions which may be tubular or villous in nature, and with low-grade or high-grade dysplasia; • SSLs/sessile serrated polyps excluded from analysis. Polypoid mucosa, inflammatory polyps and juvenile polyps also excluded from analysis; • Does not appear to limit only to high confidence diagnoses. • NPV values were 36.8% (95% CI, 21.8 to 54.0%) and 41.7% (95% CI, 22.1 to 63.4%) for autonomous CAD EYE® and endoscopist optical diagnosis, respectively.
Endoscopist optical diagnosis alone (credentialed endoscopists that had undergone 3-year training programme in optical diagnosis) Optical diagnosis based on NICE and JNET classifications	Histopathology	84.1% (74.8 to 91.0%)	47.6% (25.7 to 70.2%)	77.1% (68.0 to 84.6%)	
Outcome: classification of large (≥10 mm) colorectal polyps into neoplastic vs hyperplastic					
Li 2023 (colonoscopy for clinical signs and symptoms, polyp surveillance or screening for CRC) – 45 polyps assessed[61]					
Autonomous CAD EYE® (not adjunct) - neoplastic vs hyperplastic Optical diagnosis based on CAD EYE®	Histopathology	90.9% (78.3 to 97.5%)	100.0% (2.5 to 100.0%)	91.1% (78.8 to 97.5%)	

Endoscopist optical diagnosis alone (credentialed endoscopists that had undergone 3-year training programme in optical diagnosis) Optical diagnosis based on NICE and JNET classifications	Histopathology	90.9% (78.3 to 97.5%)	0.0% (0.0 to 97.5%)	88.9% (75.9 to 96.3%)	• Autonomous use of CAD EYE®; • Neoplastic lesions refer to all polyps that are not hyperplastic and include adenomatous lesions which may be tubular or villous in nature, and with low-grade or high-grade dysplasia; • SSLs/sessile serrated polyps excluded from analysis. Polypoid mucosa, inflammatory polyps and juvenile polyps also excluded from analysis; • Does not appear to limit only to high confidence diagnoses. • NPV values were 20.0% (95% CI, 0.5 to 71.6%) and 0.0% (95% CI, 0.0 to 60.2%) for autonomous CAD EYE® and endoscopist optical diagnosis, respectively.

Abbreviations: CI, confidence interval; CRC, colorectal cancer; JNET, Japan Narrow Band Imaging Expert Team; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; SSL, sessile serrated lesion.

Table 25. Diagnostic accuracy data for autonomous GI Genius™ optical diagnosis of ≤10 mm and 6-10 mm polyps

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of colorectal polyps ≤10 mm into adenomatous or non-adenomatous					
Baumer 2023 (colonoscopies for 14 different indications, including screening, surveillance, various symptoms, etc.) – 262 polyps assessed[60]					
Autonomous GI Genius™ (not adjunct) - adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	89.7% (84.0 to 93.9%)	75.3% (65.5 to 83.5%)	84.4% (79.4 to 88.5%)	• Autonomous use of GI Genius™; • SSLs considered to be adenomatous in the analysis; • Any confidence diagnoses included;
Endoscopist diagnosis alone - adenomatous vs non-adenomatous (<5, 5-10 or >10 years of experience) NICE and WASP classifications used	Histopathology	92.1% (86.9 to 95.7%)	69.1% (58.9 to 78.1%)	83.6% (78.5 to 87.9%)	• Excluded where an AI result of "no prediction" was made. • NPV values were 81.1% (95% CI, 73.0 to 87.2%) and 83.8% (95% CI, 75.1 to 89.8%) for autonomous GI Genius™ and endoscopist optical diagnosis, respectively.
Outcome: classification of 6 to 10 mm colorectal polyps into adenomatous or non-adenomatous					
Baumer 2023 (colonoscopies for 14 different indications, including screening, surveillance, various symptoms, etc.) – 105 polyps assessed[60]					
Autonomous GI Genius™ (not adjunct) - adenomatous vs non-adenomatous Optical diagnosis based on GI Genius™	Histopathology	94.7% (87.1 to 98.6%)	75.9% (56.5 to 89.7%)	89.5% (82.0 to 94.7%)	• Autonomous use of GI Genius™; • SSLs considered to be adenomatous in the analysis; • Any confidence diagnoses included;
Endoscopist diagnosis alone - adenomatous vs non-adenomatous (<5, 5-10 or >10 years of experience) NICE and WASP classifications used	Histopathology	97.4% (90.8 to 99.7%)	58.6% (38.9 to 76.5%)	86.7% (78.6 to 92.5%)	• Excluded where an AI result of "no prediction" was made. • NPV values were 84.6% (95% CI, 67.5 to 93.6%) and 89.5% (95% CI, 67.7 to 97.2%) for autonomous GI Genius™ and endoscopist optical diagnosis, respectively.

Abbreviations: AI, artificial intelligence; CI, confidence interval; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; SSL, sessile serrated lesion; WASP, Workgroup Serrated Polyps and Polyposis.

1.13.3.7 Specific polyp types including hyperplastic and adenomatous polyps

Table 26. Diagnostic accuracy data for GI Genius™-assisted optical diagnosis in hyperplastic and adenomatous polyps based on NICE 1, NICE 2 and JNET2a categories

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of any NICE 1 classification polyps into adenomatous or non-adenomatous					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – unclear number of polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	84.9% (95% CI, 80.0 to 89.0%)	63.3% (95% CI, 57.0 to 69.0%)	73.5% (95% CI, 70.0 to 77.0%)	• Refers to performance of GI Genius™-assisted optical diagnosis specifically in polyps within NICE 1 category (refers to hyperplastic on NICE classification); • Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses. • NPV value was 82.1% (95% CI, 76.0 to 87.0%).

Outcome: classification of any NICE 2 classification polyps into adenomatous or non-adenomatous					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – unclear number of polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	63.2% (95% CI, 57.0 to 69.0%)	83.0% (95% CI, 79.0 to 87.0%)	73.8% (95% CI, 70.0 to 77.0%)	• Refers to performance of GI Genius™-assisted optical diagnosis specifically in polyps within NICE 2 category (refers to adenomatous on NICE classification); • Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses. • NPV value was 72.2% (95% CI, 67.0 to 77.0%).
Outcome: classification of any JNET2a classification polyps into adenomatous or non-adenomatous					
Bernhofer 2025 (elective colonoscopy for any reason performed by a trainee endoscopist) – unclear number of polyps[59]					
GI Genius™-assisted optical diagnosis - adenomatous vs non-adenomatous Optical diagnosis based on NICE and JNET classifications with GI Genius™ assistance, NBI used Trainee endoscopists with no formal optical diagnosis training prior to the study, with experts (>2000 colonoscopies) able to support with polypectomies	Histopathology	NR	NR	72.0% (95% CI NR)	• Refers to performance of GI Genius™-assisted optical diagnosis specifically in polyps within JNET2a category (refers to adenomas with low-grade dysplasia on JNET classification); • Unclear how SSLs treated in analysis; • Does not appear to limit to high confidence diagnoses. • NPV value not reported and not possible to calculate.

Abbreviations: CI, confidence interval; JNET, Japan Narrow Band Imaging Expert Team; NBI, narrow-band imaging; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; NR, not reported; SSL, sessile serrated lesion.

1.13.3.8 Classification of patients having at least one neoplastic lesion

Table 27. Diagnostic accuracy data for autonomous CAD EYE® optical diagnosis – patients having at least one neoplastic lesion vs not

Index test	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	Comments
Outcome: classification of patients into having at least one neoplastic lesion or not					
Li 2023 (colonoscopy for clinical signs and symptoms, polyp surveillance or screening for CRC) – 274 patients assessed[61]					
Autonomous CAD EYE® (not adjunct) - neoplastic vs hyperplastic Optical diagnosis based on CAD EYE®	Histopathology	73.5% (66.9 to 79.4%) p-value 0.027 vs endoscopists	84.3% (73.6 to 91.9%) p-value 0.125 vs endoscopists	76.3% (70.8 to 81.2%) p-value 0.189 vs endoscopists	• Autonomous use of CAD EYE®; • Neoplastic lesions refer to all polyps that are not hyperplastic and include adenomatous lesions which may be tubular or villous in nature, and with low-grade or high-grade dysplasia; • SSLs/sessile serrated polyps excluded from analysis. Polypoid mucosa, inflammatory polyps and juvenile polyps also excluded from analysis; • Does not appear to limit only to high confidence diagnoses. • NPV values were 52.2% (95% CI, 42.6 to 61.7%) and 57.5% (95% CI, 46.8 to 67.6%) for autonomous CAD EYE® and endoscopist optical diagnosis, respectively.
Endoscopist optical diagnosis alone (credentialed endoscopists that had undergone 3-year training programme in optical diagnosis) Optical diagnosis based on NICE and JNET classifications	Histopathology	80.4% (74.3 to 85.6%)	77.1% (65.6 to 86.3%)	79.6% (74.3 to 84.2%)	

Abbreviations: CI, confidence interval; CRC, colorectal cancer; JNET, Japan Narrow Band Imaging Expert Team; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; SSL, sessile serrated lesion.

1.14 Withdrawal or inspection time

CAD EYE®

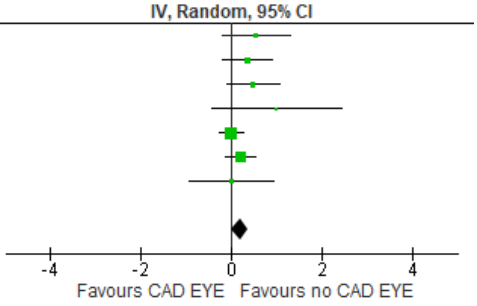
Seven RCTs reported the impact of CAD EYE®-assisted polyp detection on withdrawal time in a format that could be meta-analysed,[3, 6-8, 29, 33, 40] with results indicating increased duration with CAD EYE®, which was statistically significant (p-value 0.03), with some heterogeneity observed based on point estimates (

Figure 99). Differences in whether or not polypectomies were included in this outcome does not appear to explain heterogeneity, and this was poorly reported for many studies of this intervention (three studies excluded washing, polypectomies or other procedures, and this was unclear for the four remaining studies). A further four studies reported data as medians only;[4, 9, 11, 48] of the three that were at a lower risk of bias, one reported identical medians in both groups (9.0 minutes) and two reported a slightly higher duration with CAD EYE® (median 10.0 vs 9.0 minutes and median 8.6 vs 8.2 minutes, respectively).[4, 9, 11] Overall, it is possible that CAD EYE® may increase withdrawal time to some extent compared to standard colonoscopy, but possibly only up to one minute based on this evidence.

Figure 99. Withdrawal or inspection time in CAD EYE® studies

	CAD EYE			No CAD EYE				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Alali 2025	9.04	2.06	51	8.49	1.74	51	5.8%	0.55 [-0.19, 1.29]
Aniwan 2023	9.2	5.35	620	8.85	4.33	625	10.8%	0.35 [-0.19, 0.89]
Desai 2024	11.28	4.59	509	10.8	4.81	522	9.6%	0.48 [-0.09, 1.05]
Huneburg 2023	15	3.7	50	14	3.5	46	1.5%	1.00 [-0.44, 2.44]
Miyaguchi 2024	7	2.0347	400	7	2.0347	400	39.9%	0.00 [-0.28, 0.28]
Nakashima 2023	6.86	1.71	207	6.65	1.74	208	28.8%	0.21 [-0.12, 0.54]
Yamaguchi 2024	13.06	3.23	113	13.05	4.01	118	3.6%	0.01 [-0.93, 0.95]
Total (95% CI)			**1950**			**1970**	**100.0%**	**0.19 [0.01, 0.37]**

Heterogeneity: Tau² = 0.00; Chi² = 5.34, df = 6 (P = 0.50); I² = 0%
Test for overall effect: Z = 2.11 (P = 0.03)



Note: three studies excluded washing, polypectomies or other procedures, and this was unclear for the three remaining studies.
Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

CADDIE™

[redacted]

[redacted]

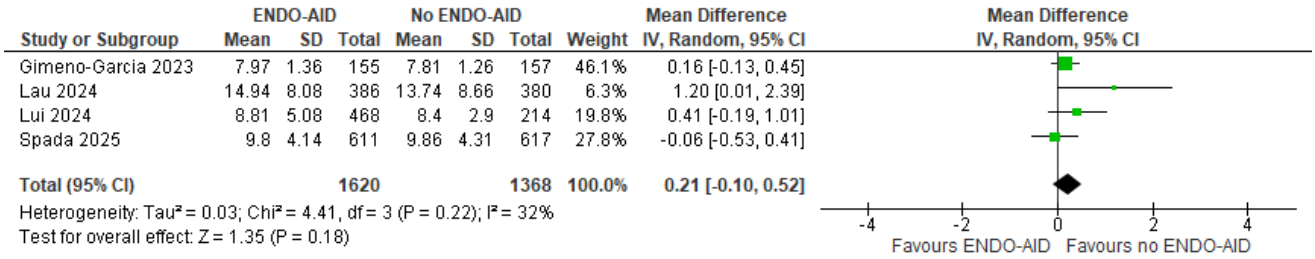
Discovery™

One RCT reported the impact of Discovery™-assisted polyp detection on withdrawal time without "interventions" but only as a comparison of median values and "interventions" was not further defined.[26] Results indicated a slightly higher median value with Discovery™ compared to standard colonoscopy (median 9.2 vs 9.0 minutes), with a p-value of 0.05 for an absolute difference of 0.2 reported, indicating that there may be a small increase in withdrawal time using Discovery™.

ENDO-AID™

Four RCTs reported the impact of ENDO-AID™-assisted polyp detection on withdrawal time in a format that could be meta-analysed,[13-16] with results indicating increased duration with ENDO-AID™, which was not statistically significant (p-value 0.18), with some variation observed based on point estimates and evidence of statistical heterogeneity based on an I^2 value of 32% (Figure 100). It is possible that studies differ with regards to whether or not polypectomies were included in this time, but this is unclear due to poor reporting for some studies (one excluded polypectomies and other interventions, one study excluded "interventions", which was not defined, and this was unclear for the remaining two studies). It is possible that ENDO-AID™ may increase withdrawal time to some extent compared to standard colonoscopy, but possibly only up to one minute based on this evidence.

Figure 100. Withdrawal time in ENDO-AID™ studies



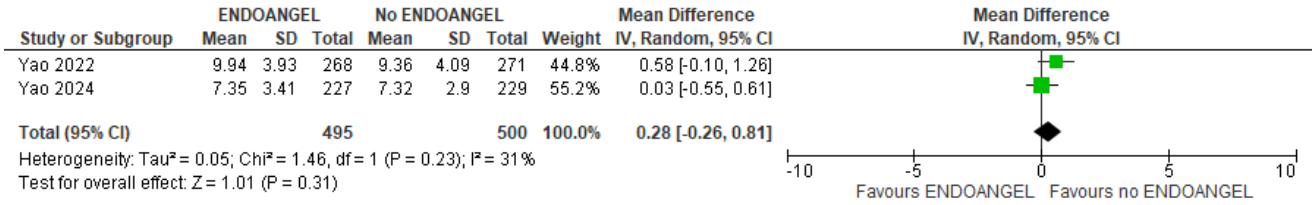
Note: one study excluded "interventions", which was not further defined, and this was unclear for the two remaining studies.
Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

ENDOANGEL®

Four RCTs reported the impact of ENDOANGEL®-assisted polyp detection on withdrawal time in a format that could be meta-analysed,[17, 18, 27, 50] with results from two of these excluded as they were considered to be at a higher risk of bias.[27, 50] Results of the meta-analysis indicate an increased duration with ENDOANGEL®, which is not statistically significant (p-value 0.31), with some statistical heterogeneity observed based on an I^2 value of 31% (

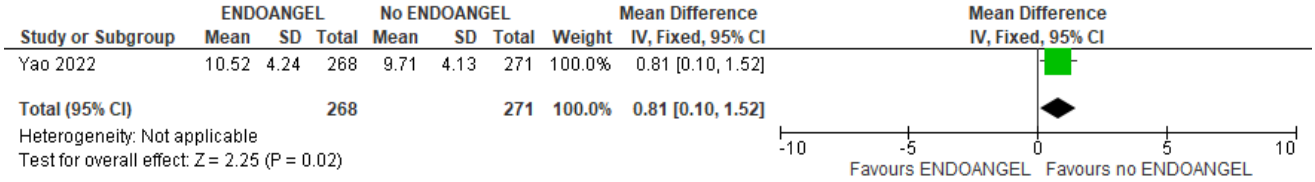
Figure 101). It is likely that the two studies are similar with regards to not including interventions such as polypectomy in this withdrawal time, as one refers to withdrawal time "without operation" and the other refers to "clean" withdrawal time. It is possible that ENDO-AID™ may increase withdrawal time to some extent compared to standard colonoscopy, but possibly only up to one minute based on this evidence. One of these studies also reported data separately for when "operations" were not excluded, which was not further defined but likely refers to procedures such as polypectomies;[17] results in Figure 102 show the difference between treatment arms increases slightly for this analysis compared to the same data from this study when "operations" are excluded, but the suggested difference between groups is still only up to ~1.5 minutes.

Figure 101. Withdrawal time in ENDOANGEL® studies – "interventions" excluded



Note: one study reports withdrawal time "without operation" and the other refers to "clean" withdrawal time, with no further definitions.
Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 102. Withdrawal time in ENDOANGEL® studies – "interventions" included



Note: reported separately without "operations" excluded, which was not further defined.

Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

EndoScreener®

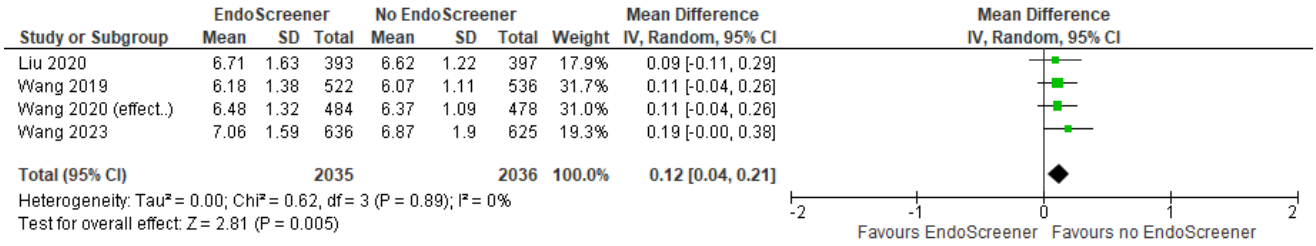
Four RCTs reported the impact of EndoScreener®-assisted polyp detection on withdrawal time in a format that could be meta-analysed,[30, 43-45] providing results separately for when "biopsies" were included and excluded, with "biopsies" not further defined. When biopsies were excluded, the results in

Figure 103 indicate a statistically significant increase in withdrawal time with ENDOANGEL® (p-value 0.005). Similarly, an increase was observed for the analysis where biopsies were included, but the difference observed was larger (p-value <0.00001;

Figure 104). These results suggest that EndoScreener® may increase withdrawal time, but likely only up to one minute based on these results.

Results from two other studies that only reported data as median values are similar to these results;[35, 36] both report higher median values with EndoScreener® without biopsy procedures included (median 6.55 vs 6.51 minutes, and median 8.47 vs 7.30 minutes), with the difference between groups higher when biopsies were included (median 7.85 vs 7.14 minutes, and median 9.52 vs 8.50 minutes).

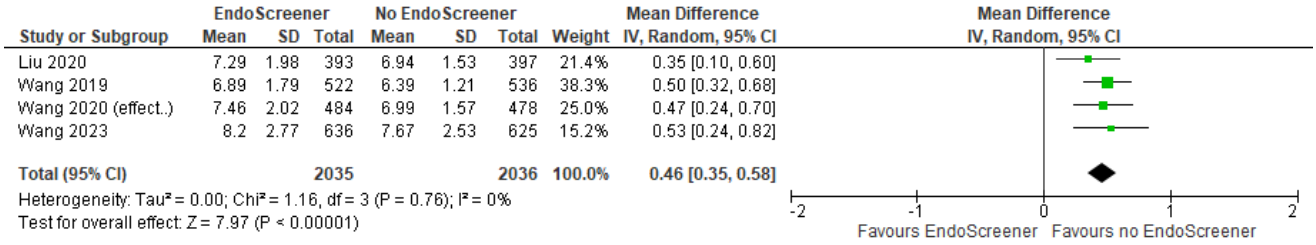
Figure 103. Withdrawal time in EndoScreener® studies – "biopsies" excluded



Note: all studies excluded "biopsies", which was not further defined.

Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 104. Withdrawal time in EndoScreener® studies – "biopsies" included



Note: all studies included "biopsies", which was not further defined.

Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

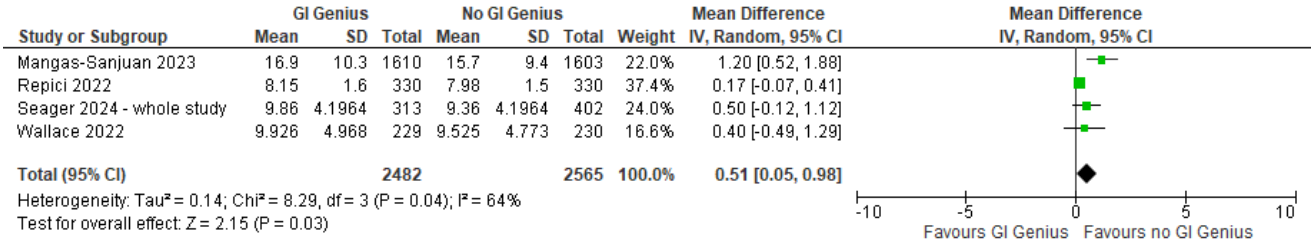
GI Genius™

Four RCTs reported the impact of GI Genius™-assisted polyp detection on withdrawal time in a format that could be meta-analysed,[20, 22, 23, 37] with results indicating increased (statistically significant; p-value 0.03) duration with GI Genius™, with substantial statistical heterogeneity observed based on an I^2 value of 64% (

Figure 105). Studies differ with regards to inclusion or exclusion of interventions such as polypectomy; two include these procedures and the other two do not, but this does not explain the observed heterogeneity as overlap remains. Based on these results, it is possible that GI Genius™ may increase withdrawal time to some extent compared to standard colonoscopy, but possibly only up to one minute based on this evidence.

A further six RCTs report these data as a comparison of medians only,[1, 19, 21, 24, 28, 46] one of which was not included given it was considered to be at a higher risk of bias.[28] Data from the additional five studies all follow the same trend for withdrawal time being slightly increased with GI Genius™, with differences between medians ranging between 0.3 and 2.0 minutes; only two of these reported a statistically significant difference (p-values 0.0013, 0.100, 0.34, <0.001 and 0.32).

Figure 105. Withdrawal time in GI Genius™ studies



Note: two studies included "biopsies" and/or polypectomies, one study excluded polypectomies and other "interventions", and the remaining study only analysed patients that did not require any polypectomies.
Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

MAGENTIQ-COLO™

One RCT reported the impact of MAGENTIQ-COLO™-assisted polyp detection on withdrawal time with and without "interventions" (interventions not defined), but only as a comparison of median and/or mean values.[31] Results indicated identical median values in both groups (median 6.5 minutes) and very similar mean values (mean 8.3 vs 8.2 minutes) when interventions during colonoscopies were excluded but a slightly higher withdrawal time with MAGENTIQ-COLO™ compared to standard colonoscopy when interventions were not excluded based on mean values (mean 10.9 vs 10.0 minutes), indicating that there may be an increase in withdrawal time using MAGENTIQ-COLO™ of up to one minute.

1.15 Total procedure time

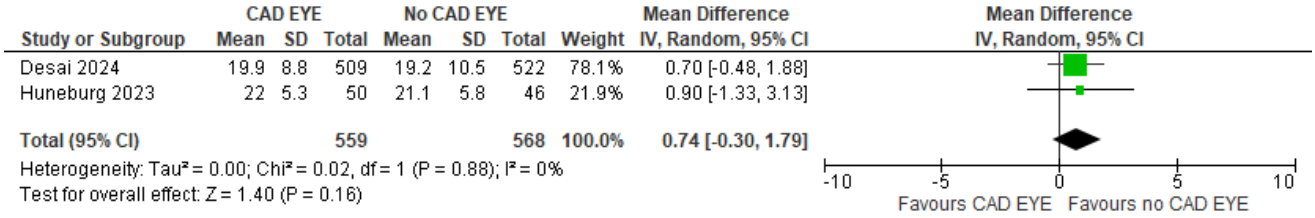
CAD EYE®

Two RCTs reported the impact of CAD EYE®-assisted polyp detection on total procedure time in a format that could be meta-analysed,[7, 8] with results indicating increased duration with CAD EYE®, which was not statistically significant (p-value 0.16;

Figure 106). No exclusions were noted and the EAG assumes that no interventions such as polypectomies were excluded from calculation of total procedure time. For both studies it was unclear if polypectomy time was captured in this outcome. It is possible that CAD EYE® may increase total procedure time to some extent compared to standard colonoscopy, but possibly only up to two minutes based on this evidence.

An additional tandem study reported observation time as median values.[34] Observation time was not further defined but the reported values were more similar to values for procedural times from other studies than withdrawal time. Results suggest almost identical median durations for the first examination (median 14 min 41 seconds with CAD EYE® vs 14 min 17 seconds for standard colonoscopy in the first examination), but increased duration in the group that received CAD EYE® as its second colonoscopy procedure compared to standard colonoscopy as the second procedure (median 11 min 5 seconds with CAD EYE® vs 9 min 27 seconds with standard colonoscopy as the second procedure). All of these differences were noted to be non-statistically significant.

Figure 106. Total procedure time in CAD EYE® studies



Note: No exclusions were noted and the EAG assumes that no interventions such as polypectomies were excluded from calculation of total procedure time.

Abbreviations: CI, confidence interval; EAG, External Assessment Group; IV, inverse variance; SD, standard deviation.

CADDIE™

[redacted]

Discovery™

One RCT reported the impact of Discovery™-assisted polyp detection on total procedure time without interventions but only as a comparison of median values.[26] No exclusions were noted and the EAG assumes that no interventions such as polypectomies were excluded from calculation of

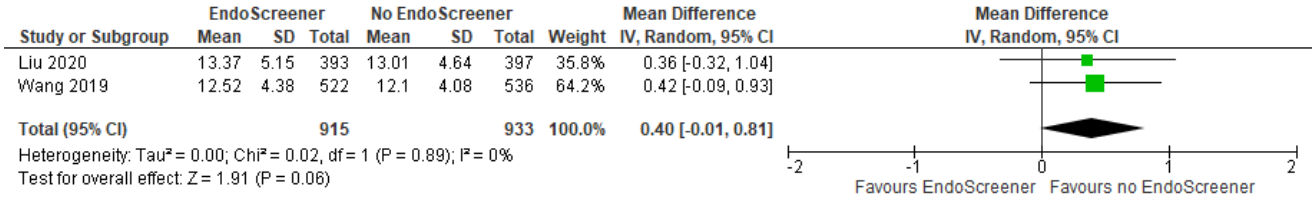
total procedure time. Results indicated identical median values with Discovery™ and standard colonoscopy (median 20.0 minutes), with a p-value of 0.43 for an absolute difference of 0.0 reported, indicating that the use of Discovery™ may not increase overall procedure time.

EndoScreener®

Two RCTs reported the impact of EndoScreener®-assisted polyp detection on total procedure time in a format that could be meta-analysed.[30, 43] No exclusions were noted and the EAG assumes that no interventions such as polypectomies were excluded from calculation of total procedure time. The results in

Figure 107 indicate an increase in total procedure time with EndoScreener®, which was not statistically significant (p-value 0.06). These results suggest that EndoScreener® may increase total procedure time, but likely only up to one minute based on these results.

Figure 107. Total procedure time in EndoScreener® studies



Note: No exclusions were noted and the EAG assumes that no interventions such as polypectomies were excluded from calculation of total procedure time.
Abbreviations: CI, confidence interval; EAG, External Assessment Group; IV, inverse variance; SD, standard deviation.

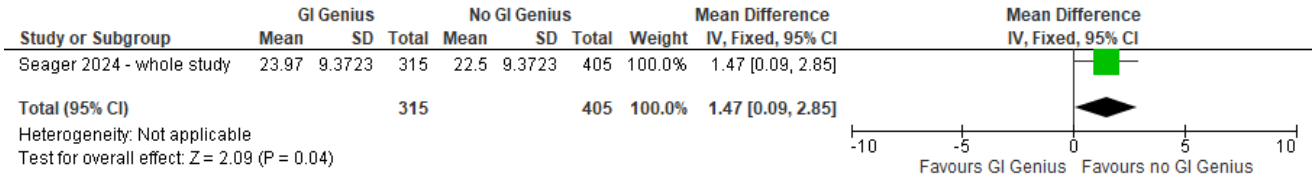
GI Genius™

One RCT reported the impact of GI Genius™-assisted polyp detection on total procedure time as mean and SD values, with results indicating increased (statistically significant; p-value 0.04; Figure 108) duration with GI Genius™.[23] Based on these results, it is possible that GI Genius™ may increase total procedure time to some extent compared to standard colonoscopy, up to three minutes based on the upper 95% CI value. It should be noted that this study only considered total procedure time in patients that had no polypectomies.

A further three RCTs report these data as a comparison of medians only (not limited to patients with no polypectomies),[1, 24, 47] with two studies at lower risk of bias focused on here.[1, 24] The results of

these two studies follow the same trend for total procedure time being slightly increased with GI Genius™, with differences between medians of 0.6 and 2.0 minutes and differences only statistically significant from one study (p-values <0.001 and 0.18). A further abstract from a non-randomised study of IBD patients (considered to be at a high risk of bias) reports results that do not align with these other studies, as procedures were shorter overall in the procedures performed with AI (median 21.0 vs 25.0 minutes; p-value <0.0001); factors associated with the study design may be contributing to this observed difference compared to other studies.[63]

Figure 108. Total procedure time in GI Genius™ studies



Note: total procedure time was only assessed in patients with no polypectomies performed in this study.

Abbreviations: CI, confidence interval; IV, inverse variance; SD, standard deviation.

1.16 Impact on decision making

1.16.1 Narrative discussion

CAD EYE®

When the CADx functionality was used, two studies reported the impact of CAD EYE®-assisted optical diagnosis on surveillance intervals, in terms of the agreement with histology-based European Society of Gastrointestinal Endoscopy (ESGE)- and/or US Multi-society Task Force on Colorectal Cancer (USMSTF) recommendations.[5, 58] Both studies covered mixed colonoscopy populations. One study only reported data for the CAD EYE® assessment and not for endoscopist optical diagnosis alone (Table 28):

- One study of 179 patients reported 82.1% agreement with USMSTF recommendations when any confidence diagnosis was included (increasing to 85.5% when only high confidence diagnoses were included).[5] When any confidence diagnosis was included, 147 (82.1%) patients had a correct recommendation, 29 were assigned a shorter interval (16.2%) and 3 assigned a longer interval (1.7%) compared to USMSTF-based recommendations;

- One study of 280 patients reported similar agreement with ESGE- and USMSTF-based recommendations in the CAD EYE®-assisted optical diagnosis compared to endoscopist optical diagnosis alone (ESGE, 97.4% vs 97.1%; USMSTF, 92.6% vs 92.6%). The percentage of patients receiving a delayed surveillance colonoscopy compared to the ESGE and USMSTF recommendations was also similar in the two groups (ESGE delayed, 2.4% vs 2.7%; USMSTF delayed, 5.3% vs 5.5%).[58]

Furthermore, one study reported that there was 100% agreement (95% CI, 93.4 to 100.0%) between CAD EYE® optical diagnosis (assume when used as an adjunct based on rest of discussion in this paper) and expert-based optical diagnosis.[56] This was a study that specifically focused on diminutive polyps that underwent a resect-and-discard or diagnose-and-leave approach, with 138 polyps included. The number of patients that these diminutive polyps were identified in is unclear. Colonoscopy indication was described as outpatient colonoscopy with no further details, and endoscopists that had training and experience in optical diagnosis with and without CADx assistance performed all colonoscopies.

CADDIE™

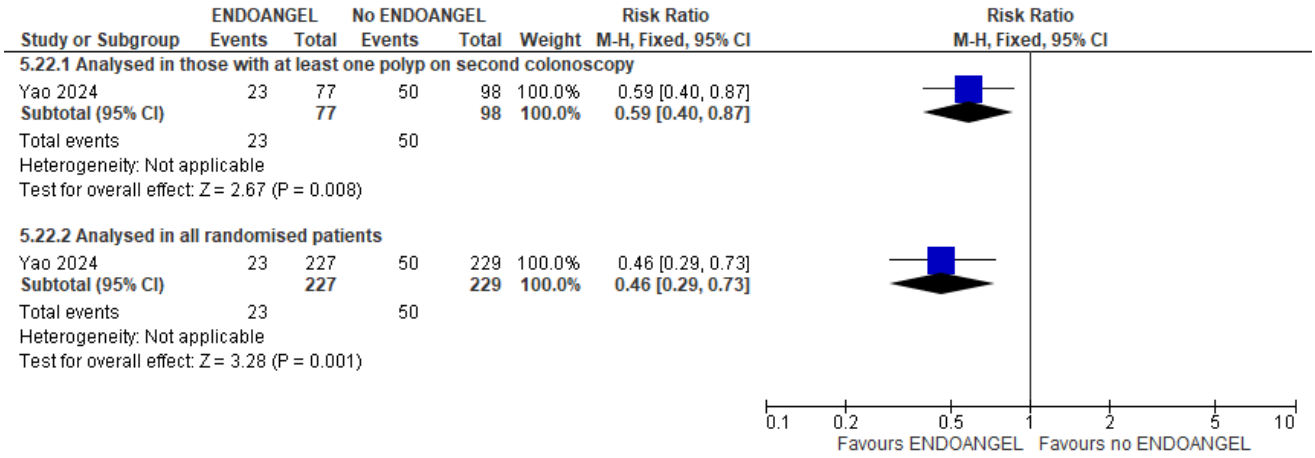
[redacted]

ENDOANGEL®

One tandem RCT using the CADe function of ENDOANGEL®, where AI-supported and standard colonoscopies were performed back-to-back, suggests that fewer patients in the group that received ENDOANGEL®-assisted colonoscopy first had their surveillance interval reduced based on the second

colonoscopy, suggesting that it is more likely that appropriate surveillance intervals would be assigned based on ENDOANGEL®-assisted colonoscopy.[18] This is likely related to the fact that there were more missed polyps with standard colonoscopy (i.e. more were picked up in the second procedure performed with ENDOANGEL®) that would lead to an adjustment of the surveillance interval. This difference between groups was statistically significant, whether it was analysed with all randomised patients as the denominator or only those with at least one polyp on the second colonoscopy as the denominator (p-values 0.001 and 0.008, respectively; Figure 109).

Figure 109. Patients with reduced surveillance interval based on second colonoscopy in ENDOANGEL® studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel..

GI Genius™

When the CADe function was used in studies, two RCTs reported some data regarding surveillance intervals. One of these was a tandem study where GI Genius™-assisted colonoscopy and standard colonoscopy were performed back-to-back in each patient, and the other was a parallel study.[23, 37]

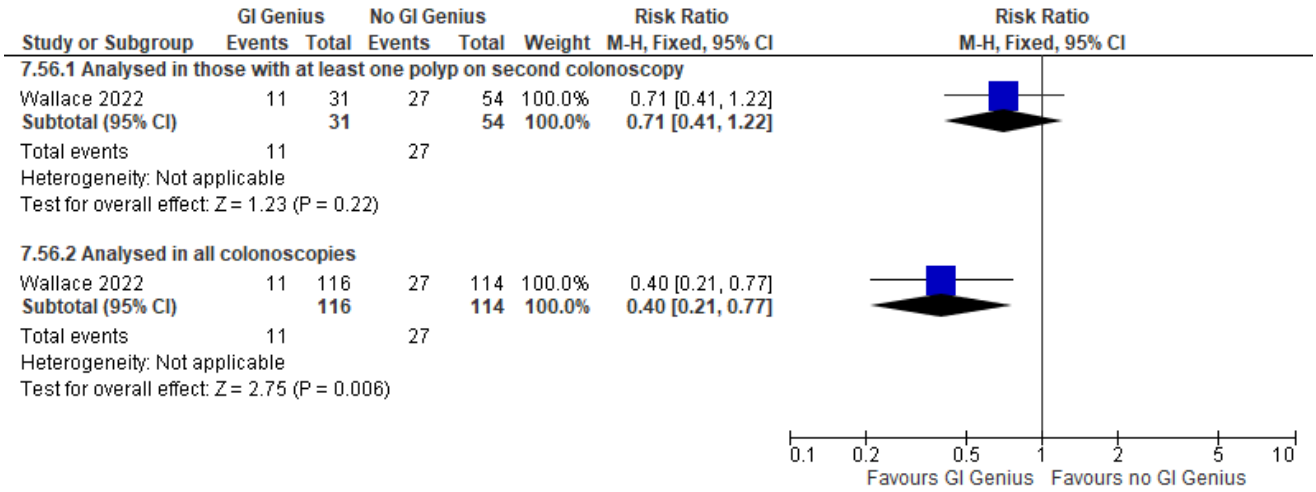
Data from the tandem RCT indicate that fewer patients who had the GI Genius™-assisted procedure first had their surveillance interval reduced based on the results of the second colonoscopy (i.e. fewer polyps were missed leading to fewer cases of the surveillance interval needing to be reduced).[37] This result was statistically significant when the total number of colonoscopies was used as the denominator but not when the number with at least one polyp in the second colonoscopy was used as the denominator (p-values 0.006 and 0.22, respectively;

Figure 110).

The parallel RCT reports data for GI Genius™-assisted colonoscopy and standard colonoscopy in terms of projected surveillance colonoscopy workload, with results in Figure 111 showing that surveillance colonoscopy workload is likely to be higher with GI Genius™-assisted colonoscopy, although this difference is not statistically significant (p-value 0.05).[23] This is in line with what would be expected as the increased identification of polyps and adenomas is likely to lead to more frequent surveillance colonoscopies, at least in some patients.

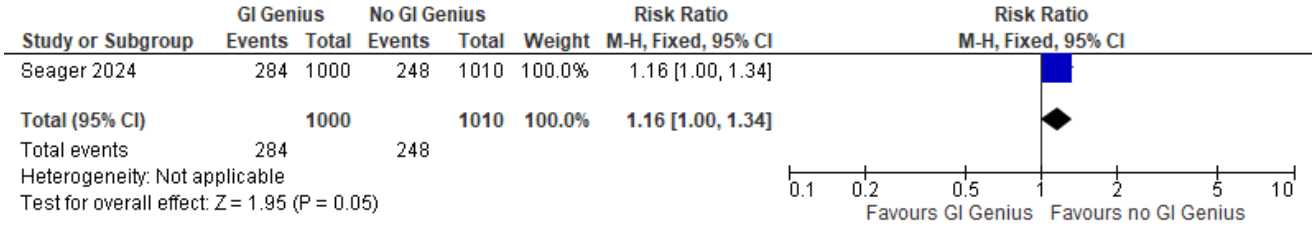
When the CADx functionality was used, one RCT reported the impact of GI Genius™-assisted optical diagnosis on surveillance intervals, in terms of agreement with ESGE and USMSTF recommendations.[55] The study covers patients undergoing colonoscopy for primary CRC screening, following a positive FIT, for post-polypectomy surveillance or symptoms/signs of CRC. It only reports data for of GI Genius™-assisted optical diagnosis and not for endoscopist only optical diagnosis. Results in 162 patients indicate a high level of agreement with ESGE and USMSTF recommendations (96.5% and 95.9%, respectively; Table 30).

Figure 110. Patients with reduced surveillance interval based on second colonoscopy in GI Genius™ studies



Abbreviations: CI, confidence interval; Mantel-Haenszel.

Figure 111. Projected future colonoscopy workload in GI Genius™ studies



Abbreviations: CI, confidence interval; Mantel-Haenszel.

1.16.2 Results tables

1.16.2.1 CAD EYE®

Table 28. Impact of CAD EYE®-assisted optical diagnosis on surveillance intervals – CADx

CAD EYE®-assisted optical diagnosis Result (number analysed)	Endoscopist optical diagnosis Result (number analysed)	Comments
Agreement of optical diagnoses with surveillance intervals		
Djinbachian 2024 (colonoscopy for screening, surveillance or diagnostic purposes) – 179 patients with at least one polyp of any size/location **Any confidence and sensitivity analyses[5]**		

Agreement with USMSTF recommendations:
• Any confidence: 82.1% (95% CI, 76.5 to 87.7%)
  ○ 147 correct (82.1%)
  ○ 29 shorter (16.2%)
  ○ 3 longer (1.7%)
• High confidence diagnosis only: 85.5% (95% CI, 79.4 to 90.3)
• Any confidence, advanced adenomas excluded: 79.8% (95% CI, 72.5 to 86.0)
• Any confidence, SSLs excluded: 80.5% (95% CI, 73.6 to 86.3)
 	
(179 patients - any confidence analysis; unclear for other sensitivity analyses)
	NA	• USMSTF guidelines used to determine appropriate surveillance intervals. Factors such as family history of CRC incorporated when assigning surveillance interval;
		• Calculated for patients with at least one polyp only. Optical diagnosis was used for all polyps of ≤ 5mm and histopathology for polyps of > 5 mm;
		• After compiling all diagnoses (optical for diminutive, pathology for >5 mm) and polyp sizes, a guideline-based surveillance interval was assigned (e.g. three years for if an adenoma >10 mm identified, 7-10 years if only two diminutive polyps were located and optically diagnosed as adenoma);
		• Surveillance intervals considered concordant if interval assigned based on optical diagnosis was within USMSTF-suggested interval when using pathology (e.g. 7-to-10-year interval on pathology considered consistent with 10-year interval based on optical diagnosis);
		• However, 3-to-5-year interval based on pathology and 5-to-10-year interval based on optical diagnosis not concordant as possible that surveillance would be performed 1 to 5 years too late.

Rondonotti 2023 (aged 18-85 years undergoing outpatient colonoscopy – no further details) – 280 patients assessed[58]		
Agreement with ESGE recommendations: 97.4% (95% CI, 95.7% to 98.9%) **Agreement with USMSTF recommendations:** 92.6% (95% CI, 90.0% to 95.2%) (280 patients)	**Agreement with ESGE recommendations:** 97.1% (95% CI, 95.4% to 98.8%) **Agreement with USMSTF recommendations:** 92.6% (95% CI 90.0% to 95.2%) (280 patients)	• Proportion of patients in which correct post-polypectomy surveillance interval advised based on optical diagnoses; • Optical diagnosis strategy based on high confidence optical diagnosis of ≤5-mm polyps, along with the histopathological assessment of both polyps ≥6-mm in size and those of ≤5mm that were evaluated with low confidence. If only diminutive polyps were detected and evaluated with high confidence, the optical diagnosis-based post-polypectomy surveillance interval was provided at the end of the endoscopic procedure; otherwise, it was made as soon as the histopathology became available; • No comparisons between assessments reported.
Delayed surveillance colonoscopies based on optical diagnoses		
Rondonotti 2023 (aged 18-85 years undergoing outpatient colonoscopy – no further details) – 280 patients assessed[58]		
Proportion delayed based on ESGE recommendations: 2.4% (95% CI, 1.1% to 4.4%) **Proportion delayed based on USMSTF recommendations:** 5.3% (95% CI, 3.2% to 8.0%) (280 patients)	**Proportion delayed based on ESGE recommendations:** 2.7% (95% CI, 1.3% to 4.8%) **Proportion delayed based on USMSTF recommendations:** 5.5% (95% CI, 3.4% to 8.3%) (280 patients)	• Proportion of patients where optical diagnoses would have led to a delayed post-polypectomy surveillance colonoscopy within ESGE and USMSTF frameworks; • Optical diagnosis strategy based on confidence optical diagnosis of ≤5-mm polyps, along with the histopathological assessment of both polyps ≥6-mm in size and those of ≤5mm that were evaluated with low confidence. If only diminutive polyps were detected and evaluated with high confidence, the optical diagnosis-based post-polypectomy surveillance interval was provided at the end of the endoscopic procedure; otherwise, it was made as soon as the histopathology became available; • No comparisons between assessments reported.
Surveillance interval agreement between CAD EYE® (assume adjunct) and expert optical diagnosis		
Taghiakbari 2025 (outpatient colonoscopy – no further details) – 138 polyps assessed (unclear number of patients)[56]		
Surveillance interval agreement was 100.0% (95% CI, 93.4 to 100.0%) between CADx optical diagnosis and expert-based optical diagnosis. Unclear but assume this is for patients that had		• Surveillance interval used (e.g. USMSTF) unclear;

the 138 diminutive polyps assessed above, as well as considering polyp histology for other polyps removed from each patient.	• Unclear number of patients analysed, assume refers to patients from which the 138 diminutive polyps undergoing a resect-and-discard or diagnose-and-leave approach were identified; • Assume refers to CAD EYE®-assisted surveillance interval agreement with expert video review surveillance interval calculation, given it is the adjunct use of CAD EYE® that is discussed in the rest of the paper.

Abbreviations: CADx, computer-aided characterisation; CI, confidence interval; CRC, colorectal cancer; ESGE, European Society of Gastrointestinal Endoscopy; NA, not applicable; SSL, sessile serrated lesion; USMSTF, US Multi-society Task Force on Colorectal Cancer.

1.16.2.2 CADDIE™

Table 29. Impact of CADDIE™-assisted optical diagnosis on surveillance intervals

CADDIE™-assisted optical diagnosis		Endoscopist optical diagnosis		Comparison between assessments	Comments
Result	**Number analysed**	**Result**	**Number analysed**		
Accuracy of optical diagnosis-derived colonoscopy surveillance interval					
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: CSR, clinical study report; NR, not reported.

1.16.2.3 GI Genius™

Table 30. Impact of GI Genius™-assisted optical diagnosis on surveillance intervals

GI Genius™-assisted optical diagnosis		Endoscopist optical diagnosis		Comparison between assessments	Comments
Result	**Number analysed**	**Result**	**Number analysed**		
Agreement of optical diagnoses with surveillance intervals					
Hassan 2022 (colonoscopy for primary CRC screening, post-polypectomy surveillance, positive FIT test or for symptoms/signs) – 162 patients **All patients with at least polyp included in the analysis[55]**					
Agreement with ESGE recommendations: 96.5% (95% CI, 91.7 to 98.6%) **Agreement with USMSTF recommendations:** 95.9% (95% CI, 90.1 to 98.4%)	162 patients	NA	NA	NA	• Considered the binary agreement (agree/disagree) when applying the 2020 ESGE post-polypectomy endoscopic surveillance guidelines and the 2020 USMSTF.

Abbreviations: CI, confidence interval; CRC, colorectal cancer; ESGE, European Society of Gastrointestinal Endoscopy; FIT, faecal immunochemical test; NA, not applicable; USMSTF, US Multi-society Task Force on Colorectal Cancer.

1.17 Ease of use/acceptability of technologies to healthcare professionals

EMIS™

Qualitative data

In a submission provided to the EAG by the manufacturer of EMIS™ in July 2025,[32] preliminary results from a trial of EMIS™ included some brief comments on clinician feedback following the trial; [redacted]

EndoScreener®

Quantitative data

One RCT assessing EndoScreener®-assisted polyp detection reported mean self-reported endoscopist fatigue levels in each trial arm on a scale of 0-10 with a higher score indicating worse fatigue.[30] The results suggest slightly increased fatigue values with EndoScreener®, which was not statistically significant based on the p-value of 0.357 reported (mean 3.40 vs 3.28; 393 vs 397 procedures).

GI Genius™

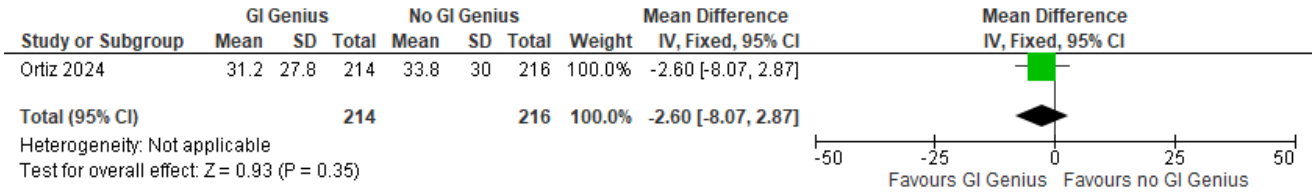
Quantitative data

Two GI Genius™ RCTs using the technology for support with polyp detection reported quantitative measures of "perceived procedural difficulties", and "comfort" when assessed by colonoscopists and nurses.[23, 46] Results for procedural difficulties (scale 0 to 100, higher better for all other than caecal intubation difficulty) suggested no large difference with GI Genius™ compared to standard colonoscopy (

Figure 112 to Figure 115) in terms of caecal intubation difficulty, scope straightness, percentage of mucosa inspected and certainty of the detected lesions.[46] Results for colonoscopist and nurse comfort (scale 0 to 4, higher better) indicate only very small differences between the two trial arms (Figure 116 and Figure 117).[23]

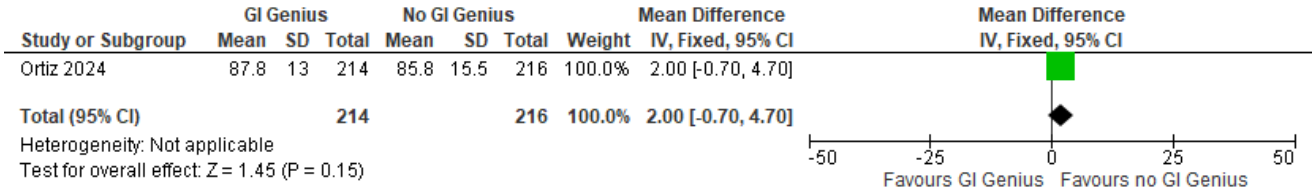
One of these studies also reported the proportion of help that the endoscopist considered the GI Genius™ system provided, on a scale of 0 to 100 with a score of 100 indicating that they were fully dependent on the system, as well as a comment on whether or not they thought the system helped them. A median value of 50.0 (IQR, 18.0 to 77.5) was reported for reliance on the system (from 214 procedures) and 109/195 (55.9%) endoscopists responded that they did consider the system to be helpful.[46]

Figure 112. Perceived procedural difficulties (caecal intubation difficulty) in GI Genius™ studies (scale 0-100, lower better)



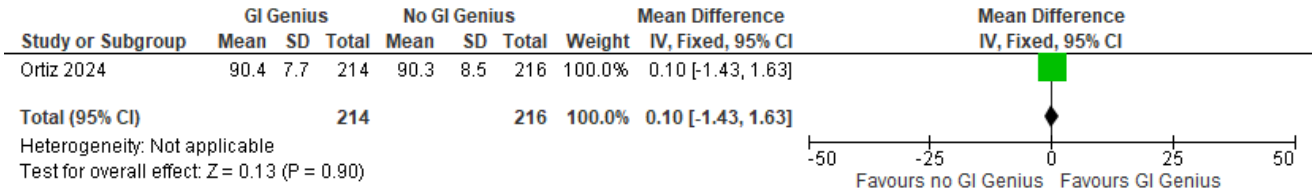
Abbreviations: CI, confidence interval; SD, standard deviation; IV, inverse variance.

Figure 113. Perceived procedural difficulties (scope straightness) in GI Genius™ studies (scale 0-100, higher better)



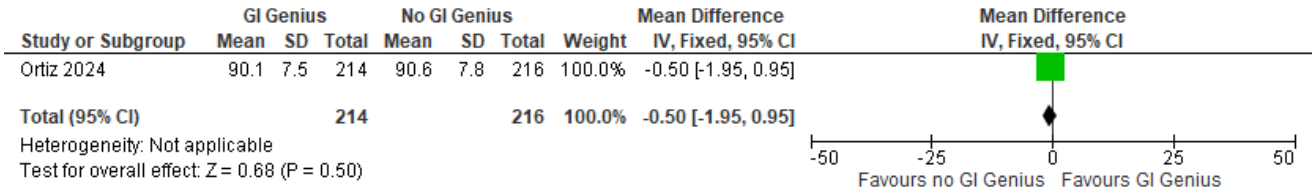
Abbreviations: CI, confidence interval; SD, standard deviation; IV, inverse variance.

Figure 114. Perceived procedural difficulties (percentage mucosa inspected) in GI Genius™ studies (scale 0-100, higher better)



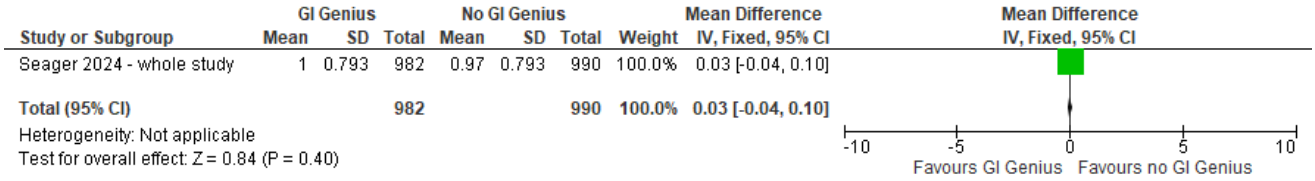
Abbreviations: CI, confidence interval; SD, standard deviation; IV, inverse variance.

Figure 115. Perceived procedural difficulties (certainty of detected lesions) in GI Genius™ studies (scale 0-100, higher better)



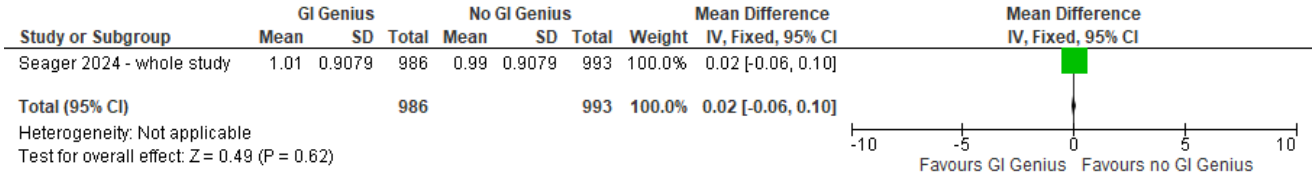
Abbreviations: CI, confidence interval; SD, standard deviation; IV, inverse variance.

Figure 116. Comfort assessed by colonoscopist in GI Genius™ studies (scale 0-4, higher better)



Abbreviations: CI, confidence interval; SD, standard deviation; IV, inverse variance.

Figure 117. Comfort assessed by nurse in GI Genius™ studies (scale 0-4, higher better)



Abbreviations: CI, confidence interval; SD, standard deviation; IV, inverse variance.

Qualitative data

An additional non-randomised full text publication and three non-randomised abstracts were included as they had additional data on the thoughts and experiences of endoscopists with GI Genius™; these were in the context of mixed colonoscopy populations and were based on experiences before and after the introduction of GI Genius™ at single centres or after participation in GI Genius™ trials NAIAD and COLO-DETECT where some may have used the technology and others not.[64-67] These studies should be considered to be at a higher risk of bias given their non-randomised

design; as described in Section 3.1.4 of the main report, formal quality assessment of these data was not performed.

One abstract reported the results of two surveys; the first was on attitudes and beliefs before and after trying GI Genius™ and the second was on reactions and thoughts regarding disappointing results when the results of the first survey were disclosed to them; the results of the latter are not considered particularly useful and have not been included here.[65] A total of 22 colonoscopists answered survey 1. In summary:

- Before trying the technology, most were enthusiastic about it and this persisted after having used it;
- Trust in the technology increased after its use;
- Most reported adequate training (80%) and found it easy to use (100%), although some found the green box or sound bothersome (43% and 40%, respectively)
- 43% agreed that the technology improved their overall performance (including by exposing the mucosa better in 48% and improving detection rate in 48%);
- Only 10% reported that the technology identified a clinically meaningful polyp that they had missed;
- 10% also reported that the technology missed a clinically meaningful polyp;
- Willingness to use the technology for all colonoscopies (agreement or strong agreement) was expressed by 72 to 86% of endoscopists, although there were some concerns about the use of monitoring metrics against them (29%) or that the technology may replace their role in important aspects of the procedure (10%).

The full text publication mentioned above primarily focused on detection-based outcomes such as ADR,[64] but these were not included in this assessment given RCT data are available for these outcomes. Feedback from physicians and endoscopy unit staff on the overall experience and opinion towards AI-assisted colonoscopy was assessed before and after the study period, representing opinions before and after the use of GI Genius™. All responding physicians were able to activate the CADe system at least once but one responding endoscopy staff member was unable to try the system. Results from 16 physicians and 16 endoscopy staff prior to the trial and 17 physicians and 13 endoscopy staff after the trial are summarised below; it should be noted that this is a very small sample size for responses and results should be interpreted with caution:

Before trial

- Most respondents (>87% in physicians and endoscopy staff) had a positive attitude towards AI prior to the study. On a scale of 0 to 4, with 4 representing fully embracing it, the mean score was ~3.0. Average enthusiasm on a scale of 0 to 10 was above 7.5 for both types of respondent (10 represents the highest enthusiasm);
- Most respondents (>60% in both respondent groups) expected AI to improve ADR, with most also expecting longer procedure times as a result. Most other responses to procedure time were for there to be no impact, with only two respondents overall expecting a shorter procedure time;
- Physicians were mainly concerned about too many false positives (68.8%), unnecessary prolonging of procedure time (37.5%), it being too distracting (25.0%) or that it would not improve ADR enough (25.0%). Other concerns raised were the expense of the technology, medicolegal concerns, potential overreliance on the technology and privacy concerns, with none having concerns about job security.

After trial

- Among physicians, the frequency of using the system was most commonly reported as none to minimal (41.2%) or high/always used (35.3%), with 11.8% using it a moderate amount and 11.8% using it a low amount. Among endoscopy staff members, moderate use was most commonly reported (61.5%), with 15.4% none to minimal use, 7.7% low use and 15.4% high/always used;
- Physicians reported an average overall experience score of 6.3 (endoscopy staff 7.1) on a scale of 0 to 10 where a higher score indicates a better experience;
- Responses to a question about what they liked most about the technology most commonly included the detection of polyps that could have been missed (41.8% physicians, 53.8% endoscopy staff) and reassurance that nothing was missed (70.6% physicians, 69.2% endoscopy staff);

- Smaller numbers of respondents reported the detection of SSLs, improved ADR, improved procedure time and the fact that the patient requested or loved the concept as additional positives with the technology;
- The most commonly reported features that respondents liked least about the technology were too many false positives (82.4% physicians, 92.3% endoscopy staff), too distracting (58.8% physicians, 38.5% endoscopy staff), audio beep being too loud (41.2% physicians, 30.8% endoscopy staff) and a prolonged procedure time (47.1% physicians, 30.8% endoscopy staff);
- Missed polyps and only identifying obvious lesions were reported by fewer respondents as being a factor that they liked least about the technology;
- When asked about their opinion and future personal use of AI in colonoscopy, most respondents considered it has a future role, with most of these reporting a potential strong role but with the need for refinement (64.7% physicians, 76.9% endoscopy staff) and a smaller proportion only considering it having a role in limited settings (29.4% physicians, 15.4% endoscopy staff). Only one respondent considered it to be not clinically useful, that it would become standard care or would not use an AI platform in the future;
- Most respondents said they would be comfortable using any AI platform (76.5% physicians, 92.3% endoscopy staff), with 64.7% physicians and 61.5% endoscopy staff wishing to continue the subscription to the current platform.

The abstract covering opinions after the NAIAD trial included responses to an online questionnaire from 89 endoscopists from the UK study,[66] which included gastroenterologists, surgeons and nurse endoscopists. The following results were noted in the abstract:

- There was a high awareness of AI use in endoscopy, with >70% having encountered AI in some form;
- Only 13% reported regular clinical use of AI in endoscopy;
- ≥60% agreed that AI use in polyp detection, diagnosis, sizing and mucosal exposure would enhance job satisfaction;
- AI application in other areas (patient consenting, bowel preparation scoring and report writing) would not affect job satisfaction;

- Endoscopists considered integration of CADe and CADx would be beneficial particularly for improving detection of small and flat lesions;
- Over half supported the potential for CADx to support resect-and-discard and leave *in situ* strategies for diminutive polyps aligning with ESGE recommendations.

Finally, endoscopist responses as part of semi-structured interviews (remotely or in-person, with audio-recording and transcription) as part of the COLO-DETECT trial were reported in one abstract.[67] The interviews were informed by a topic guide that had been informed by a normalisation process theory which was used to inform iterative thematic analysis of the transcripts. The interviews included medical endoscopists, nurse endoscopists, endoscopy nurses and endoscopy unit managers, but the number of interviews was not reported. Respondents either had exposure to the technology during the trial or were naïve to it. The following information was extracted from the abstract:

- All respondents identified the need for high quality clinical evidence to support CADe implementation, including deciding which clinicians should use the technology and for which patients. Awareness of existing evidence was limited;
- Evidence for cost-effectiveness was also deemed critical but concerns about how this could be established were noted given direct improvement of patient outcomes is difficult to demonstrate, which may limit enthusiasm for adoption;
- Some interviewees perceived that enthusiasm among colonoscopists to adopt this new technology might correlate with age (i.e. older less keep to adopt something new) or expertise (i.e. greater experienced less perceived need for an assistive device). Belief that CADe in colonoscopy will become standard practice was more common though opinions varied on whether that would occur only with appropriate scientific evidence, with recommendation by a governing body or by default;
- Devices were considered to be technically easy to operate with main issues affecting usability being distractions due to a large number of false positives and ability to optimise the human-AI collaboration to improve colonoscopy quality. This included potential use for supporting training of new colonoscopists in polyp recognition and possibility for indirect training effect on established colonoscopists by CADe enhancing awareness of previously under-recognised lesions;

- Possible risks of CADe include complacency (exercising less care with the assumption that CADe will compensate for any oversights of colonoscopists), prolonged procedure time (and patient discomfort as a result) and increased harm through increased polypectomies. However, these were not considered sufficient by any respondents to hinder the adoption of CADe;
- Main issues considered by clinical staff to affect likelihood and impact of adoption of CADe is scientific evidence of clinical and cost-effectiveness, and whether high-level recommendations by regulating bodies are made;
- Other issues relevant to users' opinions and experiences were ethics of and accountability for use or non-use of CADe and education and training (potential use of CADe to support training), but not necessarily affecting likelihood of adoption.

Mixed/unnamed technologies or no specific technology used

Qualitative data

Two abstracts reporting on clinician perspectives of AI use in colonoscopy that were either obtained after use of various unnamed technologies or were obtained from endoscopists that had been surveyed about their thoughts but had not necessarily been involved in a trial of any AI colonoscopy technology were also included in the report.[68, 69]

One of these abstracts covered a trial of three different CADe systems, with 38 endoscopists and managers completing a survey reviewing the usability and deployment experience for each of the three unnamed technologies.[68] The results indicated differences between the three technologies in terms of endoscopist responses, with the following noted with regards to the proportion of endoscopists that strongly or somewhat agreed with each statement:

- Beneficial for training lists – CADe system A, 85%; CADe system B, 47%; CADe system C, 50%;
- Easy to switch on/get started – CADe system A, 100%; CADe system B, 90%; CADe system C, 29%;
- Felt confident using it – CADe system A, 100%; CADe system B, 100%; CADe system C, 29%;
- Increased procedure duration – CADe system A, 69%; CADe system B, 50%; CADe system C, 71%;
- Enhanced patient care – CADe system A, 85%; CADe system B, 80%; CADe system C, 43%;

- Had potential to identify polyps that otherwise would have been missed – CADe system A, 100%; CADe system B, 70%; CADe system C, 43%;
- Would like to use it in routine practice – CADe system A, 92%; CADe system B, 60%; CADe system C, 0%.

With regards to endoscopist responses, the following statements were made in the conclusions:

- Majority of endoscopists considered it enhanced patient care (73%) and identified polyps that might otherwise have been missed (76.7%). There were comments that it "helped to not overlook small polyps" and was "useful to have a co-pilot that worked even when he/she was fatigued"
- Acceptability varied across the three systems but overall 60% would use a system like these in everyday practice. Endoscopists preferred systems that produced an overlay image on the pre-existing monitor.
- 63% endoscopists considered AI prolonged procedure times citing increased polyp detection rate (PDR) and false positives, which may be mitigated with user experience.

There are some formatting issues in the table with regards to manager responses making the data difficult to extract and interpret, but the conclusion states that the managers' survey received few and ranging responses so conclusions are limited, with system B requiring internet access and resulting in major governance and IT issues.

- In the second abstract, 10 gastroenterology fellows responded to a survey that was sent to 1st, 2nd and 3rd year fellows at a large urban academic tertiary care centre. They had not necessarily used any of the available AI technologies before to be included in the survey. The following statements summarise the main findings: 9/10 said they were interested in using new AI technologies to assist in polyp detection during colonoscopy;
- There was strong support towards utilisation of AI, with 80% reporting that they consider incorporating AI will become future standard of care and would improve detection of adenomas (80%) and SSLs (90%);
- Emphasis was placed on validation from AI during colonoscopies – 80% reported they would feel comfortable leaving behind a polyp perceived as hyperplastic by both endoscopic; appearance and AI, but only 30% would do so if perceived as hyperplastic by appearance but not AI;

- 80% considered that AI would increase practice costs and procedure times;
- 90% stated AI is likely to make them dependent on the technology to discriminate between polyp types;
- 90% consider AI would increase false positive polyp detections;
- 80% supported the integration of AI technology during fellowship, with most recommending it take place during the second year;
- Gastroenterology fellows show interest in optimism towards utility of AI-assisted polyp detection, but cost barriers and overreliance leading to training deficits are concerns regarding implementation.

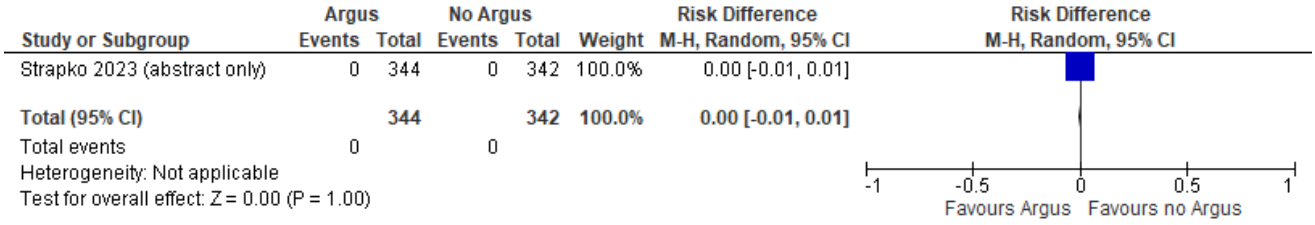
1.18 Adverse events

Argus®

Although the abstract for this technology did not comment on adverse events (AEs), the instructions for use manual provided by the manufacturer noted that no AEs or complications were reported during the study (

Figure 118).[38, 39]

Figure 118. Adverse events in Argus® studies



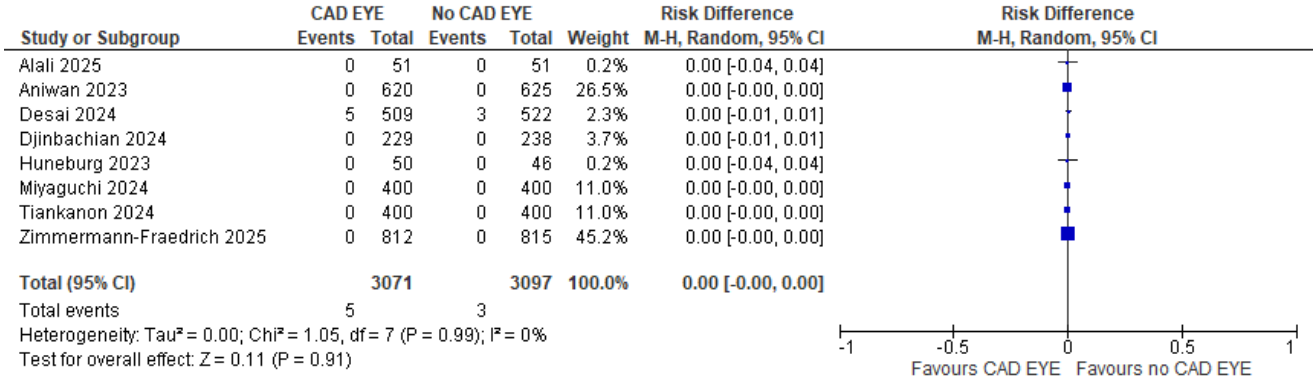
Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

CAD EYE®

Data on AEs was available from 9 parallel RCTs using CAD EYE® for polyp detection,[2, 4, 6-8, 10, 11, 29, 40] with one excluded from primary analyses as it was considered to be at a higher risk of bias.[2] Results suggest no difference between colonoscopy with and without CAD EYE® in terms of AEs (

Figure 119). All but one of these studies reported no events in either arm of the trials, with the remaining study reporting a difference of only two events (5 with CAD EYE® and 3 without). The events in this study were all minor events, including intraprocedural bleeding during polypectomy and abdominal discomfort and bloating post-procedure that did not require further follow-up or inpatient admission. Additionally, another parallel RCT using CAD EYE® for optical diagnosis of polyps reported no immediate AEs associated with the colonoscopy interventions (of 467 procedures performed using CAD EYE® either as an adjunct or autonomously) and a prospective cohort study assessing CAD EYE® for optical diagnosis reported only one patient with a grade 2 AE of lower gastrointestinal bleeding after endoscopic resection in 165 patients.[5, 53] Results in the study that was excluded were similar.

Figure 119. Adverse events in CAD EYE® studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

CADDIE™

[redacted]

Figure 120. Adverse events in CADDIE™ studies

Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

ENDO-AID™

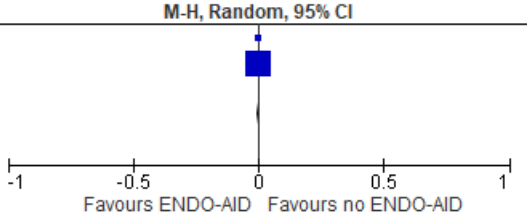
Two parallel RCTs for polyp detection using ENDO-AID™ reported no difference compared to standard colonoscopy,[14, 16] with one reporting only three events across the two arms and the other reporting zero events in both arms. When meta-analysed, the point estimate suggests no difference when analysed as a risk difference (

Figure 121). In the study where events were observed, these were defined as procedure-related serious AEs, with one subject with post-polypectomy coagulation syndrome (ENDO-AID™), and two subjects with delayed post-polypectomy bleeding (standard colonoscopy).[14]

Figure 121. Adverse events in ENDO-AID™ studies

Study or Subgroup	ENDO-AID Events	Total	No ENDO-AID Events	Total	Weight	Risk Difference M-H, Random, 95% CI
Lau 2024	1	386	2	380	11.4%	-0.00 [-0.01, 0.01]
Spada 2025	0	611	0	617	88.6%	0.00 [-0.00, 0.00]
Total (95% CI)		**997**		**997**	**100.0%**	**-0.00 [-0.00, 0.00]**
Total events	1		2			

Heterogeneity: Tau² = 0.00; Chi² = 0.53, df = 1 (P = 0.47); I² = 0%
Test for overall effect: Z = 0.20 (P = 0.84)



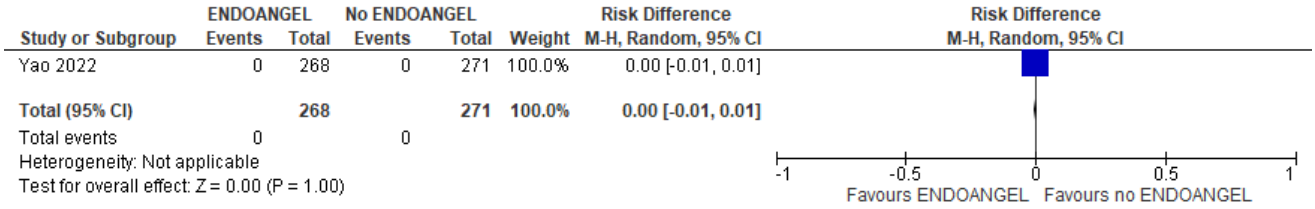
Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

ENDOANGEL®

Three parallel RCTs reported AEs for polyp detection using ENDOANGEL®,[17, 27, 50] with two studies excluded as they were at a higher risk of bias.[27, 50] Results indicate no difference compared to standard colonoscopy, with zero events in both arms of the trial (

Figure 122). Results in the studies that were excluded were similar.

Figure 122. Adverse events in ENDOANGEL® studies



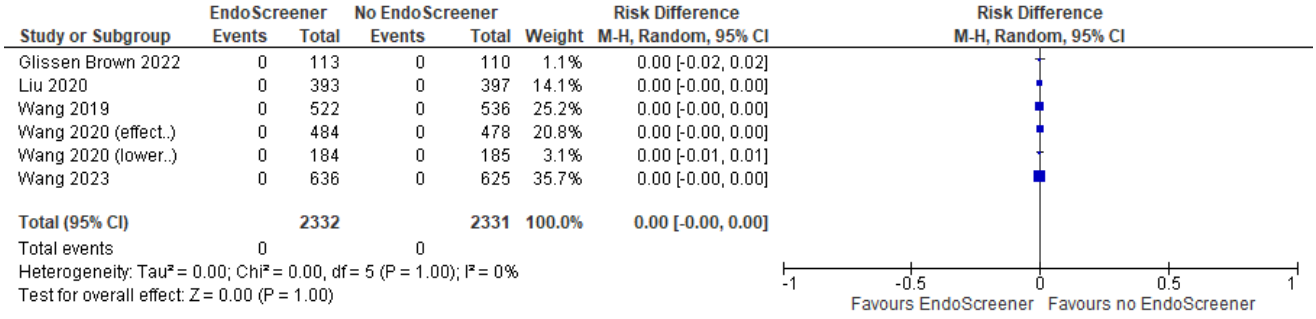
Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

EndoScreener®

All six RCTs identified for EndoScreener®-assisted colonoscopy for polyp detection reported that there were no AEs in either arm of the trials, suggesting that there is no impact of the technology on the occurrence of AEs (

Figure 123).[30, 35, 36, 43-45]

Figure 123. Adverse events in EndoScreener® studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

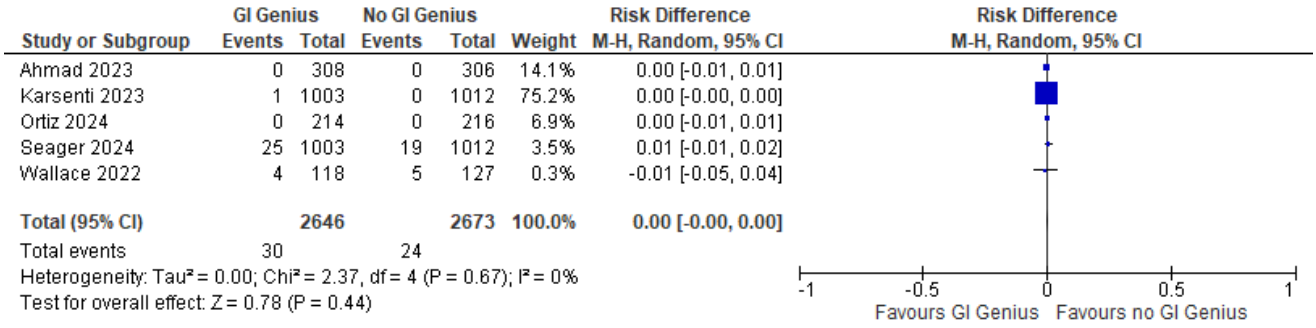
GI Genius™

Data from seven RCTs on AEs were available,[1, 2, 19, 23, 28, 37, 46] with two excluded as they were considered to be at a higher risk of bias.[2, 28] Results suggest no overall difference in AEs with and without GI Genius™ when used for polyp detection. Two of these studies reported no events in both arms, one reported a single event in the GI Genius™ arm and others reported a number of events in each arm. For each trial, there is no large difference in the number of events between arms, with the largest difference being 6 events (higher with GI Genius™). The meta-analysis was performed using risk difference given the presence of studies with zero events in both arms, and overall suggested no difference between the two treatment arms (

Figure 124). Results in the studies that were excluded were similar.

Of the studies reporting some events, two reported that none of the 44 or 9 events were thought to be related to the technology itself,[23, 37] and one reported the single event in the CADe arm as being a bleeding event without deglobulisation following a large polyp resection that was resolved with a second colonoscopy.[19]

Figure 124. Adverse events in GI Genius™ studies



Abbreviations: CI, confidence interval; M-H, Mantel-Haenszel.

1.19 Colonoscopy indication subgroups – EAG analyses

CAD EYE®

The EAG's preferred subgroup analysis for ADR was based on assignment of whole studies or reported within-trial subgroup data to categories based on which group the majority of patients were categorised as, as it allowed the inclusion of the highest number of studies. Results in

Figure 125 show an overlap of point estimates between subgroups, with one subgroup having only one study included. The EAG considers there to be no strong evidence supporting a difference in effect across colonoscopy indications. Furthermore, of studies reporting within-trial subgroup analyses based on colonoscopy indication for ADR, no large differences were identified (see Section 1.20 of this supplement). The EAG notes that a similar finding was observed with regards to APC when analysed as a mean difference (

Figure 126), but that two within-trial analyses suggested possible differences in effect based on point estimates in FIT-positive compared to primary colonoscopy screening patients, and screening compared to surveillance patients, with a large degree of uncertainty based on 95% CIs (see Section 1.20 of this supplement). Similar results were noted for APC when analysed as an IRR.

Of note, to better inform subgroup analyses as set out in the economic model (split into screening, symptomatic/diagnostic, surveillance and Lynch syndrome surveillance; see Appendix 9.8 of the main report), an additional analysis for ADR combining those where the majority was FIT-positive screening with studies or subgroups where the majority was other types of screening was performed, with results presented in Figure 127. For the purposes of the economic model, the Scholer *et al.* 2024 study was used to inform data for the symptomatic/diagnostic colonoscopy subgroup,[2] despite it being excluded from the main clinical analyses and subgroup analyses based on its high risk of bias. This is because no other studies for CAD EYE® had a majority of symptomatic colonoscopies included (see Section 3.1.5.2 and Appendix 9.8 of the main report).

Figure 125. ADR colonoscopy indication subgroup analysis with CAD EYE®- majority in whole studies and within-trial subgroup data

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FIT, faecal immunochemical test; M-H, Mantel-Haenszel.

Figure 126. APC colonoscopy indication subgroup analysis with CAD EYE®- majority in whole studies and within-trial subgroup data – reported as mean difference

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; FIT, faecal immunochemical test; IV, inverse variance; SD, standard deviation.

Figure 127. ADR colonoscopy indication subgroup analysis with CAD EYE®- majority in whole studies and within-trial subgroup data (additional analysis to inform economic model)

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FIT, faecal immunochemical test; M-H, Mantel-Haenszel.

CADDIE™

[redacted]

Figure 128. ADR colonoscopy indication subgroup analysis with CADDIE™ - majority in whole studies and within-trial subgroup data

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 129. APC colonoscopy indication subgroup analysis with CADDIE™ - majority in whole studies and within-trial subgroup data – reported as mean difference

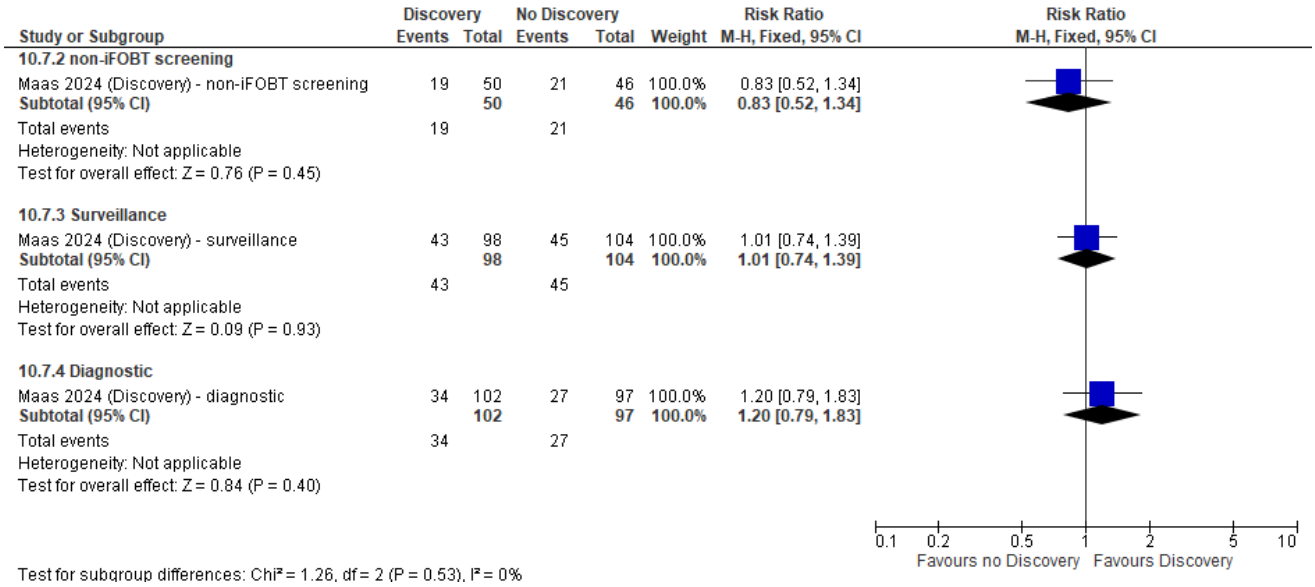
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

Discovery™

For Discovery™, only a single RCT was included.[26] Data from a within-trial analysis comparing results across non-iFOBT screening, surveillance and diagnostic colonoscopy populations suggest a potential difference in relative effect on ADR based on point estimates (

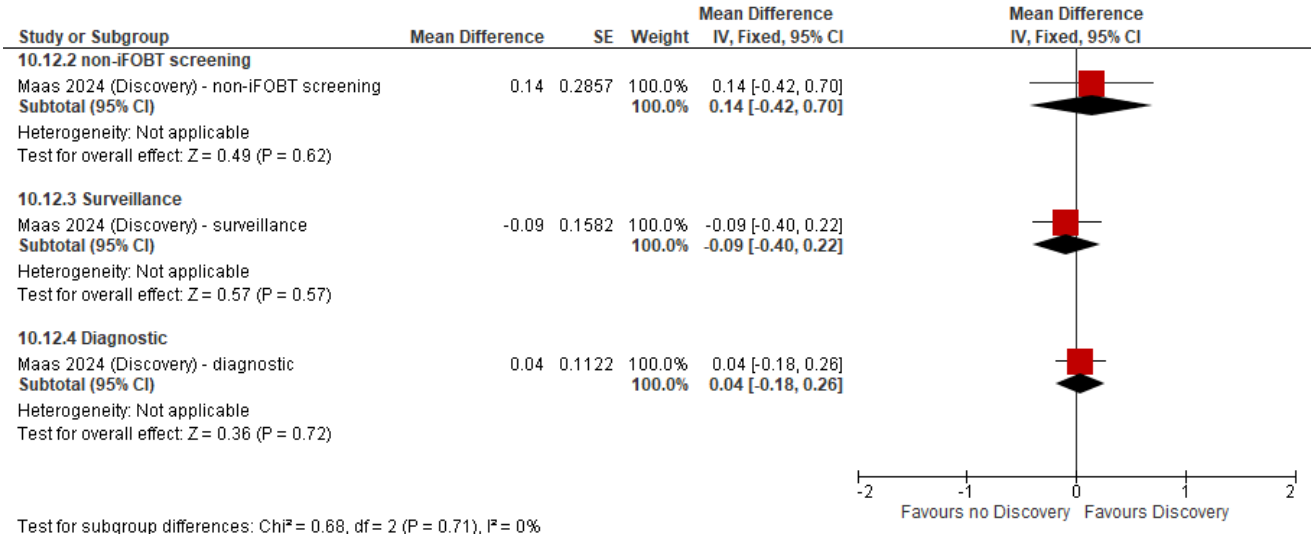
Figure 130); however, the EAG notes that this is based on a difference of very few events within each subgroup and there is a large overlap across subgroups based on 95% CIs. Therefore, the EAG considers that there is no strong evidence to support a difference in effect between colonoscopy indications, with similar conclusions based on the results reported for APC when analysed as a mean difference (Figure 131). Similar results were observed when APC was analysed as an IRR.

Figure 130. ADR colonoscopy indication subgroup analysis with Discovery™ - within-trial subgroup analysis



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; iFOBT, immunochemical faecal occult blood test; M-H, Mantel-Haenszel.

Figure 131. APC colonoscopy indication subgroup analysis with Discovery™ - within-trial subgroup analysis - reported as mean difference



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; iFOBT, immunochemical faecal occult blood test; IV, inverse variance; SE, standard error.

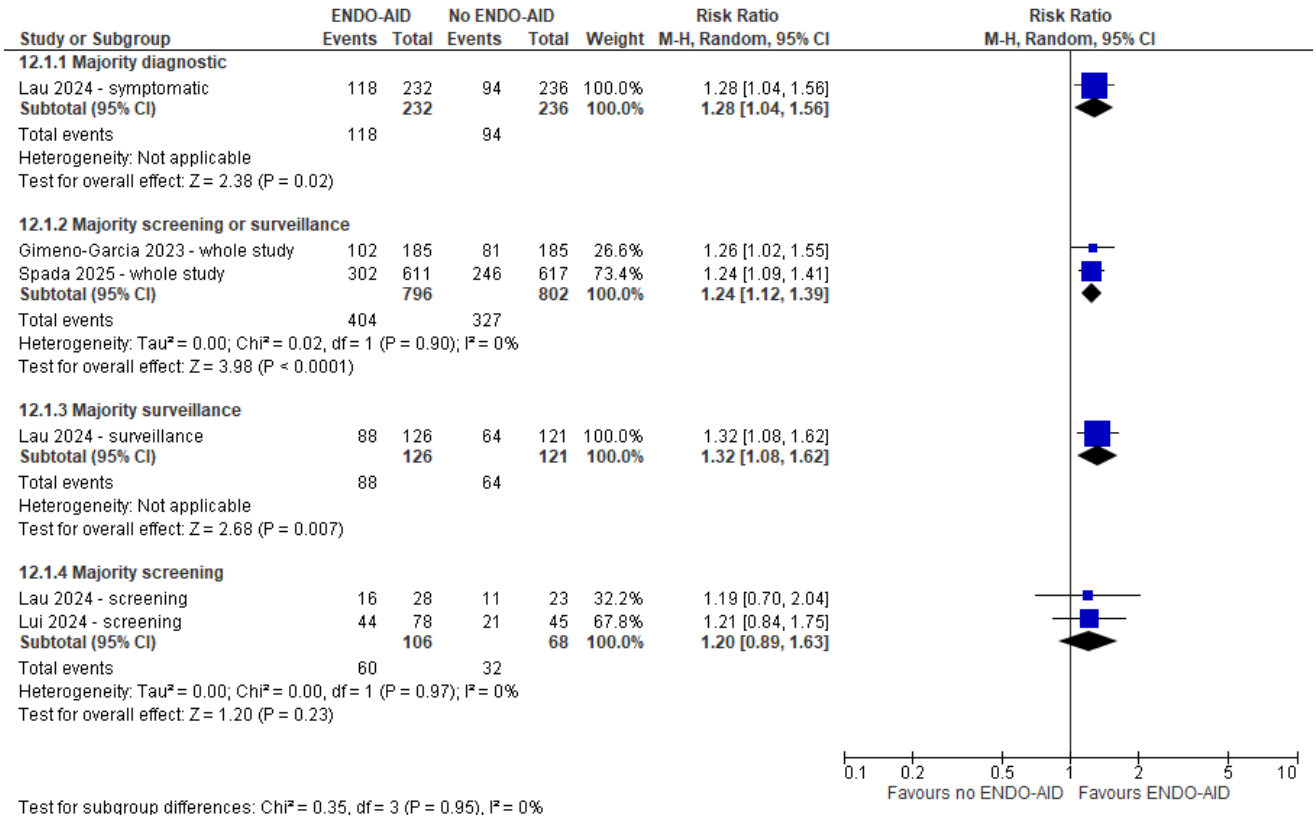
ENDO-AID™

The EAG's preferred subgroup analysis for ADR was based on assignment of whole studies or reported within-trial subgroup data to categories based on which group the majority of patients were categorised as, as it allowed the inclusion of the highest number of studies. Results in

Figure 132 show an overlap of point estimates between subgroups, with two subgroups having only one study included. The EAG considers there to be no strong evidence supporting a difference in effect across colonoscopy indications. The single study reporting within-trial subgroup analyses based on colonoscopy indication for ADR suggested no large difference between subgroups (see Section 1.20 of this supplement). The EAG notes that a similar finding was observed with regards to APC when analysed as a mean difference (

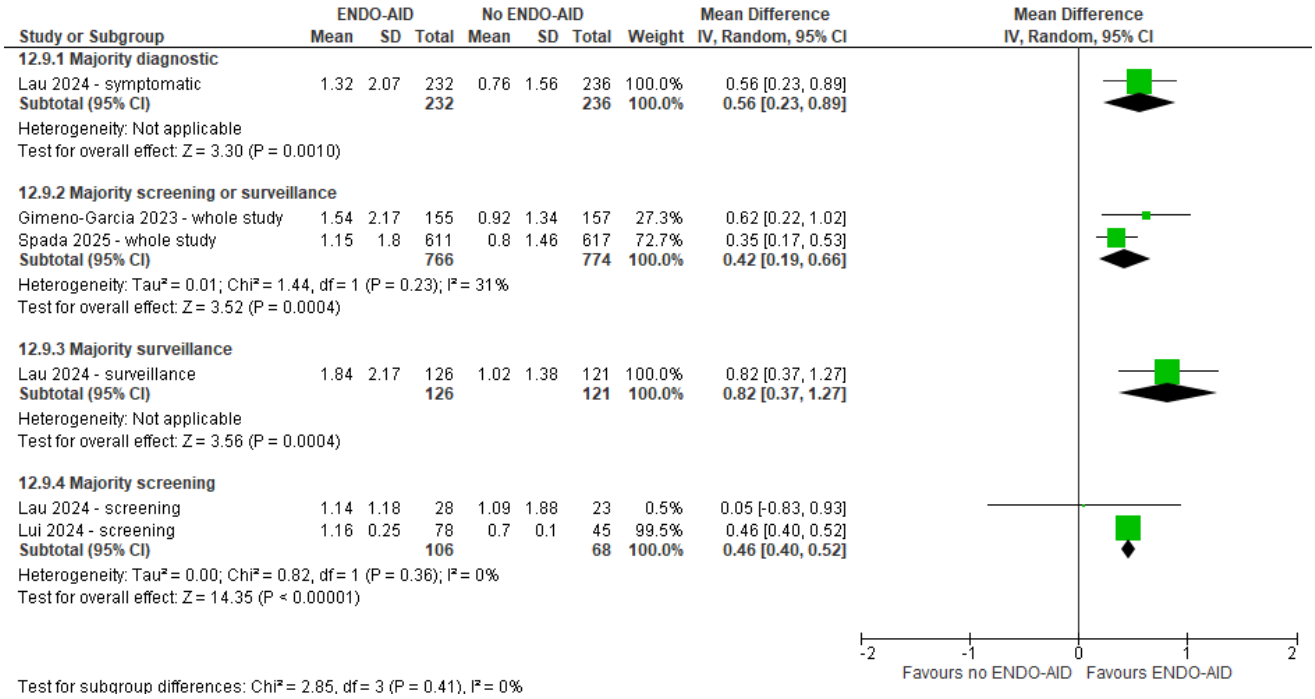
Figure 133) but with more apparent variation and the study reporting within-trial data for different subgroups suggests a notable difference for the screening population in particular compared to surveillance and symptomatic populations (see Section 1.20 of this supplement). Similar results were observed for APC when analysed as an IRR.

Figure 132. ADR colonoscopy indication subgroup analysis with ENDO-AID™- majority in whole studies and within-trial subgroup data



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FOBT, faecal occult blood test; M-H, Mantel-Haenszel.

Figure 133. APC colonoscopy indication subgroup analysis with ENDO-AID™- majority in whole studies and within-trial subgroup data – reported as mean difference



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

ENDOANGEL®

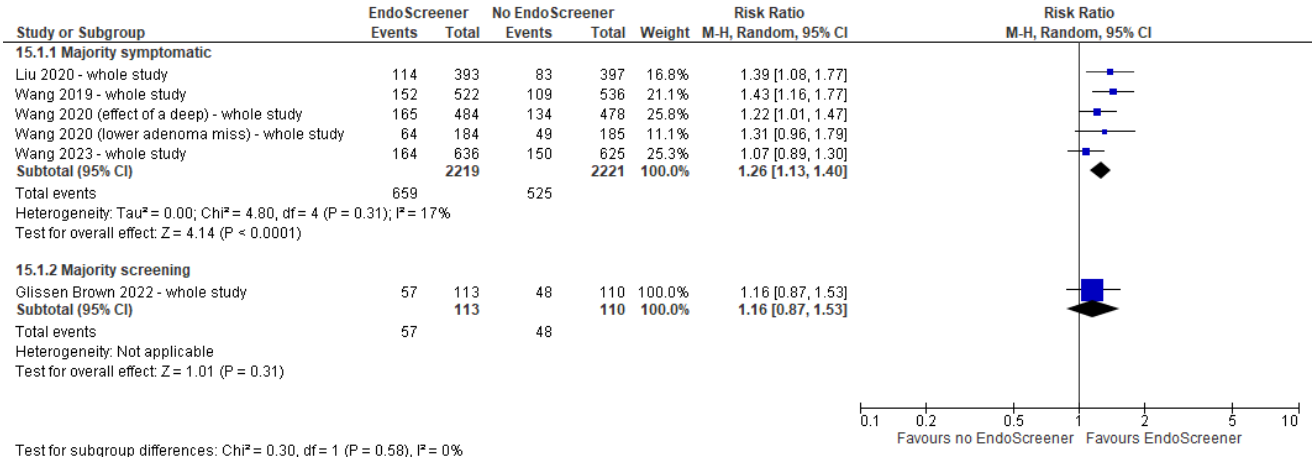
Both of the RCTs analysed in the primary analysis of ADR and APC for ENDOANGEL® were mixed colonoscopy populations with none having >80% in one particular category and no within-trial subgroup analyses reported.[17, 18] When considering the majority of patients in both studies, both were mostly screening populations, meaning it was not possible to perform any meaningful colonoscopy indication subgroup analysis for this intervention. For the purposes of the economic model, the Gong *et al.* 2020 was used to inform data for the symptomatic/diagnostic colonoscopy subgroup,[27] despite it being excluded from the main clinical analyses and subgroup analyses based on its high risk of bias. This is because no other studies for ENDOANGEL® had a majority of symptomatic colonoscopies included (see Section 3.1.5.2 and Appendix 9.8 of the main report).

EndoScreener®

Of the six RCTs reporting ADR for EndoScreener®, all were mixed colonoscopy populations with none having >80% in one particular category and no within-trial subgroup analyses were reported.[30, 35, 36, 43-45] This meant that only an analysis assigning studies to categories based on the majority of patients in each study was possible. Results in

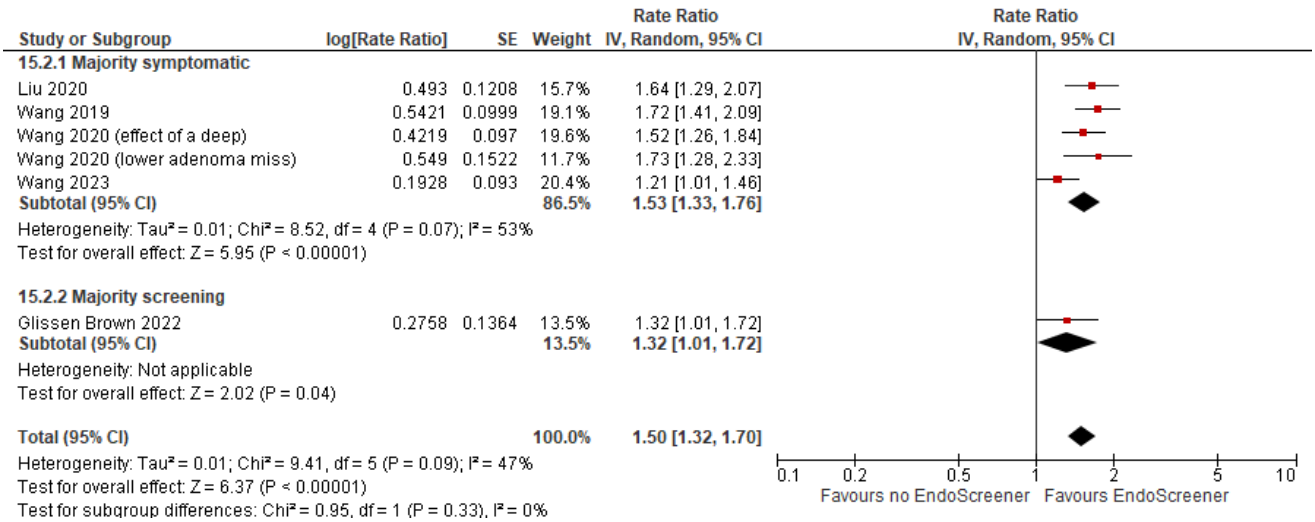
Figure 134 indicate a possible difference based on point estimates between the diagnostic (symptomatic) colonoscopy population and the screening population, with a smaller benefit of EndoScreener® on ADR in the screening subgroup. However, given one of the subgroups only includes one study, it is difficult to draw conclusions from these data. Data to analyse APC as a mean difference was only available from one study and so subgroup analyses were not possible for this outcome; however, when analysed as an IRR, results for subgroup analyses were similar to those for ADR (Figure 135).

Figure 134. ADR colonoscopy indication subgroup analysis with EndoScreener® - majority in whole studies



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 135. APC colonoscopy indication subgroup analysis with EndoScreener® - majority in whole studies - reported as IRR



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

GI Genius™

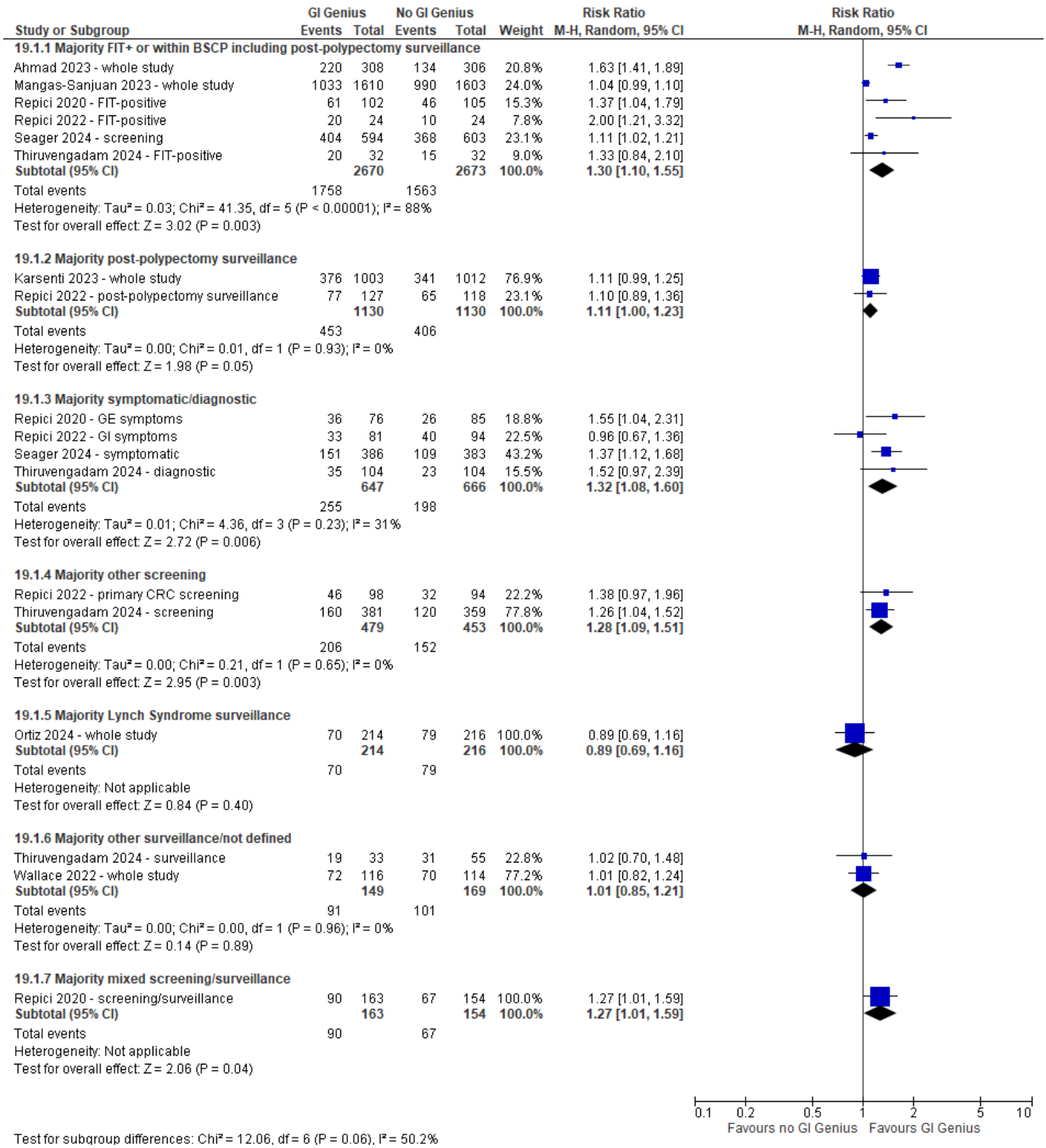
The EAG's preferred subgroup analysis for ADR was based on assignment of whole studies or reported within-trial subgroup data to categories based on which group the majority of patients were categorised as, as it allowed the inclusion of the highest number of studies. In terms of populations to be combined, the EAG explored a number of different options given the amount of variation between studies and the number of subgroups with only one or two studies included when separated in a more granular way. Results in

Figure 136 show the EAG's initial analysis with very specific subgroups, and results in Figure 137 show an analysis where any screening and surveillance populations were combined, with a separate subgroup for Lynch syndrome surveillance and symptomatic/diagnostic colonoscopies. The EAG considers that there is a wide amount of variation among studies in both analyses and does not consider there to be any strong evidence of a difference in effect estimates across subgroup populations. Similar conclusions were considered appropriate for the APC subgroup analyses when analysed as a mean difference (Figure 138 and Figure 139). Results for APC when analysed as an IRR were also similar.

Results of within-trial subgroup analyses from four RCTs at a lower risk of bias suggested some possible trends for differences between populations based on point estimate, but this was not consistent across all studies, with the possible exception of surveillance as this group tended to have a reduced benefit in terms of ADR compared to other subgroups where it was reported (see Section 1.20 of this supplement). One RCT reporting within-trial subgroup data for APC suggested a larger increase in APC in the screening subgroup compared to the symptomatic subgroup when analysed as a mean difference (see Section 1.20 of this supplement); however, when analysed as an IRR, very little difference in the IRR was noted between subgroups.

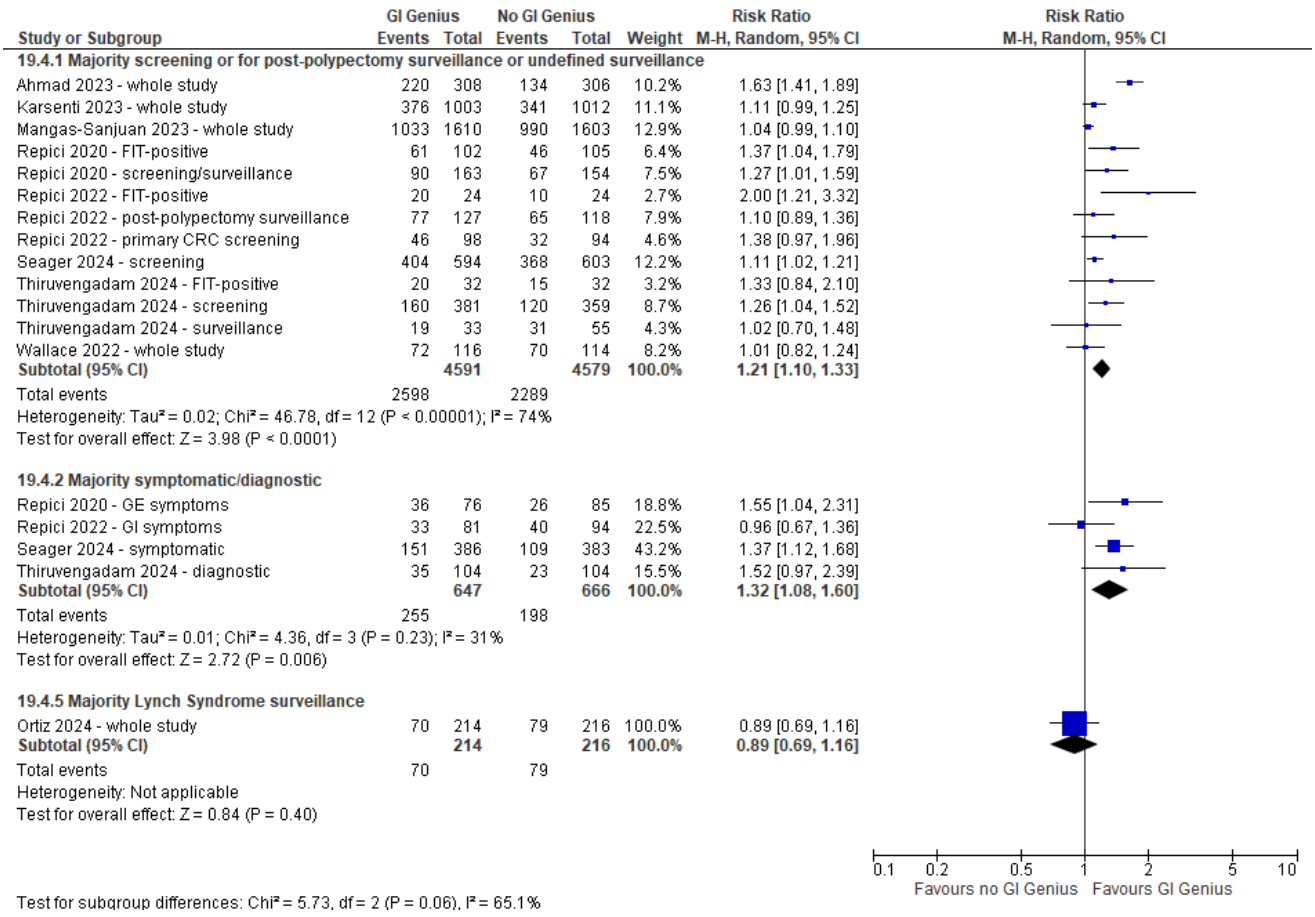
Of note, to better inform subgroup analyses as set out in the economic model (split into screening, symptomatic/diagnostic, surveillance and Lynch syndrome surveillance; see Appendix 9.8 of the main report), an additional analysis for ADR combining those where the majority was FIT-positive screening with studies or subgroups where the majority was other types of screening was performed, and those that were based on a majority of post-polypectomy surveillance were combined with studies or subgroups where the majority was other types of surveillance, with the exception of Lynch syndrome surveillance which was considered different enough to be kept separate. Results are presented in Figure 140.

Figure 136. ADR colonoscopy indication subgroup analysis with GI Genius™ - majority in whole studies and within-trial subgroup data – granular subgroups



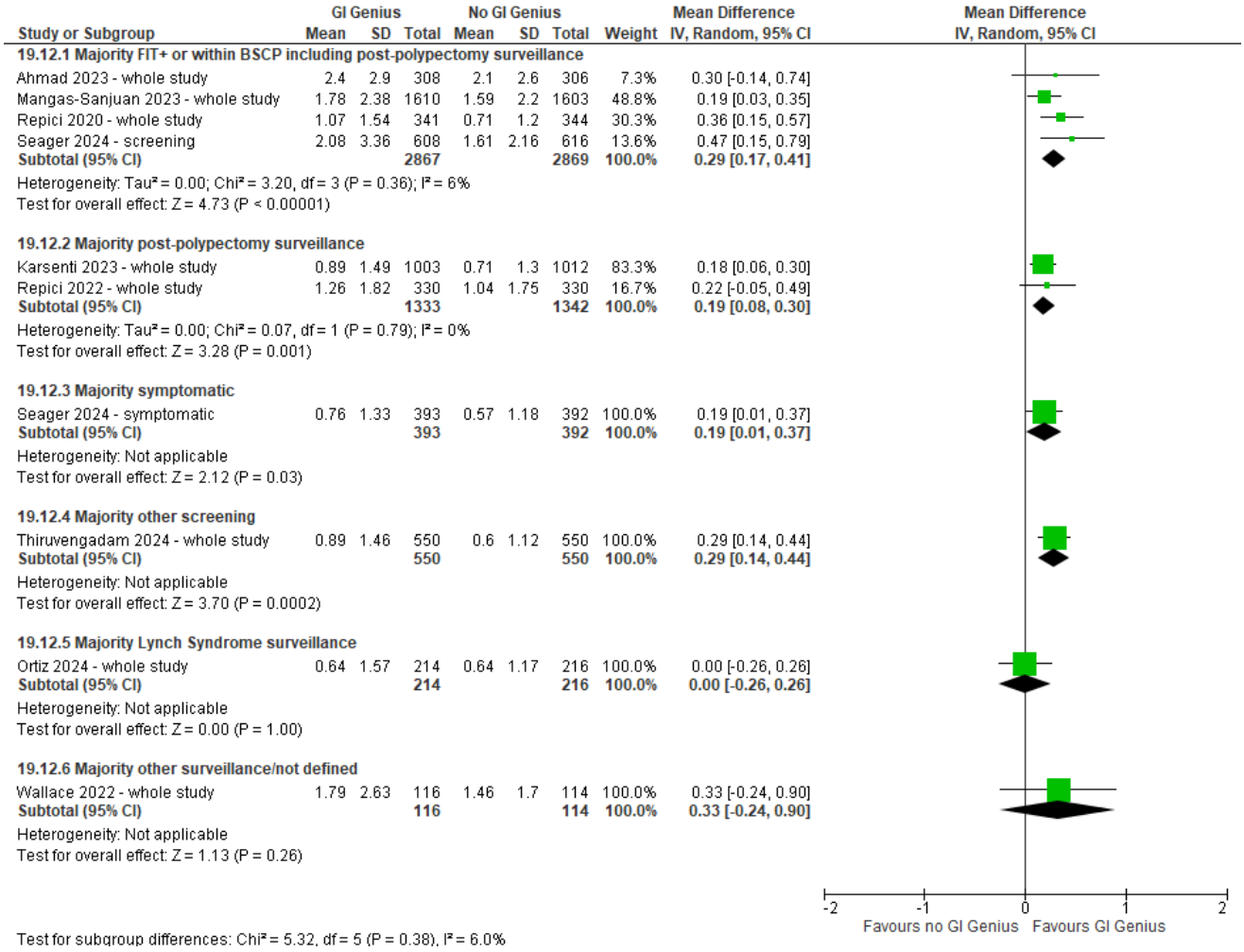
Abbreviations: ADR, adenoma detection rate; BCSP, Bowel Cancer Screening Programme; CI, confidence interval; CRC, colorectal cancer; FIT, faecal immunochemical test; GE/GI, gastrointestinal symptoms; M-H, Mantel-Haenszel.

Figure 137. ADR colonoscopy indication subgroup analysis with GI Genius™ - majority in whole studies and within-trial subgroup data – broader subgroups



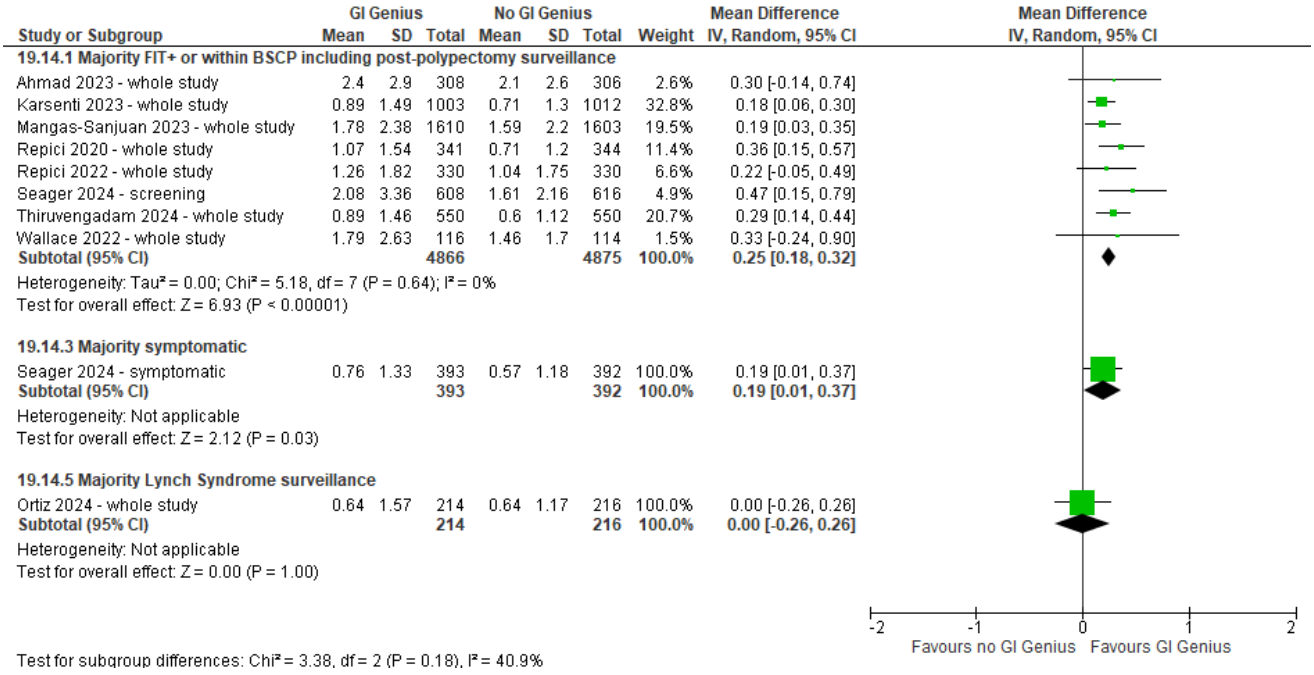
Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CRC, colorectal cancer; FIT, faecal immunochemical test; GE/GI, gastrointestinal symptoms; M-H, Mantel-Haenszel.

Figure 138. APC colonoscopy indication subgroup analysis with GI Genius™ - majority in whole studies and within-trial subgroup data – granular subgroups, reported as mean difference



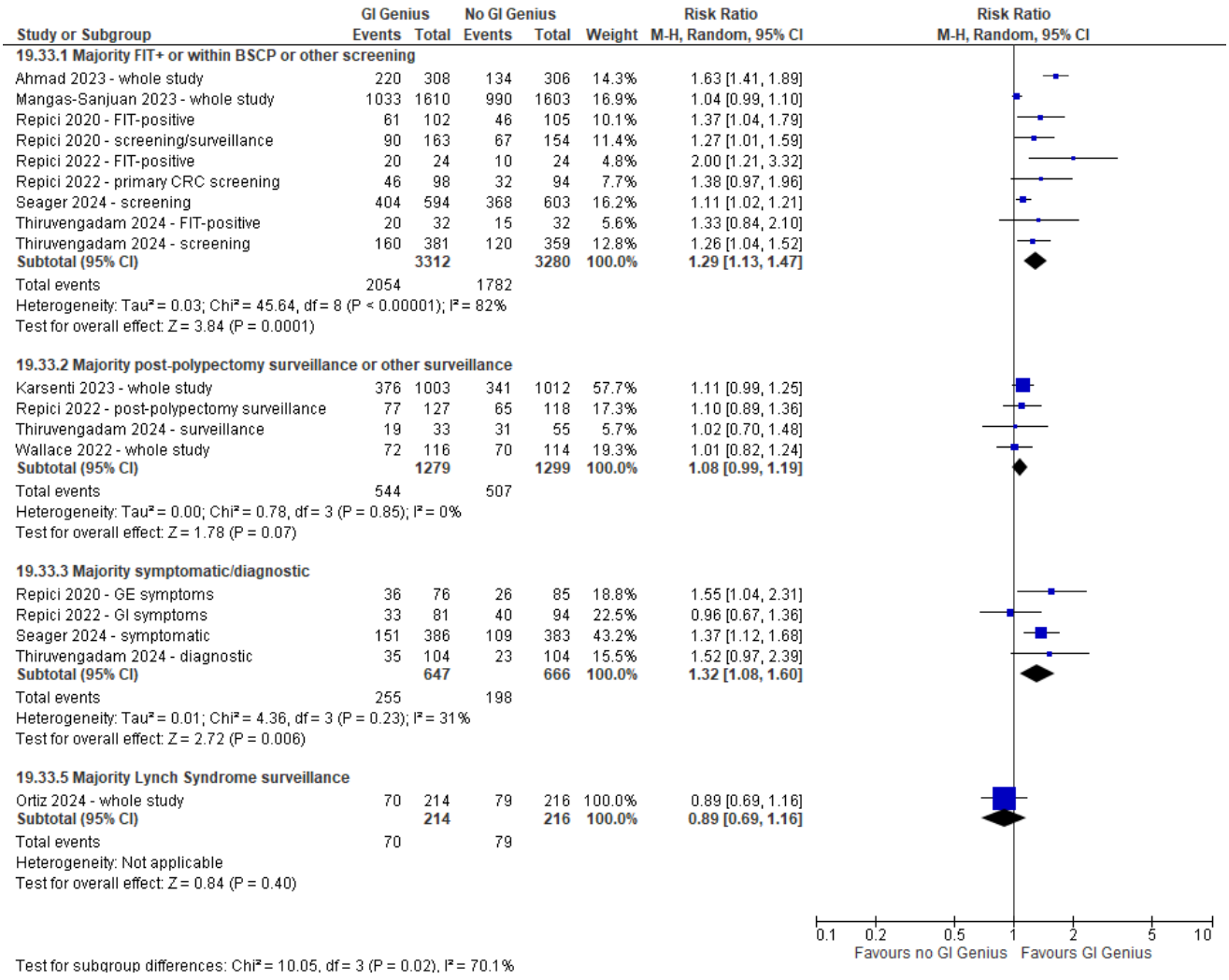
Abbreviations: APC, adenomas per colonoscopy; BCSP, Bowel Cancer Screening Programme; CI, confidence interval; FIT, faecal immunochemical test; IV, inverse variance; SD, standard deviation.

Figure 139. APC colonoscopy indication subgroup analysis with GI Genius™ - majority in whole studies and within-trial subgroup data – broader subgroups, reported as mean difference



Abbreviations: APC, adenomas per colonoscopy; BCSP, Bowel Cancer Screening Programme; CI, confidence interval; FIT, faecal immunochemical test; IV, inverse variance; SD, standard deviation.

Figure 140. ADR colonoscopy indication subgroup analysis with GI Genius™ - majority in whole studies and within-trial subgroup data (additional analysis to inform economic model)



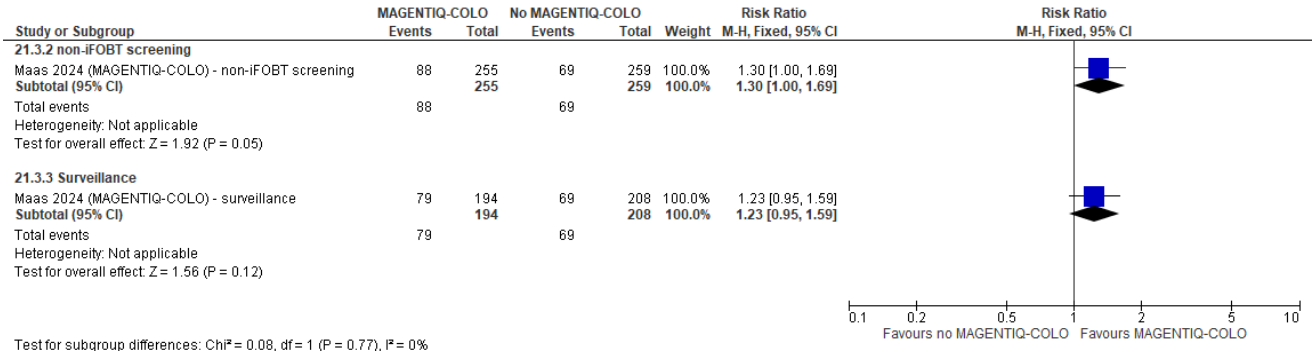
Abbreviations: ADR, adenoma detection rate; BCSP, Bowel Cancer Screening Programme; CI, confidence interval; CRC, colorectal cancer; FIT, faecal immunochemical test; GE/GI, gastrointestinal symptoms; M-H, Mantel-Haenszel.

MAGENTIQ-COLO™

For MAGENTIQ-COLO™, only a single RCT was included. Data from a within-trial analysis comparing results across non-iFOBT screening and surveillance colonoscopy populations suggest similar impacts of the technology on ADR (Figure 141), with similar conclusions based on the results reported for APC when analysed as a mean difference (

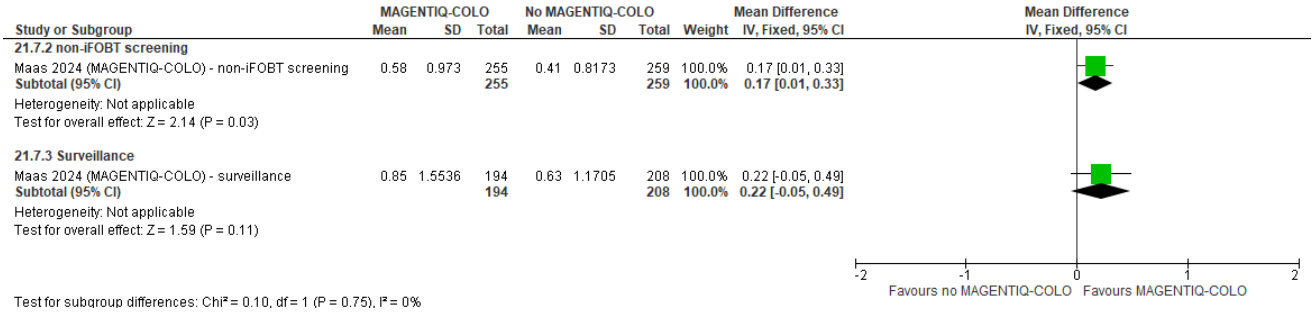
Figure 142). Results for APC when analysed as an IRR were also similar.[31]

Figure 141. ADR colonoscopy indication subgroup analysis with MAGENTIQ-COLO™ - within-trial subgroup data



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; iFOBT, immunochemical faecal occult blood test; M-H, Mantel-Haenszel.

Figure 142. APC colonoscopy indication subgroup analysis with MAGENTIQ-COLO™ - within-trial subgroup data – reported at mean difference



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; iFOBT, immunochemical faecal occult blood test; IV, inverse variance; SD, standard deviation.

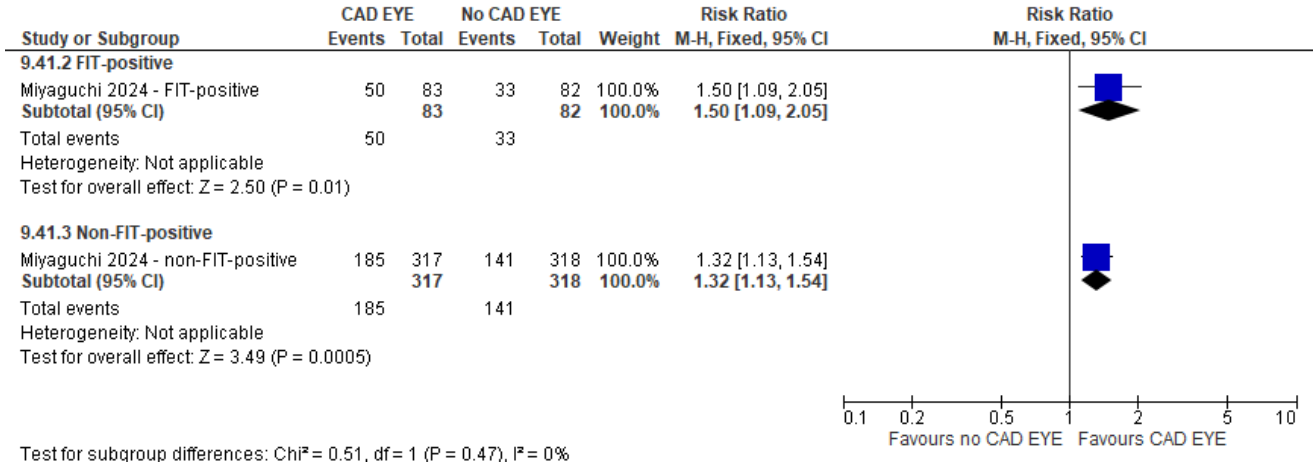
1.20 Colonoscopy indication subgroups – within trial analyses

CAD EYE®

Figure 143. ADR by colonoscopy indication – Nakashima *et al.* 2023[3]

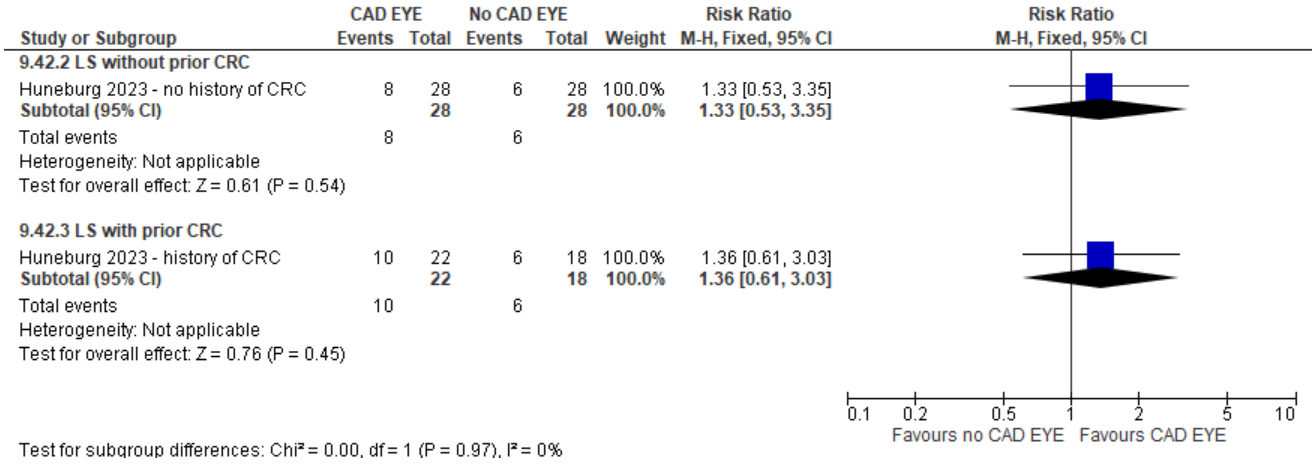
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FIT, faecal immunochemical test; M-H, Mantel-Haenszel.

Figure 144. ADR by colonoscopy indication – Miyaguchi *et al.* 2024[29]



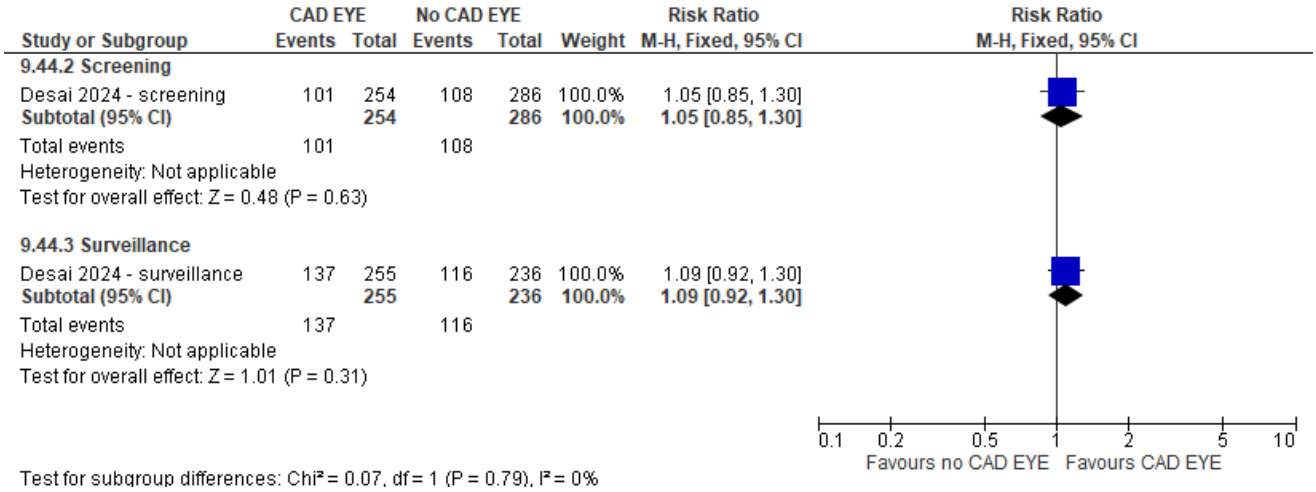
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FIT, faecal immunochemical test; M-H, Mantel-Haenszel.

Figure 145. ADR by colonoscopy indication – Huneburg *et al.* 2023[8]



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CRC, colorectal cancer; LS, Lynch syndrome; M-H, Mantel-Haenszel.

Figure 146. ADR by colonoscopy indication – Desai *et al.* 2024[7]

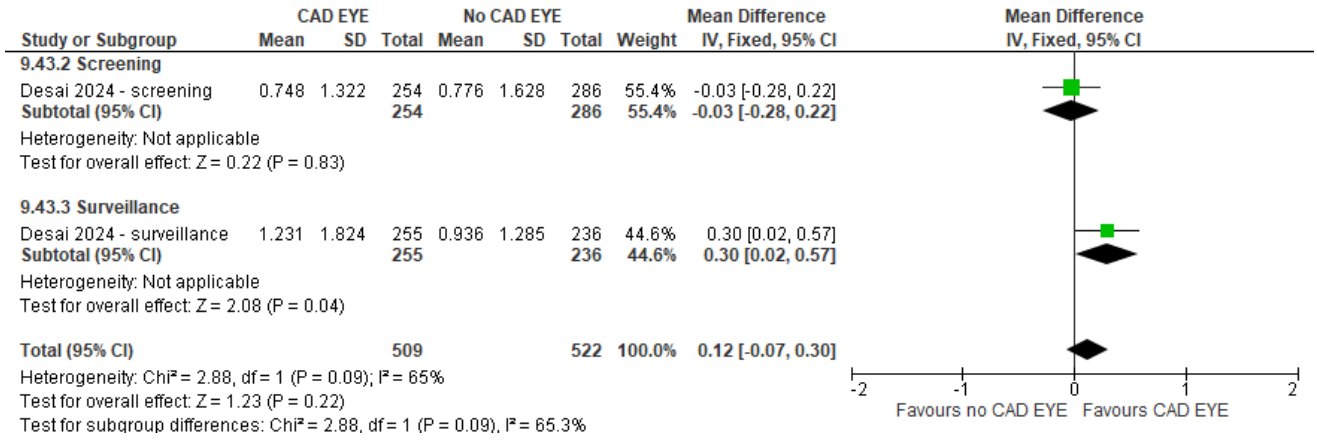


Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 147. APC by colonoscopy indication – Nakashima *et al.* 2023 - reported as mean difference[3]

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; FIT, faecal immunochemical test; IV, inverse variance; SD, standard deviation.

Figure 148. APC by colonoscopy indication – Desai *et al.* 2024 - reported as mean difference[7]



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; M-H, Mantel-Haenszel; IV, inverse variance; SD, standard deviation.

CADDIE™

Figure 149. ADR by colonoscopy indication – Odin Vision 2024 (EAGLE)[41]

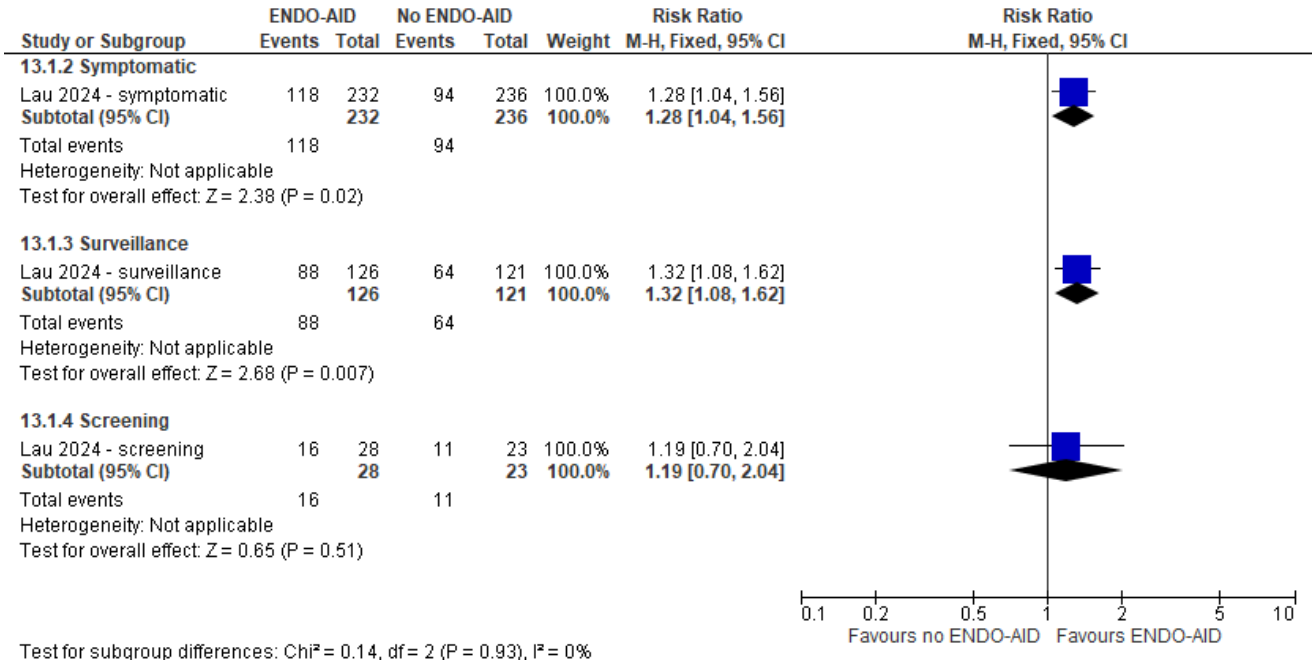
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 150. APC by colonoscopy indication – Odin Vision 2024 (EAGLE) - reported as mean difference[41]

Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

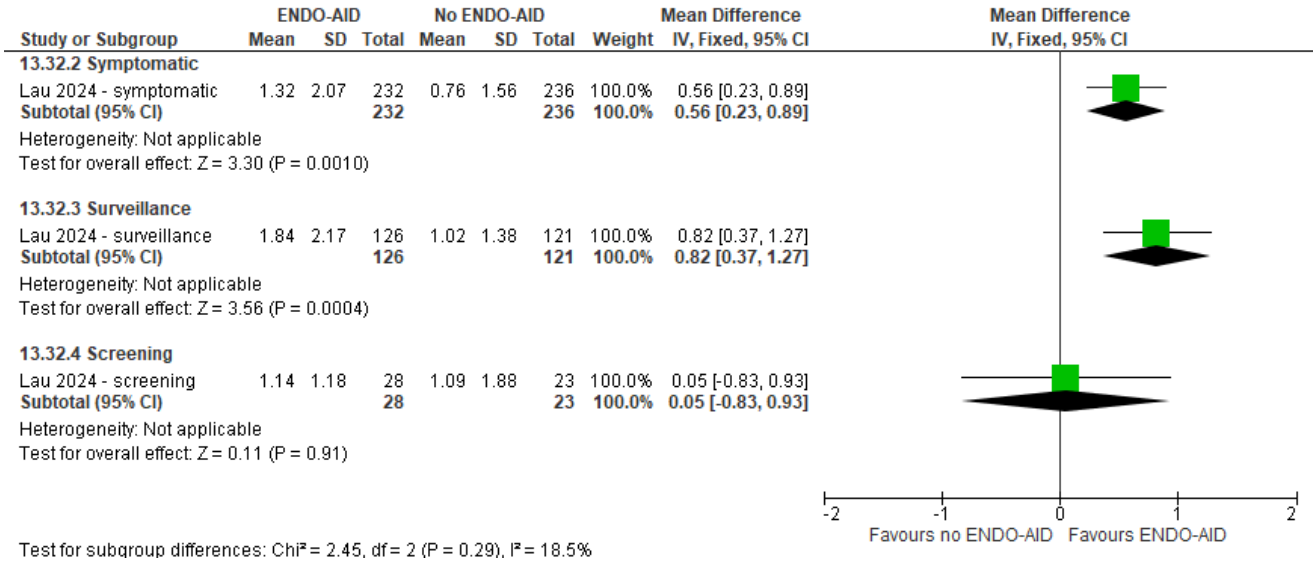
ENDO-AID™

Figure 151. ADR by colonoscopy indication – Lau *et al.* 2024[14]



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

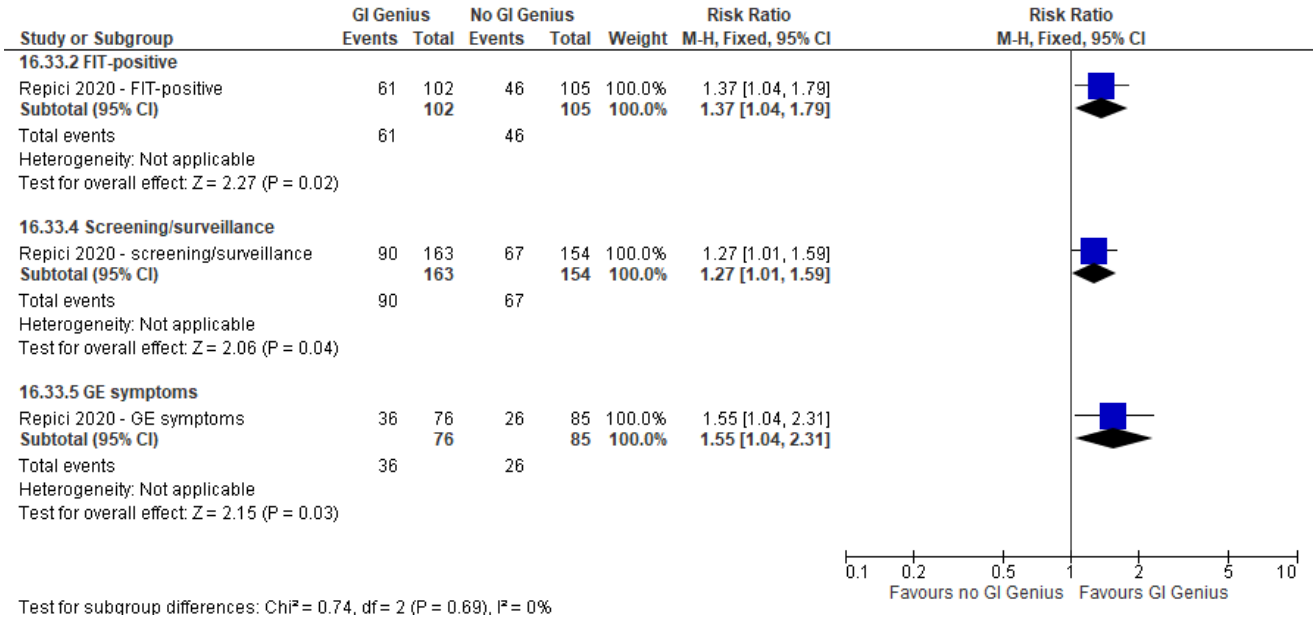
Figure 152. APC by colonoscopy indication – Lau *et al.* 2024 - reported as mean difference[14]



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

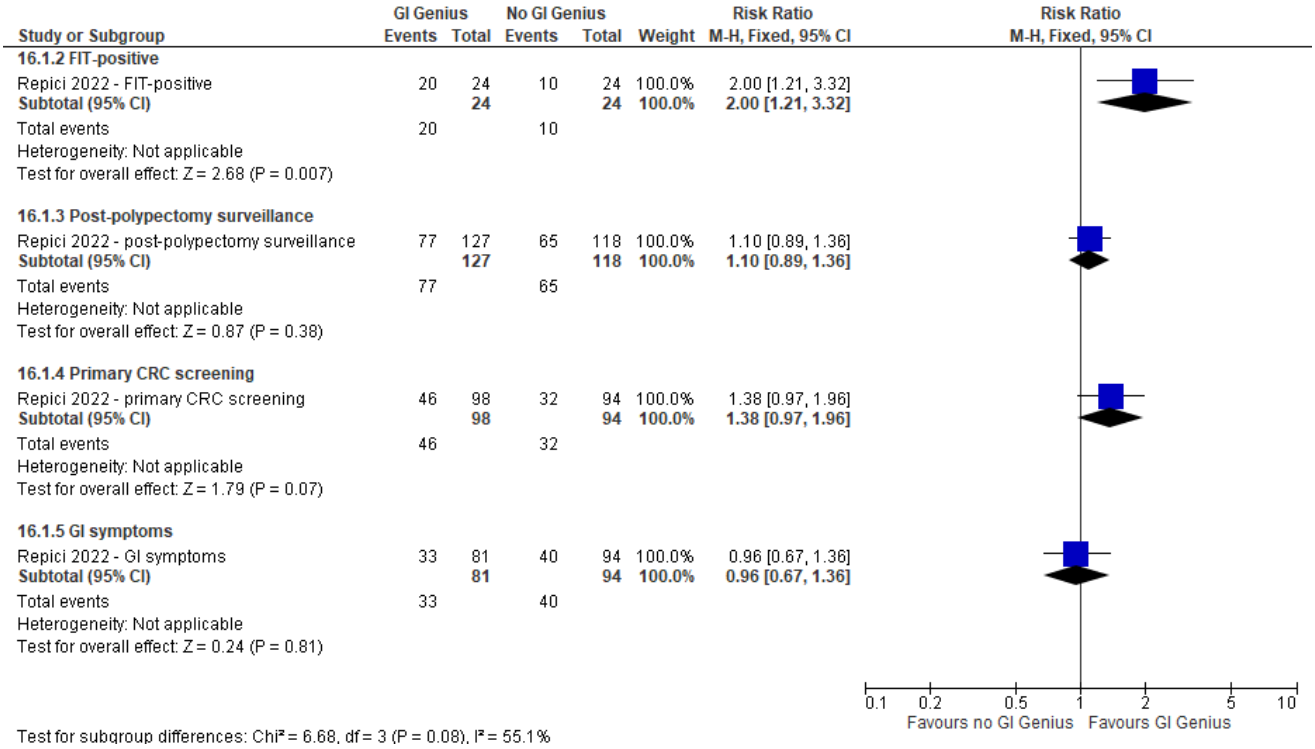
GI Genius™

Figure 153. ADR by colonoscopy indication – Repici *et al.* 2020[21]



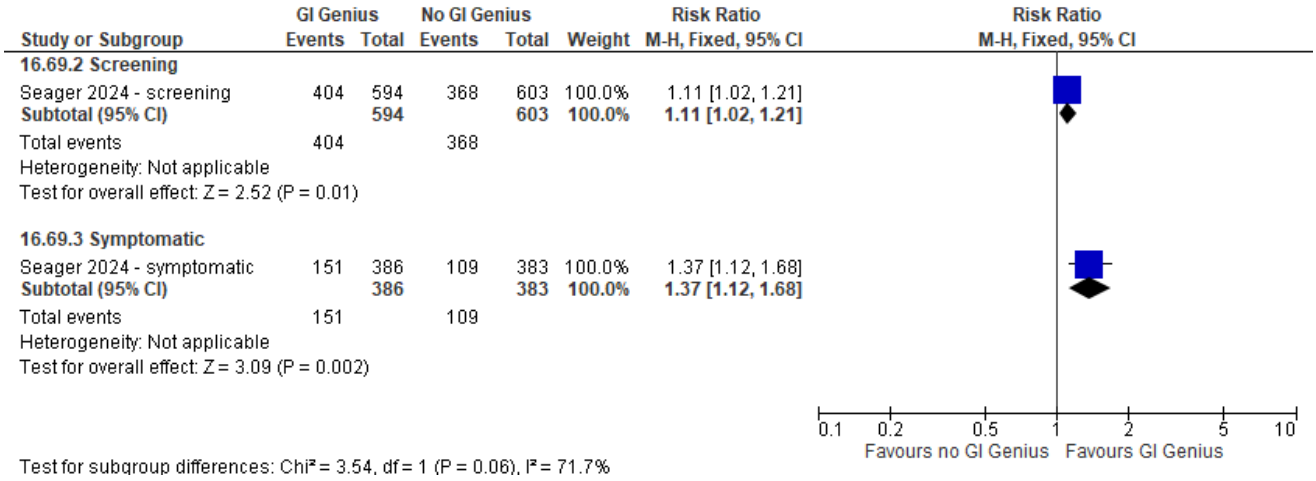
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FIT, faecal immunochemical test; GE, gastrointestinal; M-H, Mantel-Haenszel.

Figure 154. ADR by colonoscopy indication – Repici *et al.* 2022[22]



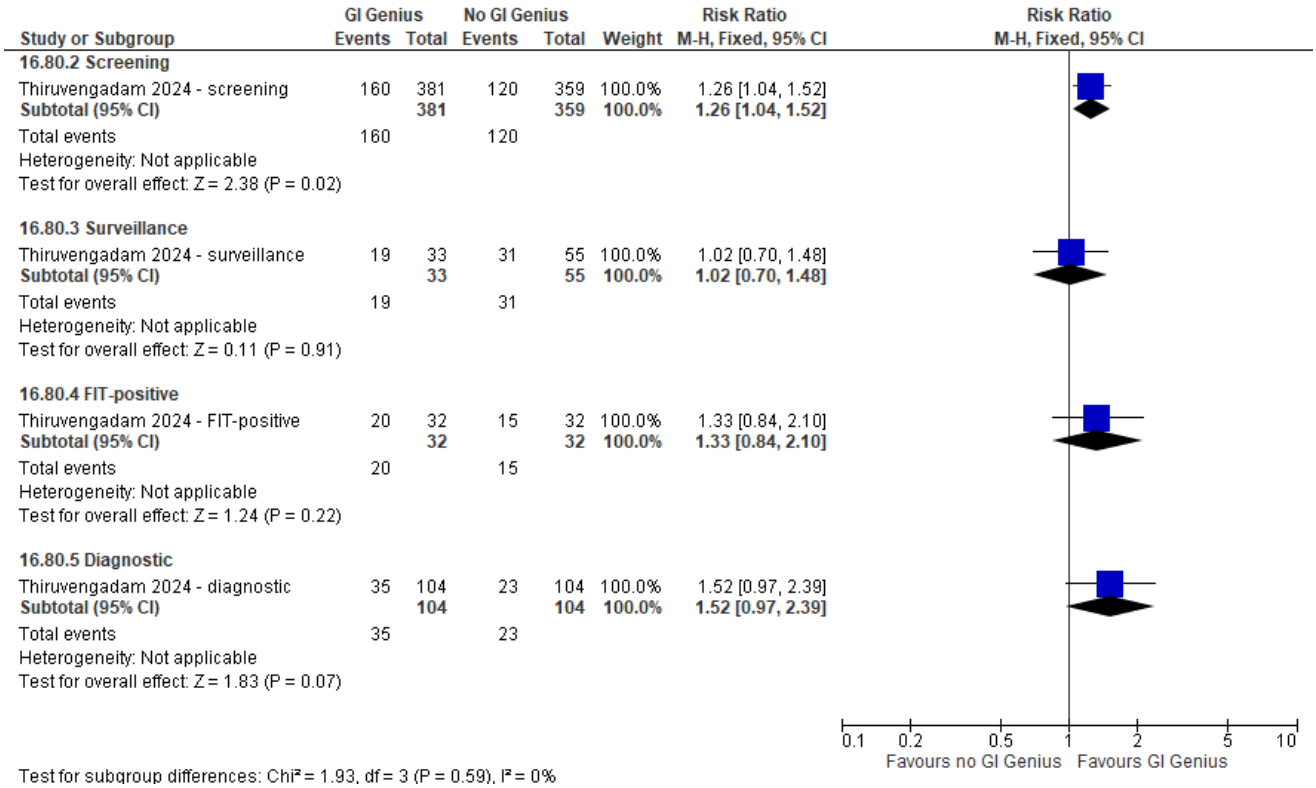
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CRC, colorectal cancer; FIT, faecal immunochemical test; GI, gastrointestinal; M-H, Mantel-Haenszel.

Figure 155. ADR by colonoscopy indication – Seager *et al.* 2024[23]



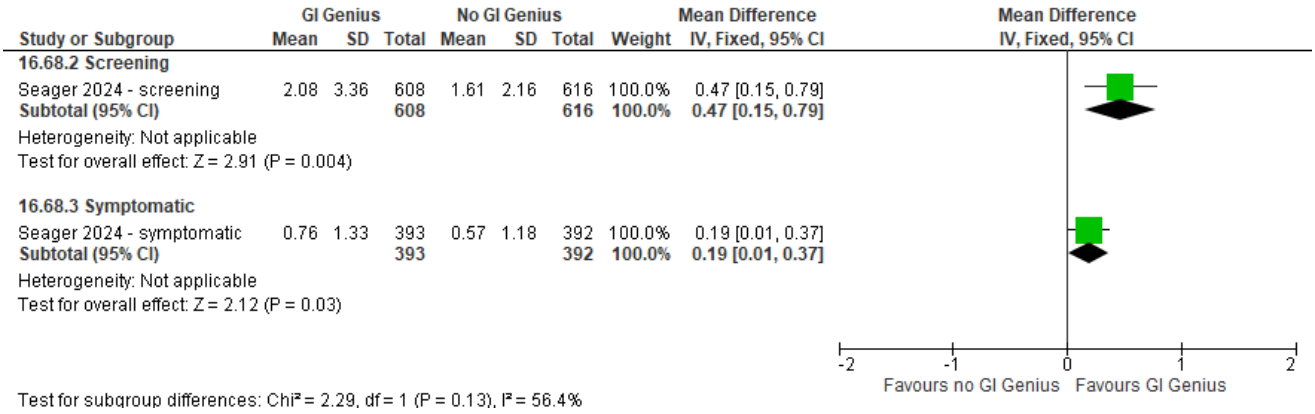
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 156. ADR by colonoscopy indication – Thiruvengadam *et al.* 2024[24]



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; FIT, faecal immunochemical test; M-H, Mantel-Haenszel.

Figure 157. APC by colonoscopy indication – Seager *et al.* 2024 – reported as mean difference[23]



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

1.21 Endoscopist experience subgroups – EAG analyses

CAD EYE®

The EAG's preferred subgroup analysis for ADR was based on assignment of whole studies or reported within-trial subgroup data to categories based on which group the majority of endoscopists were categorised as, as this allowed a better reflection of how experienced the endoscopists in the study were overall. The main differences between studies for this intervention was the inclusion of trainees or not, so studies were classified according to whether most endoscopists were trainees or not. Results in

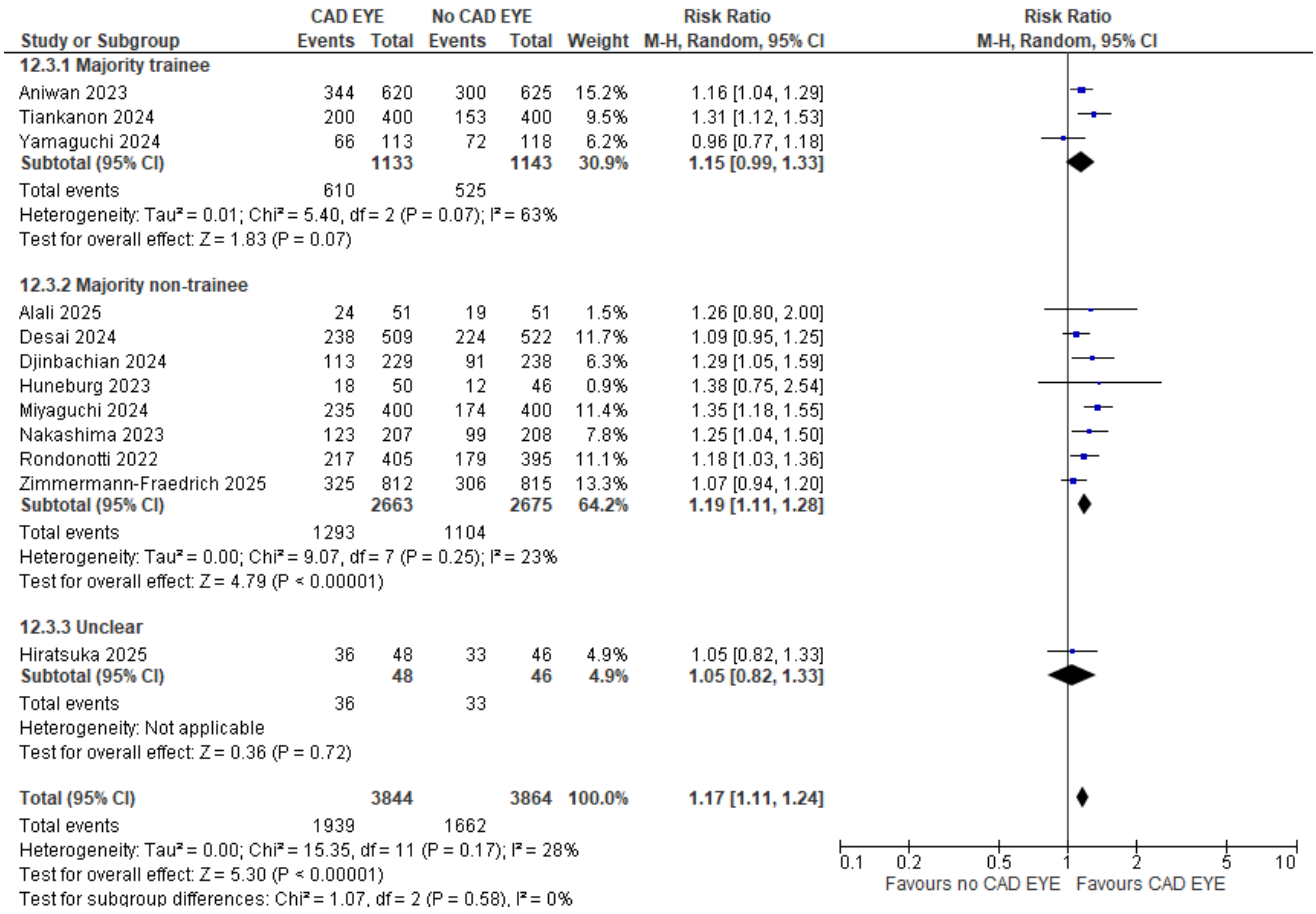
Figure 158 suggested no clear difference between the subgroups in terms of ADR given overlap between the 95% CIs of the two subgroups, although there was a trend for there being a larger ADR improvement with CAD EYE® in the studies where most endoscopists were trainees. An additional analysis based on the baseline ADR reported in trials suggested a slightly better impact of AI on ADR in the group with a higher ADR (Figure 159). Based on these, the EAG considers there to be no strong evidence supporting a difference in effect across endoscopist experience for this outcome.

Furthermore, of studies reporting within-trial subgroup analyses based on endoscopist experience for ADR, one reported no large difference across different baseline ADR categories, one suggested a bigger improvement in ADR in the trainee compared to the expert subgroup and two suggests larger improvements in ADR with CAD EYE® in the more experienced subgroups based on either baseline ADR or separated by numbers of years' experience (see Section 1.22 of this supplement). The EAG notes that similar was observed with regards to APC as a mean difference (Figure 160 and Figure 161), but was more limited for the baseline ADR analysis given that only two studies reported baseline ADR. Similar results were observed when APC was analysed as an IRR. Within-trial subgroup analysis was only possible for APC analysed as an IRR for one study, with the results suggesting a larger increase in APC in the expert subgroup compared to non-experts, with those with ≥10 years' experience defined as experts (see Section 1.22 of this supplement).

Only one study reported on differences in sensitivity and specificity when CAD EYE® was used as an adjunct to endoscopist optical diagnosis between experts and non-experts, with experts defined as those having followed dedicated training, undergoing periodical auditing and monitoring and performed optical diagnosis on a regular basis according to ESGE criteria.[58] Results suggest that AI may improve sensitivity and slightly lower the specificity value for non-expert endoscopists

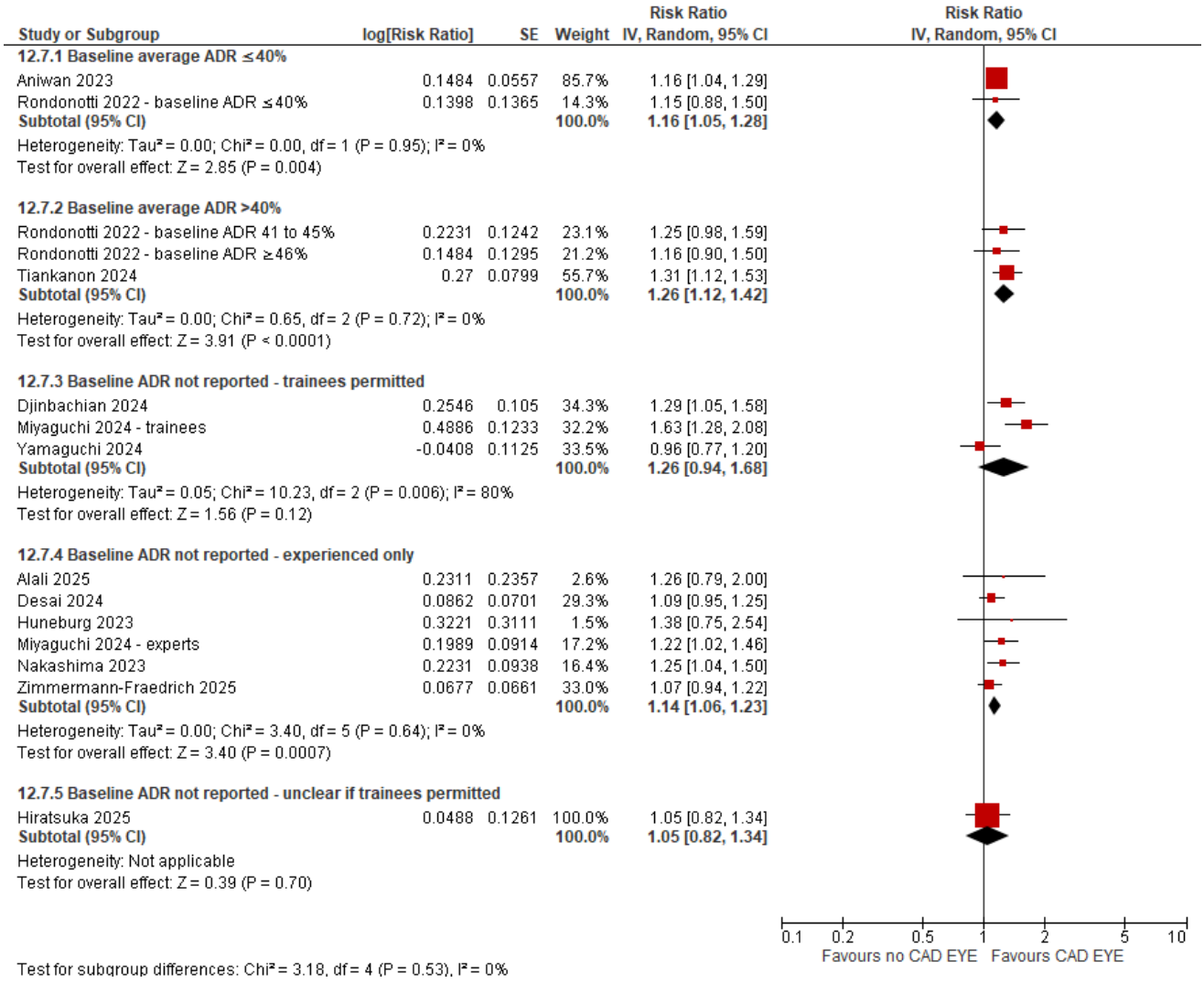
(sensitivity, 86.2 vs 81.8%; specificity, 83.3 vs 79.5%), but have minimal impact on expert endoscopists (sensitivity, 90.1 vs 90.6%; specificity, 93.3 vs 92.1%). The EAG does not consider these results sufficient to base firm conclusions on given it is a subgroup analysis from within a single trial, there is considerable overlap of CIs across the subgroups other limitations of the study are noted, such as only including high confidence diagnoses.

Figure 158. ADR endoscopist experience subgroup analysis with CAD EYE®- majority in whole studies and within-trial subgroup data (trainee vs non-trainee)



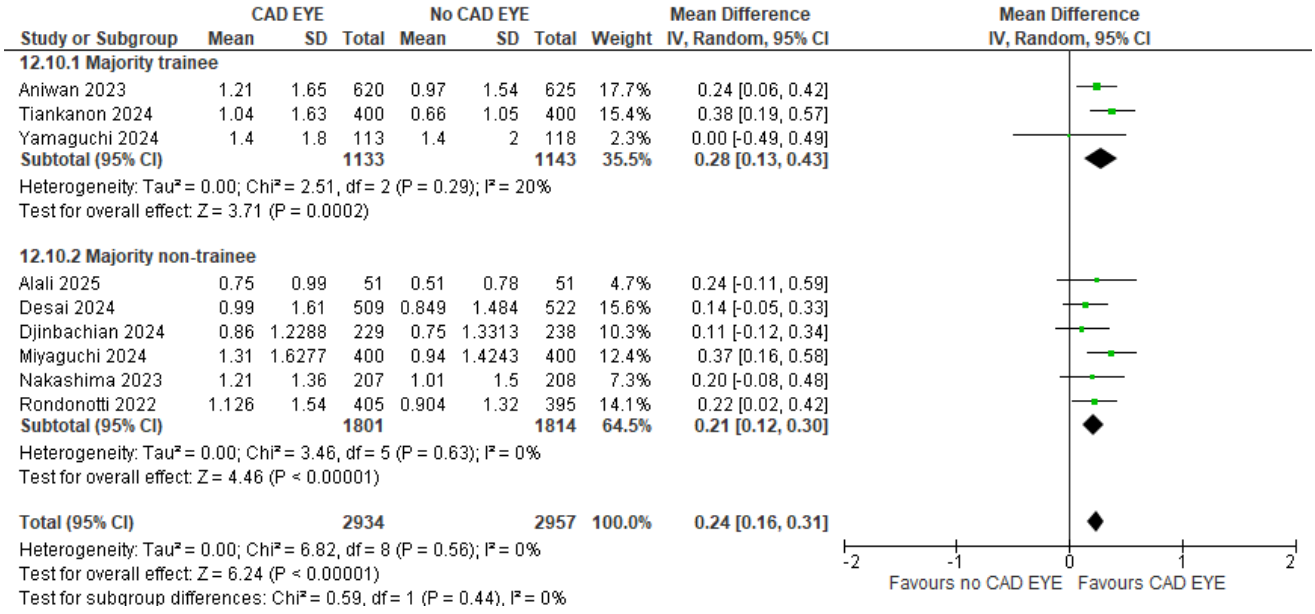
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 159. ADR endoscopist experience subgroup analysis with CAD EYE®- majority in whole studies and within-trial subgroup data (baseline ADR)



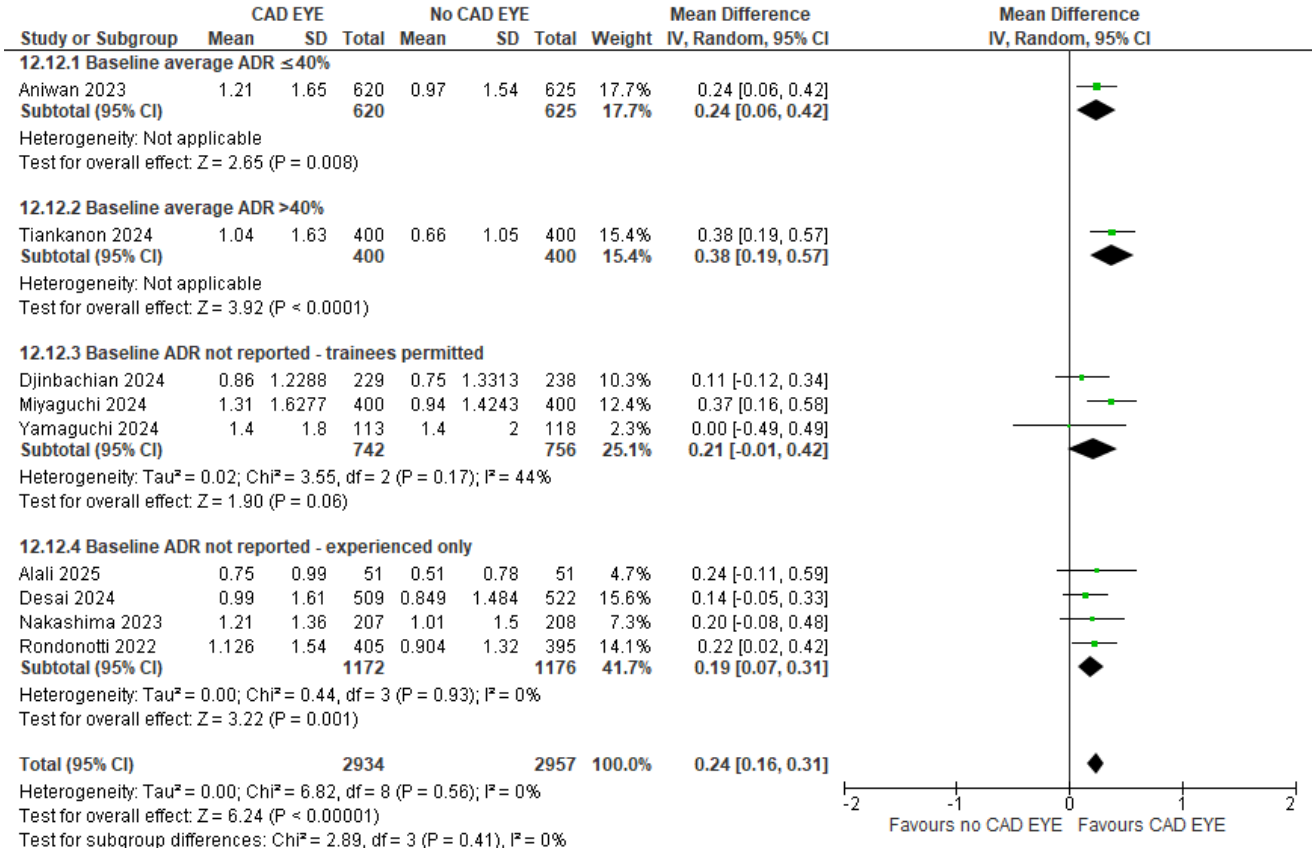
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; IV, inverse variance; SE, standard error.

Figure 160. APC endoscopist experience subgroup analysis with CAD EYE®- majority in whole studies (trainee vs non-trainee) – reported as mean difference



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 161. APC endoscopist experience subgroup analysis with CAD EYE®- majority in whole studies and within-trial subgroup data (baseline ADR) – reported as mean difference



Abbreviations: ADR, adenoma detection rate; APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

CADDIE™

[redacted]

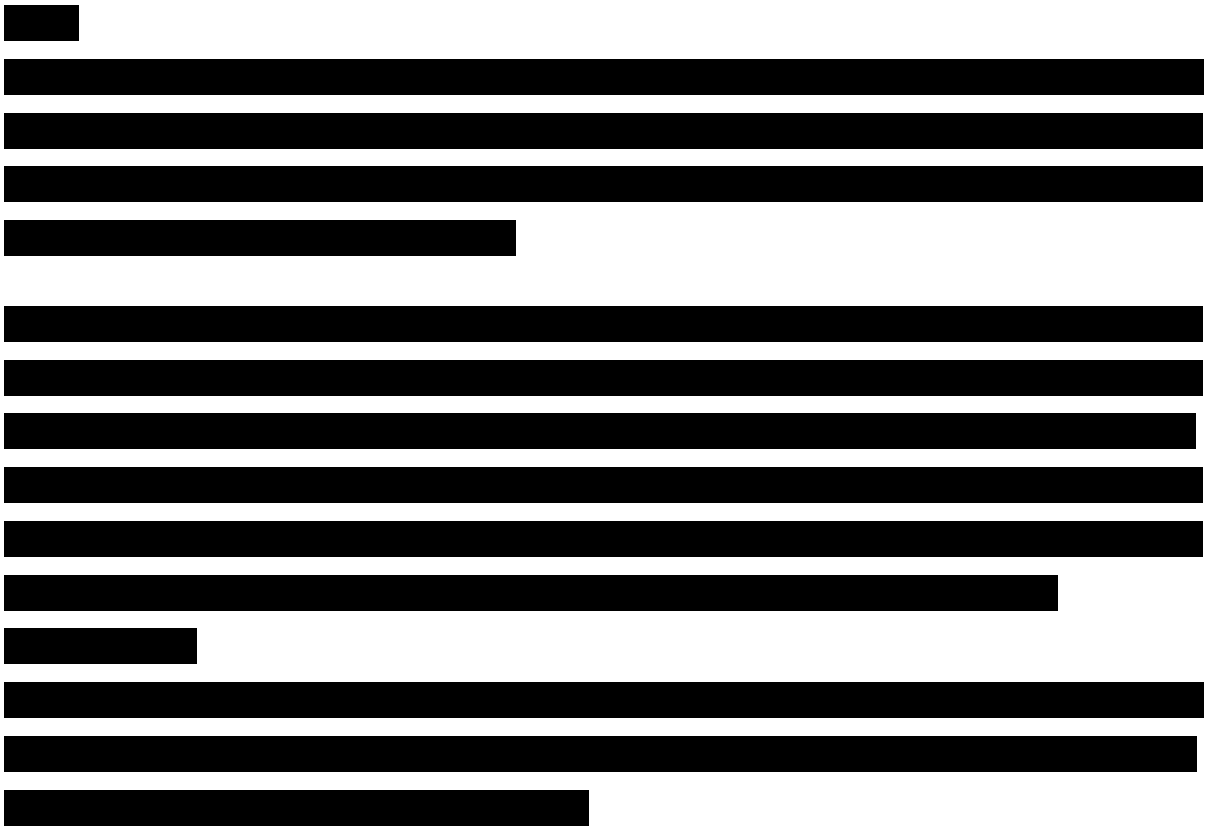


Figure 162. ADR endoscopist experience subgroup analysis with CADDIE™ - lower vs higher ADR requirements in whole study

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 163. ADR endoscopist experience subgroup analysis with CADDIE™ - baseline ADR in whole studies and within trial subgroup data

Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 164. APC endoscopist experience subgroup analysis with CADDIE™ - lower vs higher ADR requirements in whole study – reported as mean difference

Abbreviations: ADR, adenoma detection rate; APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

Figure 165. APC endoscopist experience subgroup analysis with CADDIE™ - baseline ADR in whole studies and within-trial subgroup data – reported as mean difference

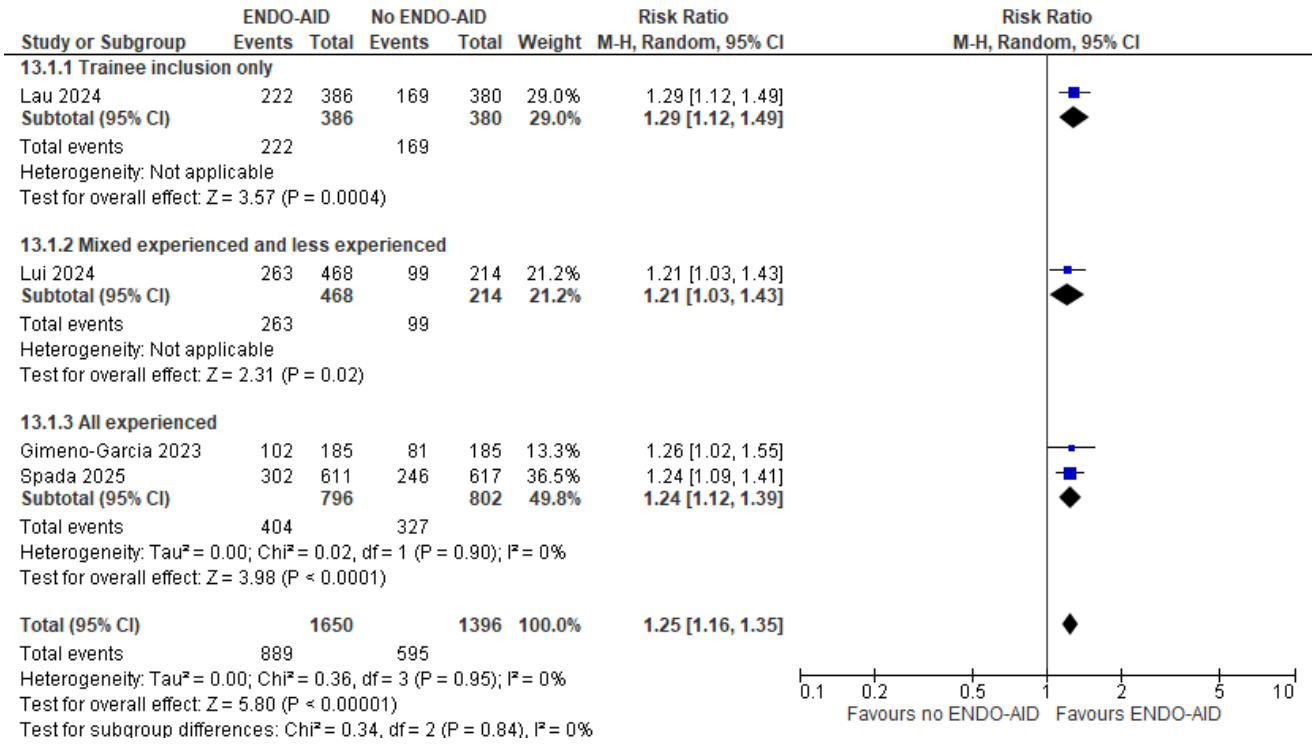
Abbreviations: ADR, adenoma detection rate; APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

ENDO-AID™

The only way that subgroup analysis for endoscopist experience could be performed for this intervention was to separate based on whether or not trainee inclusion was permitted based on the information available in the studies. Results in Figure 166 show an overlap of point estimates between subgroups, with all but one subgroup having only one study included. The EAG considers there to be no strong evidence supporting a difference of effect across colonoscopy indications. Results from one within-trial subgroup analysis suggests the potential for the improvement in ADR with AI to be slightly better in beginners compared to intermediates (see Section 1.22 of this supplement), but a similar trend was not observed in another study separating based on baseline ADR (high vs low detectors; see Section 1.22 of this supplement). Similar results were observed for APC when analysed as a mean difference (

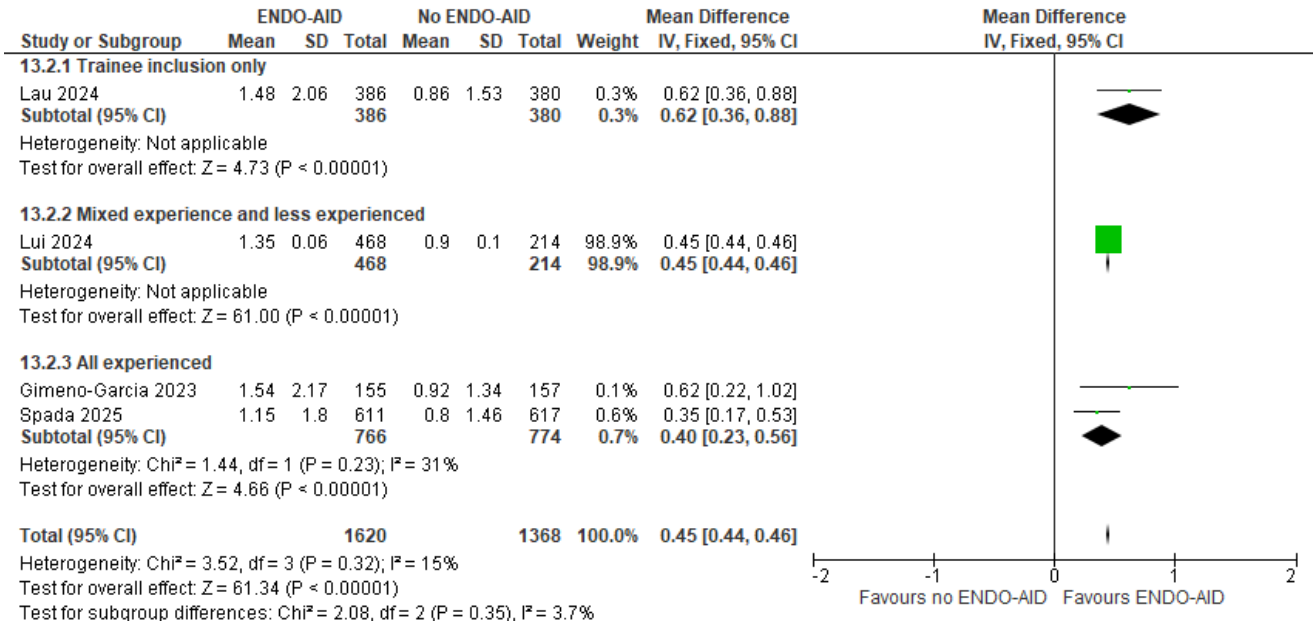
Figure 167) but with more apparent variation. One study reporting within-trial data for APC in beginners vs intermediates suggested a more beneficial impact of AI in the beginner group when analysed as a mean difference (see Section 1.22 of this supplement). Similar results were noted for APC when analysed as an IRR.

Figure 166. ADR endoscopist experience subgroup analysis with ENDO-AID™ - trainee inclusion permitted vs not permitted



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 167. APC endoscopist experience subgroup analysis with ENDO-AID™ - trainee inclusion permitted vs not permitted – reported as mean difference



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

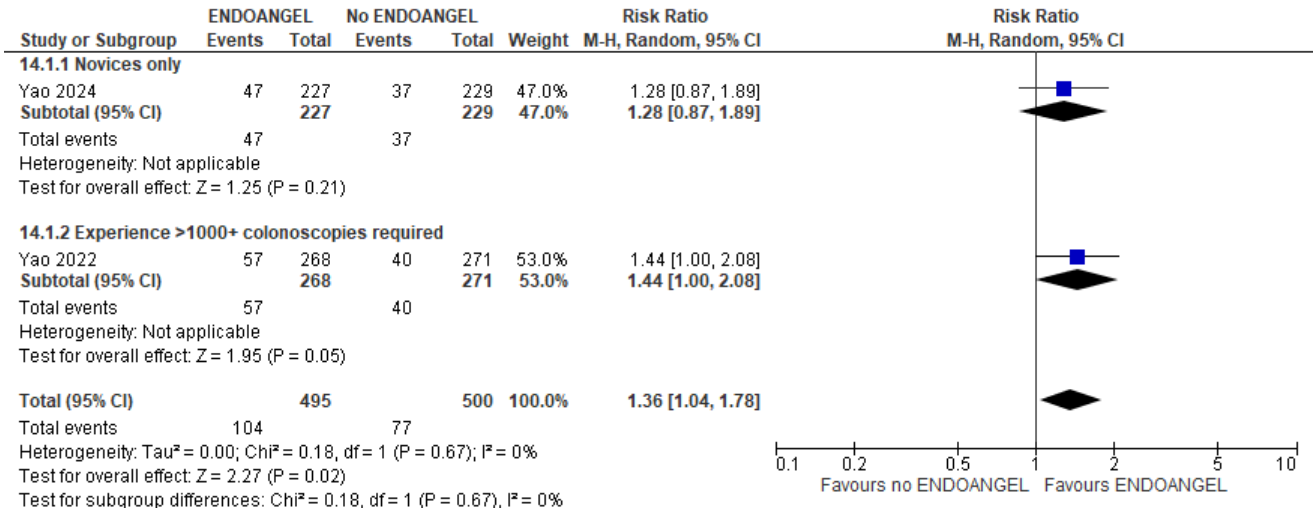
ENDOANGEL®

Of the two RCTs analysed in the primary analysis of ADR and APC for ENDOANGEL®,[17, 18] one study only included novices and the other required experience of at least 1000 prior colonoscopies. Results in

Figure 168 indicate a better improvement in ADR in the study with more experienced endoscopists included, but the difference for APC when analysed as a mean difference in

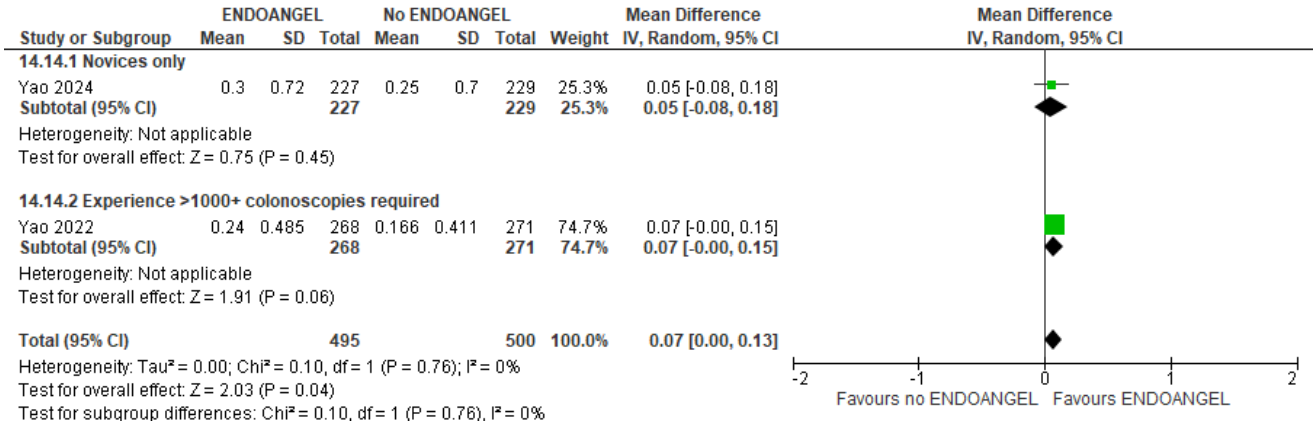
Figure 169 is very small. When APC was analysed as an IRR, results were similar to those for ADR. No studies covering ENDOANGEL® reported any within-trial subgroup analyses.

Figure 168. ADR endoscopist experience subgroup analysis with ENDOANGEL® - novices vs experienced endoscopists



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 169. APC endoscopist experience subgroup analysis with ENDOANGEL® - novices vs experienced endoscopists – reported as mean difference

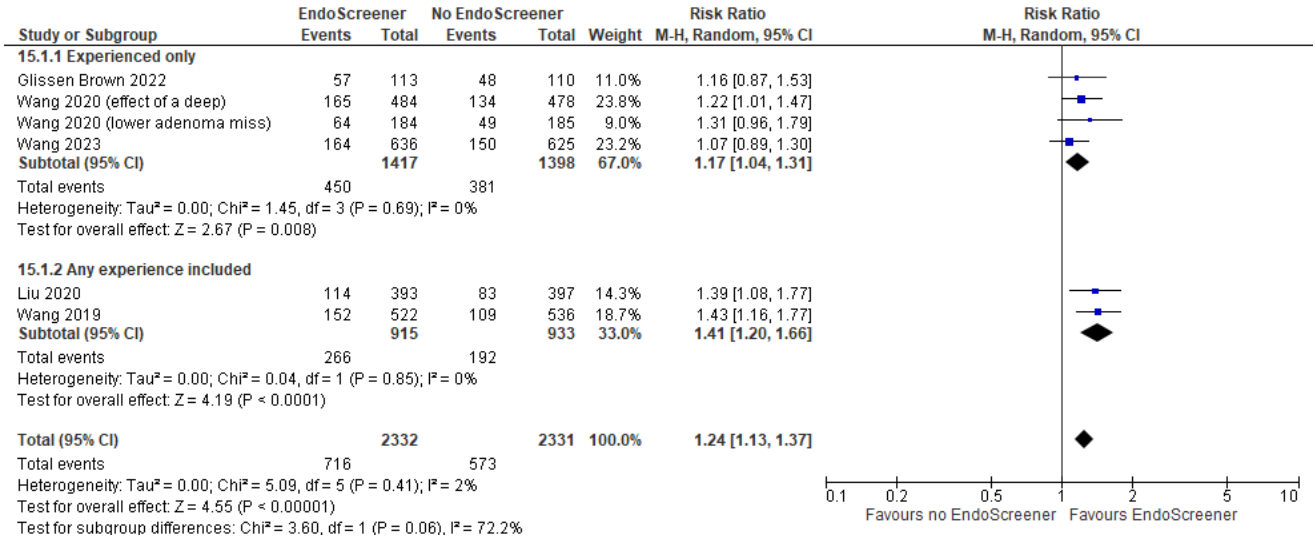


Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

EndoScreener®

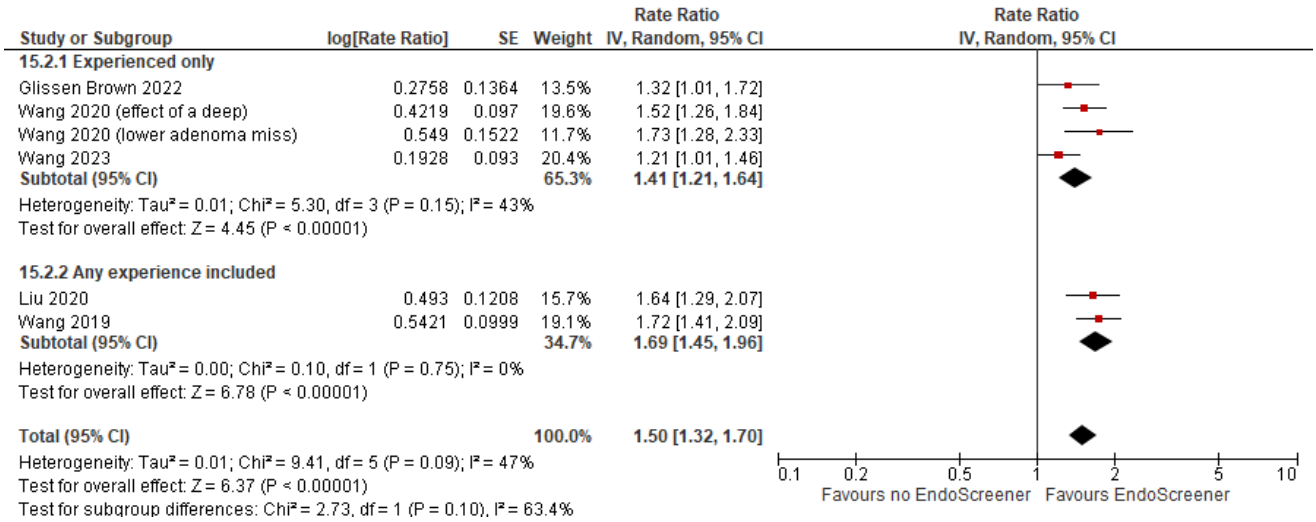
The only way that subgroup analysis for endoscopist experience could be performed for this intervention was to separate based on whether studies included a mix of endoscopist experience or only included experienced endoscopists. The EAG notes that the definition of experienced differed between studies. Results in Figure 170 suggest a trend for the improvement in ADR being larger in studies including any experience compared to those defined as experienced only. The EAG considers there may be a signal that endoscopist experience may impact improvement in ADR based on this analysis, but highlights the variation in definitions of experience across studies. No studies reported any within-trial subgroup analyses and it was only possible to assess this for APC when analysed as an IRR, as only one study reported this outcome reported data sufficiently to analyse as a mean difference. Results for APC when analysed as an IRR were similar to those described for ADR between subgroups (Figure 171).

Figure 170. ADR endoscopist experience subgroup analysis with EndoScreener® - mixed experience vs experienced only



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 171. APC as an IRR endoscopist experience subgroup analysis with EndoScreener® - mixed experience vs experienced only



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

GI Genius™

The only way that subgroup analysis for endoscopist experience could be performed for this intervention was to separate based on whether studies included only those with screening accreditation or whether there was mixed experience. The EAG notes that criteria for screening accreditation may have differed between studies as the details of this were not well reported. The EAG considers the results for ADR do not indicate any clear difference between subgroups, as while the point estimate for the screening accredited subgroup is higher compared to those where this was not a requirement, there is overlap of studies within each group (Figure 172). Therefore, the EAG does not consider there to be strong evidence of a difference between endoscopist experience subgroups.

Only one study at a lower risk of bias reported within-trial subgroup data for ADR; results suggested a trend towards a bigger improvement in ADR as basal ADR reduced across three categories from >35%, 25 to 35% and <25% (absolute differences of 2.4, 3,7 and 6.2 percentage points between AI-supported and standard colonoscopy, respectively), although none of the differences were statistically significant (p-values 0.47, 0.33 and 0.19, respectively).[19] Within the abstract that reported ADR specifically in an IBD population (see Section 3.2.2.1.1.1 of the main report), AI appeared to worsen ADR more in a subgroup of experienced gastroenterologists (≥5 years) compared to the whole study analysis, with a significant difference identified within this subgroup (p-values 0.035 and 0.15, respectively). The differences appears to be due to a very small difference in the ADR of the standard colonoscopy groups within the subgroup and the whole study population. These data are considered to be limited given it was only available in abstract form and limited details are available.

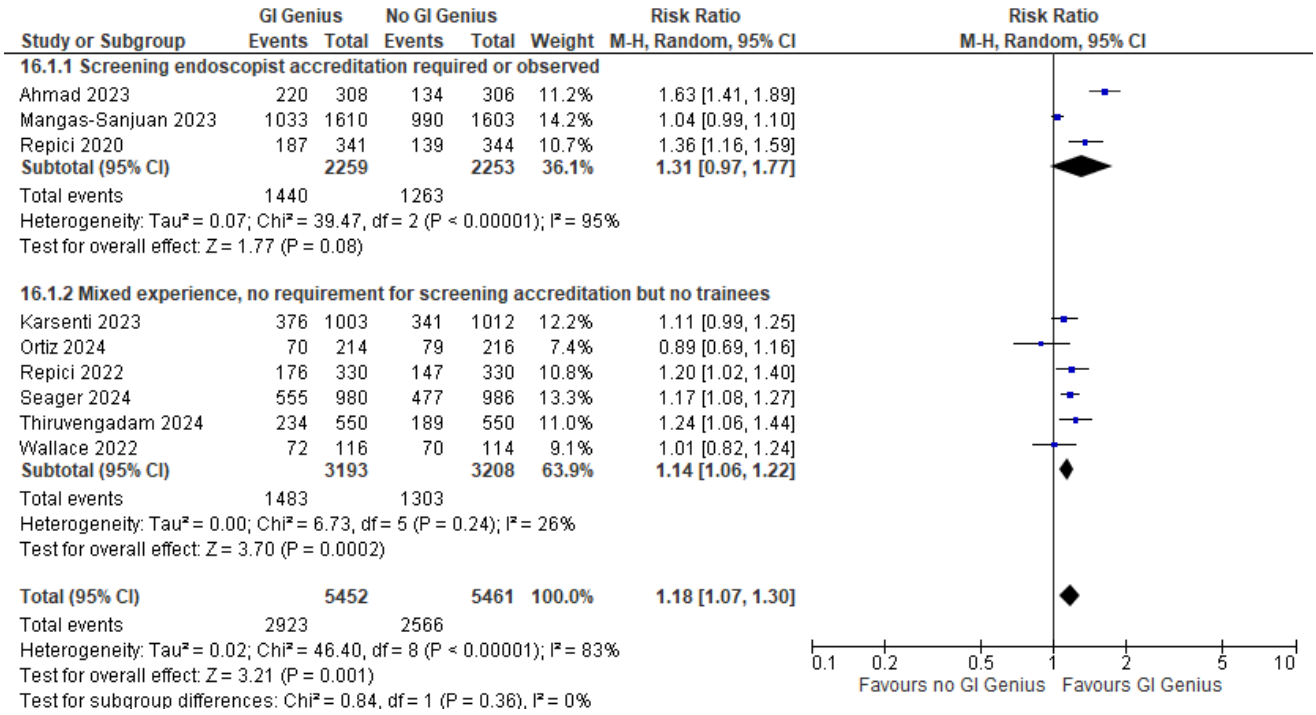
Similar conclusions can be made for APC when analysed as a mean difference, with even less of a difference noted based on point estimates for this outcome (

Figure 173). However, when analysed as an IRR, the trend was instead for a larger increase in APC within the group that did not require screening accreditation, although the EAG does not consider this to be a clear difference given the overlap between subgroups (
Figure 174). One study reporting within-trial subgroup data for APC between high and low detectors based on baseline ADR suggested an increase in APC with AI compared to standard colonoscopy within the low detectors subgroup (mean 0.71 with AI vs 0.45 without), but not for high detectors (mean 0.70 with AI vs 0.75 without), with insufficient data reported to analyse in forest plots and non-significant p-values reported for both subgroups (p-values 0.51 and 0.74, respectively).[46] A single study reported on differences in sensitivity and specificity when GI Genius™ was used as an adjunct to endoscopist optical diagnosis between experts and non-experts, with experts defined as those having followed dedicated training, participated in previous studies of optical diagnosis, undergoing periodical auditing and monitoring and performed optical diagnosis on a regular basis according to ESGE criteria.[57] Results from this study are limited given the lack of an endoscopist optical diagnosis alone arm, but results for AI-supported optical diagnosis suggest slight differences in diagnostic accuracy measures between experts and non-experts, including a slightly reduced sensitivity and more substantial reduction in specificity in non-experts compared to experts (sensitivity, 96.1% vs 93.6%; specificity, 65.0% vs 52.5%). The EAG does not consider these results sufficient to base firm conclusions on, particularly with no comparative data available for endoscopist optical diagnoses without AI support.

For the non-randomised NAIAD study that was included in the report as supportive evidence alongside the RCT meta-analyses, the EAG notes that there is some evidence to support the idea that [redacted]. However, the EAG notes that the [redacted] for both outcomes; as indicated in Table 31 the difference in ADR between phase 1 and phase 2 for experts and non-experts is [redacted], respectively, and for APC the equivalent values are [redacted], respectively. While a [redacted] Therefore, the EAG does not consider that this trial provides

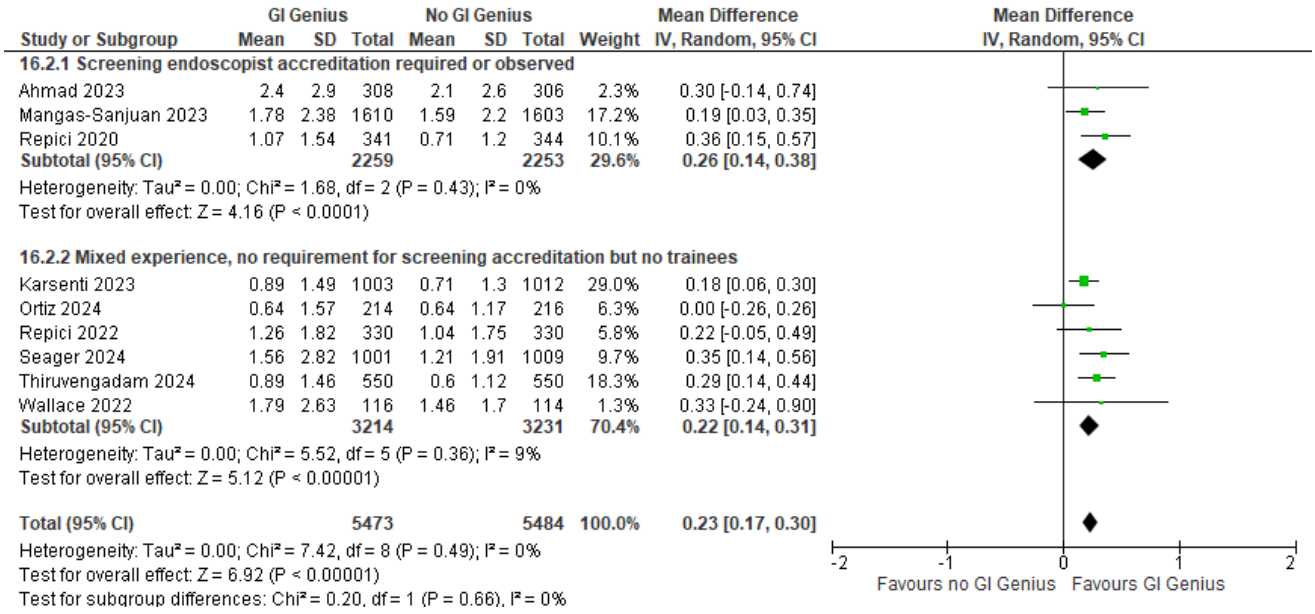
robust evidence for a difference in outcomes between endoscopists with different levels of experience when using GI Genius™ for polyp detection.

Figure 172. ADR endoscopist experience subgroup analysis with GI Genius™ - screening accreditation or mixed



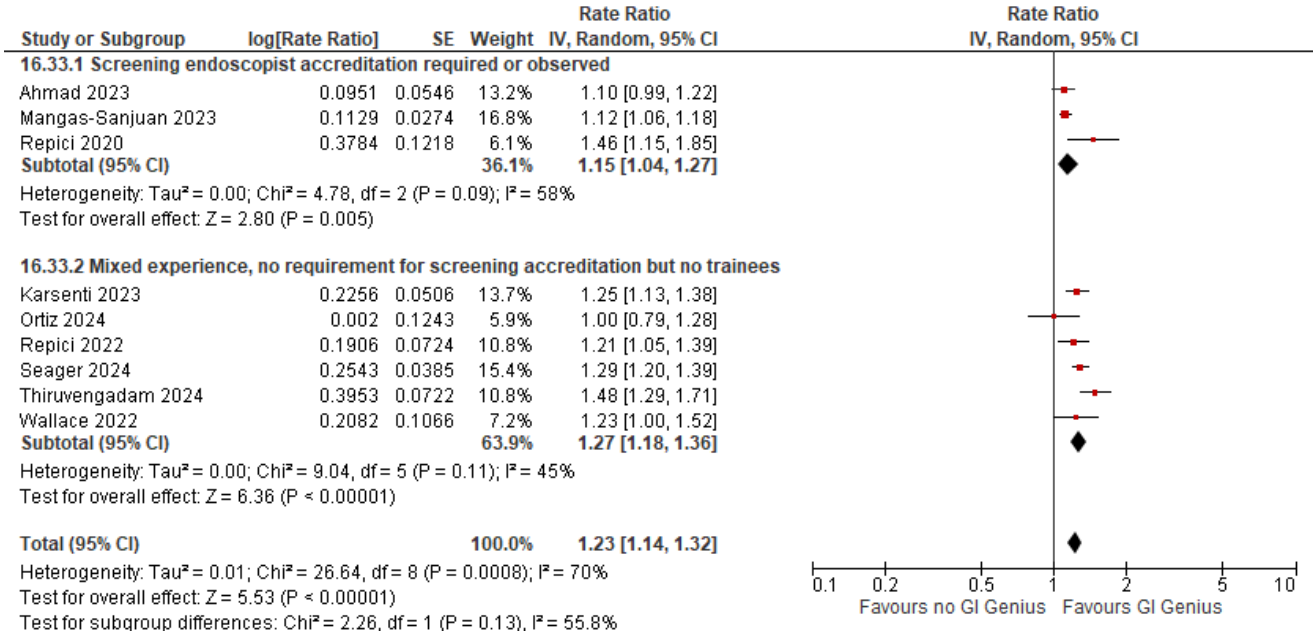
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 173. APC endoscopist experience subgroup analysis with GI Genius™ - screening accreditation or mixed, with or without trainees – reported as mean difference



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Figure 174. APC endoscopist experience subgroup analysis with GI Genius™ - screening accreditation or mixed, with or without trainees – reported as IRR

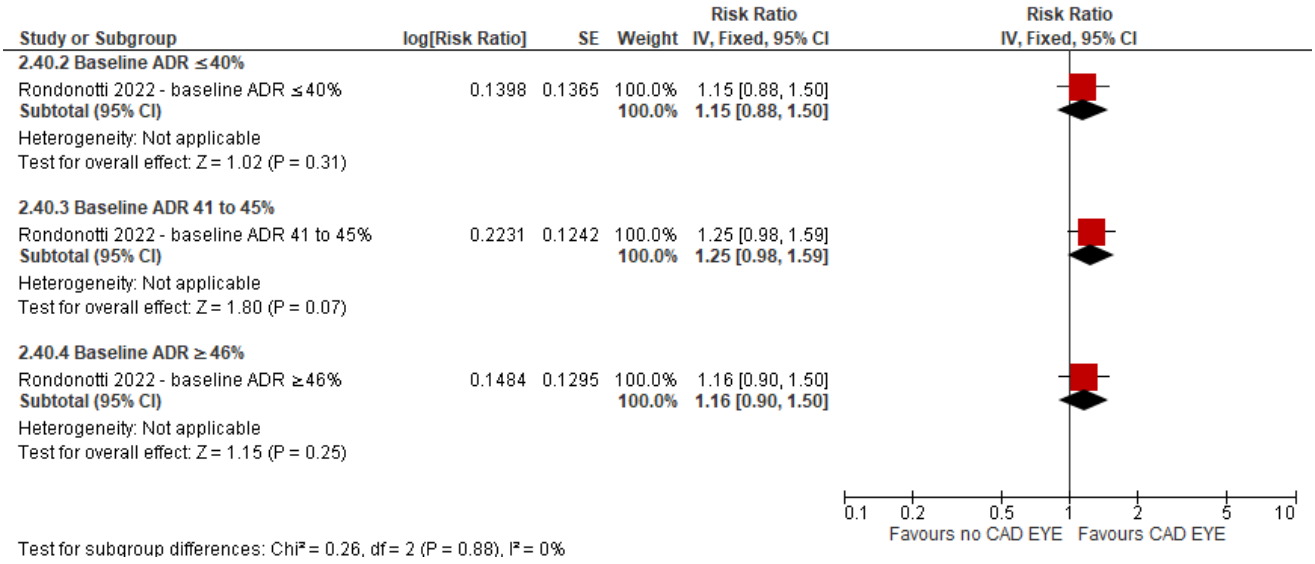


Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SE, standard error.

1.22 Endoscopist experience subgroup analyses – within-trial analyses

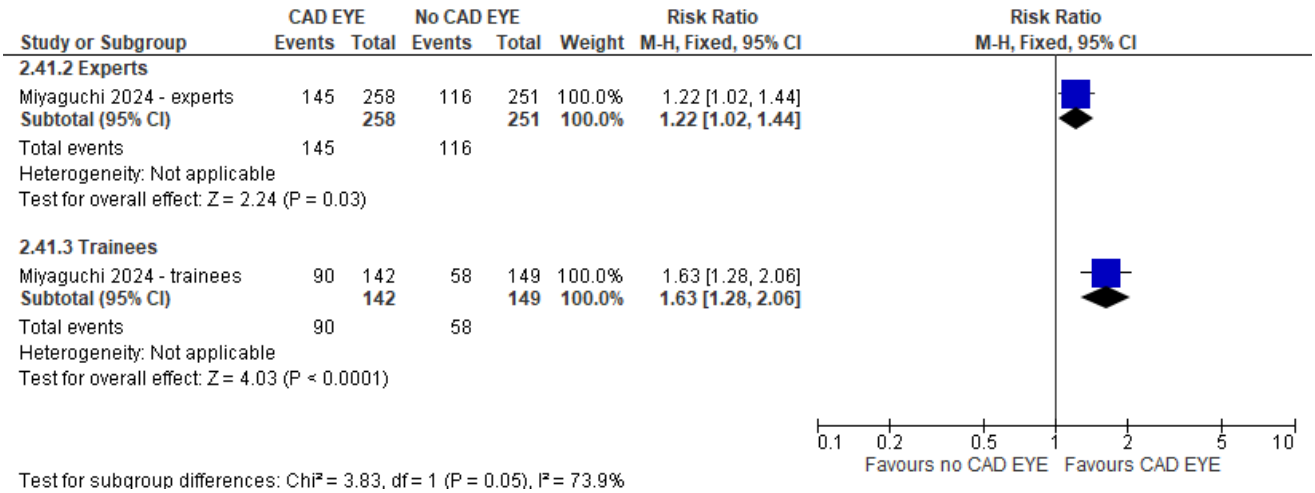
CAD EYE®

Figure 175. ADR by endoscopist experience – Rondonotti *et al.* 2022[9]



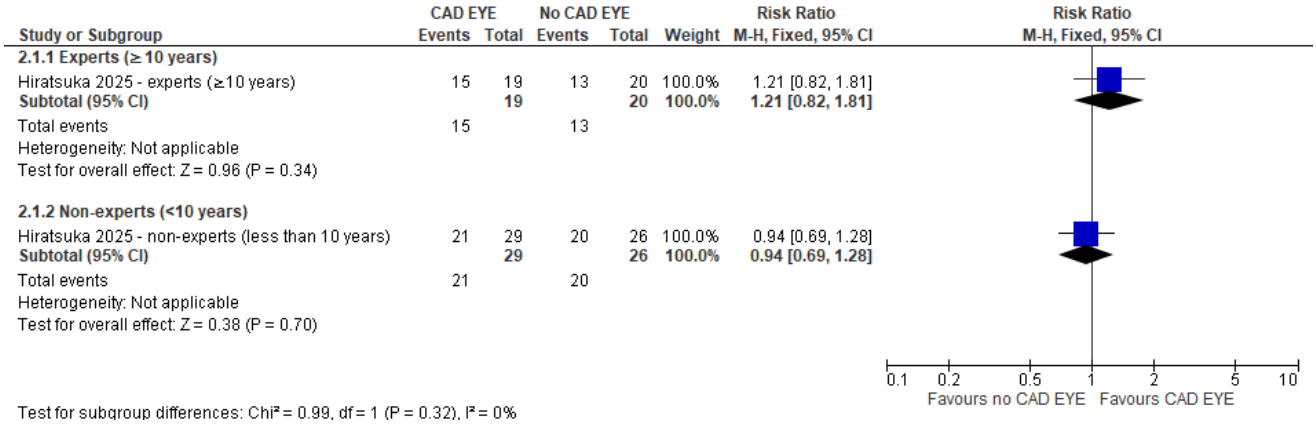
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; IV, inverse variance; SE, standard error.

Figure 176. ADR by endoscopist experience – Miyaguchi *et al.* 2024[29]



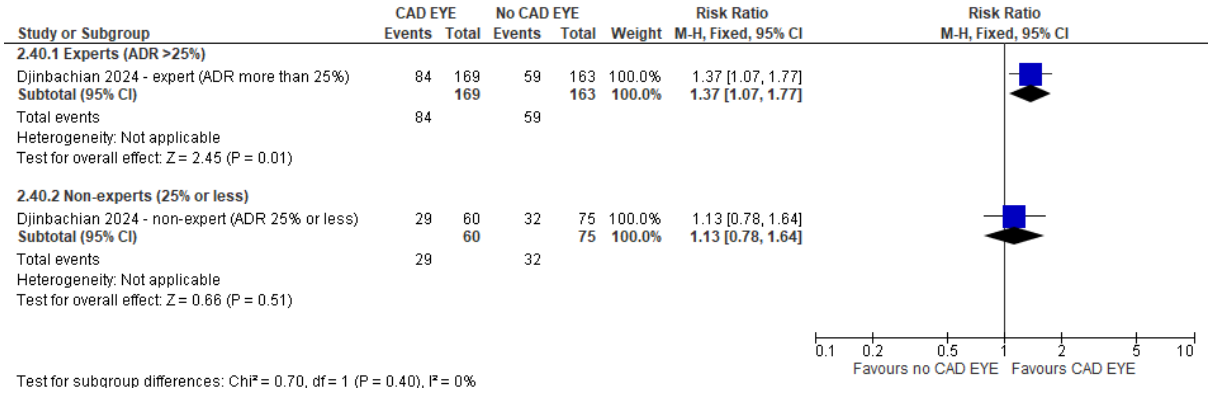
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 177. ADR by endoscopist experience – Hiratsuka *et al.* 2025[34]



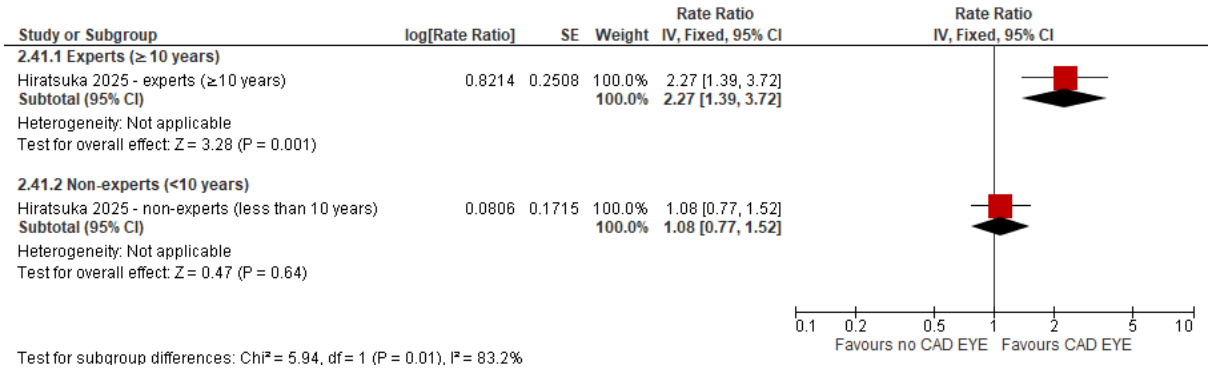
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 178. ADR by endoscopist experience – Djinbachian *et al.* 2024[10]



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 179. APC as an IRR by endoscopist experience – Hiratsuka *et al.* 2025[34]



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IRR, incidence rate ratio; IV, inverse variance; SE, standard error.

CADDIE™

Figure 180. ADR by endoscopist experience – Odin Vision 2024 (EAGLE)[41]

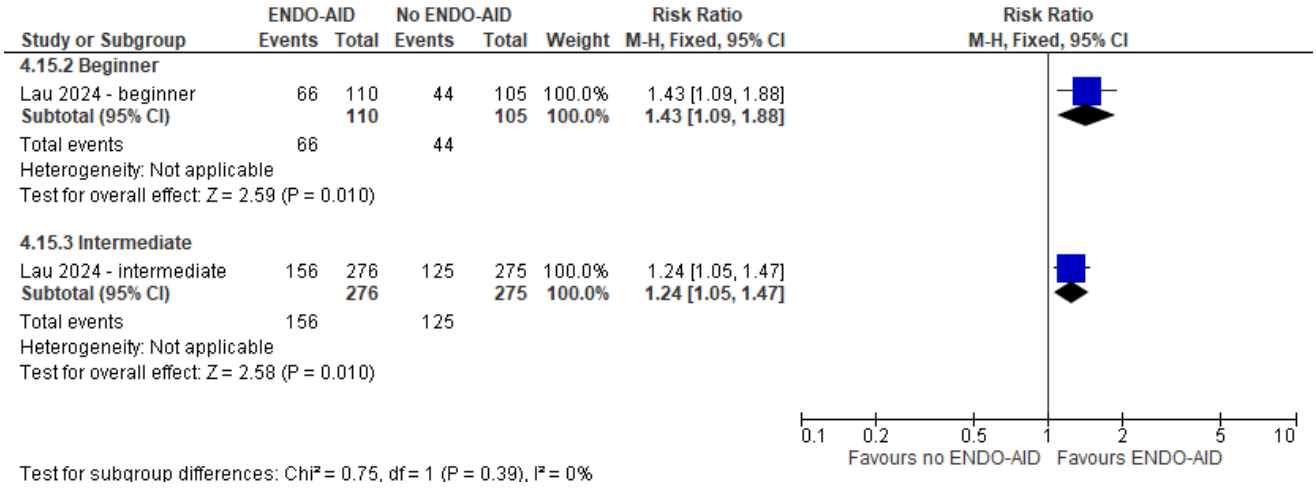
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; CSR, clinical study report; M-H, Mantel-Haenszel.

Figure 181. APC by endoscopist experience – Odin Vision 2024 (EAGLE) – reported as mean difference[41]

Abbreviations: ADR, adenoma detection rate; APC, adenomas per colonoscopy; CI, confidence interval; CSR, clinical study report; IV, inverse variance; SD, standard deviation.

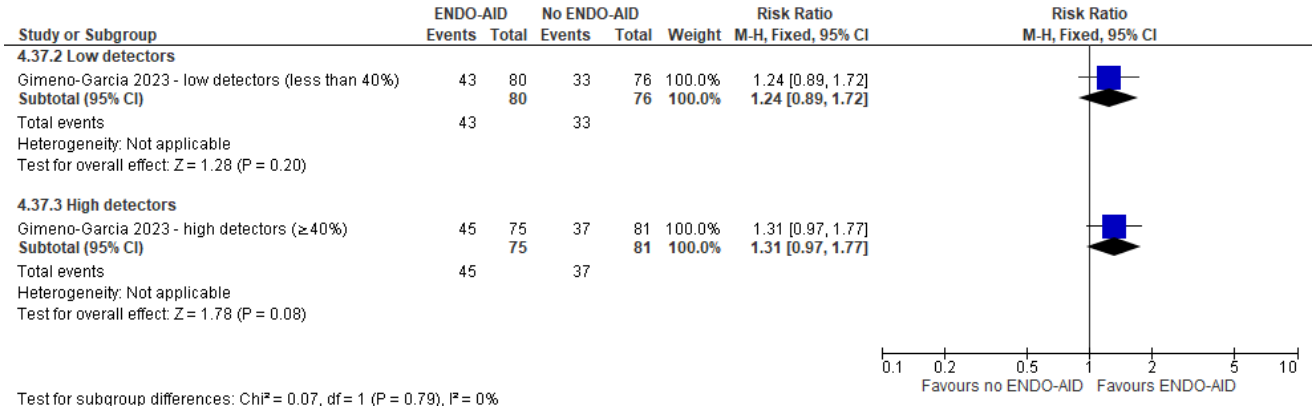
ENDO-AID™

Figure 182. ADR by endoscopist experience – Lau *et al.* 2024[14]



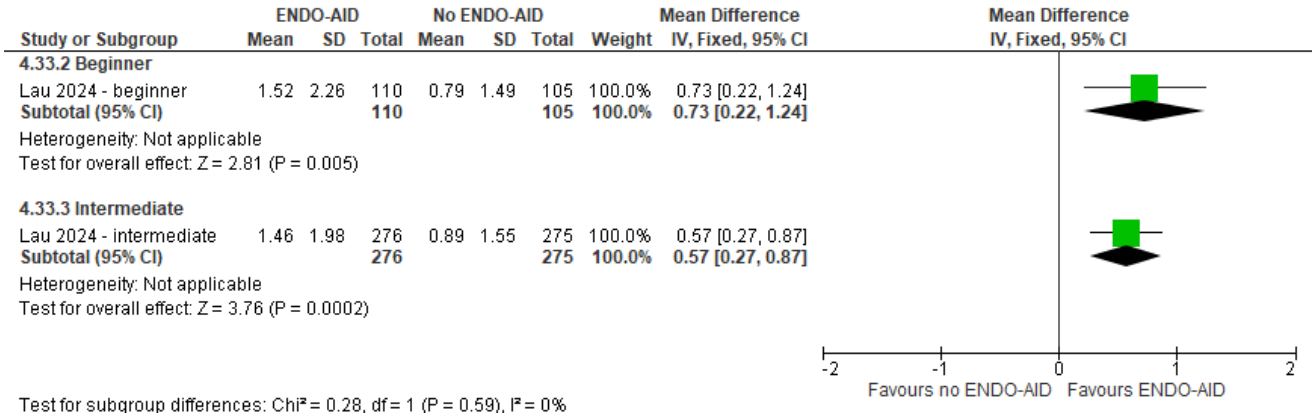
Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 183. ADR by endoscopist experience – Gimeno-Garcia *et al.* 2023[13]



Abbreviations: ADR, adenoma detection rate; CI, confidence interval; M-H, Mantel-Haenszel.

Figure 184. APC by endoscopist experience – Lau *et al.* 2024 – reported as mean difference[14]



Abbreviations: APC, adenomas per colonoscopy; CI, confidence interval; IV, inverse variance; SD, standard deviation.

GI Genius™

Table 31. ADR and APC data from the NAIAD trial broken down by endoscopist experience (adapted from Tables 2 and 8 of document provided to the EAG)

Outcome	Phase 1 (prior to GI Genius™ - [redacted])	Phase 2 (GI Genius™ use - [redacted])	Phase 3 (after GI Genius™ withdrawn - [redacted])	p-value*
ADR – unclear if per site or per endoscopist, % (SD)	Experts: [redacted]	Experts: [redacted]	Experts: [redacted]	[redacted]
	Non-experts: [redacted]	Non-experts: [redacted]	Non-experts: [redacted]	[redacted]
APC, mean (SD)	Experts: [redacted]	Experts: [redacted]	Experts: [redacted]	[redacted]
	Non-experts: [redacted]	Non-experts: [redacted]	Non-experts: [redacted]	[redacted]

*Unclear from information provided, but assume for comparison between all three groups.

Note: non-experts were defined as those with a PDR <35% and <2000 lifetime colonoscopies.

Abbreviations: ADR, adenoma detection rate; APC, adenomas per colonoscopy; EAG, External Assessment Group; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NR, not reported; PDR, polyp detection rate; SD, standard deviation.

2 Additional outcomes not covered in the main report

2.1 Polyp-related outcomes

Various outcomes were reported in some studies for outcomes related to total polyps, in addition to data specific to adenomas. Given outcomes related to adenomas and other specific types of polyp such as sessile serrated lesions (SSLs) are more clinically important, whereas overall polyps also includes polyps that are less likely to develop into cancer, data related to polyps overall are included in this supplement rather than the main report. It was also less well-reported compared to adenoma-based outcomes. This includes data on polyp detection rate (PDR; Table 32), polyps per colonoscopy (PPC; Table 33) and polyp miss rate (PMR; Table 34).

Based on these results, PDR and PPC are increased across interventions in the artificial intelligence (AI) group compared to standard colonoscopy, although differences are often not statistically significant and are based on less data than adenoma outcomes with heterogeneity a common issue. A similar trend for a benefit of AI technologies when considering PMR is noted, although this outcome is even less well-reported across studies.

2.1.1 Polyp detection rate

Table 32. Summary of analyses for polyp detection rate

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
6 RCTs (4 parallel, 1 parallel with tandem procedures performed by experts, 1 tandem), 2021 participants[7, 8, 10, 33, 34, 40]	693/1000 (69.30%)	626/1021 (61.31%)	RR 1.12 (1.00 to 1.26)	• Substantial heterogeneity noted based on visual differences in point estimates and I^2 value of 63%
CADDIE™				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Discovery™				
1 parallel RCT, 497 participants[26]	138/250 (55.20%)	127/247 (51.42%)	RR 1.07 (0.91 to 1.27)	• Single study
ENDO-AID™				

4 parallel RCTs, 2988 participants[13-16]	1149/1620 (70.93%)	769/1368 (56.21%)	RR 1.24 (1.18 to 1.32)	NA
ENDOANGEL®				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	282/495 (56.97%)	230/500 (46.00%)	RR 1.23 (1.06 to 1.43)	• Some statistical heterogeneity suggested (I^2 = 32% and point estimates vary)
EndoScreener®				
6 RCTs (2 tandem, 4 parallel), 4663 participants[30, 35, 36, 43-45]	1157/2332 (49.61%)	841/2331 (36.08%)	RR 1.35 (1.23 to 1.50)	• Some statistical heterogeneity suggested (I^2 = 54% and point estimates vary)
GI Genius™				
5 parallel RCTs, 8283 participants*[1, 19, 20, 23, 46]	2701/4138 (65.27%)	2486/4145 (59.98%)	RR 1.09 (1.04 to 1.14)	• Some statistical heterogeneity suggested (I^2 = 37%)

*Lagstrom *et al.* 2025 excluded from primary analysis due to high risk of bias.[47]

Abbreviations: CADe, computer-aided detection; CI, confidence interval; NA, not applicable; RCT, randomised controlled trial; RR, risk ratio.

2.1.2 *Polyps per colonoscopy*

Table 33. Summary of analyses for polyps per colonoscopy

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
3 RCTs (2 parallel, 1 parallel with tandem procedures performed by experts), 1364 participants[7, 33, 40]	Mean 1.51	Mean 1.36	MD 0.20 (-0.16 to 0.56)	• Substantial statistical heterogeneity suggested (I^2 = 60% and point estimates vary)
CADDIE™				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Discovery™				
1 parallel RCT, 497 participants[26]	Mean 1.20	Mean 1.09	MD 0.11 (-0.15 to 0.37)	• Single study

ENDO-AID™				
2 parallel RCTs, 1910 participants[15, 16]	Mean 1.92	Mean 1.31	MD 0.62 (0.24 to 1.00)	• Substantial statistical heterogeneity suggested (I^2 = 92% and point estimates vary)
ENDOANGEL®				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	Mean 1.92	Mean 1.49	MD 0.40 (0.10 to 0.70)	NA
EndoScreener®				
1 tandem RCT, 223 participants[35]	Mean 2.00	Mean 1.59	MD 0.41 (-0.16 to 0.98)	• Single study • Additional data from five parallel RCTs as means only demonstrating significantly higher polyps per colonoscopy with EndoScreener® vs standard colonoscopy (p-value at least <0.001 for all)
GI Genius™				
5 parallel RCTs, 8284 participants[1, 19, 20, 23, 46]	Mean 2.20	Mean 1.87	MD 0.31 (0.13 to 0.49)	• Substantial statistical heterogeneity suggested (I^2 = 60% and point estimates vary)

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NA, not applicable; RCT, randomised controlled trial.

2.1.3 *Polyp miss rate*

Table 34. Summary of analyses for polyp miss rate

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - polyp miss rate, per lesion				

1 tandem RCT, 94 participants[34]	35/206 lesions (16.99%)	53/166 lesions (31.93%)	RR 0.53 (0.37 to 0.77)	• Single study
CAD EYE® - lesion miss rate, per lesion				
No formal analysis possible[52]				• One non-randomised study (abstract only) reports lesion miss rate of 0.0% with LCI + CAD EYE® compared to 9.8% and 5.3% with standard WLE or LCI, respectively (p-value <0.05 for both) • Specific to ulcerative colitis patients, 133 lesions (62 patients)
ENDO-AID™ - supervisor-reported missed polyp rate, per-patient				
1 parallel RCT, 766 participants[14]	1/386 patients (0.26%)	1/380 patients (0.26%)	Peto OR 0.98 (0.06 to 15.77)	• Supervisors of trainees identified polyps missed in each procedure • Single study
ENDOANGEL® - polyp miss rate, per lesion				
1 tandem RCT, 456 participants[18]	138/650 lesions (21.23%)	219/619 lesions (35.38%)	RR 0.60 (0.50 to 0.72)	• Single study
EndoScreener® - polyp miss rate, per lesion				
2 tandem RCTs, 592 participants[35, 36]	96/570 lesions (16.84%)	201/508 lesions (39.57%)	RR 0.42 (0.20 to 0.90)	• Substantial statistical heterogeneity suggested (I^2 = 92% and point estimates vary)
GI Genius™ - polyp miss rate, per lesion				
1 tandem study, 230 participants[37]	44/261 (16.86%)	85/273 (31.14%)	RR 0.54 (0.39 to 0.75)	• Single study
GI Genius™ - polyp miss rate, per-patient				
1 tandem RCT, 230 participants[37]	33/116 (28.45%)	55/114 (48.25%)	RR 0.59 (0.42 to 0.83)	• Patients with at least one missed colorectal polyp • Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; LCI, linked-colour imaging; OR, odds ratio; RCT, randomised controlled trial; RR, risk ratio; WLE, white-light endoscopy.

2.2 Non-neoplastic and hyperplastic polyp outcomes

Some additional outcomes related to non-neoplastic or hyperplastic polyps are reported in some included studies (other than detection rates already covered in the main report). Outcomes covered include per colonoscopy measures of hyperplastic, diminutive hyperplastic or non-neoplastic polyps

(Table 35), hyperplastic PMR (Table 36) and proportion of patients with only hyperplastic polyps (Table 37).

Results were only reported for one or two studies per intervention, with not all interventions being covered, but overall results were mixed for whether the use of AI technologies increases the detection of non-neoplastic or hyperplastic polyps (or not) compared to standard colonoscopy. The results of some analyses suggest statistically significant differences but others suggest smaller and non-significant differences.

2.2.1 *Diminutive hyperplastic and non-neoplastic polyps per colonoscopy*

Table 35. Summary of analyses for diminutive hyperplastic and non-neoplastic polyps per colonoscopy or per patient

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - hyperplastic polyps per colonoscopy				
1 parallel RCT with tandem procedures performed by experts, 231 participants[33]	Mean 0.24	Mean 0.33	MD -0.09 (-0.26 to 0.08)	• Single study • A second parallel RCT is inconsistent with this, reporting more hyperplastic polyps per colonoscopy with CAD EYE® compared to standard colonoscopy (0.47 vs 0.36)[11]
CAD EYE® - hyperplastic polyps per patient				
1 parallel RCT, 1627 participants[11]	Median 1.0 (IQR 1.0 to 2.0)	Median 1.0 (IQR 1.0 to 2.0)	NR	• Single study • Median values only
ENDO-AID™ - non-neoplastic resections per colonoscopy				
1 parallel RCT, 766 participants[14]	Mean 1.17	Mean 0.61	MD 0.56 (0.36 to 0.76)	• Single study
ENDO-AID™ - diminutive hyperplastic polyps per colonoscopy				
1 parallel RCT, 682 participants[15]	Mean 0.70	Mean 0.40	MD 0.30 (0.28 to 0.32)	• Single study
GI Genius™ - hyperplastic polyps per colonoscopy				
2 parallel RCTs, 1044 participants[1, 46]	Mean 0.44	Mean 0.46	MD -0.02 (-0.19 to 0.15)	• Some statistical heterogeneity suggested (I^2 = 57%

				and point estimates vary)
GI Genius™ - Inflammatory polyps or normal mucosa per colonoscopy				
1 parallel RCT, 614 participants[1]	Mean 0.30	Mean 0.30	MD 0.00 (-0.10 to 0.10)	• Single study
Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial.				

2.2.2 *Hyperplastic polyp miss rate*

Table 36. Summary of analyses for hyperplastic polyp miss rate

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
EndoScreener®				
1 parallel RCT, 223 participants[35]	13/55 (23.64%)	16/41 (39.02%)	RR 0.61 (0.33 to 1.11)	• Single study
Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.				

2.2.3 *Patients with only hyperplastic polyps*

Table 37. Summary of analyses for patients with only hyperplastic polyps

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
1 parallel RCT, 1627 participants[11]	69/812 (8.50%)	66/815 (8.10%)	RR 1.05 (0.76 to 1.45)	• Single study
Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.				

2.3 Adenocarcinoma, neoplasia or colorectal cancer outcomes

Outcomes specifically referring to colorectal cancer or similar outcomes such as adenocarcinoma detected by the colonoscopy were infrequently reported but have been covered here given these are clinically important lesions. Detection rate outcomes (Table 38) and per colonoscopy outcomes (Table 39) were reported, as well as a single abstract reporting neoplasia miss rate for one intervention (Table 40). Data for these outcomes suggest limited differences between AI-supported and standard colonoscopy, with no statistically significant differences identified across analyses, although this may be partially due to the relatively low number of these types of events observed within studies.

2.3.1 Adenocarcinoma detection rate or other similar detection rate outcomes

Table 38. Summary of analyses for adenocarcinoma detection rate or other similar detection rate outcomes

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
ENDO-AID™ - advanced neoplasia detection rate				
1 parallel RCT, 312 participants[13]	20/155 (12.9%)	21/157 (13.38%)	RR 0.96 (0.55 to 1.71)	• Single study
ENDO-AID™ - colorectal cancer detection rate				
1 parallel RCT, 312 participants[13]	3/155 (1.94%)	4/157 (2.55%)	RR 0.76 (0.17 to 3.34)	• Single study
GI Genius™ - adenocarcinoma detection rate				
3 parallel RCTs, 2445 participants[21, 22, 24]	10/1221 (0.82%)	9/1224 (0.74%)	Peto OR 1.12 (0.45 to 2.77)	• Substantial statistical heterogeneity suggested (I^2 = 80% and point estimates vary)
GI Genius™ - advanced neoplasia detection rate				
2 parallel RCTs, 3898 participants[21]	605/1951 (31.01%)	589/1947 (30.25%)	RR 1.03 (0.91 to 1.16)	• Some heterogeneity noted based on visual differences in point estimates
GI Genius™ - cancer detection rate				
2 parallel RCTs, 5226 participants[23]	95/2612 (3.64%)	89/2614 (3.40%)	RR 1.07 (0.80 to 1.42)	• Some heterogeneity noted based on visual differences in point estimates

Abbreviations: CADe, computer-aided detection; CI, confidence interval; OR, odds ratio; RCT, randomised controlled trial; RR, risk ratio.

2.3.2 *Adenocarcinoma or other similar outcomes per colonoscopy*

Table 39. Summary of analyses for adenocarcinoma or other similar outcomes per colonoscopy

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CADDIE™ - neoplastic polyps per colonoscopy				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CAD EYE® - submucosal adenocarcinoma per colonoscopy				
1 parallel RCT, 800 participants[29]	Mean 0.01	Mean 0.01	MD 0.00 (-0.01 to 0.01)	• Single study
CAD EYE® - advanced carcinoma per colonoscopy				
1 parallel RCT, 800 participants[29]	Mean 0.03	Mean 0.03	MD 0.00 (-0.03 to 0.03)	• Single study
CAD EYE® - invasive cancer per colonoscopy				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.01	Mean 0.03	MD -0.02 (-0.05 to 0.01)	• Single study
CAD EYE® - neoplasias per colonoscopy				
1 parallel RCT, 1031 participants[7]	Mean 1.20	Mean 1.00	MD 0.20 (0.00 to 0.40)	• Single study
CAD EYE® - colorectal cancers detected				
No formal analysis possible[8]				• One study in Lynch syndrome reported two CRCs in a single patient in AI group (of 50 procedures), with none mentioned in standard colonoscopy group (of 47 procedures)
GI Genius™ - invasive carcinoma per colonoscopy				

1 parallel RCT, 430 participants[46]	Mean 0.00	Mean 0.01	MD -0.01 (-0.03 to 0.01)	• Single study
GI Genius™ - advanced colorectal neoplasias per colonoscopy				
1 parallel RCT, 3213 participants[20]	Mean 0.54	Mean 0.52	MD 0.02 (-0.05 to 0.09)	• Single study
GI Genius™ - advanced lesions (adenomas or serrated lesions) per colonoscopy				
1 parallel RCT, 430 participants[46]	Mean 0.06	Mean 0.09	MD -0.03 (-0.09 to 0.03)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; CRC, colorectal cancer; MD, mean difference; RCT, randomised controlled trial.

2.3.3 *Neoplasia miss rate*

Table 40. Summary of analyses for neoplasia miss rate

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
No formal analysis possible[52]				• One non-randomised study (abstract only) reports no difference (no further details) between AI and standard colonoscopy for neoplasia miss rate • Specific to ulcerative colitis patients, 133 lesions of which 18 are neoplastic (62 patients)

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CI, confidence interval.

2.4 Other adenoma outcomes

Other adenoma-based outcomes not covered in the main report are included here. Overall, the External Assessment Group (EAG) considers data to either be limited given reporting by only one or two studies and for few interventions, or notes a lack of trends across interventions, with few events and difficulty drawing robust conclusions about differences between size, location or histological categories.

Most analyses for adenomas per positive patient or per extraction indicated differences that were small and not statistically significant, with very few studies across interventions reporting these data (Table 41). Only one study for MAGENTIQ-COLO™ reported a statistically significant difference for adenomas per extraction, with a higher value in the standard colonoscopy group, suggesting a higher proportion of adenomas identified with AI may have been non-adenomas.

Only one study across all interventions reported data for advanced adenoma miss rate (AMR; Table 42) and missed adenomas per colonoscopy (APC; Table 43). Neither demonstrated statistically significant differences, with results being very similar for both outcomes when reported for EndoScreener® and CAD EYE®, respectively. Some data for missed APC were available broken down by size (Table 44), location (Table 45) and high- or low-grade dysplasia (Table 46). Only very small and non-significant differences were identified for CAD EYE® for <5, 5 to 9 and >10 mm categories from a single study. For location, one study reported missed APC across six different colon regions, with all mean differences being fairly small and not statistically significant. Similarly, one study for CAD EYE® reported no difference compared to standard colonoscopy in terms of missed adenomas that were low-grade or high-grade when considered separately.

For adenoma detection rate (ADR) by location, there were data for six interventions from at least one study (Table 47). When proximal and distal ADR were reported for the same intervention, results for CAD EYE® suggested no substantial difference between these categories, with ADR being higher with AI in both (statistically significant). Similar results were observed for GI Genius™, with statistically significant results favouring GI Genius™ in both categories, but the point estimate for distal ADR was notably larger compared to proximal ADR. Results for Discovery™ were in opposite directions for proximal and distal ADR (better with AI for proximal ADR, better with standard colonoscopy for distal ADR), although none of these results for Discovery™ were statistically significant.

ADR by location data for ENDO-AID™ were available when classified as left- or right-sided; there was a notable difference in point estimates between these two categories (larger impact on right-sided ADR) but both had a trend for ADR being higher with AI compared to standard colonoscopy. However, effect was only statistically significant for right-sided ADR and there was notable heterogeneity in both analyses. When considering the transverse colon, a statistically significant improvement in ADR was seen with AI in this location, with no obvious heterogeneity.

Two randomised controlled trials (RCTs) for ENDOANGEL® reported ADR in six different locations within the colon; results in all categories apart from the descending colon suggested a higher ADR with AI compared to standard colonoscopy, although the difference was only statistically significant for one analysis (ascending colon) and heterogeneity is a concern for many of these analyses.

[redacted]

Results for APC when divided by location were similar to those observed for ADR by location (Table 50); while there were some slight differences between location categories in some cases, this was not consistent across interventions. Point estimates for most analyses suggested increased APC with AI regardless of location, although many differences were not statistically significant.

Limited information for ADR or APC by high- or low-grade dysplasia were available for ENDO-AID™ or CAD EYE® interventions. Results for high-grade dysplasia ADR for ENDO-AID™ suggested that more patients with these were detected with standard colonoscopy, although the difference was not statistically significant (Table 48). With regards to high-grade and low-grade dysplasia APC reported for CAD EYE®, results suggested a lower APC for low-grade adenomas with AI compared to standard colonoscopy, with a slightly higher APC for high-grade adenomas with AI noted, although none of these differences were statistically significant (Table 51).

One study reported advanced ADR (Table 49) and advanced APC (Table 52) specifically for proximal location; results for both suggested increased detection with GI Genius™ compared to standard colonoscopy, although none of the differences were statistically significant.

Results for AMR by size were similar to AMR results overall, with most analyses suggesting a benefit of AI in terms of reducing missed lesions within specific size categories (Table 53). Most of these were statistically significant differences, with the exception of two analyses for GI Genius™ in 6 to 9 mm and ≥10 mm categories. The only analysis where the point estimate suggested a worse AMR with AI was for EndoScreener® in the ≥10 mm category, which was not a statistically significant difference.

A similar finding noted for AMR by location, with all but one analysis indicating reduced missed lesions with AI compared to standard colonoscopy (Table 54). However, many of these were not statistically significant. The one analysis that suggested more missed lesions with AI was for ENDOANGEL® within the caecum and was based on only one missed lesion between the two groups.

2.4.1 *Adenomas per positive patient or per extraction*

Table 41. Summary of analyses for adenomas per positive patient or per extraction

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - adenomas per positive patient				
1 tandem RCT, 222 participants[3]	Mean 2.04	Mean 2.12	MD -0.08 (-0.45 to 0.29)	• Single study
CADDIE™ - adenomas divided by number of extractions				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - positive percent agreement (percent of histologically confirmed adenomas, sessile serrated adenomas and large >10 mm hyperplastic polyps of proximal colon)				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
ENDO-AID™ - adenoma or advanced adenomas detected per polypectomy (therapeutic ratio)				
No formal analysis possible[15]				• Ratios between groups very similar (0.58, 0.61 and 0.66 for ENDO-AID™ + ENDOCUFF VISION™, ENDO-AID™ only and standard colonoscopy, respectively), with no statistically significant difference noted (p-value NR)
MAGENTIQ-COLO™ - per-patient adenomas per extraction				
1 parallel/tandem RCT (parallel arms only), 916 participants[31]	Mean 0.31	Mean 0.27	MD 0.04 (-0.02 to 0.10)	• Single study
MAGENTIQ-COLO™ - adenomas per extraction				
No formal analysis possible[31]				• Higher adenomas per extraction value with AI compared to standard

	colonoscopy (0.59 vs 0.66), which was a statistically significant difference (p-value <0.001)

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NR, not reported; RCT, randomised controlled trial; RR, risk ratio.

2.4.2 Advanced adenoma miss rate

Table 42. Summary of analyses for advanced adenoma miss rate

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
EndoScreener®				
2 tandem RCTs, 592 participants[35, 36]	2/11 (18.18%)	3/17 (17.65%)	RR 1.95 (0.44 to 8.58)	NA

Abbreviations: CADe, computer-aided detection; CI, confidence interval; NA, not applicable; RCT, randomised controlled trial; RR, risk ratio.

2.4.3 Missed adenomas per colonoscopy

Table 43. Summary of analyses for missed adenomas per colonoscopy

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE®				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.50	Mean 0.90	MD -0.40 (-0.66 to -0.14)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference.

2.4.4 *Missed adenomas per colonoscopy separated by size*

Table 44. Summary of analyses for missed adenomas per colonoscopy by size

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - missed adenomas <5 mm				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.80	Mean 0.83	MD -0.03 (-0.13 to 0.07)	• Single study
CAD EYE® - missed adenomas 5 to 9 mm				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.20	Mean 0.15	MD 0.05 (-0.05 to 0.15)	• Single study
CAD EYE® - missed adenomas >10 mm per colonoscopy				
No formal analysis possible[33]				• No statistically significant difference (p-value 0.158) for missed adenomas of this size between groups (mean 0.00 vs mean 0.02; 2 events in standard colonoscopy group, 0 with AI)

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CI, confidence interval; MD, mean difference.

2.4.5 *Missed adenomas per colonoscopy separated by location*

Table 45. Summary of analyses for missed adenomas per colonoscopy by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - missed adenomas in caecum				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.09	Mean 0.04	MD 0.05 (-0.01 to 0.11)	• Single study
CAD EYE® - missed adenomas in ascending colon				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.29	Mean 0.35	MD -0.06 (-0.18 to 0.06)	• Single study
CAD EYE® - missed adenomas in transverse colon				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.26	Mean 0.24	MD 0.02 (-0.09 to 0.13)	• Single study
CAD EYE® - missed adenomas in descending colon				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.17	Mean 0.13	MD 0.04 (-0.05 to 0.13)	• Single study
CAD EYE® - missed adenomas in sigmoid colon				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.17	Mean 0.22	MD -0.05 (-0.15 to 0.05)	• Single study
CAD EYE® - missed adenomas in rectum				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 0.04	Mean 0.02	MD 0.02 (-0.01 to 0.05)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference.

2.4.6 *Missed adenomas per colonoscopy separated by high- or low-grade dysplasia*

Table 46. Summary of analyses for missed adenomas per colonoscopy by high- or low-grade dysplasia

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - missed adenomas with low-grade dysplasia per colonoscopy				
No formal analysis possible[33]				• No statistically significant difference (p-value 0.320) for missed adenomas of this histology between groups (mean 1.00 [54 events] vs 0.99 [104 events] for AI and standard colonoscopy groups, respectively)
CAD EYE® - missed adenomas with high-grade dysplasia per colonoscopy				
No formal analysis possible[33]				• No statistically significant difference (p-value 0.320) for missed adenomas of this histology between groups (mean 0.00 [0 events] vs 0.01 [1 event] for AI and standard colonoscopy groups, respectively)

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; CI, confidence interval.

2.4.7 *ADR separated by location*

Table 47. Summary of analyses for ADR by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - distal ADR				
3 parallel RCTs, 2512 participants[6, 9, 10]	463/1254 (36.92%)	369/1258 (29.33%)	RR 1.26 (1.13 to 1.41)	NA
CAD EYE® - proximal ADR				
5 parallel RCTs, 4939 participants[4, 6, 9-11]	783/2466 (34.11%)	663/2473 (27.68%)	RR 1.18 (1.08 to 1.29)	NA
CADDIE™ - proximal ADR				

[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
Discovery™ - proximal ADR				
1 parallel RCT, 497 participants[26]	72/250 (28.80%)	53/247 (21.46%)	RR 1.34 (0.99 to 1.83)	• Single study
Discovery™ - distal ADR				
1 parallel RCT, 497 participants[26]	41/250 (16.40%)	49/247 (19.84%)	RR 0.83 (0.57 to 1.20)	• Single study
ENDO-AID™ - right-sided ADR				
2 parallel RCTs, 1078 participants[13, 14]	219/541 (40.48%)	150/537 (27.93%)	RR 1.47 (1.17 to 1.84)	• Some heterogeneity noted based on visual differences in point estimates • Transverse included as right-sided for one study but not the other
ENDO-AID™ - left-sided ADR				
2 parallel RCTs, 1078 participants[13, 14]	178/541 (32.90%)	154/537 (28.68%)	RR 1.11 (0.84 to 1.47)	• Some statistical heterogeneity suggested (I^2 = 52% and point estimates vary)
ENDO-AID™ - transverse colon ADR				
2 parallel RCTs, 1078 participants[13, 14]	126/541 (23.29%)	75/537 (13.97%)	RR 1.67 (1.29 to 2.16)	NA
ENDOANGEL® - caecum ADR				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	3/495 (0.61%)	2/500 (0.40%)	Peto OR 1.51 (0.26 to 8.75)	• Some statistical heterogeneity suggested (I^2 = 45% and point estimates vary)
ENDOANGEL® - ascending colon ADR				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	31/495 (6.26%)	14/500 (2.80%)	RR 2.24 (1.20 to 4.15)	NA
ENDOANGEL® - transverse ADR				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	25/495 (5.05%)	21/500 (4.20%)	RR 1.20 (0.68 to 2.12)	• Some heterogeneity noted based on visual differences in point estimates
ENDOANGEL® - descending ADR				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	11/495 (2.22%)	13/500 (2.60%)	RR 0.85 (0.39 to 1.89)	• Some statistical heterogeneity suggested (I^2 =

				34% and point estimates vary)
ENDOANGEL® - sigmoid ADR				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	36/495 (7.27%)	25/500 (5.00%)	RR 1.45 (0.89 to 2.39)	NA
ENDOANGEL® - rectum ADR				
2 RCTs (1 tandem, 1 parallel), 995 participants[17, 18]	16/495 (3.23%)	13/500 (2.60%)	RR 1.24 (0.61 to 2.55)	• Some heterogeneity noted based on visual differences in point estimates
GI Genius™ - proximal ADR				
3 parallel RCTs, 4558 participants[20-22]	962/2281 (42.17%)	826/2277 (36.28%)	RR 1.16 (1.08 to 1.25)	NA
GI Genius™ - distal ADR				
2 parallel RCTs, 1345 participants[21, 22]	209/671 (31.15%)	145/674 (21.51%)	RR 1.45 (1.20 to 1.74)	NA

Abbreviations: ADR, adenoma detection rate; CADe, computer-aided detection; CI, confidence interval; NA, not applicable; RCT, randomised controlled trial; RR, risk ratio.

2.4.8 ADR separated by high- or low-grade dysplasia

Table 48. Summary of analyses for ADR by histology

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
ENDO-AID™ - high-grade dysplasia ADR				
1 parallel RCT, 310 participants[13]	6/155 (3.87%)	7/155 (4.52%)	RR 0.86 (0.29 to 2.49)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.

2.4.9 Advanced ADR separated by location

Table 49. Summary of analyses for advanced ADR by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - proximal advanced ADR				
1 parallel RCT, 3213 participants[20]	163/1610 (10.12%)	148/1603 (9.23%)	RR 1.10 (0.89 to 1.35)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.

2.4.10 APC separated by location

Table 50. Summary of analyses for APC by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - distal APC				
1 parallel RCT, 800 participants[9]	Mean 0.18	Mean 0.18	MD -0.01 (-0.11 to 0.09)	• Single study
CAD EYE® - proximal APC				
3 parallel RCTs, 2845 participants[4, 6, 9]	Mean 0.73	Mean 0.53	MD 0.20 (0.12 to 0.28)	NA
CAD EYE® - APC in caecum				
1 parallel RCT, 800 participants[29]	Mean 0.10	Mean 0.06	MD 0.04 (0.00 to 0.08)	• Single study
CAD EYE® - APC in ascending colon				
1 parallel RCT, 800 participants[29]	Mean 0.30	Mean 0.20	MD 0.10 (0.02 to 0.18)	• Single study
CAD EYE® - APC in transverse colon				
1 parallel RCT, 800 participants[29]	Mean 0.28	Mean 0.21	0.07 (-0.02 to 0.16)	• Single study
CAD EYE® - APC in descending colon				
1 parallel RCT, 800 participants[29]	Mean 0.19	Mean 0.13	MD 0.06 (-0.01 to 0.13)	• Single study
CAD EYE® - APC in sigmoid colon				

1 parallel RCT, 800 participants[29]	Mean 0.36	Mean 0.28	MD 0.08 (-0.01 to 0.17)	• Single study
CAD EYE® - APC in rectum				
1 parallel RCT, 800 participants[29]	Mean 0.11	Mean 0.07	MD 0.04 (0.00 to 0.08)	• Single study
CADDIE™ - proximal APC				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - distal APC				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
ENDO-AID™ - right-sided APC				
2 parallel RCTs, 1078 participants[13, 14]	Mean 0.77	Mean 0.40	MD 0.38 (0.24 to 0.51)	• Transverse included as right-sided for one study but not the other
ENDO-AID™ - left-sided APC				
2 parallel RCTs, 1078 participants[13, 14]	Mean 0.53	Mean 0.40	MD 0.15 (0.03 to 0.28)	• Some heterogeneity noted based on visual differences in point estimates
ENDO-AID™ - transverse colon APC				
1 parallel RCT, 312 participants[13]	Mean 0.41	Mean 0.18	MD 0.23 (0.05 to 0.41)	• Single study
GI Genius™ - proximal APC				
5 parallel RCTs, 6088 participants[20-22, 24, 46]	Mean 0.66	Mean 0.56	MD 0.12 (0.05 to 0.19)	• Some heterogeneity noted based on visual differences in point estimates
GI Genius™ - distal APC				
4 parallel RCTs, 2875 participants[21, 22, 24, 46]	Mean 0.35	Mean 0.23	MD 0.11 (0.06 to 0.16)	NA

Abbreviations: APC, adenomas per colonoscopy; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NA, not applicable; RCT, randomised controlled trial.

2.4.11 APC separated by high- or low-grade dysplasia

Table 51. Summary of analyses for APC by histology

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - adenomas with low-grade dysplasia per colonoscopy				
1 parallel with tandem procedures performed by experts, 231 participants[33]	Mean 1.76	Mean 2.14	MD -0.38 (-0.99 to 0.23)	• Single study
CAD EYE® - adenomas with high-grade dysplasia per colonoscopy				
2 RCTs (1 parallel, 1 parallel with tandem procedures performed by experts), 1031 participants[29, 33]	Mean 0.08	Mean 0.06	MD 0.03 (-0.01 to 0.06)	NA

Abbreviations: APC, adenomas per colonoscopy; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; NA, not applicable; RCT, randomised controlled trial.

2.4.12 Advanced APC separated by location

Table 52. Summary of analyses for advanced APC by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - proximal advanced APC				
1 parallel RCT, 3213 participants[20]	Mean 0.14	Mean 0.12	MD 0.02 (-0.01 to 0.05)	• Single study

Abbreviations: APC, adenomas per colonoscopy; CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial.

2.4.13 AMR separated by size

Table 53. Summary of analyses for AMR by size

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
ENDOANGEL® - AMR ≤5 mm				
1 tandem RCT, 456 participants[18]	10/52 (19.23%)	33/75 (44.00%)	RR 0.44 (0.24 to 0.81)	• Single study
ENDOANGEL® - AMR 6 to 9 mm				
1 tandem RCT, 456 participants[18]	6/23 (26.09%)	8/19 (42.11%)	RR 0.62 (0.26 to 1.47)	• Single study
ENDOANGEL® - AMR ≥10 mm				
1 tandem RCT, 456 participants[18]	0/10 (0.00%)	4/9 (44.44%)	Peto OR 0.08 (0.01 to 0.68)	• Single study
EndoScreener® - AMR <5 mm				
No formal analysis possible[36]				• Lower AMR with EndoScreener® vs standard colonoscopy (13.11 vs 39.66%), which is statistically significant (p-value 0.0015) • Single study
EndoScreener® - AMR 6 to 9 mm				
No formal analysis possible[36]				• Lower AMR with EndoScreener® vs standard colonoscopy (13.75 vs 46.94%), which is statistically significant (p-value <0.0001) • Single study
EndoScreener® - AMR ≥10 mm				
No formal analysis possible[36]				• Higher AMR with EndoScreener® vs standard colonoscopy (33.33 vs 15.38%), which is not statistically significant (p-value 0.4842) • Single study
GI Genius™ - AMR ≤5 mm				
1 tandem RCT, 230 participants[37]	29/183 (15.85%)	69/193 (35.75%)	RR 0.44 (0.30 to 0.65)	• Single study

GI Genius™ - AMR 6 to 9 mm				
1 tandem RCT, 230 participants[37]	6/29 (20.69%)	8/35 (22.86%)	RR 0.91 (0.35 to 2.31)	• Single study
GI Genius™ - AMR <10 mm				
1 tandem RCT, 230 participants[37]	35/212 (16.51%)	77/228 (33.77%)	RR 0.49 (0.34 to 0.70)	• Single study
GI Genius™ - AMR ≥10 mm				
1 tandem RCT, 230 participants[37]	2/33 (6.06%)	3/19 (15.79%)	Peto OR 0.33 (0.05 to 2.22)	• Single study

Abbreviations: AMR, adenoma miss rate; CADe, computer-aided detection; CI, confidence interval; OR, odds ratio; RCT, randomised controlled trial; RR, risk ratio.

2.4.14 AMR separated by location

Table 54. Summary of analyses for AMR by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
ENDOANGEL® - caecum AMR				
1 tandem RCT, 456 participants[18]	1/4 (25.00%)	0/1 (0.00%)	RR 1.20 (0.08 to 18.75)	• Single study
ENDOANGEL® - ascending colon AMR				
1 tandem RCT, 456 participants[18]	3/18 (16.67%)	5/15 (33.33%)	RR 0.50 (0.14 to 1.76)	• Single study
ENDOANGEL® - transverse colon AMR				
1 tandem RCT, 456 participants[18]	6/19 (31.58%)	12/29 (41.38%)	RR 0.76 (0.35 to 1.68)	• Single study
ENDOANGEL® - descending colon AMR				
1 tandem RCT, 456 participants[18]	1/6 (16.67%)	8/18 (44.44%)	RR 0.38 (0.06 to 2.41)	• Single study
ENDOANGEL® - sigmoid colon AMR				
1 tandem RCT, 456 participants[18]	4/25 (16.00%)	15/27 (55.56%)	RR 0.29 (0.11 to 0.75)	• Single study
ENDOANGEL® - rectum AMR				
1 tandem RCT, 456 participants[18]	1/13 (7.69%)	5/13 (38.46%)	RR 0.20 (0.03 to 1.48)	• Single study
EndoScreener® - caecum AMR				
No formal analysis possible[36]				• Lower AMR with EndoScreener® vs

	standard colonoscopy (0.00 vs 50.00%), which is not statistically significant (p-value 0.5473) • Single study
EndoScreener® - ascending colon AMR	
No formal analysis possible[36]	• Lower AMR with EndoScreener® vs standard colonoscopy (6.67 vs 39.13%), which is statistically significant (p-value 0.0095) • Single study
EndoScreener® - transverse colon AMR	
No formal analysis possible[36]	• Lower AMR with EndoScreener® vs standard colonoscopy (16.33 vs 45.16%), which is statistically significant (p-value 0.0065) • Single study
EndoScreener® - descending colon AMR	
No formal analysis possible[36]	• Lower AMR with EndoScreener® vs standard colonoscopy (12.50 vs 40.91%), which is statistically significant (p-value 0.0364) • Single study
EndoScreener® - sigmoid colon AMR	
No formal analysis possible[36]	• Lower AMR with EndoScreener® vs standard colonoscopy (18.18 vs 40.62%), which is not statistically significant (p-value 0.0514) • Single study
EndoScreener® - rectum AMR	
No formal analysis possible[36]	• Same AMR with EndoScreener® vs standard colonoscopy (20.00% for both; p-value >0.99) • Single study
GI Genius™ - proximal AMR	

1 tandem RCT, 230 participants[37]	28/153 (18.30%)	54/166 (32.53%)	RR 0.56 (0.38 to 0.84)	• Single study
GI Genius™ - distal AMR				
1 tandem RCT, 230 participants[37]	10/93 (10.75%)	26/81 (32.10%)	RR 0.33 (0.17 to 0.65)	• Single study

Abbreviations: AMR, adenoma miss rate; CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.

2.5 Serrated lesion outcomes

Other outcomes related to serrated lesions were reported infrequently by studies but have been included here given the relevance of serrated lesions in terms of potential for development into cancer. This includes additional detection rate outcomes (Table 55), miss rate (Table 58) and per colonoscopy outcomes (Table 59). SSLs per colonoscopy broken down by size (Table 62) and location (Table 63) were also reported by one study, and some studies reported data for other serrated outcomes by size and location (Table 56, Table 57, Table 60 and Table 61). The EAG does not consider these data add much to data presented in the main report given the infrequency of their reporting, but notes that trends for increases in detection (and reduced miss rates) of these lesions with AI were observed for most analyses, with some being statistically significant differences. One additional study reported data for SSL detection rate separated by location, size and histology (with or without dysplasia), but it was unclear if these were reported on a per colonoscopy basis or as the proportion of patients with at least one lesion.[9]

2.5.1 Detection rate-based serrated lesion outcomes

Table 55. Summary of analyses for detection rate-based serrated lesion outcomes

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - serrated lesion detection rate				
1 parallel RCT, 1031 participants[7]	181/509 (35.56%)	152/522 (29.12%)	RR 1.22 (1.02 to 1.46)	• Single study
ENDO-AID™ - serrated neoplasia detection rate				
1 parallel RCT, 312 participants[13]	9/155 (5.81%)	5/157 (3.18%)	RR 1.82 (0.63 to 5.32)	• Single study
GI Genius™ - serrated lesion detection rate				

1 parallel RCT, 3213 participants[20]	343/1610 (21.30%)	273/1603 (17.03%)	RR 1.25 (1.08 to 1.44)	• Single study
GI Genius™ - advanced serrated lesion detection rate				
1 parallel RCT, 3213 participants[20]	104/1610 (6.46%)	84/1603 (5.24%)	RR 1.23 (0.93 to 1.63)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.

2.5.2 *Detection rate-based serrated lesion outcomes separated by size*

Table 56. Summary of analyses for detection-based serrated lesion outcomes by size

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - ≤5 mm serrated lesion DR				
1 parallel RCT, 3213 participants[20]	246/1610 (15.28%)	198/1603 (12.35%)	RR 1.24 (1.04 to 1.47)	• Single study
GI Genius™ - 6 to 9 mm serrated lesion DR				
1 parallel RCT, 3213 participants[20]	95/1610 (5.90%)	80/1603 (4.99%)	RR 1.18 (0.89 to 1.58)	• Single study
GI Genius™ - ≥10 mm serrated lesion DR				
1 parallel RCT, 3213 participants[20]	86/1610 (5.34%)	60/1603 (3.74%)	RR 1.43 (1.03 to 1.97)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.

2.5.3 *Detection rate-based serrated lesion outcomes by location*

Table 57. Summary of analyses for detection rate-based serrated lesion outcomes by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - proximal advanced serrated lesion DR				
1 parallel RCT, 3213 participants[20]	55/1610 (3.42%)	48/1603 (2.99%)	RR 1.14 (0.78 to 1.67)	• Single study
GI Genius™ - proximal serrated lesion DR				

3 parallel RCTs, 5658 participants[19, 20, 46]	411/2827 (14.54%)	347/2831 (12.26%)	RR 1.19 (1.04 to 1.35)	NA

Abbreviations: CADe, computer-aided detection; CI, confidence interval; NA, not applicable; RCT, randomised controlled trial; RR, risk ratio.

2.5.4 *Miss rate-based serrated lesion outcomes*

Table 58. Summary of analyses for miss rate-based serrated lesion outcomes

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
EndoScreener® - sessile serrated adenoma/polyp miss rate				
1 tandem RCT, 369 participants[36]	1/1 (100.00%)	2/3 (66.67%)	RR 1.20 (0.40 to 3.62)	• Single study
EndoScreener® - sessile serrated lesion miss rate				
1 tandem RCT, 223 participants[35]	1/14 (7.14%)	8/19 (42.11%)	RR 0.17 (0.02 to 1.21)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; RCT, randomised controlled trial; RR, risk ratio.

2.5.5 *Per colonoscopy-based serrated lesion outcomes*

Table 59. Summary of analyses for per colonoscopy-based serrated lesion outcomes

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
CAD EYE® - sessile serrated adenomas/polyps per colonoscopy				
1 parallel with tandem procedures performed by experts, 231	Mean 0.01	Mean 0.03	MD -0.02 (-0.06 to 0.02)	• Single study

participants[3] [3]				
CAD EYE® - traditional serrated adenoma per colonoscopy				
1 parallel RCT, 800 participants[2] [9]	Mean 0.06	Mean 0.02	MD 0.04 (0.01 to 0.07)	• Single study
CAD EYE® - serrated lesions per colonoscopy				
1 parallel RCT, 1038 participants[7]	Mean 0.69	Mean 0.48	MD 0.21 (0.08 to 0.35)	• Single study
CADDIE™ - sessile serrated adenomas per colonoscopy (definition 1)				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
CADDIE™ - sessile serrated adenomas per colonoscopy (definition 2)				
[redacted]	[redacted]	[redacted]	[redacted]	• [redacted]
GI Genius™ - serrated polyps per colonoscopy				
3 parallel RCTs, 4257 participants[1, 20, 46]	Mean 0.62	Mean 0.56	MD 0.07 (0.00 to 0.13)	• Some heterogeneity noted based on visual differences in point estimates
GI Genius™ - advanced serrated lesions per colonoscopy				
2 parallel RCTs, 3643 participants[20, 46]	Mean 0.06	Mean 0.06	MD 0.01 (-0.02 to 0.04)	• Some heterogeneity noted based on visual differences in point estimates

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial.

2.5.6 *Per colonoscopy-based serrated lesion outcomes separated by size*

Table 60. Summary of analyses for per colonoscopy-based serrated lesion outcomes by size

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - <5 mm serrated polyps per colonoscopy				

1 parallel RCT, 3213 participants[20]	Mean 0.25	Mean 0.19	MD 0.06 (0.01 to 0.11)	• Single study
GI Genius™ - 5 to 9 mm serrated polyps per colonoscopy				
1 parallel RCT, 3213 participants[20]	Mean 0.07	Mean 0.08	MD -0.01 (-0.04 to 0.02)	• Single study
GI Genius™ - ≥10 mm serrated polyps per colonoscopy				
1 parallel RCT, 3213 participants[20]	Mean 0.07	Mean 0.05	MD 0.02 (0.00 to 0.04)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial.

2.5.7 *Per colonoscopy-based serrated lesion outcomes separated by location*

Table 61. Summary of analyses for per colonoscopy-based serrated lesion outcomes by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - proximal advanced serrated lesions per colonoscopy				
1 parallel RCT, 3213 participants[20]	Mean 0.05	Mean 0.04	MD 0.01 (-0.01 to 0.03)	• Single study
GI Genius™ - proximal serrated lesions per colonoscopy				
1 parallel RCT, 3213 participants[20]	Mean 0.25	Mean 0.19	MD 0.06 (0.01 to 0.11)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial.

2.5.8 *Sessile serrated lesions per colonoscopy separated by size*

Table 62. Summary of analyses for SSL per colonoscopy by size

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - <5 mm SSL per colonoscopy				
1 parallel RCT, 430 participants[46]	Mean 0.41	Mean 0.39	MD 0.02 (-0.14 to 0.18)	• Single study

GI Genius™ - 5 to 9 mm SSL per colonoscopy				
1 parallel RCT, 430 participants[46]	Mean 0.14	Mean 0.06	MD 0.08 (0.01 to 0.15)	• Single study
GI Genius™ - ≥10 mm SSL per colonoscopy				
1 parallel RCT, 430 participants[46]	Mean 0.01	Mean 0.02	MD -0.01 (-0.04 to 0.02)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial; SSL, sessile serrated lesion.

2.5.9 Sessile serrated lesions per colonoscopy separated by location

Table 63. Summary of analyses for SSL per colonoscopy by location

Study type, number of studies, number of participants	Absolute effect CADe	Absolute effect standard colonoscopy	Effect estimate (95% CI)	Comments
GI Genius™ - proximal SSL per colonoscopy				
1 parallel RCT, 430 participants[46]	Mean 0.27	Mean 0.24	MD 0.03 (-0.08 to 0.14)	• Single study
GI Genius™ - distal SSL per colonoscopy				
1 parallel RCT, 430 participants[46]	Mean 0.31	Mean 0.21	MD 0.10 (-0.03 to 0.23)	• Single study

Abbreviations: CADe, computer-aided detection; CI, confidence interval; MD, mean difference; RCT, randomised controlled trial; SSL, sessile serrated lesion.

3 Quality assessment – clinical

3.1 Cochrane Risk of Bias 2 tool

Table 64. Risk of bias assessment conducted at the study level by the EAG for RCTs included in the EAG SLR – Cochrane Risk of Bias 2 tool

Study	Domain 1 – randomisation process	Domain 2 – deviations from intended interventions	Domain 3 – missing outcome data	Domain 4 – measurement of the outcome	Domain 5 – selection of the reported result	Overall bias	Comments
CAD EYE®							
Alali 2025[40]	**Some concerns** Computer-based randomisation with sealed envelopes for concealment. Mostly well-balanced but larger differences for gender and valve intubation, possibly due to small sample size.	**Low** Patients blinded, endoscopists aware of treatments but deviations from intended intervention unlikely. ITT analysis.	**Low** All randomised participants were analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention) and larger imbalances at baseline for gender and valve intubation.
Aniwan 2023[6]	**Low** Online randomisation, sealed envelopes for concealment. No concerns about baseline differences.	**Low** Patient and endoscopists aware of treatment but deviations from intended intervention unlikely. ITT analysis.	**Low** All randomised participants were analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Desai 2024[7]	**Low** Computer-based randomisation,	**Some concerns** Unclear if patients blinded, endoscopists	**Some concerns** ~9% of randomised participants were	**Some concerns** Endoscopists aware of intervention possibly	**Some concerns** No statistical analysis plan	**Some concerns**	Risk of bias mostly due to lack of endoscopist

	unclear concealment. No concerns about baseline differences.	not blinded. Some withdrawn if insufficient colonoscopy time. mITT analysis.	not analysed, similar in both groups.	introducing some operator bias, unclear if pathologists blinded.	identified but no major concerns about selective reporting.		blinding (although unavoidable for this type of intervention).
Djinbachian 2024[10]	**Low** Electronic randomisation process, with electronic concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists not blinded but deviations from intended intervention unlikely. ITT analysis.	**Low** All randomised participants were analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Hiratsuka 2025[34]	**Low** Random allocation method with minimisation described, no details on concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists not blinded but deviations from intended intervention unlikely. mITT analysis.	**Low** ~6% of randomised participants were not analysed, similar in both groups.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Huneburg 2023[8] – CADLY trial	**Some concerns** Online randomisation, sealed envelopes for concealment. Imbalance in proportion with prior extra-colonic cancer (higher in AI group; 38.0 vs 19.6%) but no concerns for other variables.	**Low** Patient and endoscopists aware of treatment but deviations from intended intervention unlikely. mITT analysis.	**Low** Only 5 patients (~5.0% randomised) excluded from analysis, similar in both groups .	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention) and imbalance in proportions with prior extra-colonic cancer.

Miyaguchi 2024[29]	**Low** Online randomisation, sealed envelopes for concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists not blinded. No concerns about deviations from intended intervention. ITT analysis.	**Low** All randomised participants were analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Nakashima 2023[3]	**Low** Computerised randomisation, allocation likely concealed by system. No concerns about baseline differences.	**Low** Patients blinded, endoscopists not blinded. No concerns about deviations from intended interventions. Unclear but possibly ITT analysis.	**Some concerns** Assume all randomised but unclear as lack of information about missing data in the published paper.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. Primary outcome aligns with registration but not all secondary outcomes listed there.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention) and lack of information regarding missing data
Rondonotti 2022[9] – AIFIT trial	**Low** Computerised randomisation, sealed envelopes for concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists not blinded. No concerns about deviations from intended interventions. mITT analysis.	**Low** <5% in each group excluded from analysis.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Scholer 2024[2a]	**Some concerns** Sealed envelopes used for randomisation. Imbalance in endoscopist	**Low** Patient and endoscopists aware of treatment. No concerns about deviations from intended interventions.	**High** ~16% those randomised excluded, including some before starting the	**Some concerns** Use of other lighting options encouraged in the AI group. Endoscopists aware of intervention possibly	**Some concerns** No statistical analysis plan identified. Limited outcomes reported for the group	**High**	Risk of bias mostly due to imbalance in endoscopist experience, missing data, and lack of endoscopist blinding (although

	experience is a concern (70.0 vs 85.0% experienced)	Possibly a mITT analysis.	procedure. Similar in both groups, but unclear breakdown for CAD EYE® specific groups.	introducing some operator bias, but pathologists blinded.	specifically receiving CAD EYE®.		unavoidable for this type of intervention).
Tiankanon 2024[4]	**Low** Computerised randomisation, allocation likely concealed by system. No concerns about baseline differences.	**Low** Patients and endoscopists not blinded. No information about deviations from intended interventions. ITT analysis.	**Low** All randomised participants appear to have been analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Yamaguchi 2024[33]	**Low** Computerised randomisation, allocation concealed through personnel not involved in other trial processes. No concerns about baseline differences.	**Low** Patients blinded, endoscopists not blinded. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~6% of randomised patients excluded from analysis	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Zimmermann-Fraedrich 2025[11]	**Low** Described as randomised with sealed envelopes for concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists not blinded but deviations from intended intervention unlikely. ITT analysis.	**Low** All randomised participants were analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
CADDIE™							

Odin Vision 2024 EAGLE trial CSR[41]	**Low** [redacted]	**Low** [redacted]	**Some concerns** [redacted]	**Some concerns** [redacted]	**Low** [redacted]	**Some concerns**	Risk of bias mostly due to concerns about missing data and lack of endoscopist blinding (although unavoidable for this type of intervention).
Odin Vision 2024 CADDIE trial CSR[12]	**Low** [redacted]	**Low** [redacted]	**Some concerns** [redacted]	**Some concerns** [redacted]	**Low** [redacted]	**Some concerns**	Risk of bias mostly due to concerns about missing data and lack of endoscopist blinding (although unavoidable for this type of intervention).
Discovery™							
Maas 2024 - Discovery™[26] – DISCOVERY II trial	**Low** Online randomisation, allocation likely concealed by system. No concerns about baseline differences.	**Low** Patient and endoscopists aware of treatment. No concerns about deviations from intended interventions. ITT/mITT analyses.	**Some concerns** ~15% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to concerns about missing data and lack of endoscopist blinding (although unavoidable for this type of intervention).
ENDO-AID™							

Gimeno-Garcia 2023[13]	**Low** Computerised randomisation, sealed envelopes for concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. ITT analysis for primary outcome.	**Low** All randomised participants analysed in ITT analysis.	**Some concerns** More advanced processor used in AI group. Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to concerns about difference in processor used between groups and lack of endoscopist blinding (although unavoidable for this type of intervention).
Lau 2024[14] – ENDOAIDT RAIN trial	**Low** Computerised randomisation, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Some concerns** ~11% randomised participants excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to concerns about lack of endoscopist blinding (although unavoidable for this type of intervention).
Lui 2024[15]	**Some concerns** Computer randomisation, research assistant not involved in other trial procedures maintained schedule. Sealed envelopes used. Small imbalance in endoscopist experience between groups.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. ITT analysis.	**Low** All randomised participants analysed	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to concerns about lack of endoscopist blinding (although unavoidable for this type of intervention).

Spada 2025[16]	**Low** Computer-based randomisation, no mention of concealment. No concerns about baseline differences.	**Low** Patients and endoscopists aware of intervention but no concerns about any deviations from interventions. ITT.	**Low** All randomised participants analysed	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified but no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to concerns about lack of endoscopist blinding (although unavoidable for this type of intervention).
Vilkoite 2023[42]	**Some concerns** No information on methods of randomisation provided. Very limited number of baseline characteristics reported to assess similarity between groups.	**Low** Patients blinded, endoscopists aware of treatment. No information on deviations from intended interventions, possibly mITT analysis.	**High** No information provided on numbers excluded from analyses and missing data.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. Very few outcomes reported.	**High**	Risk of bias mostly due to very limited reporting of methodological details, missing data and patient characteristics, and lack of endoscopist blinding (although unavoidable for this type of intervention).
ENDOANGEL®							
Gong 2020[27]	**Some concerns** Computerised randomisation, method of concealment unclear. Some imbalance noted for sex.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. ITT analysis.	**Low** All randomised participants analysed.	**High** Concerns about outcome measurement – only suspected adenomas removed and sent for histology rather than all/most polyps, difference vs other studies in the area.	**Low** Trial protocol available and no major concerns about selective reporting.	**High**	Risk of bias mostly due to concerns about outcome measurement and lack of endoscopist blinding (although unavoidable for this type of intervention).

				Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.			
Yao 2022[17]	**Low** Computerised randomisation, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~4% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Yao 2024[18]	**Low** Computerised randomisation, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~2% excluded from mITT analyses, similar across groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Low** Trial protocol reviewed and no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Zhang 2023[50]	**Some concerns** Computerised randomisation, unclear method of concealment. Limited reporting of baseline characteristics for assessment of similarity.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~5% excluded from mITT analyses, similar in both groups	**High** Outcome confirmed by expert endoscopists whereas histology would be more accurate. Endoscopists aware of intervention possibly introducing some operator bias. No mention of pathologist involvement.	**Some concerns** No statistical analysis plan identified. Some concerns about missing overall PDR but may just be an omission.	**High**	Risk of bias mostly due to concerns about outcome measurement and lack of endoscopist blinding (although unavoidable for this type of intervention).

EndoScreener®							
Glissen Brown 2022[35]	**Some concerns** Computerised randomisation, sealed envelopes used for concealment. Large imbalance in sex and smaller for ethnicity.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~4% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to some imbalances in baseline characteristics and lack of endoscopist blinding (although unavoidable for this type of intervention).
Liu 2020[30]	**Some concerns** Digital random number generator just prior to colonoscopy procedure, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~6% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Low** Trial protocol available and no concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Wang 2019[43]	**Some concerns** Digital random number generator just prior to colonoscopy procedure, unclear method of concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~6% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).

Wang 2020 (effect of a deep…)[44] - CADe-DB trial	**Low** Computerised randomisation, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. Described as per protocol analysis but similar exclusions to others described as mITT.	**Low** Only ~5% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Wang 2020 (lower adenoma miss…)[36]	**Low** Computerised randomisation, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No information about deviations from intended interventions. mITT analysis.	**Low** Only ~5% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Wang 2023[45]	**Some concerns** Digital random number generator just prior to colonoscopy procedure, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No information about deviations from intended interventions. mITT analysis.	**Low** Only ~4% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
GI Genius™							

Ahmad 2023[1] – AI-DETECT trial	**Some concerns** Computerised randomisation, unclear method of concealment. Only limited baseline characteristics reported for assessment of comparability.	**Low** Patients and endoscopists aware of treatment. No information about deviations from intended interventions. ITT analysis.	**Low** All randomised participants analysed	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Engelke 2023[28]	**High** Randomisation based on alternation not a random sequence. Unclear method of concealment. Concerns about imbalances as medians reported and some imbalances noted (experience of endoscopists and completion of colonoscopies).	**Some concerns** Unclear if patients blinded, endoscopists aware of treatment. No information about deviations from intended interventions. Possibly ITT but limited reporting.	**Some concerns** Possibly all randomised participants analysed but poor reporting of dropouts and exclusions	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**High**	Risk of bias mostly due to concerns about randomisation methods and imbalances, limited reporting of missing data and lack of endoscopist blinding (although unavoidable for this type of intervention).
Karsenti 2023[19] – COLO-Genius trial	**Some concerns** Computerised random number system, method of concealment unclear. Randomisation not performed until colon had been visualised.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~1% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).

	No concerns about baseline differences.						
Lagstrom 2025[47]	**High** Quasi-randomisation with alternation every 2 weeks, no mention of concealment. Some larger differences for diagnostic indication, gender, comorbidity, sedation and diverticulosis).	**Some concerns** Unclear if patients blinded, endoscopists not blinded but deviations from intended intervention unlikely. Per protocol analysis only.	**Some concerns** ~10% of randomised participants excluded from per protocol analyses, similar in both groups.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**High**	Risk of bias mostly due to concerns about randomisation methods and imbalances, patients excluded from per protocol analyses and lack of endoscopist blinding (although unavoidable for this type of intervention).
Mangas-Sanjuan 2023[20] – CADILLAC trial	**Low** List of random numbers used for randomisation; electronic system used for concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No information about deviations from intended interventions. mITT analysis.	**Low** Only ~5% excluded from mITT analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** Some possible inconsistencies compared with statistical analysis plan but no major concerns.	**Some concerns**	Risk of bias mostly due to possible inconsistencies with statistical analysis plan and lack of endoscopist blinding (although unavoidable for this type of intervention).
Ortiz 2024[46] – TIMELY trial	**Low** List of random numbers used for randomisation; electronic system used for	**Low** Patients blinded, endoscopists aware of treatment. No information about deviations from	**Low** All randomised participants analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Low** No major concerns compared to protocol outlined in supplementary materials.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for

	concealment. No concerns about baseline differences.	intended interventions. ITT analysis.					this type of intervention).
Repici 2020[21] – AID trial	**Low** List of random numbers used for randomisation; unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No information about deviations from intended interventions. mITT/ITT analysis.	**Low** Only ~2% excluded from analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. Some minor concerns given inconsistencies within paper in terms of whether those with inadequate bowel preparation excluded from analysis or not.	**Some concerns**	Risk of bias mostly due to uncertainty about exclusions from analysis and whether prespecified, and lack of endoscopist blinding (although unavoidable for this type of intervention).
Repici 2022[22] – AID2 trial	**Low** List of random numbers used for randomisation; unclear method of concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~3% excluded from analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, unclear if pathologists blinded.	**Some concerns** No statistical analysis plan identified. Some minor concerns about whether mITT analysis with exclusion of inadequate bowel preparation prespecified given description as ITT analysis in the paper.	**Some concerns**	Risk of bias mostly due to uncertainty about exclusions from analysis and whether prespecified, and lack of endoscopist blinding (although unavoidable for this type of intervention).

Scholer 2024[2b]	**Some concerns** Sealed envelopes used for randomisation. Imbalance in endoscopist experience is a concern (70.0 vs 85.0% experienced)	**Low** Patients and endoscopists aware of treatment. No concerns about deviations from intended interventions. Possibly a mITT analysis.	**High** ~16% those randomised excluded, including some before starting the procedure. Similar in both groups, but unclear breakdown for CAD EYE® specific groups.	**Some concerns** Use of other lighting options encouraged in the AI group. Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. Limited outcomes reported for the group specifically receiving GI Genius™	**High**	Risk of bias mostly due to imbalance in endoscopist experience, missing data, and lack of endoscopist blinding (although unavoidable for this type of intervention).
Seager 2024[23] – COLO-DETECT trial	**Low** Web-based randomisation system which likely retained concealment. Randomisation just before procedure. No concerns about baseline differences.	**Low** Patients and endoscopists aware of treatment. No concerns information about deviations from intended interventions. ITT analysis with some imputation.	**Some concerns** Only 7% with missing data required imputation. Differs slightly between groups. Sensitivity analyses performed to explore limits to some concerns.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Low** Statistical analysis plan available and no major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to concerns about missing data and lack of endoscopist blinding (although unavoidable for this type of intervention).
Thiruvengadam 2024[24]	**Low** Online randomisation system, unclear method of concealment. No concerns about baseline differences.	**Low** Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. ITT analysis.	**Low** All randomised participants analysed.	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting.	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).
Wallace 2022[37]	**Low**	**Low**	**Some concerns**	**Some concerns**	**Some concerns**	**Some concerns**	Risk of bias mostly due to lack of

	Online randomisation system, which likely maintained allocation concealment. No concerns about baseline differences.	Patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. FAS/mITT analysis.	~8% randomised excluded from analysis, not reported separately to compare between groups	Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	No statistical analysis plan identified. No major concerns about selective reporting.		endoscopist blinding (although unavoidable for this type of intervention).
MAGENTIQ-COLO™							
Maas 2024 – MAGENTIQ-COLO™[31]	**Low** Online randomisation system, which likely maintained allocation concealment. No concerns about baseline differences.	**Low** Unclear if patients blinded, endoscopists aware of treatment. No concerns about deviations from intended interventions. mITT analysis.	**Low** Only ~4% excluded from analyses, similar in both groups	**Some concerns** Endoscopists aware of intervention possibly introducing some operator bias, but pathologists blinded.	**Some concerns** No statistical analysis plan identified. No major concerns about selective reporting	**Some concerns**	Risk of bias mostly due to lack of endoscopist blinding (although unavoidable for this type of intervention).

[a]Risk of bias assessment based on whole trial population rather than just those receiving CAD EYE® for colonoscopy, but similar concerns likely to apply;

[b]Risk of bias assessment based on whole trial population rather than just those receiving GI GENIUS™ for colonoscopy, but similar concerns likely to apply.

Abbreviations: AI, artificial intelligence; CSR, clinical study report; EAG, External Assessment Group; ITT, intention to treat; mITT, modified intention to treat; PDR, polyp detection rate; RCT, randomised controlled trial; SLR, systematic literature review.

3.2 QUADAS-2

Table 65. Risk of bias assessment conducted at the study level by the EAG for diagnostic accuracy studies included in the EAG SLR – QUADAS-2

Study	Domain 1 – patient selection	Domain 2 – index test	Domain 3 – reference standard	Domain 4 – flow and timing

	SQ 1[a]	SQ2[b]	SQ3[c]	RoB[d]	Applicability[e]	SQ 1[f]	SQ2[g]	RoB[d]	Applicability[e]	SQ 1[h]	SQ2[i]	RoB[d]	Applicability[e]	SQ 1[j]	SQ2[k]	SQ3[l]	SQ4[m]	RoB[d]
CAD EYE®																		
Djinbachian 2024 – CAD EYE®-assisted optical daignosis[5]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Yes	Yes	LOW	LOW	Unclear	Yes	Yes	No	LOW
Li 2023 – autonomous CAD EYE® optical diagnosis[61]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	HIGH[n]	Yes	Unclear	LOW	LOW	Unclear	Yes	Yes	No	HIGH[o]
Li 2023 – endoscopist optical diagnosis alone[61]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Yes	Unclear	LOW	LOW	Unclear	Yes	Yes	No	HIGH[o]
Rondonotti 2023 – CAD EYE®-assisted optical diagnosis[58] – ABC trial	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Yes	LOW	HIGH[p]	Unclear	Yes	Yes	No	HIGH[o]
Rondonotti 2023 – endoscopist optical diagnosis alone[58] – ABC trial	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Yes	LOW	HIGH[p]	Unclear	Yes	Yes	No	HIGH[o]

Sato 2024 – CAD EYE®-assisted optical diagnosis[53]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Yes	LOW	HIGH[p]	Unclear	Yes	Yes	No	LOW
Sato 2024 – endoscopist optical diagnosis alone[53]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Yes	LOW	HIGH[p]	Unclear	Yes	Yes	No	LOW
Taghiakbari 2025 – CAD EYE®-assisted optical diagnosis[56]	Unclear	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Unclear	HIGH[q]	LOW	Unclear	Yes	Yes	No	LOW
Zavyalov 2024 – autonomous CAD EYE® optical diagnosis[48]	Unclear	Yes	Unclear	UNCLEAR	UNCLEAR	Yes	NA	LOW	HIGH[n]	Unclear	Unclear	LOW	UNCLEAR	Unclear	Yes	Yes	Unclear	UNCLEAR
CADDIE™																		
Odin Vision 2024 CADDIE trial CSR – CADDIE™-assisted optical diagnosis[12]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Unclear	LOW	HIGH[p]	Unclear	Yes	Yes	No	HIGH[o]
Odin Vision 2024 CADDIE trial CSR – endoscopist optical diagnosis alone[12]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Unclear	LOW	HIGH[p]	Unclear	Yes	Yes	No	LOW
Discovery™																		

Lopez-Serrano 2024 – Discovery™-assisted classification[49] – CUDISIA trial	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	HIGH[r]	Yes	Unclear	LOW	LOW	Unclear	Yes	Yes	No	HIGH[o]
Lopez-Serrano 2024 – VCE-assisted classification[49] – CUDISIA trial	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	UNCLEAR	Yes	Unclear	LOW	LOW	Unclear	Yes	Yes	No	HIGH[o]
GI Genius™																		
Baumer 2023 – autonomous GI Genius™ optical diagnosis[60]	Unclear	Yes	Yes	LOW	LOW	Yes	NA	LOW	HIGH[n]	Yes	Unclear	LOW	LOW	Unclear	Yes	Yes	No	HIGH[o]
Baumer 2023 – endoscopist optical diagnosis alone[60]	Unclear	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Yes	Unclear	LOW	LOW	Unclear	Yes	Yes	No	HIGH[o]
Bernhofer 2025 – GI Genius™-assisted optical diagnosis[59]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Unclear	LOW	Unclear[s]	Unclear	Yes	Yes	No	LOW
Hassan 2022 – GI Genius™-assisted optical diagnosis[55] – CHANGE trial	Unclear	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Yes	LOW	HIGH[p]	Unclear	Yes	Yes	No	HIGH[o]
Koh 2024 – autonomous GI Genius™ optical diagnosis[62]	Unclear	Unclear	Unclear	UNCLEAR	UNCLEAR	Yes	NA	LOW	HIGH[n]	Yes	Unclear	LOW	LOW	Unclear	Unclear	Yes	No	HIGH[o]

Rondonotti 2024 – GI Genius™-assisted optical diagnosis[57]	Yes	Yes	Yes	LOW	LOW	Yes	NA	LOW	LOW	Unclear	Yes	LOW	HIGH[p]	Unclear	Yes	Yes	No	HIGH[o]

[a]Was a consecutive or random sample of patients enrolled?

[b]Was a case-control design avoided?

[c]Did the study avoid inappropriate exclusions?

[d]RoB rated as low, high or unclear

[e]Applicability rated low if no concerns about applicability, high if concerns about applicability and unclear if limited information available

[f]Were the index test results interpreted without knowledge of the results of the reference standard?

[g]If a threshold was used, was it pre-specified?

[h]Is the reference standard likely to correctly classify the target condition?

[i]Were the reference standard results interpreted without knowledge of the results of the index test?

[j]Was there an appropriate interval between index test(s) and reference standard?

[k]Did all patients receive a reference standard?

[l]Did patients receive the same reference standard?

[m]Were all patients included in the analysis?

[n]Rated high for applicability of index test as technology used autonomously rather than as an adjunct to endoscopist judgement

[o]Concerns about exclusions or limited information on exclusions

[p]Rated high for applicability of reference standard as classification of SSLs as hyperplastic polyps/non-adenomatous may not be appropriate or may be a limitation of the analysis

[q]Reference standard was expert review by video rather than histopathology, which is likely to be less robust though required when implementing a resect-and-discard or diagnose-and-leave strategy

[r]Potentially interpreted detections on Discovery™ as neoplasias, which is not how the technology works, but information is unclear. Uncertainty with regards to applicability of this study given Discovery™ not outlined as having a CADx function in manufacturer submission

[s]Rated unclear for applicability as it is unclear how SSLs were treated in the analysis

[t]Rated unclear for risk of bias and applicability as very limited information is reported.

Abbreviations: CADx, computer-aided characterisation; CSR, clinical study report; EAG, External Assessment Group; RoB, risk of bias; SLR, systematic literature review; SSL, sessile serrated lesion; SQ, signalling question; VCE, virtual chromoendoscopy.

3.3 Risk of bias of other studies

As outlined in Section 3.1.4 of the main report, various studies included in this report, including data reported in abstracts only and five other studies where a suitable quality assessment checklist could not be identified or only very limited information was available via the manufacturer, were considered to be at a high risk of bias and a formal quality assessment was not performed. This high risk of bias rating applied to 10 abstracts and 2 studies where limited data was provided via the manufacturer (covering 12 different studies).[25, 32, 39, 51, 52, 54, 63, 65-69] For the full text non-randomised studies where the only relevant data for inclusion in this assessment was results from clinician or patient surveys,[64, 70, 71] the following limitations are noted:

Nehme *et al.* 2023:[64]

- Physicians/staff could choose when and when not to activate the computer-aided detection (CADe) system, meaning results may be skewed towards those that are more in favour of artificial intelligence (AI)-assisted procedures as a concept or, equally, some may only have used the system a few times before deciding not to continue with it in other patients – supported by a substantial proportion reporting no or minimal use of the technology in the follow-up survey results;
- Physician choice also meant there were potentially important differences between CADe and control groups, and demonstrated potential uptake preferences:
    - The CADe system was significantly more likely to be activated for screening and surveillance indications compared with diagnostic and therapeutic indications (55.8 vs 43.6%, p-value <0.001);
    - Endoscopists with an adenoma detection rate (ADR) above 45% in the year before the study period (n=15) were more likely to activate the CADe system compared with those with an ADR below 45% (n = 8; 63.6 vs 31.6%, p-value <0.001);

- Where it was used relatively infrequently, responses may not be reflective of opinion had the system been used very frequently, for example, when more familiar with the technology and some concerns may no longer be an issue;
- The questionnaire includes a list of suggested responses which may have directed responses to some degree, although there were options for “other” responses to be recorded for

some, but not all, questions. This also means that detail regarding specific responses is limited with limited interpretation possible;

- A relatively small number of physicians/staff were captured in this study;
- Survey-based rather than a formal qualitative study;
- Associated with general limitations of non-randomised, retrospective studies, such as concerns about selection bias and potential lack of applicability to other settings. For example, processes or workload within specific centres might impact how useful clinicians deem AI-assisted colonoscopy to be.

Burton *et al.* 2025:[70]

- There is no mention of any information or education on the concept of AI in colonoscopy before the survey, meaning it is unclear if patients were aware of what this involved before answering the survey questions. While a team member was available to answer questions, formal information on the background would have addressed the potential lack of knowledge more robustly as many patients may not have asked questions;
- Based on responses from a single institution, which may not capture representative view of all patients undergoing colonoscopy given perspectives may differ with different healthcare settings;
- It is a survey-based study involving close-ended yes/no questions or ratings on a 5-point Likert scale rather than structured interviews, meaning insights are more limited than would be possible with more formal interviews and analysis of such interviews;
- Survey was delivered in the waiting room prior to their scheduled colonoscopy procedure, which might impact responses for example if respondents were anxious and wanting to rush through the survey compared to if it were completed in a more relaxed environment;
- It is a study based in the USA and much of the content of the study, such as factors important for choosing a colonoscopist, are likely to be less relevant to the National Health Service (NHS) population. Perspectives between different countries may also differ given the differences in the healthcare systems and patient expectations.

Schmidt *et al.* 2025:[71]

- Patient education was included in the study with attempts to make the language of the survey patient-friendly, but the authors note that may not have been sufficient to ensure full understanding of the concept of AI in colonoscopy;
- Based on responses from a single institution with a mostly white population, which may not capture representative view of all patients undergoing colonoscopy given perspectives may differ with different demographic characteristics and healthcare settings;
- Limited to outpatient colonoscopy which does not include diagnostic colonoscopy and other procedures, for which perspectives may differ;
- It is a survey-based study involving close-ended yes/no questions or ratings on a 5-point Likert scale rather than structured interviews, meaning insights are more limited than would be possible with more formal interviews and analysis of such interviews;
- Survey was delivered in the waiting room prior to their scheduled colonoscopy procedure, which might impact responses for example if respondents were anxious and wanting to rush through the survey compared to if it were completed in a more relaxed environment;
- It is a study based in the USA and perspectives between different countries may differ given the differences in the healthcare systems and patient expectations.

4 Data abstraction tables – clinical

Table 66. Summary of study characteristics – included clinical studies - CADe

Study (study design; country)	Inclusion and exclusion criteria	Colonoscopy procedure, AI use and histology	Analyses[a]
Argus® (Endosoft)			
Strapko 2023[39]	Inclusion: ≥40 years; screening, surveillance or diagnostic colonoscopy; informed consent by patient or legal representative Exclusion: <40 years; therapeutic colonoscopy; Lynch syndrome or FAP; contraindication for colonoscopy or biopsies of the colon;	Procedure: not reported AI use: CADe, adjunct (no further details. Unclear when activated Histology: not reported	Stratification: unclear Analysis population: mITT[b]

(parallel RCT – abstract only; USA)	uncontrolled coagulopathy; confirmed diagnosis of IBD prior to colonoscopy; short bowel or ileostomy; pregnancy		Subgroups: none
CAD EYE® (Fujifilm Healthcare UK Ltd.)			
Alali 2025[40] (parallel RCT; Ku	Inclusion: ≥45 years; average-risk screening or surveillance colonoscopy; provided informed consent; adequate bowel preparation (BBPS ≥2 per segment and overall score ≥6) Exclusion: history of IBD; alarm symptoms (e.g. weight loss or rectal bleeding); known or suspected familial polyposis syndrome (e.g. FAP or Lynch syndrome); history of colon resection; poor bowel preparation; caecum not reached on colonoscopy	Procedure: HD white-light colonoscopy – no further details. AI use: CADe (adjunct) and CADx (unclear, possibly autonomous). Activated during withdrawal. Histology: All polyps removed using varying techniques and sent for histopathological examination by expert pathologists blinded to intervention. Vienna and WHO classifications used.	Stratification: unclear Analysis population: ITT Subgroups: none

wait)			
Aniwan 2023[6] (parallel RCT; Thailand)	Inclusion: 50 to 75 years; asymptomatic; routine screening colonoscopy or screened after a positive FIT Exclusion: IBD, familial polyposis syndrome, history of CRC or symptoms of CRC; post-polypectomy surveillance; prior colonic resection; prior pelvic radiation	Procedure: White-light; HD colonoscope; ENDOCUFF VISION™ used two of four arms; withdrawal time set to 6 to 10 min excluding irrigation and polypectomy AI use: CADe, adjunct. Activated prior to insertion. Histology: All detected polyps other than rectosigmoid polyps that appeared hyperplastic were resected and sent to expert pathologist	Stratification: unclear Analysis population: ITT Subgroups: none
Desai 2024[7] (parallel	Inclusion: ≥45 years; screening or surveillance colonoscopy for history of polyps (surveillance interval of 3 years or greater); able to provide informed consent Exclusion: History of colon resection; IBD; FAP; severe comorbidity, including end-stage CV/pulmonary/liver/renal disease; pregnancy; unable to provide or refused to provide informed consent	Procedure: HD colonoscope; Endoscopists adhered to usual withdrawing technique with minimum 6 min withdrawing and examining colonic mucosa; use of advanced imaging or VCE not permitted AI use: CADe, adjunct. Unclear when activated. EW10-EC02 CADe software-only medical device	Stratification: none reported Analysis population: mITT[c] Subgroups: screening and

RCT; USA)		Histology: Each polyp detected was removed or biopsied according to endoscopist judgement and sent to histology	surveillance populations
Djinbachian 2024[10] (parallel RCT; Canada)	Inclusion: 45 to 80 years; elective colonoscopy for screening, surveillance or diagnostic purposes Exclusion: known IBD; active colitis; coagulopathy; FAP; poor general health with ASA >3; emergency colonoscopy	Procedure: ELUXEO 7000 system with EC-706S-A/M and EC-760S-A/L colonoscopes. AI use: CADe, adjunct. Activated during withdrawal. EW01-EC02 software. AI group also had water exchange and caecal retroflexion, whereas standard colonoscopy group did not. Histology: all detected polyps resected and histologically assessed.	Stratification: unclear Analysis population: ITT Subgroups: endoscopist ADR >25% vs ≤25%
Hiratsuka 2025	Inclusion: ≥20 years; scheduled for lower GI endoscopy Exclusion: prior colectomy; IBD, FAP or other polyposis; experiencing difficulty with deep insertion; deemed difficult to safely examine (e.g.	Procedure: Fujifilm ELUXEO 7000 endoscope system used with EC-760ZP colonoscope. Similarly skilled endoscopists performed first and second procedures in each patient but was a different endoscopist for the two procedures.	Stratification: history of colorectal polyps (yes/no); age <70 vs

[34] (tandem RCT; Japan)	advanced dementia); some eventually excluded due to poor bowel preparation	AI use: CADe, adjunct. Unclear when activated. EX-1 expansion unit with EW10-EC02 software. Histology: all polyps other than whitish polyps and small polyps of sigmoid colon or rectum that were considered to be endoscopically hyperplastic were biopsied.	≥70 years; male vs female Analysis population: mITT[d] Subgroups: endoscopists with ≥10 vs <10 years' experience
Hueburg 2023 [8] (parallel RCT; Germany)	Inclusion: ≥18 years; pathogenic germline variant in MLH1, MSH2 or MSH6 (Lynch Syndrome); written informed consent; ability to follow study instructions and likely to attend and complete all required visits; interval to last colonoscopy 10-36 months (had to have at least one prior colonoscopy) Exclusion: Inability to understand the study; physical or psychiatric condition/ a systemic disease which may compromise safety of the subject, confound the trial results, interfere with the subject's participation in the study or prevent sufficient compliance; simultaneous participation in another clinical trial or participation in trial of investigational medicinal product within 30 days prior to trial start; screening laboratory test results within the following parameters (quick >50%, thrombocytes >50.000 G/l); current or planned pregnancy or nursing women; previous extensive colorectal surgery (proctocolectomy or colectomy with ileorectal anastomosis); index	Procedure: HD white-light endoscopy; endoscopists used LCI, BLI and AI characterisation mode (for AI group) to assess each lesion; lesions resected endoscopically using standard polypectomy techniques. AI use: CADe, adjunct. Activated during withdrawal Histology: Histology of all lesions assessed using Vienna criteria by experienced blinded GI pathologist	Stratification: previous colorectal surgery (yes/no) and affected MMR gene (MLH1/MSH2/MSH6) Analysis population: mITT[e] Subgroups: history vs no history of CRC

	colonoscopy; insufficient bowel preparation (BBPS score <2 by colonic segment)		
Miyaguchi 2024[29] (parallel RCT; Japan)	Inclusion: ≥20 years; colonoscopy for positive FIT, follow-up of colon polyps or abdominal symptoms; written informed consent Exclusion: colonoscopy without bowel preparation; intestinal obstruction, stenosis or fistula; history of colorectal surgery; active IBD; diverticulitis; active or suspected colorectal bleeding; ileus, alcoholism, hyperthyroidosis, severe heart failure, liver disease or renal dysfunction, and pregnancy also mentioned in trial record	Procedure: LCI colonoscopy using attached transparent hoods; white-light imaging during anal insertion and LCI during withdrawal AI use: CADe, adjunct. Activated during withdrawal. CAD EYE® EW10-EC02 Histology: Biopsy or resection of observed polyps performed and sent for histopathological analysis	Stratification: unclear Analysis population: ITT Subgroups: FIT vs other indication, trainee vs expert endoscopists
Nakashima 2023[3] (ta	Inclusion: 21 to 81 years; undergoing endoscopy as a primary endoscopic screening for CRC, patients who tested positive for the FIT for occult blood or patients with colorectal neoplasia undergoing endoscopic resection (surveillance post-resection of polyps in trial record); willingness to participate in the RCT; written informed consent Exclusion: prior colorectal surgery; IBD	Procedure: white-light imaging without magnification, chromoendoscopy, or image-enhanced endoscopy; adenomas >6 mm indicated for endoscopic resection, diminutive polypoid adenomas ≤5 mm could be followed up rather than removed; tandem procedures performed by same examiner and process of insertion and withdrawal repeated	Stratification: unclear Analysis population: possibly ITT - unclear Subgroups: none

nd e m R C T; Ja pa n)		AI use: CADe, adjunct. Unclear when activated. Histology: performed by single pathologist specialising in GI tract blinded to endoscopy results	
R on do no tti 20 22 [9] (p ar all el R C T; Ita ly)	Inclusion: 50 to 74 years; within CRC screening programme with a positive FIT screening test Exclusion: not eligible for screening program (i.e. colonoscopy within previous 5 years, personal history of CRC, colonic adenomas, IBD, severe comorbidity); prior colonic resection; antithrombotic therapy precluding polyp resection and pathology assessment; inadequate bowel preparation (defined as BBPS <2 in at least one colonic segment); caecal intubation not achieved; refusal to give informed written consent	Procedure: HD white-light colonoscopy; withdrawal time of at least 6 min (2 min in right, transverse and left colon) was mandatory; all identified polyps removed or biopsied other than diminutive (1 to 5 mm) hyperplastic polyps in the rectum and judged as not clinically significant by the endoscopist AI use: CADe, adjunct. Activated prior to insertion. Characterisation mode not used. Histology: Vienna and WHO classifications described; histology assessed by expert pathologists qualified for FIT-based CRC screening programme	Stratification: endoscopy centre Analysis population: mITT[f] Subgroups: endoscopist baseline ADR ≤40%, 41 to 45% and ≥46%

Scholer 2024[2] (parallel RCT; Sweden)	Inclusion: 40 to 90 years; cancer screening, alarm symptoms (i.e., iron-deficiency anaemia, suspicion of malignancy following rectal examination and CT findings that raise suspicion of malignancy), inconclusive CT findings (suggestive of a benign but inconclusive cause) and other (positive faecal occult blood stool test, polyp surveillance, hereditary CRC, diarrhoea) Exclusion: history of IBD; contraindication for polypectomy or known polyps; incomplete examinations due to factors such as obstructive cancer, technical issues or inadequate bowel preparation; BBPS <2 in one segment or a total BBPS <6	Procedure: white-light imaging or LCI depending on preference of examiner; standard of paediatric HD colonoscopes AI use: CADe, adjunct. Activated during withdrawal. Histology: assessed by pathologists blinded to intervention.	Stratification: endoscopist experience Analysis population: per protocol[g] Subgroups: none for CAD EYE® data specifically
Tiankanon 2024[4] (parallel R	Inclusion: 50 to 75 years; routine screening colonoscopy or screened after positive FIT; asymptomatic Exclusion: known CRC history; IBD; familial polyposis syndrome; prior colonic resection; also prior pelvic radiation listed in trial record	Procedure: white-light using HD colonoscopes without magnification; polypectomy during insertion and withdrawal AI use: CADe, adjunct. Activated prior to insertion. EW10-EC02 software and compatible expansion unit EX-1 Histology: all resected polyps sent to GI pathologists blinded to intervention; WHO criteria used	Stratification: none reported Analysis population: ITT Subgroups: none

CT; Thailand)			
Yamaguchi 2024[33] (parallel RCT; Japan)	Inclusion: ≥20 years; scheduled for outpatient colonoscopy due to positive FIT, surveillance after colonic polypectomy (trial record also suggests digestive symptoms, GI cancer screening indication, family history of CRC or colorectal adenoma, or others needing lower GI endoscopy by physician in charge would initially have been eligible); understand and agree to consent document Exclusion: ileus; suspected bowel obstruction; toxic megacolon; prior abdominal or pelvic surgery; IBD; advanced malignancy; severe liver damage (Child-Pugh grade C); dementia or other cognitive disorders; hypersensitivity to bowel preparation drugs for colonoscopy; pregnancy or lactation	Procedure: Performed by trainee in back-to-back method with an expert; expert could support with advancing endoscope to caecum as needed; each section of colon observed by trainee followed by expert in turn; trainee first observed and measured the polyps in absence of expert followed by expert assessment; expert confirmed polyps and adenomas and performed additional observation, endoscopic polypectomy or endoscopic mucosal resection as needed. AI use: CADe, adjunct. Activated during withdrawal. Characterisation function used to diagnose lesions if necessary when measuring polyps Histology: not reported	Stratification: unclear Analysis population: mITT[h] Subgroups: none
Zimmerman	Inclusion: ≥50 years; screening colonoscopy (current age cut-offs 50 years for men and 55 years for women) or diagnostic colonoscopy (including polyp follow-up and symptom evaluation)	Procedure: colonoscopes from 700 series used – no further details AI use: CADe, adjunct. Activated prior to insertion.	Stratification: unclear Analysis population: ITT

n-Fraedrich 2025[11] (parallel RCT; Germany)	Exclusion: not reported	Histology: all detected polyps removed and sent for histological analysis by histopathologists specialised in GI pathology.	Subgroups: none
CADDIE™ (Odin Vision)			
Odin Vision 2024 CA	[redacted]	[redacted]	[redacted]

DIECSR[12] (parallel RCT; UK)	[redacted]		
Odin Vision 2024 EAGLECSR[41]	[redacted]	[redacted]	[redacted]

(parallel RCT; Italy, Poland, Germany, Spain)			
Discovery™ (Pentax Medical UK)			
Maas 2024 - Disc	Inclusion: ≥18 years; scheduled for non-iFOBT screening, surveillance, or diagnostic (excluding iFOBT-positive referrals) colonoscopy Exclusion: known colorectal tumours or polyps upon referral; referral for therapeutic procedures; inadequately corrected coagulation	Procedure: HD PENTAX colonoscopes used; aim minimum withdrawal time 6 min (excluding polypectomies or other interventions) with upper withdrawal time of 10 min; all lesions collected other than diminutive (1 to 5 mm) polyps located in rectum and considered hyperplastic by endoscopist	Stratification: index colonoscopy vs not Analysis population: mITT[l]

overy™ [26] (parallel RCT; Canada, France, Germany, Italy, Netherlands,	disorder or continued use of anticoagulation medication; ASA score of ≥3; known or suspected IBD	AI use: CADe, adjunct. Activated before insertion, mandatory use during withdrawal. Software versions 1.0.3.1 and 1.0.4 were used. Histology: Vienna classification used by experienced pathologists for histological assessment of all resected polyps; pathologists blinded to intervention and endoscopic diagnosis	Subgroups: screening, surveillance and diagnostic indications; baseline endoscopist ADR (low, medium and high detector tertiles)

Russia)			
Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC., formerly EndoMetric Corporation)			
Data provided for EMIS™ trial by manufacturer in 2025[32],	Inclusion: [redacted] Exclusion[redacted]	Procedure: not reported AI use: not reported – note that reported that [redacted] Histology: not reported	Stratification: unclear Analysis population: unclear – only preliminary results from one of three sites provided Subgroups: none

72 (sequential RCT; USA; preliminary data from one of three sites)			
ENDO-AID™ (Olympus Medical Systems Corp.)			

Gimeno-Garcia 2023[13] (parallel RCT; Tenerife)	Inclusion: ≥18 years; colonoscopy scheduled for morning shift (requirements for colonoscopy indication unclear or did not apply) Exclusion: colon resection; treatment with anticoagulants or antiplatelet agents that may preclude polyp resection; a recent good-quality colonoscopy (<6 months) (i.e., scheduled for endoscopic therapy); IBD; incomplete colonoscopy; inadequate preparation assessed by the BBPS; diagnosis or high suspicion for hereditary CRC; patients with polyposis syndromes	Procedure: minimum 6 min withdrawal time (excluding biopsy and resections); white-light imaging; use of add-on devices not permitted; techniques such as NBI or dye-based chromoendoscopy only used for characterisation of detected lesions at discretion of endoscopists; all polyps removed other than tiny hyperplastic polyps in rectum AI use: CADe, adjunct. Activated during withdrawal. Target mode at most sensitive setting (type A) used Histology: two pathologists specialising in colon pathology blinded to assignment group performed histological assessment; Vienna classification used for histology	Stratification: unclear Analysis population: ITT Subgroups: endoscopist experience (high vs low detectors - ≥40% vs <40% baseline ADR)
Lau 2024[14] (parallel	Inclusion: ≥18 years; undergoing elective colonoscopies for screening, surveillance, or diagnostic purposes Exclusion: incomplete colonoscopies or inadequate bowel preparation; contraindications to colonoscopy or polypectomy; known colorectal lesions for staged procedures; previous colonic resection; personal history of CRC/polyposis syndrome/IBD, advanced comorbid	Procedure: white-light HD endoscopy; NBI or other enhanced imaging only permitted for characterisation; no magnification or chromoendoscopy permitted; use of distal attachment devices not permitted; performed by trainees with supervisors present (minimal interference in junior endoscopists' decisions) – could alert when polyp missed and support with caecal intubation, could also advise during resection or take over the resection; all polyps removed with	Stratification: age (<65 years vs ≥65 years), sex and endoscopist experience (beginner vs intermediate level)

RCT; Hong Kong)	conditions (ASA grade ≥4); pregnancy; unable to obtain informed consent	exception of diminutive non-neoplastic hyperplastic polyps as judged by operators AI use: CADe, adjunct. Activated during withdrawal. Target mode of technology used in this study. Histology: Vienna classification used for histological assessment by independent pathologists blinded to intervention	Analysis population: mITT[m] Subgroups: symptomatic, screening and surveillance indications; beginner vs intermediate level endoscopists
Lui 2024[15] (parallel RCT; Hong Kong)	Inclusion: ≥40 years; scheduled for elective colonoscopy for screening, surveillance, or diagnostic workup. Exclusion: pregnant women; inability to provide written informed consent; prior colorectal resection; personal history of CRC; IBD; FAP, Peutz-Jeghers syndrome or other polyposis syndromes; deemed unsuitable or high risk for polypectomy (with bleeding tendencies or severe comorbid illnesses)	Procedure: white-light HD colonoscopy; ENDOCUFF VISION™ used within one randomised group; all detected polyps removed during withdrawal only; minimum 6 min withdrawal time AI use: CADe, adjunct. Activated during withdrawal. Histology: WHO classification used for histological assessment by experienced pathologists blinded to intervention	Stratification: Colonoscopy indication and endoscopist experience Analysis population: ITT Subgroups: screening population separate

Spada 2025[16] (parallel RCT; Italy)	Inclusion: 40 to 85 years; screening (opportunistic or immunological FOBT based) or surveillance colonoscopy Exclusion: IBD; history of surgical resection of any part of the colon; known polyps on referral; polyposis syndrome; referral for therapeutic procedures; inadequately managed anticoagulation disorders or use of anticoagulation medications; unable to provide informed consent	Procedure: HD procedures. Vital staining and VCE not permitted for polyp detection. Withdrawal time minimum of 6 min from caecum excluding interventions. AI use: CADe, adjunct. Activated during withdrawal. Of two modes available, mode B used (suppress more false positives compared to A) Histology: Resected polyps sent for histopathological examination according to Vienna criteria by experienced pathologists.	Stratification: male vs female; age categories (40 to 50, 51 to 50, 61 to 70, 71 to 80 and 81 to 85 years) Analysis population: ITT for some outcomes, mITT only for others[n] Subgroups: none
Vilkoite 2023[42] (parallel RCT; Latvia)	Inclusion: ≥18 years; any patient sent for colonoscopy examination by the family doctor; signed informed consent form Exclusion: previously undergone colonoscopy examination; IBD; hereditary polyposis syndrome; known CRC; previously undergone colorectal surgery; contraindications for polypectomy; bad bowel preparation on a BBPS of 0 to 1 in any of the three bowel segments; standard contraindications to colonoscopy such as acute diverticulitis and known or suspected perforation	Procedure: minimum withdrawal time 7 min; methylene blue staining used to detect flat polyps of right colon; at least two pieces from polyps taken before polypectomy AI use: CADe, adjunct. Activated during withdrawal. Histology: all removed polyps and specimens sent for histological assessment by expert pathologists according to WHO criteria	Stratification: unclear Analysis population: mITT[o] Subgroups: none

ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.)			
Gong 2020[27] (parallel RCT; China)	Inclusion: 18 to 75 years; consecutive patients undergoing colonoscopy - trial record expands on this (colonoscopy for screening, clinical symptoms or surveillance); able to provide informed consent and willing to comply with all study process Exclusion: contraindications to colonoscopy indication; history of IBD; CRC or colorectal surgery; previous unsuccessful colonoscopy; contraindication for biopsy; suspected or known bowel obstruction of perforation; or currently pregnant or lactating; trial record also includes known polyposis syndrome and other high-risk diseases or special circumstances that researcher believes makes them unsuitable for participation	Procedure: advanced optical imaging required following detection to assess morphology with biopsies or removal of suspected adenomas performed – those not removed of biopsied considered non-adenomatous AI use: CADe, adjunct. Activated prior to insertion. Histology: adenomas diagnosed based on pathological results of those resected or biopsied (only suspected adenomas were removed or biopsied)	Stratification: unclear Analysis population: ITT Subgroups: none
Yao 2022[17] (parallel RC	Inclusion: ≥18 years; attended endoscopy centre between 1 July and 15 October 2020 (colonoscopy indication requirements unclear or did not apply); ability to sign and understand informed consent documents Exclusion: known contraindications to biopsy; bowel obstruction or perforation; pregnant or lactating; suffering from polyposis syndromes; history of IBD, CRC, or colorectal surgery; caecum was not reached; suspicion for polyposis syndromes, IBD, intestinal tuberculosis or	Procedure: HD colonoscopes; minimum 6 min withdrawal time; all polyps removed or biopsied with exception of diminutive hyperplastic-appearing polyps located in the rectum according to endoscopist judgement; unbiopsied rectal polyps arranged for resection one month after examination and pathology followed up AI use: CADe, adjunct. Activated during withdrawal.	Stratification: unclear Analysis population: mITT[p] Subgroups: none

T; China)	CRC; others also listed in trial record - other clinical trial participation, drug or alcohol abuse or mental disorder in last 5 years	Histology: not reported	
Yao 2024[18] (tandem RCT; China)	Inclusion: >18 years; colonoscopy for diagnostic, screening or surveillance; able to read, understand and sign informed consent form Exclusion: known contraindication for biopsy; bowel obstruction or perforation; currently pregnant or lactating; experiencing polyposis syndromes; history of IBD, CRC or colorectal surgery; caecum not reached during procedure; highly suspected of having polyposis syndromes, IBD, intestinal tuberculosis or CRC; insertion time >15 minutes in the first pass; drug or alcohol abuse or mental illness within the last 5 years; known intestinal stenosis or space-occupying tumour; trial record also mentions history of allergy to pre-used spasmolysis, unable to perform biopsy and polyp removal due to coagulation disorders or oral anticoagulation, and high-risk diseases or other special conditions that the investigator considers to be unsuitable for inclusion	Procedure: white-light endoscopy with NBI at discretion of endoscopist; tandem colonoscopies on same day; all detected polyps biopsied or removed with exception of diminutive hyperplastic-appearing polyps located in rectum and according to judgement of standby expert endoscopists; insertion performed by experts in all three groups with withdrawal phase performed by novices in two of three groups; second-pass endoscopists not blinded to results of first procedure; minimum 6 min withdrawal time AI use: CADe, adjunct. Activated during withdrawal. Histology: pathological assessment reported, no further details	Stratification: unclear Analysis population: mITT[q] Subgroups: none
Zhang 2023[50] (p	Inclusion: 18 to 75 years; colonoscopy for diagnosis or screening; able to provide written informed consent; full legal capacity Exclusion: contraindications to colonoscopy (history of acute myocardial infarction within 6 months, severe hypohepatia, renal	Procedure: when detected, routine diagnostic and treatment processes at each hospital followed to decide whether to perform a polypectomy	Stratification: unclear Analysis population: FAS/mITT[r]

arallelRCT; China)	failure, and mental disorders); use of anticoagulants (aspirin, warfarin, etc.); known polyposis syndromes, familial polyposis or IBD; known or highly suspected CRC; prior colorectal surgery; pregnancy; currently participating in other clinical trials	AI use: CADe, adjunct. Activated during withdrawal. Histology: no histology – videos of procedure reviewed by an independent evaluation group (two experts with experience >5 ears and total volume >3000 colonoscopies) which labelled if examination was positive (polyp detected) or not. Third endoscopist involved if disagreement.	Subgroups: none
EndoScreener® (WISION AI)			
GlissenBrown2022[35] (tandemRCT; USA)	Inclusion: ≥22 years; presenting for colonoscopy for CRC screening or surveillance Exclusion: diagnostic colonoscopy (for indications such as GI haemorrhage); IBD; colorectal masses >2 cm in size; referred for endoscopic mucosal resection; standard contraindications to colonoscopy such as acute diverticulitis and known or suspected perforation; diminished cognitive capacity also mentioned in trial record.	Procedure: HD white-light colonoscopy; all polyps removed at detection using standard polypectomy techniques or biopsied other than diminutive hyperplastic polyps of rectum at discretion of endoscopist if deemed clinically insignificant AI use: CADe, adjunct. Activated during withdrawal. Histology: assessed by clinical pathologists blinded to intervention	Stratification: unclear Analysis population: mITT[s] Subgroups: none

Liu 2020[30] (parallel RCT; China)	Inclusion: 14 to 90 years; underwent colonoscopy for any indication between September 2018 and February 2019 Exclusion: history of IBD and highly suspected cases during colonoscopy examination; history of adenoma polyposis and highly suspected cases during colonoscopy examination; history of CRC and highly suspected cases during colonoscopy examination; history of colon surgery; contradiction of biopsy; failed procedure to insertion to cecum.	Procedure: high image-quality colonoscopes and HD monitors; routine colonoscopy procedure; all polyps identified by endoscopist taken as cold forceps biopsy for pathological examination AI use: CADe, adjunct. Activated during withdrawal. Histology: pathological assessment mentioned, no further details	Stratification: unclear Analysis population: mITT[t] Subgroups: none
Wang 2019[43] (parallel RCT; Chi	Inclusion: age inclusion criterion unclear or did not apply; underwent a colonoscopy from September 2017 to February 2018 Exclusion: history of IBD; CRC; colorectal surgery; contraindication for biopsy; prior failed colonoscopy; high suspicion of polyposis syndromes, IBD or typical advanced CRC	Procedure: HD colonoscopes and monitors; detected polyps underwent cold forceps biopsy for histology AI use: CADe, adjunct. Activated during withdrawal. Histology: pathological assessment mentioned, no further details	Stratification: unclear Analysis population: mITT[u] Subgroups: none

na)			
Wang 2020 (effect of a deep …)[44] (parallel RCT; China)	Inclusion: 18 to 75 years; presenting for diagnostic (symptomatic) or screening colonoscopies Exclusion: history of IBD, CRC or colorectal surgery; contraindication for biopsy (e.g., use of anticoagulants); previously unsuccessful colonoscopy (i.e. did not reach caecum); at high suspicion for polyposis syndromes, IBD or CRC	Procedure: white-light HD colonoscopy; sham system used for comparator arm; cold forceps biopsy used to obtain samples for pathology AI use: CADe, adjunct. Activated during withdrawal. Histology: pathological assessment mentioned, no further details	Stratification: unclear Analysis population: mITT[u] Subgroups: none

Wang 2020 (lower adenoma miss …)[36] (tandem RCT; China)	Inclusion: 18 to 75 years; referred for diagnostic, screening colonoscopy or surveillance colonoscopy (for patients who underwent previous polypectomy) Exclusion: history of IBD, CRC, colorectal surgery or contraindication for biopsy; caecum was not reached; high suspicion for polyposis syndromes, IBD or CRC; cases of difficult insertion, defined as insertion time >7 minutes in first pass	Procedure: same day tandem HD colonoscopies performed by same endoscopist in each patient; white-light only with NBI at discretion of endoscopists; all polyps biopsied or removed by cold forceps biopsy with larger ones referred for later resection, with exception of diminutive (≤2 mm) rectal polyps considered to be hyperplastic by endoscopist AI use: CADe, adjunct. Activated during withdrawal. Histology: all biopsies sent for pathological examination, no further details	Stratification: unclear Analysis population: mITT[v] Subgroups: none
Wang 2023	Inclusion: 18 to 75 years; symptomatic, screening or surveillance colonoscopy	Procedure: white-light HD colonoscopy with other imaging modalities at endoscopist discretion; all polyps verified by endoscopist biopsied or removed suing cold forceps biopsy other than diminutive (≤2 mm)	Stratification: unclear

45 (parallel RCT; China)	Exclusion: history of IBD, CRC, polyposis syndromes or colorectal surgery; contraindication for biopsy; current lower GI bleeding; poor general condition; did not consent before randomisation; during colonoscopy, those highly suspected of suffering from polyposis syndromes, IBD or CRC mass, or the caecum was not reached; after colonoscopy, patients who withdrew their consent or failed the pathology assessment due to insufficient tissue from cold-forceps biopsy.	rectal polyps deemed to be hyperplastic by endoscopist; standard colonoscopy group included trainees as observers for comparison against AI AI use: CADe, adjunct. Activated during withdrawal. Version 1.01 used. Histology: all biopsies sent for pathological examination, no further details	Analysis population: mITT[w] Subgroups: none
GI Genius™ (Medtronic)			
Ahmad 2023[1] (parallel RCT; UK)	Inclusion: 60 to 74 years; positive FIT attending for screening colonoscopy within the NHS BCSP or an established history of adenomas attending for surveillance colonoscopy within the BCSP, or patients aged 55 years referred for colonoscopy due to large or multiple adenomas being found during screening flexible sigmoidoscopy. Exclusion: risk profile (family history or other reasons); follow-up was conducted outside the BCSP; did not give consent to the study	Procedure: routine HD colonoscopy with option of ENDOCUFF VISION™ or transparent plastic cap; typical-appearing small, hyperplastic, shiny rectosigmoid polyps left *in situ* and not included in assessment of polyps detected AI use: CADe, adjunct. Activated prior to insertion. First commercially available GI Genius™ system used (CB1708-EU) Histology: post-procedure histology results reviewed within 2 weeks	Stratification: unclear Analysis population: ITT Subgroups: none

Engelke 2023[28] (parallel RCT; Sweden)	Inclusion: ≥18 years; colonoscopy for primary screening, post-polypectomy surveillance, tumour follow-up or work-up for GI symptoms such as bleeding and anaemia, IBD, diarrhoea and tumour search (diagnostic colonoscopy); obtained informed consent Exclusion: pre-planned partial colonoscopy or planned repetition of colonoscopy due to an unprepared colon	Procedure: HD colonoscopy; polypectomies performed using forceps, cold snare or diathermic snares depending on size AI use: CADe, adjunct. Unclear when activated. Histology: all resected specimens underwent histopathological examination, no further details	Stratification: unclear Analysis population: unclear but possibly ITT Subgroups: diagnostic colonoscopy vs pre-planned colonoscopies (also broken down into more specific subgroups for indication); expert endoscopists (>200 colonoscopies annually and >50 polypectomies within last three years) vs inexperienced endoscopists
Karsenti 20	Inclusion: ≥18 years; undergoing total colonoscopy; ASA score 1 to 3;	Procedure: limited procedural details reported	Stratification: none

23[19] (parallel RCT; France)	Exclusion: referred for polyp resection; previous colonic surgery; colonic stenosis; recent acute diverticulitis (<6 weeks before colonoscopy); IBD; pregnancy; haemostasis disorders (e.g., partial thromboplastin time >42 seconds, prothrombin time <50% or platelet count <50,000 platelets per µL); treated with clopidogrel, ticagrelor or prasugrel; participating in another clinical study; incomplete colonoscopy or inappropriate bowel preparation score	AI use: CADe, adjunct. Activated during withdrawal. Version 2.0.2 used. Histology: histopathological data collected 1 to 2 weeks following colonoscopy; pathologists were blinded to intervention	Analysis population: mITT[x] Subgroups: endoscopist experience (low, medium and high baseline ADR)
Lagstrom 2025[47] (parallel RCT; Denm	Inclusion: ≥18 years; screening following positive FIT (>100 µg/L), surveillance or diagnostic colonoscopy Exclusion: colonoscopy for removal of previously detected polyps; control colonoscopies due to IBD; emergency colonoscopies; bowel preparation so poor that prevented colonoscopy being performed; cancer suspected during the colonoscopy	Procedure: limited procedural details reported AI use: CADe, adjunct. Activated during withdrawal. Histology: not reported	Stratification: unclear Analysis population: per protocol[y] Subgroups: expert (>1000 colonoscopies) vs non-expert (≤1000 colonoscopies)

ark)			
Levartovsky 2023[63] (retrospective study – abstract only; Israel)	Inclusion: colonoscopies 11 months prior to introduction of technology and 15 months after Exclusion: colonoscopy for evaluation of IBD severity, for known or suspected malignancy or therapeutic endoscopy; incomplete colonoscopies; colonoscopies with inadequate preparation	Procedure: compared results from before (11 months prior) and after (15-month period) introduction of AI technology. No further details. AI use: CADe, adjunct. Unclear when activated. Histology: not reported	Stratification: NA - retrospective Analysis population: NA - retrospective Subgroups: none

Mangas-Sanjuan 2023[20] (parallel RCT; Spain)	Inclusion: ≥18 years; presenting for colonoscopy after a first positive FIT on CRC screening (haemoglobin 20 microg/g faeces) Exclusion: personal history of CRC, IBD, colorectal surgery, terminal illness or severe disease; familial CRC or family history of inherited CRC syndrome; lack of written informed consent	Procedure: HD endoscopes; minimum 6 min withdrawal time; all polyps removed other than those considered non-resectable and diminutive hyperplastic-appearing polyps in rectum judged not to be clinically significant; targeted indigo carnine or VCE could be used for characterisation but not detection; AI use: CADe, adjunct. Activated during withdrawal. Version 2.0.0 used. Histology: pathologists specialising in GI oncology and blinded to intervention evaluated polyp histology using WHO classification	Stratification: centre, sex and age Analysis population: mITT[z] Subgroups: endoscopist baseline ADR <60% vs ≥60%
Ortiz 2024[46] (parallel R	Inclusion: ≥18 years; surveillance colonoscopy for Lynch syndrome (pathogenic or likely pathogenic, according to American College of Medical Genetics and Genomics guidelines, germline variant in MLH1, MSH2, MSH6, or EPCAM) Exclusion: history of total colectomy; concomitant IBD; inability or refusal to sign the informed consent; colonoscopy within the past 12	Procedure: HD white-light endoscopy; use of add-on devices permitted; minimum 6 min withdrawal time; VCE and other imaging techniques only for characterisation; removal of lesions using current guidelines for polypectomy techniques; all detected lesions resected and sent for histology with exception of diminutive (≤5 mm) rectosigmoid polyps with a high-confidence of being hyperplastic	Stratification: centre Analysis population: ITT Subgroups: low vs high detector endoscopists

CT; Belgium, Germany, Italy, Spain)	months; inadequate bowel preparation; incomplete procedure; PMS2 mutation.	AI use: CADe, adjunct. Activated during withdrawal. Histology: pathology assessed by expert pathologists specialising in GI pathology using the Vienna classification, European guidelines for quality assurance in CRC screening and WHO criteria	
Pinto 2022[51] (NRS, tandem proced	Inclusion: Lynch syndrome undergoing screening colonoscopy Exclusion: not reported	Procedure: tandem assessments of ascending colon and caecum, with first using AI technology and second using HD white-light endoscopy only; all identified polyps were removed AI use: CADe, adjunct. Unclear when activated. Histology: not reported	Stratification: NA – not randomised Analysis population: NA – not randomised Subgroups: none

ures – abstract only; Portugal)			
Repici 2020[21] (parallel RCT; Italy)	Inclusion: 40 to 80 years; colonoscopy for primary CRC screening, post-polypectomy surveillance, or work up following positive FIT (threshold 20 µg/Hb/g faeces) or for symptoms/signs Exclusion: personal history of CRC, IBD or a colonic resection; antithrombotic therapy precluding polyp resection; lack of informed written consent	Procedure: HD colonoscopy; minimum 6 min withdrawal time; all polyps removed or biopsied with exception of diminutive hyperplastic-appearing polyps located in rectum and judged not to be clinically significant by endoscopist; magnification, chromoendoscopy or light-modification technologies restricted to polyp characterisation at endoscopist discretion AI use: CADe, adjunct. Activated prior to insertion. Histology: expert pathologists participating in the organised screening programme and blinded to intervention assessed histology using Vienna classification	Stratification: gender, age, personal history of adenomas and site Analysis population: mITT[aa] Subgroups: FIT+, GI symptoms and screening/surveillance indications

Repici 2022[22] (parallel RCT; Italy, Switzerland)	Inclusion: 40 to 80 years; colonoscopy for colorectal neoplasia diagnosis, divided into primary screening colonoscopy (outside regional screening programme), work up following positive FIT test (threshold 20 µg Hb/g faeces) within national screening programme, post-polypectomy surveillance, and work up for symptoms/signs (diagnostic colonoscopy) Exclusion: personal history of CRC, IBD or colonic resection; antithrombotic therapy precluding polyp resection; lack of informed written consent	Procedure: HD colonoscopy; minimum 6 min withdrawal time AI use: CADe, adjunct. Activated prior to insertion. Histology: Vienna classification used for histology, no further details	Stratification: gender, age, personal history of adenomas and site Analysis population: mITT[aa] Subgroups: FIT+, post-polypectomy surveillance, primary CRC screening and GI symptom indications
Scholer 2024[2] (parallel RC	Inclusion: 40 to 90 years; cancer screening, alarm symptoms (i.e., iron-deficiency anaemia, suspicion of malignancy following rectal examination and CT findings that raise suspicion of malignancy), inconclusive CT findings (suggestive of a benign but inconclusive cause) and other (positive faecal occult blood stool test, polyp surveillance, hereditary CRC, diarrhoea) Exclusion: history of IBD; contraindication for polypectomy or known polyps; incomplete examinations due to factors such as obstructive	Procedure: white-light imaging or LCI depending on preference of examiner; standard of paediatric HD colonoscopes AI use: CADe, adjunct. Activated during withdrawal. Histology: assessed by pathologists blinded to intervention.	Stratification: endoscopist experience Analysis population: per protocol[g]

T; Sweden)	cancer, technical issues or inadequate bowel preparation; BBPS <2 in one segment or a total BBPS <6		Subgroups: none for GI Genius™ data specifically
Seager 2024[23] (parallel RCT; UK)	Inclusion: ≥18 years; planned colonoscopy for GI symptoms, surveillance after previous colonic pathology (e.g. previous polyps, cancer or other colorectal pathology other than IBD) or due to family history of CRC (one first-degree relative with CRC diagnosed before age of 50 years, or two first-degree relatives with CRC diagnosed at any age), or for CRC screening Exclusion: unable to provide written informed consent; absolute contraindications to colonoscopy; established or suspected large bowel obstruction or pseudo-obstruction; known CRC or polyposis syndromes, colonic strictures or active colitis; undergoing colonoscopy for assessment or surveillance of IBD; pregnant (confirmed or suspected); undergoing planned assessment or treatment of a known and current pathology or lesion (including polypectomy site checks); referred with polyps identified on a bowel scope procedure (a previous national screening programme comprised of one-off flexible sigmoidoscopy at 55 years); remained on therapeutic anticoagulation for the procedure (excluding low-dose aspirin 75 mg once daily, which could be contained)	Procedure: ENDOCUFF VISION™ used in minority of patients; standard procedures followed AI use: CADe, adjunct. Activated prior to insertion. Version 2.0 used. Histology: histology assessments mentioned but no further details	Stratification: age category, sex, colonoscopy subpopulation and NHS Trust Analysis population: ITT Subgroups: screening vs symptomatic colonoscopy indications

Thiruvengadam 2024[24] (parallel RCT; USA)	Inclusion: ≥30 years; colonoscopy for any indication Exclusion: prior colectomy; lack of informed consent	Procedure: white-light HD colonoscopy; use of magnification, chromoendoscopy and light modification techniques at discretion of endoscopist; minimum withdrawal time 8 min; required to removal all polyps proximal to sigmoid colon/rectum, with removal in sigmoid colon/rectum left to endoscopist discretion (diminutive polyps deemed to be hyperplastic could be left *in situ*); biopsies were taken if resections not feasible AI use: CADe, adjunct. Activated prior to insertion. Histology: Vienna classification and 5th WHO classification used for histological assessment by two independent pathologists blinded to intervention	Stratification: procedural indication Analysis population: ITT Subgroups: screening, surveillance positive FIT and diagnostic colonoscopy indications
Wallace 2022[37] (tandem	Inclusion: ≥45 years; screening or surveillance colonoscopy for CRC; average risk for CRC Exclusion: pregnant women or women planning pregnancy; history of IBD, colon resection, FAP, serrated polyposis syndrome, overt lower GI bleeding, colonic stricture or radiation therapy to the abdomen; contraindications to colonoscopy (e.g., acute diverticulitis or toxic megacolon); symptoms requiring random biopsy of the colon.	Procedure: minimum 6 min withdrawal time; all detected polyps removed using standard polyp resection techniques; some endoscopist discretion permitted for diminutive (≤5 mm) polyps that appeared hyperplastic and were within 25 cm of the anus and biopsies could be taken where resection not feasible; use of VCE, NBI, LCI or other techniques including magnification or zoom was not permitted for detection but could be used for characterisation	Stratification: study endoscopist, age and colonoscopy indication Analysis population: FAS/mITT[ab] Subgroups: none

RCT; USA, Italy, UK)		once detected; spray chromoendoscopy was not permitted; tandem procedures performed on same day by same endoscopist AI use: CADe, adjunct. Activated prior to insertion. Histology: Vienna classification or serrated lesion classification used by expert histopathologist blinded to intervention	
NAIAD trial[25] (prospective observational multicen	Inclusion: [redacted] Exclusion: [redacted]	Procedure: not reported AI use: [redacted] Histology: not reported	Stratification: NA Analysis population: [redacted] Subgroups: expert vs non-experts [redacted]

tretrial; UK – [redacted])			
MAGENTIQ-COLO™ (MAGENTIQ-EYE)			
Maas 2024 – MAGENTIQ-COLO™[31] (par	Inclusion: 18 to 90 years; scheduled for non- iFOBT screening (not referred following a positive iFOBT test) or surveillance colonoscopy if last colonoscopy performed at least 3 years prior to scheduled colonoscopy; able to provide written informed consent prior to study procedures; able to communicate clearly with investigators and study staff Exclusion: known or suspected colorectal tumour or polyp; therapeutic colonoscopy (e.g. endoscopic mucosal resection, or intervention to stop lower GI bleeding); inadequately corrected anticoagulation use or disorder; pregnancy or potential pregnancy; inadequate bowel preparation (BBPS <6 or score <2 in any segment); known IBD; any clinically significant condition in opinion of investigator that would preclude study participation; unable or unwilling to comply with requirements of protocol; employees of investigator and study site or sponsor, or family members of these; new diagnosis of active colitis,	Procedure: routine HD colonoscopy; distal devices excluded; minimum withdrawal time 6 to 10 min excluding interventions; diminutive polyps (≤5 mm) in the rectum could be left *in situ* if determined to be hyperplastic AI use: CADe, adjunct. Activated prior to insertion. Version 1.0 with software version 1.7.2 Histology: each resected polyp sent for histopathological examination using Vienna classification; experienced pathologists performed assessments	Stratification: study site and colonoscopy indication Analysis population: mITT[ac] Subgroups: screening vs surveillance colonoscopy indication

all el and ta nd e m R C T; G er m an y, Isr ae l, N et he rla nd s, U S A)	polyposis syndrome, colonic stricture, or obstructing colorectal cancer not allowing complete colonoscopy		

[a]Stratification refers to stratification at randomisation, subgroups refers to colonoscopy indication or endoscopist experience subgroups

[b]Following excluded from analysis: colonic inflammation of >30 cm during colonoscopy, incomplete colonoscopy for any reason, incomplete recording or technical failure of AI system

[c]Following excluded from analysis: screening or randomisation failures, poor or inadequate bowel prep, inadequate withdrawal time or incomplete colonoscopy

[d]Following excluded from analysis: difficulty with deep insertion, poor bowel preparation and history of colorectal surgery

[e]Following excluded from analysis: those with insufficient bowel preparation

[f]Following excluded from analysis: no caecal intubation achieved or inadequate bowel preparation (<2 in any segment)

[g]Following excluded from analysis: ineligible age, IBD, BBPS <6 or incomplete examination

[h]Following excluded from analysis: unsuccessful caecal intubation or procedure cancellation

[i]Included in CADx table as well given CADe and CADx data available from this study

[j]Following excluded from analysis: procedures performed by six endoscopists that did not perform minimum required procedures, those using antithrombotic therapy, prior CRC resection, procedures by endoscopists not included in study and procedures incorrectly performed without CADDIE™/cloud-access

[k]Following excluded from analysis: procedure abandoned/not performed as planned, participant withdrew, did not meet inclusion/exclusion criteria or technical issues, inadequate quality procedure, use of unapproved equipment, FIT+ patients, non-US cleared scope, randomisation protocol deviation, endoscopist completed <10 cases

[l]Following excluded from analysis: inadequate or missing BBPS score (score <6), active colitis, polyposis syndrome, colonic stricture or obstructing CRC impeding a complete colonoscopy, those for whom a quality colonoscopy could not be performed, and participants in the Yaroslavl, Russia, study site enrolled after 24 February 2022

[m]Following excluded from analysis: those with inadequate bowel preparation, incomplete colonoscopy or where distal attachment device used

[n]Following excluded from mITT analysis: those with inadequate bowel preparation (BBPS <2 in any segment), missed caecal intubation or withdrawal time <6 min

[o]Following excluded from analysis: incomplete colonoscopy or poor bowel preparation (score 0 or 1 in any of three bowel sections)

[p]Following excluded from analysis: those with CRC, inadequate bowel preparation or IBD

[q]Following excluded from analysis: those with intestinal tuberculosis, IBD or insertion time too long

[r]Following excluded from analysis: video recording failed, unable to complete evaluation (e.g. due to inability to tolerate exam or unable to insert colonoscope) or researcher considered inappropriate for exclusion as too many polyps

[s]Following excluded from analysis: poor bowel preparation (score 0 to 1 in on BBPS any of three segments), patient discomfort, partial colectomy not reported, clinician decision, caecum not reached and computer hardware failure

[t]Following excluded from analysis: failed procedures, IBD, CRC or polyposis

[u]Following excluded from analysis: failed procedures, IBD, CRC

[v]Following excluded from analysis: caecum not reached in first or second procedure, CRC identified or other (unclear)

[w]Following excluded from analysis: failed procedures, IBD, CRC, polyposis or unable to make slice (presumably biopsy)

[x]Following excluded from analysis: those with misplaced consent forms

[y]Following excluded from analysis: poor bowel cleansing, pain/difficult colonoscopy/minor adverse events, tumour identified, pathology sample lost after sending

[z]Following excluded from analysis: incomplete colonoscopy or inadequate colon cleansing

[aa]Following excluded from analysis: inadequate bowel cleansing

[ab]Following excluded from analysis: prior to start of second colonoscopy due to adverse events, subject withdrawal, technical problems, incomplete colonoscopy due to poor bowel preparation, investigator decision, safety reasons or other reasons not defined

[ac]Following excluded from analysis: inadequate bowel preparation, inability to examine colon, missing bowel preparation score data or not completing both tandem procedures for the tandem analyses

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; ASA, American Society of Anesthesiologists; BBPS, Boston Bowel Preparation Scale; BCSP, Bowel Cancer Screening Programme; BLI, blue-light imaging; CADe, computer-aided detection; CADx, computer-aided characterisation; CRC, colorectal cancer; CSR, clinical study report; CT, computed tomography; CV, cardiovascular; EMIS™, Endoscopic Multimedia Information System; EPCAM, epithelial cell adhesion molecule gene; FAP, familial adenomatous polyposis; FAS, full analysis set; FIT, faecal immunochemical test; FOBT, faecal occult blood test; GI, gastrointestinal; HD, high-definition; IBD, inflammatory bowel disease; iFOBT, immunochemical faecal occult blood test; ITT, intention to treat; LCI, linked-colour imaging; mITT, modified intention to treat; MLH1, mutL homolog 1; MMR, mismatch repair; MSH2, mutS homolog 2; MSH6, mutS homolog 2; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NBI, narrow-band imaging; NHS, National Health Service; NRS, non-randomised study; PDR, polyp detection rate; PMS2, PMS1 homolog 2, mismatch repair system component; RCT, randomised controlled trial; VCE, virtual chromoendoscopy; WHO, World Health Organization.

Table 67. Summary of study characteristics – included clinical studies - CADx

Study (study de	Inclusion criteria	Exclusion criteria	Colonoscopy procedure	Histology/reference standard and comparator	AI use	Analyses[a]

s i g n ; c o u n t r y)						
CAD EYE® (Fujifilm Healthcare UK Ltd.)						
C a s s i n o tt i 2 0 2 3	UC patients undergoing endoscopic surveillance	Not reported	Not reported	Reference standard: histology Comparison: WLI and LCI separately	CADe (adjunct) and CADx (unclear)[b] CAD EYE®. Used with LCI. BLI also mentioned. Unclear when activated.	Exclusions: not reported SSLs: not reported No subgroup data

52 (prospective NRS – abstract only; Ital						

y)						
Dji nba chi an 202 4[5] (pa ral lel RC T; Ca n	45 to 80 years; undergoing colonoscopy between September 2022 and June 2023	Known coagulopathy (INR of >2.5 or platelet count of <50,000/mm^3); IBD; emergency colonoscopy; poor general health (ASA class of >3); trial record also suggests active colitis, familial polyposis syndrome and poor bowel prep (BBPS total score <6 and right segment score <2)	Polyps between 1 and 5 mm in size were analysed according to group randomly assigned to; HD endoscopes used.	Reference standard: histology by board-certified pathologists blinded to intervention Comparison: none (autonomous AI but not prioritised given adjunct data available from this study)	CADx, adjunct CAD EYE®. Unclear when CADx system activated. Polyp held at centre of screen for at least 5 seconds with consistent CADx diagnosis (neoplastic vs hyperplastic). Endoscopist input based on WLI and BLI. Final diagnosis based on endoscopist judgement with high/low confidence noted.	Exclusions: polyps >5 mm, unresected or unretrieved polyps, normal mucosa/inflammatory polyps or polyps where no OD performed SSLs: serrated pathology could be assigned based on endoscopist judgement No subgroup data but sensitivity analyses for high confidence diagnoses only and with removal

ada)						of SSLs or advanced adenomas
Li 2023[61] (prospective NRS; Singa	≥40 years; scheduled for colonoscopy for evaluation of clinical signs and symptoms, polyp surveillance or screening for CRC; at least one polyp detected	Prior bowel resection; IBD; known unresected CRC; pregnancy; incomplete colonoscopy	Polyps resected and sent to histology. Detection of polyps without AI system. Endoscopist OD with WLI and BLI with and without magnification.	Reference standard: histology assessed by pathologists Comparison: endoscopist alone OD (using NBI NICE and JNET classifications)	CADx, autonomous CAD EYE®. After endoscopist alone OD, system activated and CADx prediction recorded (neoplastic vs hyperplastic).	Exclusions: SSLs/polyps, polypoid mucosa, inflammatory polyps, juvenile polyps, patients with no polyps, incomplete colonoscopy SSLs: SSLs/polyps excluded from main analysis Some subgroup data for endoscopist experience reported (1000 to 2000 procedures, 2001 to 3000

pore)						procedures and >3000 procedures)
Picardo2023[54] (NRS–abstraction	IBD patients undergoing surveillance	Not reported	Non-magnified images first assessed by endoscopist only using BLI, followed by CADx assessment. Polyps then resected. Still images of non-resected pseudopolyps could be included if verified as inflammatory by two IBD experts (max five per patient).	Reference standard: histology for resected lesions, IBD experts for non-resected pseudopolyps Comparison: endoscopist alone OD (criteria used not reported)	CADx, autonomous CAD EYE®. Activated following endoscopist alone OD. Used with BLI to characterise lesions (neoplastic vs hyperplastic).	Exclusions: not well reported SSLs: unclear how analysed No subgroup data

ly; Australia)						
Rondonottii2023[58] (prosp	18 to 85 years; adults undergoing outpatient colonoscopy with at least one DRSP detected	history of CRC; hereditary polyposis syndromes or hereditary non-polyposis CRC; inadequate bowel preparation (i.e. BBPS <2 in at least one colonic segment); incomplete colonic examination (caecal intubation not achieved scheduled for partial examinations); polypectomy not performed due to ongoing anticoagulation; urgent colonoscopy scheduled.	All polyps identified by endoscopist assessed in terms of size, location and morphology. Resected and sent for histology. All polyps ≤5 mm characterised, with each step using BLI. Magnification not used for OD. No prespecified observation time. BASIC criteria used by endoscopists to classify as adenoma or non-adenoma. Confidence	Reference standard: histology assessed by expert pathologists blinded to OD using Vienna classification. Second pathologist if disagreement between histology and high-confidence	CADx, adjunct CAD EYE®. AI system switched on after endoscopist OD performed. Automatic classification by system (neoplastic vs hyperplastic) in BLI mode recorded. Only recorded when technically reliable and stable over	Exclusions: low confidence OD, polyps not retrieved, polyps other than DRSPs SSLs: considered within same group as hyperplastic polyps Some subgroup data for expert vs non-expert endoscopists. Also sensitivity

ective NRS; Italy)			level recorded (high or low).	AI-assisted OD of DRSPs Comparison: endoscopist OD alone (BASIC criteria)	time. Final diagnosis of adenoma or non-adenoma based on judgement of endoscopist on review of AI results. Confidence level (high or low) noted.	analyses for high vs low confidence diagnoses and rectosigmoid vs non-rectosigmoid location.
Sato 2024[53] (prospec	20 to 85 years; scheduled to undergo colonoscopy (positive FIT, symptoms such as abdominal pain or constipation, screening colonoscopy or where endoscopist otherwise deemed colonoscopy necessary); written informed consent provided	IBD; FAP; history of colorectal resection other than appendectomy; colorectal stenosis; pregnancy; abnormal blood coagulation function; inability to manage anticoagulation and antiplatelet medication according to Japanese guidelines; severe organ failure; inappropriate for enrolment by endoscopist	Colonoscopies routinely performed with magnification using HD colonoscopes. WLI for detection. OD using WLI non-magnified BLI and magnified BLI without CADx. CADx diagnoses using non-magnified BLI and magnified BLI. Paris, JNET and NICE	Reference standard: histology performed by at least two pathologists blinded to endoscopist assessments. Classification into neoplastic vs non-neoplastic.	CADx, adjunct CAD EYE®. Can be used with WLI and BLI with or without magnification. AI system switched on after endoscopist OD performed. Final assessment and confidence based on endoscopist review of AI	Exclusions: endoscopist classified as diminutive polyps in rectosigmoid colon, invasive cancers or submucosal tumours; no histological assessment; colonoscopies not performed

tiveNRS; Japan)			classifications mentioned.	Comparison: endoscopist assessment alone (autonomous AI also reported but not prioritised)	diagnoses to supplement their own judgement. Confidence level (high or low) noted.	SSLs: considered within same group as hyperplastic polyps Some subgroup data for expert vs non-expert endoscopists (≥1500 vs <1500 colonoscopies).
Taghiakbari2025[5][6]	45 to 80 years; outpatient colonoscopy – focuses on polyps that were not sent for histology	Not reported	BLI mode used with CADx. Magnification colonoscopes available for most colonoscopies – high magnification could be used when there were doubts about advanced histology for a diminutive lesion. WASP and JNET criteria used to identify	Reference standard: expert review of videos by three experts (not histology, as polyps undergoing resect-and-discard and diagnose-and-leave approaches not	CADx, adjunct CAD EYE®. Adenomatous or non-adenomatous classification.	Exclusions: polyps that did not undergo resect-and-discard or diagnose-and-leave approach (i.e. where they were sent for histology instead); CADx-assisted OD not eventually performed

(prospective NRS; Canada)			serrated polyps and polyps with advanced histology, respectively.	sent for histology) Comparison: none		SSLs: likely excluded as these were supposed to be resected and sent for histology when identified by endoscopists No subgroup data
Zavyalov 2022	Not reported	Not reported	Endoscopist and AI system detected lesions in WLI. Differential diagnosis of lesions then performed using BLI mode.	Reference standard: histology mentioned, no further details. Classification into neoplastic vs hyperplastic.	CADe and CADx – possibly autonomous for both but unclear[a] Characterisation mode works with BLI. Classifies into	Exclusions: not reported SSLs: unclear how analysed No subgroup data

448 (prospective NRS; Russia)				Comparison: endoscopist assessment alone	neoplastic vs hyperplastic. Possibly activated after detection complete.	
CADDIE™ (Odin Vision)						
Odin V	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

ision2024CADDIECSR12(parallelRCT;U	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

K)						
Discovery™ (Pentax Medical UK)						
Lopez-Serrano 2024[49] (prospecti	≥18 years; surveillance colonoscopy in UC patients at risk of CRC[d]; written informed consent to perform colonoscopy and deep sedation	personal history of CRC or high-grade dysplasia; previous colectomy (partial or complete); coagulopathy that prevents biopsies or polypectomy; colonoscopy performed in the previous 6 months; pregnant or nursing women; inadequate bowel preparation (stool remnants that could not be washed off, corresponding to BBPS <2 in at least one segment); presence of endoscopic UC activity (Mayo endoscopic subscore for UC ≥2); colonic stenosis; incomplete colonoscopy	HD WLE used up to caecum, with no iSCAN processor settings selected. Two endoscopists worked in parallel, one assessing using VCE and one using AI system. Only suspicious areas were resected for further analysis (mucosal irregularities not entirely secondary to chronic or active UC)	Reference standard: histology according to Vienna classification by experienced GI pathologist Comparison: VCE with iSCAN assessment (Paris and Kudo pit classifications)	CADx, adjunct Discovery™. Activated during withdrawal.	Exclusions: active inflammation during colonoscopy, inadequate bowel preparation, lost with no histology possible SSLs: serrated adenomas with dysplasia classified as dysplastic, serrated adenomas without dysplasia grouped as non-dysplastic No subgroup data

veNRS; Spain)						
GI Genius™ (Medtronic)						
Baumer 2023[60] (pros	≥18 years; inpatients or outpatients presenting for diagnostic colonoscopy or planned polypectomy; able to provide consent	polyps with a diameter >10 mm; chronic IBD; coagulation disorders or drugs that excluded polypectomy; poor general condition (from ASA IV); pregnancy.	Endoscopist and doctoral student reviewed separate screens, with AI classification reviewed by student. Endoscopist performed colonoscopy according to standard procedures. Endoscopist OD made and high or low confidence noted.	Reference standard: histology assessed by two experienced pathologists Comparison: endoscopist alone OD (Paris, NICE and WASP classifications)	CADx, autonomous GI Genius™. Classifies as adenoma, non-adenoma or no prediction. Unclear when activated.	Exclusions: polyps >10 mm, carcinomas >10 mm, patients with no polyps, polyp retrieval failed, no AI analysis possible (i.e. “no prediction” returned)

pectiveNRS; Germany)			Polyps resected at endoscopist discretion.			SSLs: treated as adenomas in the main analysis Some subgroup data for endoscopist experience (<5 vs ≥5 years)
Bernhofer2025[5]	≥18 years; elective colonoscopy for any reason performed by a trainee endoscopist; informed consent obtained	Uninterrupted oral anticoagulation; history of CRC; history of IBD; colonoscopy taken over by non-trainee endoscopist except for lesion resection purposes	Procedures performed with AI active using HD-WLE and NBI during withdrawal. OD based on NICE and JNET classifications. Trainees performed all procedures, but experts could support with resections. All polyps	Reference standard: histology mentioned, no further details Comparison: none (autonomous AI and expert	CADx, adjunct GI Genius™ CADx module (version 3.0.0). Classification as adenomatous or non-adenomatous.	Exclusions: colonoscopy taken over by non-trainee endoscopist except for lesion resection purposes; missing histology

[9] (prospective NRS; Austria)			resected and sent for histopathological evaluation.	endoscopist assessment but not prioritised given adjunct AI use data available from this study and experts only reviewed videos)		SSLs: unclear how SSLs treated in the analysis No subgroup data
Hassan 2022	≥40 years; colonoscopy for primary CRC screening, post-polypectomy surveillance, post-FIT positive (20 μh	Personal history of CRC or IBD (or hereditary polyposis or non-polyposis syndromes from trial record); previous colonic resection; emergency colonoscopy; antithrombotic therapy precluding polyp resection; lack of informed written consent	WLE used for detection of polyps. HD endoscopy systems used. CADx prediction performed first. Blue-light chromoendoscopy system then used for	Reference standard: histology using Vienna classification by single expert pathologist	CADx, adjunct GI Genius™. Version 3.0.0. No zoom or VCE permitted for CADx characterisation.	Exclusions: polyps not retrieved SSLs: treated as non-adenomas in analysis

[55] (prospective NRS; Italy)	haemoglobin/g faeces) or for symptoms/signs		endoscopist OD. Confidence in OD recorded as high or low.	blinded to AI and endoscopist diagnosis Comparison: none (autonomous AI but not prioritised given adjunct data available from this study)	White-light used.AI predictions include adenoma, non-adenoma and no prediction. Final diagnosis based on endoscopist judgement considering AI results and own assessment.	No subgroup data but scenarios with any confidence diagnoses included
Koh2024[62] (	Not reported	Not reported	Performed as per standard of care at the institution. EVIS EXERA III 190 video endoscopy system used. Polyps resected	Reference standard: histology mentioned, no further details.	CADx, autonomous GI Genius™. Classification into adenoma, non-adenoma or no prediction.	Exclusions: no polypectomies; CADx returned no prediction; endoscopists removed polyp before CADx

prospective NRS; Singapore)			for comparison against histology.	Comparison: none		characterisation available SSLs: treated as non-adenomas in analysis No subgroup data but scenarios with any confidence diagnoses included
Rondonotti	18 to 80 years; adult outpatients referred for screening, symptomatic or post-polypectomy surveillance	Increased risk of harbouring adenomatous lesions (e.g., history of CRC, hereditary polyposis syndrome or hereditary non-polyposis colorectal cancer); newly diagnosed IBD; polypectomy not performed because of ongoing anticoagulation; urgent colonoscopy scheduled	Polyps other than 1 to 3 mm located in rectum with obvious hyperplastic appearance were resected and sent for	Reference standard: histology evaluated by expert pathologists	CADx, adjunct GI Genius™. Version 3.0.1. Non-magnified white-light. Final OD based on	Exclusions: polyps >5 mm, not retrieved for histology, high confidence

2024[57] (prospective NRS; Italy)	colonoscopy; at least one diminutive (≤5 mm) polyp detected		histology. If AI detected polyps endoscopist had overlooked, asked to check marked area again. AI assessment performed first using white-light, with endoscopist able to use BLI to obtain AI-assisted OD. Confidence high or low noted.	blinded to OD. Vienna and WHO classifications used. Comparison: none (autonomous AI but not prioritised given adjunct data available from this study)	endoscopist judgement including interpretation of AI results and own assessment.	endoscopist OD could not be made SSLs: treated as non-adenomatous in the analysis Some subgroup data for expert vs non-expert endoscopists

[a]Only subgroup data relevant to the review protocol (i.e. colonoscopy indication or endoscopist experience) have been mentioned here

[b]Limited CADe data available so included in CADx tables only;

[c]Included in CADe table as well given CADe and CADx data available from this study

[d]UC requirements included: confirmed colonic disease by endoscopy and histology, involvement of ≥30% of the colonic surface or any extent if concomitant with primary sclerosing cholangitis and duration of disease >7 years (or any duration if concomitant with primary sclerosing cholangitis)

Abbreviations: AI, artificial intelligence; ASA, American Society of Anesthesiologists; BBPS, Boston Bowel Preparation Scale; BLI, blue-light imaging; CADe, computer-aided detection; CADx, computer-aided characterisation; CRC, colorectal cancer; CSR, clinical study report; DRSP, diminutive rectosigmoid polyp; FAP, familial adenomatous polyposis; FIT, faecal immunochemical test; GI, gastrointestinal; HD, high-definition; IBD, inflammatory bowel disease; INR, international normalised ratio; JNET, Japan Narrow Band Imaging Expert Team; LCI, linked-colour imaging; NBI, narrow-band imaging; NICE, NBI International Colorectal Endoscopic criteria; NRS, non-randomised study; OD, optical diagnosis; RCT, randomised controlled trial; SSL, sessile serrated lesion; UC, ulcerative colitis; VCE, virtual chromoendoscopy; WASP, Workgroup Serrated Polyps and Polyposis; WHO, World Health Organization; WLE, white-light endoscopy; WLI, white-light imaging.

Table 68. Summary of study characteristics – included clinical studies – other studies

Study (study design; country)	Inclusion criteria	Exclusion criteria	Study aims	Colonoscopy and AI details	Analyses	Comment
GI Genius™ (Medtronic)						
Ladabaum 2023[65] (before/after study – abstract only; USA)	Colonoscopists participating in a pragmatic trial of GI Genius™	Not reported	Survey colonoscopists to learn about AI and human interactions	GI Genius™ system	Comparison of attitudes/beliefs of colonoscopists before and after GI Genius™ use	NA
Nehme 2023[64] (before/after study; USA)	Unclear requirements for clinicians	Not reported for clinicians	Evaluated attitudes towards AI-assisted colonoscopy	GI Genius™ system. Decision to activate CADe system at	Historical control group included 6-month time period	Main focus of study was to assess impact on outcomes such as APC, but only results

				discretion of endoscopist.	before GI Genius™ introduced 10-question survey on background and opinions on AI-assisted colonoscopy circulated to physicians and endoscopy staff before and after introduction of GI Genius™	relating to endoscopist opinions were extracted as other data covered by RCTs
Olabintan 2025[66] (non-randomised survey; UK)	Endoscopists (gastroenterologists, surgeons and nurse endoscopists) that participated in NAIAD study	Not reported	Endoscopists surveyed online about perspectives on AI in colonoscopy following the NAIAD study	GI Genius™ system used in NAIAD, not all respondents necessarily used the technology as part of this study	Assessment of endoscopist perspectives on AI use in colonoscopy, including awareness, usage and impact on satisfaction and outcomes	NA
Seager 2024[67] (non-randomised interviews following an RCT; UK)	Medical endoscopists, nurse endoscopists, endoscopy nurses	Not reported	Semi-structured interviews of clinicians involved in COLO-DETECT RCT about	GI Genius™ system used in COLO-DETECT. Not all respondents	Assessment of clinician perspectives on AI use in colonoscopy, including	NA

	and endoscopy unit managers involved in COLO-DETECT trial		perspectives on AI use in colonoscopy. Conducted remotely or in-person using topic guide.	necessarily used the technology as part of this study	evidence required for its use to be accepted, enthusiasm for the technology and concerns	
No technology or unnamed technologies						
Anderson 2024[68] (non-randomised survey; UK)	Endoscopists and managers involved in a trial of three unnamed CADe technologies in NHS trusts	Not reported	Endoscopists and managers surveyed about experience with three unnamed CADe technologies	Three unnamed CADe technologies used	Assessment of experience with use and implementation of the three technologies	NA
Burton 2025[70] (non-randomised survey; USA)	All patients presenting for colonoscopy for any indication	Not reported	Patients completed survey in waiting room prior to procedure including perceptions on AI use in colonoscopy	No specific AI technology, perceptions on AI in colonoscopy as a concept	Surveyed about importance of AI in colonoscopy and factors important in choosing a colonoscopist	NA
Magahis 2023[69] (non-randomised survey; USA)	1st, 2nd and 3rd year gastroenterology	Not reported	Online survey completed by gastroenterology fellows including	No specific AI technology, perceptions on AI in	Surveyed about experience, interest, potential of AI in colonoscopy and	NA

	fellows at a single site		perspectives on AI use in colonoscopy	colonoscopy as a concept	attitudes towards implementation	
Schmidt 2025[71] (non-randomised survey; USA)	Outpatient colonoscopy for screening or surveillance	Not reported	Patients completed survey in waiting room prior to procedure including perceptions on AI use in colonoscopy	No specific AI technology, perceptions on AI in colonoscopy as a concept	Surveyed about familiarity with AI, current use of AI in their healthcare, importance of AI use in colonoscopy and comfort with this	NA

Note: baseline characteristics for these studies, as provided below for CADe and CADx studies, are not provided for these two studies as they were not reported for endoscopists participating in the survey specifically.

Abbreviations: AI, artificial intelligence; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided characterisation; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; RCT, randomised controlled trial.

Table 69. Summary of patient characteristics – included clinical studies - CADe

Study and treatment arm	Age	Sex	Colonoscopy indication	History of bowel conditions	Endoscopist experience	Bowel preparation score

Argus® (Endosoft)						
Strapko 2023[39] (parallel RCT – abstract only; USA)	AI: mean 63 (SD 9.9) years No AI: mean 62.9 (SD 9.2) years	AI: 43.0% male No AI: 48.0% male	Breakdown not reported	• History of CRC and adenomas unclear • IBD excluded	Not reported	Not reported
CAD EYE® (Fujifilm Healthcare UK Ltd.)						
Alali 2025[40] (parallel RCT;	AI: mean 51.1 (SD 7.7) years No AI: mean 54.5 (SD 8.3) years	AI: 58.8% male	• Screening, 94.1% AI vs 94.1% no AI • Surveillance, 5.9% AI vs 5.9% no AI	• History of CRC and adenomas unclear • IBD and prior resections excluded	• Experienced endoscopists (≥1000 colonoscopies) included	**Overall BBPS:** AI: median 8.0 (IQR 6.0 to 9.0)

Kuwait)		No AI: 41.2% male				No AI: median 8.0 (IQR 6.0 to 9.0) BBPS overall score ≥6 (≥2 each segment) required for inclusion
Aniwan 2023[6] (parallel RCT; Thailand)[a]	AI: mean 62.3 (SD 6.9) years No AI: mean 62.1 (SD 6.9) years	AI: 42.7% male No AI: 38.1% male	Full breakdown not reported. 11.6% (AI) and 10.2% (no AI) faecal occult blood positive	• Personal history of CRC excluded • 13.4% (AI) and 11.7% (no AI) with family history of CRC • History of adenomas unclear • IBD excluded	• Average baseline ADR of 33.0% • Included 7 staff attendings and 10 trainees under supervision • 48.7% (AI) and 46.6% (no AI) performed by staff attendings	**Overall BBPS:** AI: mean 8.0 (SD 1.3) No AI: mean 8.1 (SD 1.2)
Desai 2024[7] (parallel RCT; USA)	AI: mean 58.9 (SD 9.5) years No AI: mean 59.3 (SD 10.1) years	AI: 51.5% male No AI: 48.3% male	• Screening, 49.9% AI vs 54.8% no AI; • Surveillance for polyp history (≥3-year interval), 50.1% AI vs 45.2% no AI	• History of CRC and adenomas unclear • IBD excluded	• ADR 25 to 40% required and ≥1000 colonoscopies	BBPS score ≥6 required for inclusion in analysis

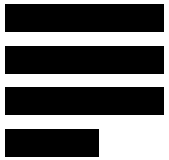
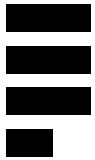
Djinbachian 2024[10] (parallel RCT; Canada)	AI: mean 64.0 (IQR 8.4) No AI: 64.1 (IQR 8.7)	AI: 49.8% male No AI: 51.7% male	• FIT-positive, 6,6% AI vs 7.1% no AI; • Screening, 14.0 AI vs 15.5% no AI • Surveillance, 55.0% AI vs 52.5% no AI • Diagnostic, 18.3% AI vs 21.8% no AI • Other, 6.1% AI vs 2.9% no AI	• History of CRC and adenomas unclear • Family history of CRC: 26.6% AI vs 26.4% no AI • IBD and colitis excluded	• Board-certified gastroenterologists (n=4) or trainees (n=1) • Diverse specialities (one expert in therapeutic endoscopy, one early career gastroenterologist specialised in IBD, one expert in neuromotility, one expert in genetics and hereditary polyposis and one fellow in first year of training)	84.3% in AI and 89.0% in no AI reported to have adequate bowel preparation – scale and threshold used to define this unclear
Hiratsuka 2025[34] (tandem RCT; Japan)	AI: mean 67.4 (SD 3.6) No AI: 70.7 (SD 2.6)	AI: 64.6% male No AI: 63.0% male	• Screening, 60.4% AI vs 58.7% no AI • Symptomatic, 8.4% AI vs 17.4% no AI • Surveillance, 31.2% AI vs 23.9% no AI	• CRC history: 37.5% AI vs 41.3% no AI • History of adenomas not reported • Prior colectomy excluded • FAP or other polyposis excluded • IBD or other bowel conditions unclear	• Expert (≥10 years' endoscopy experience) and non-expert (<10 years' endoscopy experience) permitted • 39.6% in AI and 43.5% in non-AI groups performed by experts	**Overall BBPS:** AI: mean 8.52 (SD 0.62) No AI: mean 8.4 (SD 0.8)
Hunebu rg 2023[8] (par	AI: mean 50.3 (SD 11.9) years	AI: 40.0% male	Specific to Lynch syndrome patients: • MLH1 variant: 34.0% AI vs 37.0% no AI	• 44.0% (AI) and 39.1% (no AI) with personal history of CRC and colon surgery	• Extensive experience in Lynch syndrome endoscopic surveillance • >1000 total colonoscopies and >300 colonoscopies in Lynch Syndrome	BBPS score ≥2 in all segments required for inclusion

allel RCT; Germany)	No AI: mean 46.3 (SD 11.8) years	No AI: 45.6% male	• MSH2 variant: 50.0% AI vs 50.0% no AI • MSH6 variant: 16.0% AI vs 13.0% no AI	• 22.0% (AI) and 17.4% (no AI) with history of adenomas • 44 • IBD or other bowel conditions unclear		
Miyaguchi 2024[29] (parallel RCT; Japan)	AI: mean 65.1 (95% CI, 63.7 to 66.5) years No AI: mean 66.1 (95% CI, 64.7 to 67.4) years	AI: 55.8% male No AI: 57.3% male	• FIT positive, 34.0% AI vs 32.2% no AI; • Symptomatic, 20.8% AI vs 20.5% no AI • Polyp surveillance, 18.8% AI vs 19.3% no AI • Screening, 26.5% AI vs 28.0% no AI	• History of CRC and adenomas unclear • 20.0% (AI) and 18.1% (no AI) with prior abdominal surgery • 27.7% in both groups with diverticulitis • 18.1% (AI) and 16.9% (no AI) with ulcerative colitis	• Experts (>1000 colonoscopies) and trainees (<1000 colonoscopies) included • 64.5% (AI) and 62.8% (no AI) of procedures performed by experts	Aronchick *et al.* score of fair or good required for inclusion
Nakashima 2023[3] (tandem RCT; Japan)	AI: mean 54.9 (SD 10.9) years No AI: mean 55.9 (SD 10.4) years	AI: 73.9% male No AI: 69.7% male	• Screening, 7.2% AI vs 8.2% no AI • FIT positive, 56.5% AI vs 51.9% no AI • Surveillance, 36.2% AI vs 39.9% no AI	• History of CRC and adenomas unclear • IBD excluded	• Board Certified Trainers of the Japan Gastroenterological Endoscopy Society. Experienced.	**Overall BBPS:** AI: mean 8.61 (SD 0.69) No AI: mean 8.68 (SD 0.67)

Rondonotti 2022[9] (parallel RCT; Italy)	AI: median 62.0 (IQR 56 to 68) years No AI: median 61.0 (IQR 55 to 67) years	AI: 52.6% male No AI: 49.6% male	All FIT positive	• History of CRC and adenomas excluded • IBD excluded	• Qualified to work in the FIT-based screening programme (300+ colonoscopies/year, caecal intubation rate ≥95%, ADR ≥25%). • 30-min training using CADe system and performed ≥10 colonoscopies using system before entry	BBPS score ≥2 in all segments required for inclusion
Scholer 2024[2] (parallel RCT; Sweden)[b]	AI: mean 65.9 (SD 11.5) years No AI: mean 66.8 (SD 11.5) years	AI: 53.0% male No AI: 47.0% male	• Screening, 1.0% in both groups • Alarm symptoms (iron-deficiency anaemia), 58.0% AI vs 53% no AI • Inconclusive CT findings, 2.0% AI vs 5.0% no AI • Other (positive FOBT, polyp surveillance, hereditary CRC, diarrhoea, etc.), 39.0% AI vs 41.0% no AI	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	• Experienced and inexperienced included (inexperienced defined as those with fewer than 400 prior colonoscopies) • 70.5% (AI) and 84.7% (no AI) procedures performed by experienced endoscopists	**Overall BBPS:** AI: mean 8.2 (SD 1.2) No AI: mean 8.3 (SD 1.1) BBPS score ≥2 in all segments required for inclusion

Tiankan on 2024[4] (parallel RCT; Thailand)	AI: mean 63.2 (SD 6.5) years No AI: mean 62.2 (SD 7.3) years	AI: 35.8% male No AI: 38.5% male	• FIT positive, 11.3% AI vs 16.0% no AI • Routine screening, 88.8% AI vs 84.0% no AI	• History of CRC excluded • History of adenomas unclear • IBD excluded • 7.5% (AI) and 10.5% (no AI) with family CRC history	• Baseline ADR ≥35% required from mix of primary colonoscopies and FIT positive colonoscopies within last 5 years across ≥100 procedures • Baseline average all endoscopists was 42.6% • Complete ≥20 CADe procedures before study initiation • Includes attending physicians and trainees - 38.8% (AI) and 39.3% (no AI) procedures performed by attending physicians	**Overall BBPS:** AI: 9.0 (8.0 to 9.0) – assume median and IQR No AI: 9.0 (8.0 to 9.0) – assume median and IQR
Yamaguchi 2024[33] (parallel RCT; Japan)	AI: mean 63.1 (SD 10.8) years No AI: mean 63.3 (SD 11.8) years	AI: 73.9% male No AI: 69.7% male	• FIT positive, 46.9% AI vs 54.2% no AI • Detailed examination, 19.5% AI vs 22.0% no AI • Polyp surveillance, 13.3% AI vs 11.0% no AI • Abdominal symptoms, 11.5% AI vs 8.5% no AI • Other, 8.9% AI vs 4.2% no AI	• History of CRC and adenomas unclear • 11.5% (AI) and 11.0% (no AI) with family history of CRC • IBD excluded	• Trainees in third or fourth year as physician with limited colonoscopy experience (0 to 20 cases) • Performed in conjunction with gastroenterology experts (>5000 prior colonoscopies)	**Overall BBPS:** AI: mean 8.4 (SD 1.2) No AI: mean 8.2 (SD 1.5) 98.2% (AI) and 95.8% with fair, good or excellent rating on Modified Aronchick scale.

Zimmermann-Fraedrich 2025[11] (parallel RCT; Germany)	AI: mean 63.0 (SD 8.8) years No AI: mean 63.2 (SD 8.7) years	AI: 59.9% male No AI: 60.5% male	• Screening, 71.9% AI vs 71.0% no AI • Diagnostic (polyp follow-up and symptom evaluation), 28.1% AI vs 29.0% no AI	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	• Experienced examiners included (not defined)	**Overall BBPS – simplified version used, scale unclear:** AI: median 3.0 (IQR 2.0 to 3.0) – 98.2% adequate No AI: median 3.0 (IQR 2.0 to 3.0) – 97.4% adequate
CADDIE™ (Odin Vision)						
Odin Vision 2024 CADDIE CSR[12]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

(parallel RCT; UK)						
Odin Vision 2024 EAGLE CSR[41] (parallel RCT; Italy, Poland, Germany, Spain)						

Discovery™ (Pentax Medical UK)						
Maas 2024 - Discovery™[26] (parallel RCT; Canada, France, Germany, Italy, Netherlands, Russia)	AI: median 61.0 (IQR 52 to 69) years No AI: median 61.0 (IQR 52 to 69) years	AI: 43.6% male No AI: 44.9% male	• Screening (non-iFOBT), 20.0% AI vs 18.6% no A • Surveillance, 39.2% AI vs 42.1% no AI • Diagnostic, 40.8% AI vs 39.3% no AI	• History of CRC and adenomas unclear • 24.0% (AI) and 18.2% (no AI) with family history of CRC • IBD excluded	• Experienced endoscopists with at least 500 prior colonoscopies requirement (all had at least 2000) • Training with CADe with minimum of five procedures before study start	Total BBPS score ≥6 required for inclusion

Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC., formerly EndoMetric Corporation)						
Data provided for EMIS™ trial by manufacturer in 2025[32, 72] (sequential RCT; USA; preliminary data from one	Not well reported for each arm, mean age [redacted]	Not reported	[redacted]	• [redacted]	• Not reported	Not reported

of three sites)						
ENDO-AID™ (Olympus Medical Systems Corp.)						
Gimeno-Garcia 2023[13] (parallel RCT; Tenerife)	AI: mean 62.99 (SD 10.26) years No AI: mean 64.71 (SD 11.79) years	AI: 52.9% male No AI: 52.9% male	• Average risk population screening, 31.6% AI vs 35.7% no AI • Post-polypectomy surveillance, 32.9% AI vs 31.8% no AI • Rectal bleeding, 12.9% AI vs 10.2% no AI • Anaemia, 9.0% AI vs 7.6% no AI • Familial CRC screening, 5.8% AI vs 6.4% no AI • Change in bowel habits, 3.9% AI vs 3.2% no AI • Chronic diarrhoea, 2.6% AI vs 3.2% no AI • Suspicion of CRC, 1.3% AI vs 1.9% no AI	• History of CRC excluded • History of adenomas unclear	• High (ADR ≥40%) and low (ADR <40%) detectors included • >2000 lifetime colonoscopies required	**Overall BBPS:** AI: mean 7.37 (SD 1.4) No AI: mean 7.23 (SD 1.2) 85.4% in both groups with BBPS score ≥6 and score ≥2 in each segment

Lau 2024[14] (parallel RCT; Hong Kong)	AI: mean 66.0 (SD 10.1) years No AI: mean 65.4 (SD 11.3) years	AI: 53.1% male No AI: 55.5% male	• Screening, 7.3% AI vs 6.1% no AI • Surveillance, 32.6% AI vs 31.8% no AI • Symptomatic, 60.1% AI vs 62.1% no AI	• History of CRC excluded • 19.5% (AI) and 15.6% (no AI) with family history of CRC • History of adenomas unclear • IBD excluded	• Endoscopists in training with <500 procedures and <3 years' experience (gastroenterologists or surgeons in training) • Of these, beginners and intermediates included (beginner <200 procedures, intermediate 200 to 500 procedures) • All performed at least 20 colonoscopies under supervision and received training on CADe system before study initiation • 28.5% (AI) and 27.6% (no AI) performed by beginners	**Overall BBPS:** AI: mean 7.85 (SD 1.2) No AI: mean 7.84 (SD 1.2) 100.0% in both groups with BBPS score ≥2 in each segment
Lui 2024[15] (parallel RCT; Hong Kong)[c]	AI: mean 65.2 (SD 10.2) years No AI: mean 65.5 (SD 10.7) years	AI: 53.2% male No AI: 50.5% male	• Screening, 16.7% AI vs 21.0% no AI • Surveillance, 28.0% AI vs 29.0% no AI • Diagnostic, 55.3% AI vs 50.0% no AI	• History of CRC excluded • History of adenomas unclear • IBD excluded	• Experienced (>7 years) and less experienced included • Range 1 to 23 years' experience, historical ADR range 30 to 53% • 45.9% (AI) and 40.7% (no AI) had procedures performed by experienced endoscopists	**Overall BBPS:** AI: mean 7.1 (SD 1.7) No AI: mean 7.1 (SD 1.8)
Spada 2025[16] (par	AI: mean 62.3 (SD 10.5) years	AI: 50.9% male	• Post-polypectomy surveillance, 19.6% AI vs 17.8% no AI	• History of CRC unclear; • 19.6% AI and 17.8% no AI with prior polypectomies (unclear	• Experienced endoscopists (>2000 examinations)	94.6% AI and 94.0% no AI considered to have

allel RCT; Italy)	No AI: mean 61.9 (SD 10.0) years	No AI: 47.3% male	• Direct screening, 38.0% AI vs 38.1% no AI • FIT-positive, 17.2% AI vs 20.3% no AI • Symptoms, 25.2% AI vs 23.7% no AI	if all had at least one adenoma) • IBD excluded • Prior colon resection excluded • Polyposis syndromes excluded	• Minimum of 5 CADe procedures to familiarise with system prior to study	adequate BBPS overall score (≥6)
Vilkoite 2023[42] (parallel RCT; Latvia)	AI: 50.1 (15.4) years – assume mean and SD No AI: 51.2 (14.5) years – assume mean and SD	AI: 46.9% male No AI: 49.5% male	Breakdown not reported	• History of CRC excluded • Prior colonoscopy excluded (and presumably prior adenomas) • IBD excluded	• Two endoscopists with average of 2000 colonoscopies pr year (one 8 years' experience, one >15 years' experience)	BBPS score ≥2 in each segment required for inclusion in analysis
ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.)						
Gong 2020[27] (parallel RCT;	AI: 50.0 (37 to 58) years – assume median and IQR	AI: 53.0% male	• Health examination, 17.0% AI vs 18.0% no AI • Diagnostic, 79.0% AI vs 76.0% no AI	• History of CRC excluded • History of adenomas unclear • IBD excluded	• Endoscopists with experience of 1 to 3 years and total colonoscopy volume 1500 to 4000 procedures	94.1% (AI) and 93.7% (no AI) had total BBPS score ≥6 and score of ≥2 in each segment

China)	No AI: 49.0 (36 to 57) years – assume median and IQR	No AI: 45.0% male	• Surveillance, 4.0% AI vs 6.0% no AI			
Yao 2022[17] (parallel RCT; China)	AI: mean 50.69 (SD 13.15) years No AI: mean 50.85 (SD 13.56) years	AI: 45.2% male No AI: 42.1% male	• Screening, 88.81% AI vs 88.93% no AI • Diagnostic, 0.75% AI vs 1.11% no AI • Surveillance, 10.45% AI vs 9.96% no AI	• History of CRC excluded • 5.6% (AI) and 4.8% (no AI) with family history of CRC • History of adenomas unclear • IBD excluded	• Experienced endoscopists with >2000 prior screening colonoscopies	84.7% (AI) and 85.2% (no AI) with BBPS score ≥2 in all segments
Yao 2024[18] (tandem RCT; China)[d]	AI: mean 50.6 (SD 12.3) years No AI: mean 49.9 (SD 11.7) years	AI: 51.5% male No AI: 53.7% male	• Screening, 63.9% AI vs 63.8% no AI • Diagnostic, 26.4% AI vs 28.0% no AI • Surveillance, 9.7% AI vs 8.3% no AI	• History of CRC excluded • 8.8% (AI) and 7.0% (no AI) with family history of CRC • History of adenomas unclear • IBD excluded	• Novices (>1 year gastroenterology fellowship experience and no prior experience or training in colonoscopy) • Hands on teaching with 20 colonoscopies before study initiation • Tandem procedures performed by experts with >5000 to >15000 prior colonoscopies	86.3% (AI) and 88.2% (no AI) with BBPS total score ≥6 and score ≥2 in all segments

Zhang 2023[50] (parallel RCT; China)	AI: mean 52.9 (SD 12.4) years No AI: mean 53.2 (SD 12.4) years	AI: 40.4% male No AI: 44.8% male	Breakdown not reported	• History of CRC excluded • 17.0% (AI) and 17.2% (no AI) with family history of CRC • History of adenomas unclear • IBD excluded	• >1 year colonoscopy experience and at least 100 prior colonoscopies	**Overall BBPS:** AI: mean 7.2 (SD 1.3) No AI: mean 7.2 (SD 1.4)
EndoScreener® (WISION AI)						
Glissen Brown 2022[35] (tandem RCT; USA)	AI: mean 61.2 (SD 9.8) years No AI: mean 60.5 (SD 8.5) years	AI: 47.8% male No AI: 61.8% male	• Screening, 60.2% AI vs 59.1% no AI • Surveillance, 39.8% AI vs 40.9% no AI	• History of CRC and adenomas unclear • IBD excluded	• Experienced endoscopists with high baseline ADR (first-pass ADR in no AI first group was 44.0%)	**Overall BBPS:** AI: 9.0 (IQR 8.0 to 9.0) – assume median No AI: 9.0 (IQR 8.0 to 9.0) – assume median 96.5% (AI) and 98.2% (no AI) with total BBPS score ≥6 and score ≥2 in each segment

Liu 2020[30] (parallel RCT; China)	AI: mean 49.8 (SD 13.1) years No AI: mean 48.8 (SD 13.0) years	AI: 45.8% male No AI: 48.9% male	• Screening, 24.9% AI vs 21.2% no AI • Symptomatic, 75.1% AI vs 78.8% no AI	• History of CRC excluded • 9.2% (AI) and 5.8% (no AI) with family history of CRC • 6.9% (AI) and 7.1% (no AI) with history of adenomas • IBD excluded	• Experienced and junior endoscopists included • 30.5% (AI) and 32.0% (no AI) performed by senior doctor	**Overall BBPS:** AI: mean 6.7 (SD 1.5) No AI: mean 6.7 (SD 1.4) 79.1% (AI) and 84.1% (no AI) with total BBPS score ≥6 and score ≥2 in each segment
Wang 2019[43] (parallel RCT; China)	AI: mean 51.1 (SD 13.2) years No AI: mean 49.4 (SD 13.8) years	AI: 50.4% male No AI: 46.5% male	• Screening, 7.7% AI vs 8.2% no AI • Symptomatic, 92.3% AI vs 91.8% no AI	• History of CRC excluded • 6.1% (AI) and 6.5% (no AI) with family history of CRC • 2.9% (AI) and 2.6% (no AI) with history of adenomas • IBD excluded	• Experienced and junior endoscopists included • Juniors defined as those with between 100 and 500 colonoscopies, experienced had at least 3000 prior colonoscopies • 38.9% (AI) and 43.5% (no AI) performed by senior doctor	**Overall BBPS:** AI: mean 6.6 (SD 1.2) No AI: mean 6.6 (SD 1.3) 86.0% (AI) and 85.3% (no AI) with total BBPS score ≥6 and score ≥2 in each segment

Wang 2020 (effect of a deep…)[44] (parallel RCT; China)	AI: median 49.0 (IQR 39.0 to 60.0) years No AI: median 49.0 (IQR 40.3 to 56.0) years	AI: 50.0% male No AI: 53.0% male	• Screening, 17.0% AI vs 16.0% no AI • Symptomatic, 83.0% AI vs 84.0% no AI	• History of CRC excluded • 8.7% (AI) and 8.0% (no AI) with family history of CRC • 9.9% (AI) and 8.0% (no AI) with history of adenomas • IBD excluded	• Senior endoscopists with ≥5 years' experience and ≥1000 colonoscopies per year	**Overall BBPS:** AI: mean 6.8 (SD 1.4) No AI: mean 7.0 (SD 1.4) 85.0% (AI) and 86.0% (no AI) with total BBPS score ≥6 and score ≥2 in each segment
Wang 2020 (lower adenoma miss…)[36] (tandem RC	AI: mean 47.7 (SD 10.8) years No AI: mean 47.2 (SD 10.4) years	AI: 50.5% male No AI: 46.5% male	• Screening, 31.5% AI vs 29.8% no AI • Symptomatic, 58.2% AI vs 63.2% no AI • Surveillance, 10.3% AI vs 7.0% no AI	• History of CRC excluded • 7.1% (AI) and 7.0% (no AI) with family history of CRC • 5.4% (AI) and 3.2% (no AI) with history of adenomas • IBD excluded	• Experienced endoscopists (no further details)	**Overall BBPS:** AI: mean 7.1 (SD 1.4) No AI: mean 7.2 (SD 1.4) 86.4% (AI) and 87.0% (no AI) with total BBPS score ≥6 and score ≥2 in each segment

T; China)						
Wang 2023[45] (parallel RCT; China)	AI: median 46.0 (IQR 36.8 to 54.0) years No AI: median 47.0 (IQR 37.0 to 55.0) years	AI: 57.2% male No AI: 52.2% male	• Screening, 17.6% AI vs 16.3% no AI • Symptomatic, 76.6% AI vs 78.4% no AI • Surveillance, 5.8% AI vs 5.3% no AI	• History of CRC excluded • 5.4% (AI) and 6.2% (no AI) with family history of CRC • 2.0% (AI) and 3.0% (no AI) with history of adenomas • IBD excluded	• Experienced endoscopists (>2000 screening colonoscopies)	**Overall BBPS:** AI: mean 6.8 (SD 1.3) No AI: mean 6.9 (SD 1.3) 83.0% (AI) and 81.4% (no AI) with total BBPS score ≥6 and score ≥2 in each segment
GI Genius™ (Medtronic)						
Ahmad 2023[1] (parallel RCT; UK)	AI: mean 66.2 (SD 5.4) years No AI: mean 66.4 (SD 5.4) years	AI: 35.7% male No AI: 32.0% male	All within NHS BCSP, breakdown of specific indications not reported	• History of CRC and adenomas unclear • 5.4% (AI) and 6.2% (no AI) with family history of CRC • 2.0% (AI) and 3.0% (no AI) with history of adenomas	• Experienced endoscopists working within NHS bowel cancer screening centre • Performed between 46 and 109 screening colonoscopies with PDR between 63 and 85% (and ADR between 56 and 80%)	Not reported

				• IBD excluded		
Engelke 2023[28] (parallel RCT; Sweden)	AI: median 66.0 (IQR 49.0 to 76.0) years No AI: median 67.0 (IQR 51.0 to 78.0) years	AI: 47.0% male No AI: 51.0% male	• Primary screening, 3.3% AI vs 4.5% no AI • Pre-planned polypectomy, 5.7% AI vs 1.8% no AI • Tumour follow-up, 4.1% AI vs 3.6% no AI • Diagnostic, 86.9% AI vs 90.0% no AI	• History of CRC and adenomas unclear • 5.4% (AI) and 6.2% (no AI) with family history of CRC • 2.0% (AI) and 3.0% (no AI) with history of adenomas • 6.5% of whole trial had IBD as indication (unclear if others had IBD where not primary indication)	• Trained endoscopists • Those with >200 colonoscopies annually and >50 polypectomies annually in last 3 years considered experts • 59.0% (AI) and 53.0% (no AI) performed by experienced investigator	**Overall BBPS:** AI: median 8.0 (IQR 5.0 to 9.0) No AI: mean 7.0 (IQR 5.0 to 9.0) 58.2% (AI) and 60.0% (no AI) with total BBPS score ≥6 and score ≥2 in each segment
Karsenti 2023[19] (parallel RCT; France)	AI: mean 58.4 (SD 11.4) years No AI: mean 58.4 (SD 11.8) years	AI: 48.0% male No AI: 49.2% male	• Family history of polyps or cancer, 17.2% AI vs 17.4% no AI • Personal history of polyps or cancer, 24.8% AI vs 27.5% no AI • Individual screening, 13.8% AI vs 16.1% no AI	• History of CRC and adenomas unclear – but some had this as indication for colonoscopy • IBD excluded	• Experienced endoscopists with history of >2000 colonoscopies	98.0% (AI) and 97.8% (no AI) with total BBPS score ≥6 and score ≥2 in each segment

			• FIT positive, 7.9% AI vs 6.3% no AI • Haematochezia, 10.6% AI vs 9.3% no AI • Digestive symptoms, 16.4% AI vs 16.0% no AI • Other, 9.4% AI vs 7.4% no AI			
Lagstrom 2025[47] (parallel RCT; Denmark)	AI: mean 64.0 (SD 11.1) years No AI: mean 63.4 (SD 11.1) years	AI: 55.8% male No AI: 50.6% male	• Diagnostic (cancer suspected), 17.0% AI vs 27.3% no AI • Diagnostic (benign disease suspected), 12.3% AI vs 9.9% no AI • FIT-positive (>100 µg/L), 40.0% AI vs 40.5% no AI • Post-polypectomy surveillance, 22.3% AI vs 14.2% no AI • Post-CRC surgery control, 3.3% AI vs 3.5% no AI	• History of CRC not excluded (3.3% AI and 3.5% no AI with prior CRC surgery) • 22.3% AI and 14.2% no AI with prior polypectomies (unclear if all had at least one adenoma) • IBD control colonoscopies excluded • Other bowel conditions unclear	• Experts (>1000 colonoscopies) and non-experts (≤1000 colonoscopies) permitted • 83.3% in AI and 79.2% in no AI group has procedure performed by expert	56.8% and 54.7% of those randomised has bowel preparation of "good" on Modified Aronchick score

			• HNPCC control, 2.5% AI vs 2.5% no AI • Diverticulitis follow-up, 2.8% AI vs 2.0% no AI			
Levartovsky 2023[63] (retrospective study – abstract only; Israel)	Pre-AI: median 43.8 (IQR 28.7 to 61.2) years AI: median 44.5 (IQR 30.7 to 59.1)years	Pre-AI: 55.3% males AI: 54.3% males	All patients had IBD (colonoscopies for IBD severity assessment excluded) 62.9% (pre-AI) and 57.2% (AI) Crohn's disease	• History of CRC and adenomas unclear • IBD patients included (100%)	• Experienced and inexperienced endoscopists appear to be included • No definitions provided	Not reported
Mangas-Sanjuan 2023[20] (parallel	AI: mean 60.7 (SD 5.8) years No AI: mean 60.6 (SD 5.7) years	AI: 53.7% male	All within FIT-based screening programme	• History of CRC excluded • History of adenomas unclear • IBD excluded	• ≥10 procedures with CADe prior to recruitment • Unclear experience but all FIT-based screening	**Overall BBPS:** AI: mean 7.8 (SD 1.3) No AI: mean 7.8 (SD 1.3)

RCT; Spain)		No AI: 53.2% male				All required BBPS score of ≥2 in each segment to be included in analysis
Ortiz 2024[46] (parallel RCT; Belgium, Germany, Italy, Spain)	AI: mean 47.8 (SD 14.0) years No AI: mean 50.1 (SD 14.5) years	AI: 41.0% male No AI: 40.0% male	All surveillance for Lynch syndrome • MLH1, 35.0% AI vs 30.0% no AI • MSH2, 42.0% AI vs 44.0% no AI • MSH6, 22.0% AI vs 22.0% no AI • EPCAM, 1.0% AI vs <1.0% no AI	• 20.0% (AI) and 19.0% (no AI) with history of CRC • History of adenomas unclear • 29.0% (AI) and 24.0% (no AI) with prior non-CRC neoplasia • IBD excluded	• ADR ≥20% screening and ≥35% FIT screening • ≥2000 colonoscopies • Trained in optical diagnosis and chromoendoscopy techniques • ≥10 colonoscopies with CADe prior to study	96.0% (AI) and 97.0% (no AI) with BBPS total score ≥6 and score ≥2 in each segment
Pinto 2022[51] (NR	Median age 50 years in whole study	72.2% male in	All screening colonoscopies in Lynch syndrome	• History of CRC and adenomas unclear	• Expert endoscopist mentioned, no definition provided	Not reported

S, tandem procedures – abstract only; Portugal)		whole study		• IBD or other bowel conditions unclear		
Repici 2020[21] (parallel RCT; Italy)	AI: mean 61.5 (SD 9.7) years No AI: mean 61.1 (SD 10.6) years	AI: 50.4% male No AI: 48.0% male	• FIT positive, 29.9% AI vs 30.5% no AI • Primary CRC screening, 22.6% AI vs 22.1% no AI • Surveillance, 25.2% AI vs 22.7% no AI • GI symptoms, 22.3% AI vs 24.7% no AI	• History of CRC excluded • History of adenomas unclear • IBD excluded	• Experienced endoscopists - >2000 colonoscopies	99.4% in both groups with BBPS score ≥2 in each segment
Repici 2022[22] (par	AI: mean 61.9 (SD 9.8) years	AI: 52.7% male	• FIT positive, 7.3% AI vs 7.3% no AI	• History of CRC excluded • 38.5% in both groups with history of adenomas	• Non-expert endoscopists - <2000 colonoscopies • Eligible to perform screening colonoscopies and non-complex	99.7% (AI) and 99.4% (no AI) with BBPS score >2 in each segment

allel RCT; Italy, Switzerland)	No AI: mean 62.6 (SD 10.2) years	No AI: 47.3% male	• Primary CRC screening, 29.7% AI vs 28.5% no AI • Surveillance, 38.5% AI vs 35.7% no AI • GI symptoms, 24.5% AI vs 28.5% no AI	• IBD excluded	therapeutic procedures autonomously (not novices)	
Scholer 2024[2] (parallel RCT; Sweden)[b]	AI: mean 65.9 (SD 11.5) years No AI: mean 66.8 (SD 11.5) years	AI: 53.0% male No AI: 47.0% male	• Screening, 1.0% in both groups • Alarm symptoms (iron-deficiency anaemia), 58.0% AI vs 53% no AI • Inconclusive CT findings, 2.0% AI vs 5.0% no AI • Other (positive FOBT, polyp surveillance, hereditary CRC, diarrhoea, etc.), 39.0% AI vs 41.0% no AI	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	• Experienced and inexperienced included (inexperienced defined as those with fewer than 400 prior colonoscopies) • 70.5% (AI) and 84.7% (no AI) procedures performed by experienced endoscopists	**Overall BBPS:** AI: mean 8.2 (SD 1.2) No AI: mean 8.3 (SD 1.1) BBPS score ≥2 in all segments required for inclusion
Seager 2024[23] (parallel	AI: mean 62.5 (SD 10.8) years	AI: 55.9% male	• Screening – FIT positive, 60.4% AI vs 60.8% no AI	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	• Pre-trial CADe training • Median 10 years as independent colonoscopist • 49.3% BCSP accredited	Not reported

RCT; UK)	No AI: mean 62.2 (SD 10.8) years	No AI: 55.6% male	• Symptomatic, 39.6% AI vs 39.2% no AI		• Qualified to perform colonoscopy independent of supervision	
Thiruvengadam 2024[24] (parallel RCT; USA)	AI: median 56.0 (IQR 50.0 to 62.0) years No AI: median 54.0 (IQR 49.0 to 62.0) years	AI: 40.7% male No AI: 37.3% male	• Screening, 69.3% AI vs 65.3% no AI • Surveillance, 6.0% AI vs 10.0% no AI • FIT positive, 5.8% AI vs 5.8% no AI • Diagnostic, 18.9% AI vs 18.9% no AI	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	• ≥1000 colonoscopies • Baseline ADR ≥25% • No trainees included • Up to 5 colonoscopies with CADe before study initiation	91.5% (AI) and 90.4% (no AI) with BBPS total score ≥6 and score ≥2 in each segment
Wallace 2022[37] (tandem RCT; USA, Italy, UK)	AI: mean 63.0 (SD 8.2) years No AI: mean 64.6 (SD 8.1) years	AI: 69.0% male No AI: 67.5% male	• Screening, 35.3% AI vs 36.0% no AI • Surveillance <3 years, 10.3% AI vs 12.3% no AI • Surveillance 3 to 10 years, 54.3% AI vs 51.8% no AI	• History of CRC and adenomas unclear • IBD excluded	• ≥1000 colonoscopies • ADR between 20 and 40% (or PDR between 30 and 70%)	**Overall BBPS:** AI: mean 8.0 (SD 1.3) No AI: mean 8.1 (SD 1.5) 97.4% (AI) and 93.9% (no AI) with total BBPS score ≥6 and score ≥2 in each segment

NAIAD trial[25] (prospective observational multicentre trial; UK – [redacted])	NR	NR	• [redacted]	• [redacted]	• [redacted] • [redacted]	[redacted]
MAGENTIQ-COLO™ (MAGENTIQ-EYE)						
Maas 2024 – MAGENTIQ-COLO	AI: median 59.7 (IQR NR for combined groups) years No AI: median 60.1 (IQR NR	AI: 52.6% male No AI: 55.0% male	• Non-iFOBT screening, 56.8% AI vs 55.5% no AI • Surveillance, 43.2% AI vs 44.5% no AI	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	• ADR between 25 and 40%	All had BBPS total score ≥6 and score ≥2 in each segment to be included in analysis

™31 (parallel and tandem RCT; Germany, Israel, Netherlands, USA)[e]	for combined groups) years					

[a]Data for two CADe and two standard colonoscopy arms (with and without ENDOCUFF VISION™) combined for purpose of this review

[b]Reported for overall trial rather than specifically for CAD EYE® or GI Genius™ interventions

[c]Data for two CADe arms (with and without ENDOCUFF VISION™) combined for purpose of this review

[d]Data for two novice arms included in analysis only, as expert colonoscopy group not comparable

[e]Parallel and tandem groups for CADe and standard colonoscopy groups combined for most outcomes (based on which procedure performed first for tandem arms)

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; BBPS, Boston Bowel Preparation Scale; BCSP, Bowel Cancer Screening Programme; CADe, computer-aided detection; CRC, colorectal cancer; CSR, clinical study report; CT, computed tomography; EMIS™, Endoscopic Multimedia Information System; FAP, familial adenomatous polyposis; FIT, faecal immunochemical test; FOBT, faecal occult blood test; GI, gastrointestinal; HNPCC, hereditary nonpolyposis colorectal cancer; IBD, inflammatory bowel disease; iFOBT, immunochemical faecal occult blood test; IQR, interquartile range; MLH1, mutL homolog 1; MSH2, mutS homolog 2; MSH6, mutS homolog 6; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NHS, National Health Service; NR, not reported; NRS, non-randomised study; PDR, polyp detection rate; RCT, randomised controlled trial; SD, standard deviation.

Table 70. Summary of patient characteristics – included clinical studies - CADx

Study[a]	Age	Sex	Colonoscopy indication	History of bowel conditions	Endoscopist experience	Bowel preparation
CAD EYE® (Fujifilm Healthcare UK Ltd.)						
Cassinotti 2023[52] (prospective NRS – abstract only; Italy)	AI: mean 54.0 (SD NR) years No AI: mean 54.0 (SD NR) years	Not reported	All endoscopic surveillance of ulcerative colitis	• History of CRC and adenomas unclear • IBD included – all ulcerative colitis patients	Not reported	Not reported
Djinbachian 202	Mean 64.0 (SD 8.4) years	49.8% male	• Screening, 20.5% • Surveillance, 55.0%	• History of CRC and adenomas unclear	• Between 1 and >30 years' experience in optical diagnosis	Trial recor

4[5] (parallel RCT; Canada)			• Diagnostic, 18.3%	• 26.6% with family history of CRC • IBD and active colitis excluded	• Procedural volume between 300 and 1500 colonoscopies per year	d suggests those with inadequate bowel preparation (total BBPS score <6 or score <2 in right segment) excluded

Li 2023[61] (prospective NRS; Singapore)	Mean 63.5 (SD 9.9) years	55.9% male	Not reported	• History of CRC and adenomas unclear • IBD excluded	• Credentialed endoscopists completed 3-year structured training programme including image-enhanced endoscopy for polyp characterisation • Work in participating sites where image-enhanced endoscopy performed routinely for all polyps detected • ≥20 procedures using CADx system	Not reported
Picardo 2023[54] (NRS – abstract only; Australia)	Average 49.6 (SD not reported) years	52.0% male	All surveillance in IBD	• History of CRC and adenomas unclear • IBD included – all IBD surveillance	Not reported	Not reported
Rondon otti 2023[58] (prospec	Mean 63.7 (SD 10.4) years	52.5% male	• Symptoms, 25.0% • Surveillance, 36.1%	• History of CRC excluded • History of adenomas unclear	• Experts and non-experts included • Experts followed dedicated training programme, auditing and performed optical diagnosis regularly • Formal 45 min training on optical diagnosis, BLI, BASIC system and AI features	Those with inadequate

tive NRS; Italy)			• FIT positive screening, 17.8% • Primary screening, 21.1%	• IBD or other bowel conditions unclear		bowel preparation excluded (BBPS score <2 in any segment)
Sato 2024[53] (prospective NRS; Japan)	Median 70.0 (range 32 to 85) years	68.0% male	Includes positive faecal immunochemistry tests, symptoms such as abdominal pain or constipation, screening colonoscopy or where endoscopist otherwise deemed colonoscopy necessary – no breakdown provided	• History of CRC and adenomas unclear • IBD excluded • FAP excluded • Prior colorectal resection other than appendectomy excluded	• Experts (≥1500 colonoscopies) and non-experts (<1500 colonoscopies) permitted • 70% of colonoscopies performed by experts	Poor or inadequate bowel preparation (not defined) not

						inclu ded
Tag hiak bari 202 5[56] (pro spec tive NRS ; Can ada)	Mean 67.2 (SD 8.8) years	50.5% male	Outpatient colonoscopy – no breakdown provided	• History of CRC and adenomas unclear • IBD and other bowel conditions unclear	• Academic endoscopists with training and experience in CADx-assisted and CADx-unassisted OD performed all cases	Not repor ted
Zav yalo v 202 4[48] (pro spec tive NRS ; Rus sia)	AI: average 64.3 (SD NR) years Endoscopist: average 67.9 (SD NR) years	AI: 41.1% male Endoscopi st: 27.8% male	Not reported	• History of CRC and adenomas unclear • IBD or other bowel conditions unclear	Not reported	Not repor ted
CADDIE™ (Odin Vision)						

Odin Vision 2024 CADDIE CSR[12] (parallel RCT; UK)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Discovery™ (Pentax Medical UK)						
Lopez-Serrano 2024[49] (prospective NRS; Spain)	Median 54.0 (IQR 48.0 to 63.0) years at index colonoscopy	57.7% male	All surveillance colonoscopy in ulcerative colitis patients at risk of CRC	• History of CRC excluded • 27.0% with family history of CRC • 23.1% with history of colorectal dysplasia • IBD included – all ulcerative colitis patients	• Senior endoscopist with extensive experience in DCE and VCE • Assisted by experienced nurse	Those with inadequate bowel preparation excluded

						(BBPS score <2 in any segment)
GI Genius™ (Medtronic)						
Baumer 2023[60] (prospective NRS; Germany)	Mean 67.0 (SD 12.3) years	68.9% male	• Polypectomy, 10.7% • Screening, 14.6% • Surveillance, 23.3% • Tumour screening, 13.6% • EMR follow-up, 5.8% • Surgery follow-up, 1.0% • iFOBT, 4.0% • Visible bleeding, 7.0% • Anaemia, 2.0% • Abdominal pain, 11.0% • Diarrhoea, constipation or	• History of CRC and adenomas unclear • Chronic IBD excluded	• Range of experience from <5, 5 to 10 and >10 years endoscopy experience	**Overall BBPS:** Mean 7.9 (SD 1.3)

			change of bowel habits, 3.0% • Pre-op, 3.0% • Surveillance following radio-chemotherapy, 1.0% • Surveillance following recurrent diverticulitis, 1.0%			
Bernhofer 2025[59] (prospective NRS; Austria)	Mean 63.8 (SD 12.7) years	48.9% male	• Screening, 38.2% • Surveillance, 20.9% • Polypectomy, 15.6% • GI complaints, 14.7% • Other, 10.7%	• History of CRC excluded • History of adenomas unclear • IBD excluded • Other bowel conditions unclear	• Trainee endoscopists performed procedures (<500 colonoscopies) with experts (>2000 colonoscopies) able to support with polypectomies	Not reported
Hassan 2022[55] (prospective NRS;	Mean 66.6 (SD 10.2) years	46.3% male	• FIT positive, 16.6% • Screening, 25.9% • Post-polypectomy surveillance, 24.7% • Diagnostic, 32.7%	• History of CRC excluded • History of adenomas unclear • IBD excluded	• Experienced endoscopists (>2000 screening colonoscopies) • Trained in optical diagnosis and participation in previous polyp characterisation studies with BLI	Not reported

Italy)						
Koh 2024[62] (prospective NRS; Singapore)	Not reported	Not reported	Not reported	• History of CRC and adenomas unclear • IBD and other bowel conditions unclear	• Colonoscopies performed by accredited trainees and specialists in endoscopy unit	Not reported
Rondonotti 2024[57] (prospective NRS; Italy)	Median 66.0 (IQR 57.0 to 73.0) years	55.0% male	• Symptoms, 32.5% • Surveillance, 37.0% • FIT positive, 21.0% • Primary screening, 9.5%	• History of CRC excluded • History of adenomas unclear • IBD excluded	• Experts and non-experts in optical diagnosis • Experts followed training, participated in prior studies of optical diagnosis, had auditing and monitoring and performed optical diagnosis on a regular basis • Median 20 years endoscopy practice • All at least 300 colonoscopies	Not reported

[a]For most studies of CADx, both assessments were performed on the same patients meaning characteristics reported apply to both assessments.

Abbreviations: ADR, adenoma detection rate; AI, artificial intelligence; BBPS, Boston Bowel Preparation Scale; BLI, blue-light imaging; CADx, computer-aided characterisation; CRC, colorectal cancer; CSR, clinical study report; DCE, dye-based chromoendoscopy; FAP, familial adenomatous polyposis; FIT, faecal immunochemical test; GI, gastrointestinal; IBD, inflammatory bowel disease; iFOBT, immunochemical faecal occult blood test; IQR, interquartile range; OD, optical diagnosis; NRS, non-randomised study; RCT, randomised controlled trial; SD, standard deviation; VCE, virtual chromoendoscopy.

Table 71. Summary of extracted outcomes from clinical studies - CADe

Study	Adenoma detection outcomes	Serrated lesion detection outcomes	Other polyp detection outcomes	Other outcomes	Colonoscopy indication subgroup data	Endoscopist experience subgroup data	Outcomes not analysed
Argus® (Endosoft)							
Strapko 2023[39] (parallel RCT – abstract only; USA)	ADR; APC	NA	NA	AEs	NA	NA	NA
CAD EYE® (Fujifilm Healthcare UK Ltd.)							
Alali 2025[40] (parallel RCT; Kuwait)	ADR; APC	NA	PDR; PPC	Withdrawal time; insertion time; AEs; CADx accuracy (autonomous)	NA	NA	Insertion time; CADx accuracy (autonomous)

Aniwan 2023[6] (parallel RCT; Thailand)	ADR; advanced ADR; ADR by size (<10 and ≥10 mm) and location (proximal and distal); flat ADR; APC; advanced APC; proximal APC	SSL DR	NA	Withdrawal time; caecal intubation time; AEs	NA	Staff vs trainee: ADR	Flat ADR; caecal intubation time
Desai 2024[7] (parallel RCT; USA)	ADR; advanced ADR; diminutive ADR; APC	SSL DR; SSL per colonoscopy; serrated lesion DR; serrated lesions per colonoscopy	PDR; PPC; neoplasias per colonoscopy	Total procedure time; withdrawal time; AEs; PPV of a polyp being an adenoma[a]; positive percent agreement for neoplastic lesions, SSL and hyperplastic polyps in the proximal colon[b]; true histology rate[c]	Screening vs surveillance: ADR; APC; PPV of a polyp being an adenoma[a]	NA	Positive percent agreement for neoplastic lesions, SSL and hyperplastic polyps in the proximal colon

Djinbachian 2024[10] (parallel RCT; Canada)	ADR; advanced ADR; ADR by location; APC	SSL DR	PDR;	AEs	NA	Expert (ADR >25%) vs non-expert (ADR ≤25%): ADR	NA
Hiratsuka 2025[34] (tandem RCT; Japan)	AMR; ADR; APC	NA	PMR; PDR; PPC	Insertion time; observation time	NA	Expert (≥10 years' experience) vs non-expert (<10 years' experience): AMR; PMR; ADR; PDR; APC; PPC	Insertion time; endoscopist experience subgroup analyses for AMR, PMR, PDR and PPC
Huneburg 2023[8] (parallel RCT; Germany)	ADR; advanced ADR; completely flat ADR; data to calculate APC as IRR	SSL DR	PDR; hyperplastic polyp DR	Total procedure time; caecal intubation time; withdrawal time; AEs	Prior vs no prior CRC: ADR	NA	Completely flat ADR; caecal intubation time
Miyaguchi 2024[29] (parallel RCT; Japan)	ADR; APC; APC by size (≤5, 6 to 9 and ≥10 mm), location (six categories), morphology (sessile, non-	SSL DR	NA	Withdrawal time; caecal intubation time; AEs	FIT vs non-FIT: ADR	Expert vs trainee: ADR	APC by morphology and histopathology; caecal intubation time

	polypoid and pedunculated) and histopathology (eight categories)						
Nakashima 2023[3] (tandem RCT; Japan)	ADR; advanced ADR; APC; adenomas per positive patient; AMR rectosigmoid	NA	NA	Withdrawal time	FIT vs primary screening: ADR; APC; withdrawal time	NA	NA
Rondonotti 2022[9] (parallel RCT; Italy)	ADR; advanced ADR; ADR by location (proximal and distal) and morphology (polypoid and non-polypoid); APC; APC by size (<10 and ≥10 mm), location (proximal and distal) and morphology (polypoid and non-polypoid)	SSL DR; SSL DR by size (≤5, 6 to 9 and ≥10 mm), histology (with and without dysplasia), location (proximal and distal) and morphology (polypoid and non-polypoid)	Non-neoplastic polyp DR	Insertion time; inspection time	NA	Baseline ADR ≤40, 41 to 45 and ≥46%: ADR	ADR, APC and SSL DR by morphology; insertion time

Scholer 2024[2] (parallel RCT; Sweden)	ADR	SSL DR	NA	NA	NA	NA	Only outcomes reported separately for CAD EYE® intervention analysed
Tiankanon 2024[4] (parallel RCT; Thailand)	ADR; advanced ADR; proximal ADR; APC; advanced APC; proximal APC	NA	NA	Caecal intubation time; withdrawal time; AEs	NA	NA	Caecal intubation time
Yamaguchi 2024[33] (parallel RCT; Japan)	ADR; APC; AMR; missed lesions per colonoscopy	NA	PDR; PPC; PPC by size (<5, 5 to 10 and >10 mm), location (six categories), histopathology (seven categories) and morphology (six categories)	Withdrawal time; AEs	NA	NA	PPC by size, location, histopathology and morphology

Zimmermann-Fraedrich 2025[11] (parallel RCT; Germany)	ADR; APC; advanced ADR; advanced adenomas per patient; ADR by size; proximal ADR;	SSL DR	Hyperplastic polyp DR; patients with only hyperplastic polyps; hyperplastic polyps per patient; hyperplastic polyps per colonoscopy;	Withdrawal time; AEs	NA	NA	NA
CADDIE™ (Odin Vision)							
Odin Vision 2024 CADDIE CSR[12] (parallel RCT; UK)	ADR; advanced ADR; ADR by size (≤5, 6 to 9 and ≥10 mm); proximal ADR; APC; adenomas per extraction	SSL DR; SSL per colonoscopy	PDR; PPC; PPC by location (proximal and distal) and morphology (polypoid and non-polypoid); neoplastic polyp DR; false positive rate[d]	Insertion time; withdrawal time; achievement of caecal intubation; AEs; concordance of surveillance intervals with histology; CADx-related	NA	NA	PPC by location and morphology; insertion time; achievement of caecal intubation

				outcomes listed in Table 72			
Odin Vision 2024 EAGLE CSR[41] (parallel RCT; Italy, Poland, Germany, Spain)	ADR; APC; APC by size (≤5, 6 to 9 and ≥10 mm); APC by location (proximal and distal)	Sessile serrated adenomas per colonoscopy	PPC; neoplastic polyps per colonoscopy; positive percent agreement[e]	Withdrawal time; procedure time; AEs; device deficiencies	Surveillance vs screening: ADR; APC; positive percent agreement	ADR <31, 31 to 40 and >40%: ADR; APC; positive percent agreement	NA
Discovery™ (Pentax Medical UK)							
Maas 2024 - Discovery™[26] (parallel RCT; Canada, France, Germany, Italy, Netherlands, Russia)	ADR; ADR by size (≤5, 6 to 9 and ≥10 mm), location (proximal and distal, and six categories) and morphology (six categories); APC	SSL DR; SSL per colonoscopy	PDR; PPC	Total procedure time; withdrawal time; false positives	Non-iFOBT screening, surveillance and diagnostic: ADR; SSL DR; PDR; APC; SSL per colonoscopy; PPC	Low, medium and high detectors: ADR; SSL DR; PDR; APC; SSL per colonoscopy; PPC	ADR by morphology
Endoscopic Multimedia Information System (EMIS™; EndoPerv LLC., formerly EndoMetric Corporation)							

Data provided for EMIS™ trial by manufacturer in 2025[32, 72] (sequential RCT; USA; preliminary data from one of three sites)	ADR (adenomatous polyps); ADR (adenomatous, sessile and tubulovillous polyps)	NA	NA	Clinician feedback on technology	NA	NA	NA
ENDO-AID™ (Olympus Medical Systems Corp.)							
Gimeno-Garcia 2023[13] (parallel RCT; Tenerife)	ADR; advanced ADR; non-advanced ADR; ADR by size (≤5, 6 to 9 and ≥10 mm), location (right-sided, transverse and left-sided) and morphology (four categories); APC; APC by size (≤5, 6 to 9 and ≥10 mm), location (right-sided, transverse	Serrated neoplasia DR	PDR; advanced neoplasia DR; CRC DR; non-neoplastic lesion DR	Insertion time; withdrawal time	NA	High vs low detectors: ADR	ADR and APC by morphology; insertion time

	and left-sided) and morphology (flat and protruding)						
Lau 2024[14] (parallel RCT; Hong Kong)	ADR; advanced ADR; ADR by size (<5, 5 to 10 and >10 mm), location (eight categories) and morphology (non-pedunculated and pedunculated); APC; APC by size (<5, 5 to 10 and >10 mm), location (right and left) and morphology (non-pedunculated and pedunculated)	SSL DR	PDR; supervisor-reported missed polyps; non-neoplastic polyp resection rate; non-neoplastic resections per colonoscopy	Withdrawal time; caecal intubation time; AEs; false positives	Symptomatic, screening and surveillance: ADR; ADR by size (<5, 5 to 10 and >10 mm); ADR by location (right and left); ADR by morphology (non-pedunculated and pedunculated); APC; PDR; non-neoplastic resection rate; non-neoplastic resections per colonoscopy	Beginner vs intermediate: ADR; ADR by size (<5, 5 to 10 and >10 mm); ADR by location (right and left); ADR by morphology (non-pedunculated and pedunculated); APC; PDR; non-neoplastic resection rate; non-neoplastic resections per colonoscopy	ADR and APC by morphology; caecal intubation time
Lui 2024[15] (parallel RCT; Hong Kong)	ADR; advanced ADR; APC; advanced APC; adenoma or advanced	SSL DR; SSL per colonoscopy	PDR; PPC by size (1 to 4, 5 to 9 and ≥10 mm); diminutive hyperplastic	Caecal intubation time; withdrawal time	Screening vs surveillance: ADR; advanced ADR; APC; advanced APC; SSL DR; SSL per	NA	PPC by size; caecal intubation time

	adenoma per polypectomy; APC by size (1 to 4, 5 to 9 and ≥10 mm)		polyps per colonoscopy		colonoscopy; PDR; PPC; PPC by size (1 to 4, 5 to 9 and ≥10 mm)		
Spada 2025[16] (parallel RCT; Italy)	ADR; APC; advanced ADR	SSL DR	PDR; PPC	Withdrawal time; AEs	NA	NA	NA
Vilkoite 2023[42] (parallel RCT; Latvia)	ADR	NA	PDR	NA	NA	NA	NA
ENDOANGEL® Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Equipment (Wuhan ENDOANGEL Medical Technology Co. Ltd.)							
Gong 2020[27] (parallel RCT; China)	ADR; ADR by size (≤5, 6 to 9 and ≥10 mm) and location (six categories); APC	NA	PDR; PDR by size (≤5, 6 to 9 and ≥10 mm) and location (six categories); PPC	Withdrawal time; AEs	NA	NA	PDR by size and location
Yao 2022[17] (parallel RCT; China)	ADR; advanced ADR; non-advanced ADR; ADR by size (≤5, 6 to 9 and ≥10	SSL DR	PDR; non-precancerous PDR; PDR by size (≤5, 6 to 9 and ≥10 mm) and	Withdrawal time; AEs; false positives	NA	NA	PDR by size and location

	mm) and location (six categories); APC		location (six categories); PPC				
Yao 2024[18] (tandem RCT; China)	ADR; advanced ADR; ADR by size (≤5, 6 to 9 and ≥10 mm), location (six categories) and morphology (sessile, flat and pedunculated); APC; AMR; AMR by size (≤5, 6 to 9 and ≥10 mm), location (six categories), morphology (sessile, flat and pedunculated) and visibility (visible and invisible); advanced AMR	NA	PDR; PDR by size (≤5, 6 to 9 and ≥10 mm), location (six categories) and morphology (sessile, flat and pedunculated); PPC; PMR; PMR by size (≤5, 6 to 9 and ≥10 mm), location (six categories), morphology (sessile, flat and pedunculated) and visibility (visible and invisible)	Caecal insertion time; withdrawal time; impact on surveillance intervals	NA	NA	ADR, AMR, PDR and PMR by morphology; PDR and PMR by size and location; AMR and PMR by visibility; caecal insertion time

Zhang 2023[50] (parallel RCT; China)	NA	NA	PDR; PDR by size (≤5, 6 to 9 and ≥10 mm); PDR by location (ascending, transverse and descending); PDR by morphology (flat, pedunculated and sub pedicle); miss detection rate	Successful caecal insertion; withdrawal time; AEs; diagnostic accuracy for polyp detection (polyp and patient level)	NA	NA	PDR by size, location and morphology; successful caecal insertion
EndoScreener® (WISION AI)							
Glissen Brown 2022[35] (tandem RCT; USA)	ADR; APC; AMR; advanced AMR	SSL per colonoscopy; SSL miss rate	PDR; PPC; PMR; hyperplastic polyp miss rate	Withdrawal time; AEs; false positive rate; false negative rate	NA	NA	NA
Liu 2020[30] (parallel RCT; China)	ADR; APC	SSL DR	PDR; PPC; missed polyps	Withdrawal time; total procedure time; insertion	NA	NA	Insertion time

				time; withdrawal time in those with no polyps; AEs; false detections; endoscopist fatigue			
Wang 2019[43] (parallel RCT; China)	ADR; APC	NA	PDR; PPC	Withdrawal time; total procedure time; insertion time; AEs; false positives; false negatives	NA	NA	Insertion time
Wang 2020 (effect of a deep…)[44] (parallel RCT; China)	ADR; APC; missed adenomas	Missed sessile serrated adenomas/polyps	PDR; PPC; missed polyps	Withdrawal time; insertion time; withdrawal time in those with no polyps; AEs; false detections; missed polyps	NA	NA	Insertion time

Wang 2020 (lower adenoma miss…)[36] (tandem RCT; China)	ADR; APC; AMR (per-patient and per-polyp); advanced AMR; AMR by size (<5, 5 to 9 and ≥10 mm), location (six categories), morphology (pedunculated, non-pedunculated and laterally spreading); and visibility (visible and invisible)	Sessile serrated adenoma/polyp miss rate	PDR; PPC; PMR; PMR by visibility (visible and invisible)	Caecal insertion time; withdrawal time; AEs; false detections	NA	NA	AMR by morphology and visibility; PMR by visibility; caecal insertion time
Wang 2023[45] (parallel RCT; China)	ADR; APC	NA	PDR; PPC; missed polyps	Withdrawal time; withdrawal time in those with no polyps; insertion time; AEs; false detections	NA	NA	Insertion time
GI Genius™ (Medtronic)							

Ahmad 2023[1] (parallel RCT; UK)	ADR; APC	SSL DR; SSL per colonoscopy; serrated polyps per colonoscopy	PDR; significant PDR[f]; PPC; hyperplastic polyps per colonoscopy; inflammatory polyps and normal mucosa per colonoscopy	Total procedure time; insertion time; withdrawal time; caecal intubation rate; AEs; SP6[g]	NA	NA	Insertion time; caecal intubation rate
Engelke 2023[28] (parallel RCT; Sweden)	ADR; ADR by size (≤10 and >10 mm) and morphology (sessile, pedunculated and flat); APC	NA	PDR; PPC; polypectomy rate (per colonoscopy and per-polyp); carcinoma DR	Withdrawal time; AEs	Diagnostic vs pre-planned (or separately for nine categories): ADR; PDR	Experienced vs inexperienced: ADR	ADR by morphology
Karsenti 2023[19] (parallel RCT; France)	ADR; advanced ADR; APC	Proximal serrated polyp DR	PDR; PPC	Caecal intubation time; colonic exploration time; colonic withdrawal time; AEs	NA	Low, medium and high detectors: ADR	Caecal intubation time; colonic exploration time

Lagstrom 2025[47] (parallel RCT; Denmark)	ADR; APC; adenomas per positive colonoscopy	NA	PDR; non-neoplastic resection rate; non-adenomas per colonoscopy	Procedure duration	Screening population: ADR	Expert (>1000 colonoscopies) vs non-expert (≤1000 colonoscopies): ADR	NA
Levartovsky 2023[63] (retrospective study – abstract only; Israel)	ADR	NA	NA	Total procedure time	NA	Experienced gastroenterologists only: ADR	NA
Mangas-Sanjuan 2023[20] (parallel RCT; Spain)	ADR; ADR by size (≤5, 6 to 9 and ≥10 mm); advanced ADR; advanced ADR by feature (three categories); proximal ADR; proximal advanced ADR; APC; APC by size (≤5, 6 to 9 and ≥10 mm);	Serrated lesion, advanced serrated lesion, proximal serrated lesion and proximal advanced serrated lesion DR; serrated lesions per colonoscopy; advanced serrated lesions	PDR; PDR by size (≤5, 6 to 9 and ≥10 mm); PPC; PPC by size (≤5, 6 to 9 and ≥10 mm); advanced colorectal neoplasia DR; advanced colorectal neoplasias per colonoscopy;	Withdrawal time	NA	ADR ≥60% vs <60%: advanced colorectal neoplasia DR; advanced colorectal neoplasias per colonoscopy	Advanced ADR, advanced APC, advanced serrated lesion DR and advanced serrated lesions per colonoscopy by feature; PDR and PPC by size; non-polypoid lesion DR; non-polypoid lesions per colonoscopy

	advanced APC; advanced APC by feature (three categories); proximal APC; proximal advanced APC	per colonoscopy; proximal serrated lesions per colonoscopy; proximal advanced serrated lesions per colonoscopy; serrated lesion DR and serrated lesions per colonoscopy by size (≤5, 6 to 9 and ≥10 mm); advanced serrated lesion DR and advanced serrated lesions per colonoscopy by feature (three categories)	CRC DR; non-polypoid lesion DR; non-polypoid lesions per colonoscopy				
Ortiz 2024[46] (parallel RCT; Belgium, Germany, Italy, Spain)	ADR; APC; APC by size (1 to 4, 5 to 9 and ≥10 mm) and location	Serrated lesions per colonoscopy; SSL per colonoscopy; SSL	PDR; PPC; PPC by size (1 to 4, 5 to 9 and ≥10 mm) and location	Withdrawal time: AEs; false positives; perceived	NA	Low vs high detectors: APC; perceived procedural difficulties	Flat APC; PPC by size and location

	(proximal and distal); flat APC; advanced APC	per colonoscopy by size (1 to 4, 5 to 9 and ≥10 mm) and location (proximal and distal); advanced serrated lesions per colonoscopy; proximal serrated lesion DR	(proximal and distal); advanced lesions (adenomas or serrated lesions) per colonoscopy; invasive carcinoma per colonoscopy; hyperplastic polyps per colonoscopy	procedural difficulties			
Pinto 2022[51] (NRS, tandem procedures – abstract only; Portugal)	NA	NA	PDR; PMR	False positives; sensitivity for polyp detection	NA	NA	PDR and PMR[h]
Repici 2020[21] (parallel RCT; Italy)	ADR; ADR by size (≤5, 6 to 9 and ≥10 mm), location (proximal and distal) and morphology (polypoid and non-	SSL DR	Advanced neoplasia DR; adenocarcinoma DR; non-neoplastic polyp DR; non-	Insertion time; inspection time; caecal intubation rate	FIT, GE symptoms and screening/surveillance: ADR; APC by size (<10 and ≥10 mm); APC by location (proximal and distal);	NA	ADR and APC by morphology; patients with ≥2 adenomas; insertion time; caecal intubation rate

	polypoid); advanced ADR; non-advanced ADR; APC; APC by size (≤5, 6 to 9 and ≥10 mm), location (proximal and distal) and morphology (polypoid and non-polypoid); patients with ≥2 adenomas		neoplastic resection rate		APC by morphology (polypoid and non-polypoid)		
Repici 2022[22] (parallel RCT; Italy, Switzerland)	ADR; advanced ADR; non-advanced ADR; ADR by size (≤5, 6 to 9, <10 and ≥10 mm), location (proximal and distal) and morphology (polypoid and non-polypoid); APC; APC by size (<10 and ≥10 mm),	SSL DR	Adenocarcinoma DR; atypia/dysplasia DR; non-neoplastic polyp DR	Retraction time; withdrawal time; insertion time; caecal intubation achieved	FIT, post-polypectomy surveillance, primary CRC screening and GI symptoms: ADR	NA	ADR and APC by morphology; atypia/dysplasia DR; retraction time; insertion time; caecal intubation achieved

	location (proximal and distal) and morphology (polypoid and non-polypoid)						
Scholer 2024[2] (parallel RCT; Sweden)	ADR	SSL DR	NA	NA	NA	NA	Only outcomes reported separately for GI Genius™ intervention analysed
Seager 2024[23] (parallel RCT; UK)	ADR; advanced ADR; APC	SSL DR	PDR; PPC; cancer DR	Procedural time (without polyps); withdrawal time (without polyps); insertion time; caecal intubation rate; AEs; surveillance colonoscopy rate; comfort assessed by colonoscopist; comfort	Screening vs symptomatic: ADR; advanced ADR; APC; SSL DR; PDR; PPC; cancer DR; surveillance colonoscopy rate; procedural time (without polyps); withdrawal time (without polyps); insertion time; comfort assessed by	NA	Insertion time; caecal intubation rate

				assessed by nurse	colonoscopist; comfort assessed by nurse; caecal intubation rate		
Thiruvengadam 2024[24] (parallel RCT; USA)	ADR; advanced ADR; non-advanced ADR; APC; APC by size (<5, 5 to 9 and ≥10 mm) and location (proximal and distal)	SSL DR; SSL per colonoscopy	Adenocarcinoma DR; non-neoplastic DR	Total procedure time; total withdrawal time; withdrawal time (with no polyps removed)	Screening, surveillance, FIT and diagnostic: ADR	NA	NA
Wallace 2022[37] (tandem RCT; USA, Italy, UK)	ADR; APC; AMR; AMR by size (≤5, 6 to 9, <10 and ≥10 mm), location (proximal and distal), morphology (polypoid and non-polypoid) and histology (four categories); false negative rate[i]; patients with ≥1	NA	PPC; PMR; PMR by size (≤5, 6 to 9, <10 and ≥10 mm), location (proximal and distal) and morphology (polypoid and non-polypoid); patients with ≥1 missed colorectal polyp; false	Caecal insertion time; withdrawal time; successful caecal insertion; AEs; impact on surveillance intervals	NA	NA	AMR and PMR by morphology; AMR by histology; PMR by size and location; caecal insertion time; successful caecal insertion

	missed adenoma or carcinoma		positives for polyps				
NAIAD trial[25] (prospective observational multicentre trial; UK – [redacted])	ADR (average site and average endoscopist); advanced ADR; non-advanced ADR; APC; non-advanced APC	SSL DR	NA	Inspection time; withdrawal time; procedure time	NA	Experts vs non-expert endoscopists: ADR, advanced ADR, non-advanced ADR, SSL DR, APC and non-advanced APC	Experts vs non-expert endoscopists: advanced ADR, non-advanced ADR, SSL DR and non-advanced APC
MAGENTIQ-COLO™ (MAGENTIQ-EYE)							
Maas 2024 – MAGENTIQ-COLO™[31] (parallel and tandem RCT; Germany, Israel, Netherlands, USA)	ADR; APC; adenomas per extraction; per-patient adenomas per extraction; AMR; mean per-patient AMR	SSL DR	NA	Withdrawal time	Non-iFOBT screening vs surveillance: ADR; APC; adenomas per extraction; AMR; SSL DR	NA	NA

[a]Calculated by dividing all adenomas identified by all of the polyps removed;

[b]Total number of histologically confirmed neoplastic lesions, SSL and hyperplastic polyps in the caecum, ascending colon, hepatic flexure and transverse colon divided by the total number of excisions;

[c]Total number of histologically confirmed adenomas (adenoma, villous adenoma and high-grade dysplasia), SSL (sessile serrated, traditional serrated adenoma and serrated lesion with cytological dysplasia) and large >10 mm hyperplastic polyps of the proximal colon (transverse colon, hepatic flexure, ascending colon and caecum) resected in relation to all polyps resected

[d]Defined as total number of resections that were not histologically confirmed adenomas, SSLs or hyperplastic polyps divided by total number of resections (excludes adenocarcinomas and diminutive rectosigmoid hyperplastic polyps)

[e]Percent of histologically confirmed adenomas, sessile serrated adenomas and large (>10 mm) hyperplastic polyps of proximal colon (caecum, ascending colon, hepatic flexure, transverse colon) out of total number of resections

[f]Number of patients with at least one significant polyp (adenoma or SSL) identified divided by the total number of colonoscopies performed

[g]Mean number of adenomas and SSLs detected per 6-minute withdrawal time at colonoscopy

[h]PDR and PMR outcomes not analysed from this study as it was a NRS abstract and detection rate outcome data for this population already available from at least one full publication of an RCT for this intervention

[i]Proportion of patients negative on first colonoscopy that had at least one adenoma or carcinoma detected at the second examination

Abbreviations: ADR, adenoma detection rate; AE, adverse events; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided characterisation; CRC, colorectal cancer; CSR, clinical study report; DR, detection rate; EMIS™, Endoscopic Multimedia Information System; FIT, faecal immunochemical test; GE/GI, gastrointestinal; iFOBT, immunochemical faecal occult blood test; IRR, incidence rate ratio; NA, not applicable; NAIAD, Nationwide study of Artificial Intelligence in Adenoma Detection; NRS, non-randomised study; PDR, polyp detection rate; PPC, polyps per colonoscopy; PPV, positive predictive value; PMR, polyp miss rate; RCT, randomised controlled trial; SSL, sessile serrated lesion

Table 72. Summary of extracted outcomes from clinical studies - CADx

Study	Diagnostic accuracy outcomes	Other outcomes	Colonoscopy indication subgroup data	Endoscopist experience subgroup data	Outcomes not analysed
CAD EYE® (Fujifilm Healthcare UK Ltd.)					
Cassinotti 2023[52] (prospective NRS – abstract only; Italy)	Characterisation of identified lesions into neoplastic or not – presumably any lesions	Lesion miss rate; neoplasia miss rate	NA	NA	NA

Djinbachian 2024[5] (parallel RCT; Canada)	Characterisation of the following into adenoma, hyperplastic and serrated histologies: • ≤5 mm polyps in any location • ≤5 mm polyps in the rectosigmoid	AEs; alignment with histology-based surveillance intervals	NA	NA	NA
Li 2023[61] (prospective NRS; Singapore)	Characterisation of the following into neoplastic or hyperplastic polyps: • Any identified polyps; • Polyps ≤5 mm, 6 to 9 mm and ≥10 mm, separately • Polyps in difficult location or not, separately • Left- and right-sided polyps, separately • Diminutive rectosigmoid polyps (NPV only) Classification of patients with at least one neoplastic lesion vs not	Agreement with surveillance intervals based on guidelines	NA	1000 to 2000, 2001 to 3000 and >3000 prior colonoscopies: characterisation of any identified polyps into neoplastic or hyperplastic	Polyps ≤5 mm[a], diminutive rectosigmoid polyps[a] and polyps in difficult location or not
Picardo 2023[54] (NRS – abstract only; Australia)	Characterisation of the following into neoplastic or hyperplastic polyps: • All lesions identified • All resected lesions	Procedure time; withdrawal time	NA	NA	Procedure time; withdrawal time
Rondonotti 2023[58] (prospective NRS; Italy)	Characterisation of the following into adenomatous or non-adenomatous polyps: • Diminutive rectosigmoid polyps	Agreement of post-polypectomy surveillance	NA	Expert and non-expert: characterisation of diminutive	NA

	• Diminutive non-rectosigmoid polyps	intervals; rate of delayed surveillance colonoscopy; unable to characterise or unstable characterisations		rectosigmoid polyps into adenomatous and non-adenomatous; agreement of post-polypectomy surveillance intervals	
Sato 2024[53] (prospective NRS; Japan)	Characterisation of any polyps into neoplastic and non-neoplastic categories	AEs	NA	Expert (≥1500 colonoscopies) vs non-expert (<1500 colonoscopies): characterisation of any polyps into neoplastic and non-neoplastic categories	NA

Taghiakbari 2025[56] (prospective NRS; Canada)	Characterisation of the following into adenomatous or non-adenomatous polyps: • Diminutive polyps underwent a resect-and-discard or diagnose-and-leave strategy • Diminutive polyps underwent a resect-and-discard strategy • Diminutive polyps underwent a diagnose-and-leave strategy	Surveillance interval agreement between CADx-assisted and expert-based optical diagnosis; patient acceptance of AI in colonoscopy	NA	NA	NA
Zavyalov 2024[48] (prospective NRS; Russia)	Characterisation of polyps into neoplastic or hyperplastic – presumably any polyps	Withdrawal time; accuracy for polyp detection	NA	NA	NA
CADDIE™ (Odin Vision)					
Odin Vision 2024 CADDIE CSR[12] (parallel RCT; UK)	Characterisation of the following into adenoma or non-adenoma: • Any identified polyps • Diminutive polyps • Diminutive rectosigmoid polyps	AEs; impact on surveillance intervals; characterisation by device was uncertain	NA	NA	NA

Discovery™ (Pentax Medical UK)					
Lopez-Serrano 2024[49] (prospective NRS; Spain)	Characterisation of polyps into dysplasia or no dysplasia – presumably any polyps	Accuracy for polyp detection	NA	NA	NA
GI Genius™ (Medtronic)					
Baumer 2023[60] (prospective NRS; Germany)	Characterisation of the following into adenoma, non-adenoma or SSL: • Any polyps ≤10 mm • Rectosigmoidal polyps ≤10 mm • Proximal polyps ≤10 mm • Polyps ≤5 mm and 6 to 10 mm, separately • Diminutive rectosigmoid and non-rectosigmoid polyps, separately • Any SSL ≤10 mm	Device returned no prediction or unstable prediction	NA	Experienced and non-experienced: characterisation of any polyps ≤10 mm into adenoma, non-adenoma or SSL	Polyps ≤5 mm[a]; diminutive rectosigmoid polyps[a]
Bernhofer 2025[59] (prospective NRS; Austria)	Characterisation of the following into adenoma or non-adenoma: • Diminutive rectosigmoid polyps • Any rectosigmoid polyps (JNET1) • Rectosigmoid polyps sized 1 to 2 mm, 3 to 5 mm and 6 to 30 mm	Incidence that technology does not function	NA	NA	NA

	• Any NICE1 polyps (hyperplastic) • Any NICE 2 polyps (adenomatous) • Any JNET2a polyps (adenomas with low-grade dysplasia)				
Hassan 2022[55] (prospective NRS; Italy)	Characterisation of the following into adenoma or non-adenoma: • Any polyps • Any diminutive polyps • Diminutive rectosigmoid polyps	Correct estimation of post-polypectomy surveillance intervals; device characterisation not feasible	NA	NA	NA
Koh 2024[62] (prospective NRS; Singapore)	Characterisation of the following into adenoma or non-adenoma: • Any polyps • Polyps located in the colon • Polyps located in the rectosigmoid	Incidence that technology does not function	NA	NA	Any polyps[a]
Rondonotti 2024[57] (prospective NRS; Italy)	Characterisation of the following into adenoma or non-adenoma: • Any diminutive polyps • Distal and proximal diminutive polyps, separately	No prediction provided by device	NA	Expert and non-expert endoscopists: characterisation of any	NA

				diminutive polyps into adenoma or non-adenoma	

[a]Not analysed as data for these polyp categories available from studies using the technology as an adjunct rather than autonomously.

Abbreviations: AE, adverse event; CADx, computer-aided characterisation; CSR, clinical study report; JNET, Japan Narrow Band Imaging Expert Team; NA, not applicable; NICE, NBI International Colorectal Endoscopic criteria; NPV, negative predictive value; NRS, non-randomised study; RCT, randomised controlled trial; SSL, sessile serrated lesion.

Table 73. Summary of extracted outcomes from clinical studies – other studies

Study	Outcomes extracted	Colonoscopy indication subgroup data	Endoscopist experience subgroup data	Outcomes not analysed
GI Genius™ (Medtronic)				
Ladabaum 2023[65] (before/after study – abstract only; USA)	Results of two surveys of endoscopists on attitudes and beliefs before and after trying CADe.	NA	NA	NA

Olabintan 2025[66] (non-randomised survey; UK)	Results of survey of endoscopists on awareness and perceptions of AI use in colonoscopy following NAIAD trial involvement	NA	NA	NA
Nehme 2023[64] (before/after study; USA)	Results of pre- and post-AI colonoscopy surveys completed by physicians and endoscopy unit staff. Surveys covered overall experience and opinion towards the implementation of AI-assisted colonoscopy, opinions on continuing its use after the trial period, perceived advantages and disadvantages of the technology, willingness to implement AI in endoscopy and expected impact on polyp detection and procedure times.	NA	NA	Study reports detection outcomes such as APC but not extracted given RCTs cover these outcomes for this intervention
Seager 2024[67] (non-randomised interviews following an RCT; UK)	Results of semi-structured interviews with clinicians on perceptions of AI in colonoscopy following COLO-DETECT trial involvement	NA	NA	NA
No technology or unnamed technologies				
Anderson 2024[68] (non-randomised survey; UK)	Results of surveys of endoscopists and managers involved in a trial of three unnamed AI systems regarding experience with use and implementation	NA	NA	NA

Burton 2025[70] (non-randomised survey; USA)	Results of surveys of patients performed prior to the colonoscopy procedure including perceptions of AI in colonoscopy and importance	NA	NA	NA
Magahis 2023[69] (non-randomised survey; USA)	Results of survey delivered to 1st, 2nd and 3rd year gastroenterology fellows with regards to perspectives on AI in colonoscopy	NA	NA	NA
Schmidt 2025[71] (non-randomised survey; USA)	Results of surveys of patients performed prior to the colonoscopy procedure including perceptions of AI in colonoscopy, importance and comfort	NA	NA	NA

Abbreviations: AI, artificial intelligence; CADe, computer-aided detection; NA, not applicable; RCT, randomised controlled trial.

5 Tables of excluded studies with rationale – clinical

Table 74. Table of studies excluded at the full-text appraisal stage of the database searches of the clinical systematic literature review.

Study/trial register number	Title	Reason for exclusion
Abdelrahim 2021[73]	Validation of a novel AI system (CADEYE) for in vivo characterization of colorectal polyps	Abstract only and have full texts covering outcomes
Abdelrahim 2024[74]	New AI model for neoplasia detection and characterisation in inflammatory bowel disease.	Technology not relevant to review

ACTRN12622000866707 2022[75]	Does Artificial Intelligence Improve Polyp Detection at Colonoscopy?	Trial record only
Adiwinata 2023[76]	The Impact of Artificial Intelligence in Improving Polyp and Adenoma Detection Rate During Colonoscopy: Systematic-Review and Meta-Analysis.	Systematic review used for reference checking
Agazzi 2021[77]	Real-time artificial intelligence-aided colonoscopy experience: The impact on routine clinical practice in a high-volume center-preliminary data	Non-randomised study and outcomes covered by randomised trials
Ahmad 2021[78]	Early evaluation of a computer assisted polyp detection system in bowel cancer screening	Non-randomised study and outcomes covered by randomised trials
Ahsan 2024[79]	IS THERE A BENEFIT FOR COMPUTER-AIDED DETECTION OF POLYPS DURING SCREENING COLONOSCOPY AMONG EXPERIENCED ENDOSCOPISTS IN A COMMUNITY HOSPITAL SETTING?	Non-randomised study and outcomes covered by randomised trials
Ahsan 2024[80]	The Impact of Computer-aided Detection Technology in Adenoma Detection Rate Among Experienced Endoscopists in the Community Setting.	Non-randomised study and outcomes covered by randomised trials

Alahmad 2024[81]	REAL WORLD EVIDENCE ON THE EFFICIENCY OF AI- ENHANCED COLONOSCOPY: A CASE-CONTROL STUDY	Non-randomised study and outcomes covered by randomised trials
Ali 2024[82]	ADHERENCE OF COMPUTER-AIDED POLYP DETECTION (CADE) CLINICAL TRIALS TO THE CONSOLIDATED STANDARDS OF REPORTING TRIALS-ARTIFICIAL INTELLIGENCE (CONSORT-AI) EXTENSION GUIDELINE - EVIDENCE REPORT FROM A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Ali 2021[83]	Adenoma and polyp detection rates by implementing artificial intelligence systems: A metaanalysis	Abstract of systematic review
Aljabiri 2023[84]	THE USE OF ARTIFICAL INTELLIGENCE IN COLONOSCOPY IMPROVES ADENOMA DETECTION RATES AND INVERSELY REDUCES THE RISK OF INTERVAL COLORECTAL CANCER; FIRST COMPARATIVE STUDY IN UAE	Unnamed intervention
Akram 2025[85]	EFFECTIVENESS OF THE COMBINATION OF ENDOCUFF-ASSISTED AND COMPUTER-AIDED COLONOSCOPY: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS	Abstract of systematic review
Alahmad 2023[86]	Impact of Artificial Intelligence Enhanced Colonoscopy in a Clinical Practice Setting	Unnamed intervention

Anand 2023[87]	Artificial Intelligence-Aided Colonoscopy in a Real World Setting	Non-randomised study and outcomes covered by randomised trials
Anderer 2024[88]	Meta-Analysis: AI-Assisted Colonoscopy Increases Detection of Polyps, Adenomas	Summary of article only
Aniwan 2022[89]	THE DIFFERENCES IN ADENOMA DETECTION RATES AND OTHER INDICES BETWEEN STANDARD SCREENING COLONOSCOPY VS. COMPUTER-AIDED DETECTION VS. MUCOSAL EXPOSURE DEVICE VS. THE COMBINATION: A RANDOMIZED TRIAL	Abstract of full publication identified
Anonymous 2024[90]	Artificial Intelligence-Assisted Colonoscopy for Detecting Polyps, Adenomas, Precancerous Lesions, and Colorectal Cancer: Health Technologies	Systematic review used for reference checking
Antonelli 2025[91]	ARTIFICIAL INTELLIGENCE FOR LEAVING IN SITU COLORECTAL POLYPS: RESULTS FROM A RANDOMISED TRIAL	Abstract of full publication identified
Areia 2022[92]	Cost-effectiveness of artificial intelligence for screening colonoscopy: a modelling study	Health economic assessment only
Areia 2022[93]	Cost-effectiveness of artificial intelligence for screening colonoscopy: a modelling study	Health economic assessment only

Armonis 2024[94]	COMPUTER-AIDED DETECTION IMPROVES ADENOMA DETECTION RATE FOR SCREENING COLONOSCOPY: A PROSPECTIVE TANDEM STUDY	Abstract only and have full texts covering outcomes
Ashat 2021[95]	Impact of real-time use of artificial intelligence in improving adenoma detection during colonoscopy: A systematic review and meta-analysis.	Systematic review used for reference checking
Aslam 2023[96]	The effectiveness of real-time computer-aided and quality control systems in colorectal adenoma and polyp detection during colonoscopies: a meta-analysis.	Systematic review used for reference checking
Aziz 2022[97]	COMPARISON OF ARTIFICIAL INTELLIGENCE WITH OTHER INTERVENTIONS TO IMPROVE ADENOMA DETECTION RATE FOR COLONOSCOPY: A NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS	Abstract of systematic review
Aziz 2020[98]	The impact of deep convolutional neural network-based artificial intelligence on colonoscopy outcomes: A systematic review with meta-analysis.	Systematic review used for reference checking
Aziz 2024[99]	Comparison of Artificial Intelligence With Other Interventions to Improve Adenoma Detection Rate for Colonoscopy: A Network Meta-analysis.	Systematic review used for reference checking

Bai 2019[100]	Establishment and real-world validation of a computer-assisted polyp identification and localization system based on deep learning	Unnamed intervention
Bai 2025[101]	The role of artificial intelligence in colorectal cancer and polyp detection: A systematic review	Abstract of systematic review
Bang 2021[102]	Computer-Aided Diagnosis of Diminutive Colorectal Polyps in Endoscopic Images: Systematic Review and Meta-analysis of Diagnostic Test Accuracy.	Systematic review used for reference checking
Barkun 2022[103]	COST-EFFECTIVENESS ANALYSIS OF ARTIFICIAL INTELIGENCE-AIDED COLONOSCOPY FOR ADENOMA DETECTION IN COLORECTAL CANCER - A CANADIAN PERSPECTIVE	Health economic assessment only
Barkun 2023[104]	Cost-effectiveness of Artificial Intelligence-Aided Colonoscopy for Adenoma Detection in Colon Cancer Screening.	Health economic assessment only
Barua 2021[105]	Artificial intelligence for polyp detection during colonoscopy: a systematic review and meta-analysis.	Systematic review used for reference checking
Barua 2022[106]	ARTIFICIAL INTELLIGENCE FOR REAL-TIME OPTICAL DIAGNOSIS OF NEOPLASTIC POLYPS DURING COLONOSCOPY	Unnamed intervention

Barua 2022[107]	ARTIFICIAL INTELLIGENCE FOR REAL-TIME OPTICAL DIAGNOSIS OF NEOPLASTIC POLYPS DURING COLONOSCOPY	Unnamed intervention
Barua 2022[108]	Real-Time Artificial Intelligence-Based Optical Diagnosis of Neoplastic Polyps during Colonoscopy.	Technology not relevant to review
Behncke 2023[109]	Does Current Reimbursement Drive the Adoption of Computer-Aided Applications to Increase the Adenoma Detection in Colonoscopies - a Provider-Based Impact Model for Germany, France, and Italy	Health economic assessment only
Beran 2025[110]	ENDOCUFF WITH OR WITHOUT ARTIFICIAL INTELLIGENCE-ASSISTED COLONOSCOPY FOR DETECTION OF COLORECTAL ADENOMA: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS	Abstract of systematic review
Bergagnini 2023[111]	COMPUTER-AIDED DETECTION WITH ENDOCUFF IMPROVES ADENOMA DETECTION RATE: A QUALITY IMPROVEMENT INITIATIVE	Abstract only and have full texts covering outcomes
Bergna 2023[112]	ARTIFICIAL INTELLIGENCE SYSTEM USING WHITE LIGHT FOR REAL-TIME OPTICAL CHARACTERIZATION OF COLONIC POLYPS	Abstract only and have full texts covering outcomes

Bernhofer 2021[113]	The impact of artificial intelligence on the adenoma detection rate (ADR): A comparison between experienced and trainee endoscopists' adr	Non-randomised study and outcomes covered by randomised trials
Bernhofer 2024[114]	Augmented Colonoscopy with Computer- Aided polyp characterization - evaluation of the performance of an artificial intelligence application in the classification of colorectal polyps	Abstract only and have full texts covering outcomes
Bilal 2020[115]	Using Computer-Aided Polyp Detection During Colonoscopy.	Non-randomised study and outcomes covered by randomised trials
Bin Goh 2024[116]	SENIOR ENDOSCOPISTS ARE MORE LIKELY TO TRUST AND ACCEPT AI-ASSISTED COLONOSCOPY FOR DETECTION AND TREATMENT OF POLYPS COMPARED TO JUNIOR ENDOSCOPISTS	Unnamed intervention
Biscaglia 2022[117]	REAL-TIME ARTIFICIAL INTELLIGENCE-AIDED COLONOSCOPY ELIMINATES DIFFERENCES IN ADENOMA DETECTION RATE BETWEEN TRAINEES AND EXPERIENCED ENDOSCOPISTS IN TANDEM-COLONOSCOPIES	Unnamed intervention
Biscaglia 2022[118]	Real-time, computer-aided, detection-assisted colonoscopy eliminates differences in adenoma detection rate between trainee and experienced endoscopists.	Non-randomised study and outcomes covered by randomised trials

Brand 2020[119]	Influence of artificial intelligence on polyp detection in a real life scenario	Abstract only and have full texts covering outcomes
Brand 2021[120]	Artificial intelligence for polyp detection during colonoscopy-an in-depth analysis of a commercially available system	Non-randomised study and outcomes covered by randomised trials
Bretthauer 2025[121]	Use of computer-assisted detection (CADe) colonoscopy in colorectal cancer screening and surveillance: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement	Systematic review used for reference checking
Budzyn 2024[122]	Endoscopist De-Skilling after Exposure to Artificial Intelligence in Colonoscopy: A Multicenter Observational Study	Non-randomised study and outcomes covered by randomised trials
Burke 2024[123]	Artificial intelligence-assisted adenoma detection in people with Lynch syndrome	Full text not retrieved
Burton 2024[124]	PATIENT PERSPECTIVE OF USE OF ARTIFICIAL INTELLIGENCE DURING COLONOSCOPY	Unnamed intervention
Bustamante-Balen 2025[125]	Cost-effectiveness analysis of artificial intelligence-aided colonoscopy for adenoma detection and characterization in Spain	Health economic assessment only
Bustamante-Balen 2024[126]	EE600 Cost-Effectiveness and Budget Impact Analysis of Introducing Artificial Intelligence-Aided Colonoscopy for Adenoma Detection and Characterization in Spain	Abstract only of health economic assessment

Caillo 2024[127]	COLODETECT 1: comparative evaluation of endocuff with computer-aided detection versus computer-aided detection alone versus standard colonoscopy for enhancing adenoma detection rates during screening colonoscopy-a pilot study	Non-randomised study and outcomes covered by randomised trials
Calce 2025[128]	ENDOSCOPISTS AND COMPUTER-AIDED DECISION SUPPORT INTERACTION FOR DETECTION OF COLORECTAL POLYPS	Unnamed intervention
Carlini 2025[129]	Large language models for detecting colorectal polyps in endoscopic images	Full text not retrieved
Chadha 2024[130]	Artificial Intelligence Improves Adenoma Detection Amongst Gastroenterology Fellows	Unnamed intervention
Chang 2024[131]	AI-ASSISTED COLONOSCOPY IMPROVES ADR IN GASTROENTEROLOGY FELLOWS: AN INTERIM ANALYSIS OF A RANDOMIZED CONTROL TRIAL	Abstract only and have full texts covering outcomes
Chaudhary 2024[132]	Novel Artificial Intelligence (AI) Systems in Detecting Adenomas in Colonoscopy: A Systematic Review and Network Meta-Analysis	Abstract of systematic review
Cheng 2025[133]	EVALUATION OF ARTIFICIAL INTELLIGENCE FOR ADENOMA DETECTION IN WATER EXCHANGE COLONOSCOPY: INTERIM ANALYSIS OF THE WEAID RANDOMIZED CONTROLLED TRIAL	Abstract only and have full texts covering outcomes

Cheng 2023[134]	Evaluation of a Computer-Aided Detection Device During Water Exchange Colonoscopy: A Pragmatic Implementation Performance Improvement Study	Non-randomised study and outcomes covered by randomised trials
Cheng 2024[135]	Evaluating the Performance of a Computer-Aided Diagnosis System in Implementing Diagnose-and-Leave and Resect-and-Discard Strategies for Diminutive Colorectal Polyps: A Real-World Pragmatic Study	Abstract only and have full texts covering outcomes
Cheng 2024[136]	PERFORMANCE OF REAL-TIME COMPUTER-AIDED POLYP DETECTION USING WATER EXCHANGE COLONOSCOPY: A PRELIMINARY PILOT STUDY	Abstract of full publication identified
Cheong 2024[137]	Colon AI-scopy: Artificial Intelligence Influence on Detection and Removal of Non-Neoplastic Polyps, Diminutive Hyperplastic Polyps, and Sessile Serrated Polyps in Screening Colonoscopy	Unnamed intervention
ChiCTR2400088486 2024[138]	The effect of artificial intelligence-assisted shortening of colonoscopy withdrawal time on adenoma detection	Trial record only
ChiCTR2400091641 2024[139]	Study on the detection value of colorectal adenomas by different artificial intelligence-assisted diagnostic devices	Trial record only
ChiCTR2500095651 2025[140]	Comparison between AI+Magic-Cap-assisted colonoscopy and traditional colonoscopy	Trial record only

ChiCTR1800017675 2018[141]	The impact of a computer aided diagnosis system based on deep learning on incresing polyp detection rate during colonoscopy, a prospective double blind study	Trial record only
ChiCTR1900021984 2019[142]	A multicenter randomized controlled study for evaluating the effectiveness of artificial intelligence in improving colonoscopy quality	Trial record only
ChiCTR1900023086 2019[143]	The impact of a colon polyp detection CAD system based on deep learning on colon adenoma miss rate: a randomized prospective tandem study	Trial record only
ChiCTR1900025235 2019[144]	A multicenter prospective randomized controlled trial for the impact of a computer-aided colon polyp detection system based on deep learning on colon adenoma detection during colonoscopy in comparison with junior endoscopist second observer	Trial record only
ChiCTR1900026726 2019[145]	The comparison of AI-assisted colonoscopy and conventional colonoscopy for the detection of polyps in colorectal cancer screening in White Light and LCI mode	Trial record only
ChiCTR1900027307 2019[146]	Artificial Intelligence-assisted Colonoscopy for Detection of Colon Polyps: a Prospective Randomized Cohort Study	Trial record only

ChiCTR2000034887 2020[147]	Difference Analysis of Colonoscopy Detection Rate of Adenoma Assisted by Artificial Intelligence	Trial record only
ChiCTR2000034889 2020[148]	Comparing adenoma detection rate of cap-assisted colonoscopy and conventional colonoscopy with and without artificial intelligence: a prospective, randomized, single-center trial	Trial record only
ChiCTR2100045262 2021[149]	Effects of phased application of artificial intelligence-assisted polyp diagnosis system on independent colonoscopy performance of endoscopists: a multicenter randomized controlled trial	Trial record only
ChiCTR2200063455 2022[150]	A prospective, multicenter, randomized control trial of a real-time quality-control system for the colonoscopy examination of outpatient	Trial record only
ChiCTR2200063891 2022[151]	Research on Artificial Intelligence Disease Identification System Based on Dynamic Big Data of Digestive Endoscope	Trial record only
ChiCTR2200064399 2022[152]	Effect of an Artificial Intelligence Computer-Aided Detection System on Adenoma Detection: a Multicenter Randomized Controlled Trial	Trial record only
ChiCTR2300067573 2023[153]	A multi-center study to observe the adenoma detection rate for different colonoscopy withdrawal time with AI-assisted detection system or not	Trial record only

ChiCTR2300071120 2023[154]	A Clinical Trial of the Effectiveness and Safety of Software Assisting Diagnose the Intestinal Polyp Digestive Endoscopy by Analysis of Colonoscopy Medical Images From Electronic Digestive Endoscopy Equipment	Trial record only
ChiCTR2300073421 2023[155]	A clinical trial to validate the effectiveness and safety of AI-assisted colonoscopy	Trial record only
ChiCTR2400082293 2024[156]	To verify the effect of artificial intelligence-assisted diagnosis combined with water exchange technology on the diagnostic efficiency of colonoscopy	Trial record only
ChiCTR2400082752 2024[157]	The effect of artificial intelligence on the adenoma detection rates and missed rates in water-assisted colonoscopy	Trial record only
Chieng 2022[158]	Effect of artificial intelligence on adenoma detection during colonoscopy: The first New Zealand experience	Non-randomised study and outcomes covered by randomised trials
Chikatimalla 2025[159]	REAL-TIME ARTIFICIAL INTELLIGENCE VS STANDARD COLONOSCOPY IN THE EARLY DETECTION OF COLORECTAL CANCER: A META-ANALYSIS	Abstract of systematic review
Chilakapati 2024[160]	Enhancing Colorectal Cancer Detection by Using Artificial Intelligence-Driven Colonoscopy to Detect Polyp and Adenoma Rates	Abstract of systematic review

Chin 2023[161]	One-year review of real-time artificial intelligence (AI)-aided endoscopy performance.	Non-randomised study and outcomes covered by randomised trials
Cho 2022[162]	THE PERFORMANCE OF CAD-EYETM FOR DIFFERENTIAL DIAGNOSIS OF COLORECTAL POLYPS	Abstract only and have full texts covering outcomes
Chow 2024[163]	LONG-TERM IMPACT OF ARTIFICIAL INTELLIGENCE ON COLORECTAL ADENOMA DETECTION IN A SAFETY-NET HOSPITAL: A ONE-YEAR FOLLOW-UP	Abstract of full publication identified
Chow 2024[164]	Long-term impact of artificial intelligence on colorectal adenoma detection in high-risk colonoscopy.	Non-randomised study and outcomes covered by randomised trials
Chow 2023[165]	Impact of Artificial Intelligence on Colorectal Adenoma Detection in High-Risk Colonoscopy: Initial Experience at a Safety-Net Hospital	Non-randomised study and outcomes covered by randomised trials
Chowdary 2023[166]	Application of machine learning approaches in the diagnosis and management of colorectal cancer	Abstract of systematic review
Chung 2024[167]	A prospective comparison of two computer aided detection systems with different false positive rates in colonoscopy	Technology not relevant to review

Claassen 2025[168]	IMPROVING ADENOMA AND POLYP DETECTION RATES WITH COMPUTER-AIDED DETECTION: LESSENING DISPARITIES IN COLORECTAL CANCER SCREENING IN RURAL AMERICA	Unnamed intervention
Contreras 2023[169]	The Impact of CADe on Sessile Serrated Adenomas Detection Rate During Colonoscopy	Unnamed intervention
Contreras 2023[170]	The Evaluation of Artificial Intelligence on Adenoma Detection Rate in a Latin American Community Setting	Unnamed intervention
Contreras 2025[171]	IMPACT OF CADE ON ADENOMA DETECTION RATES DURING LINKED COLOR IMAGING-ENHANCED COLONOSCOPIES IN A NON-ACADEMIC OUTPATIENT FACILITY IN THE DOMINICAN REPUBLIC	Unnamed intervention
Contreras 2022[172]	Adenoma Detection Rate Using LCI vs White Light Colonoscopy Both With and Without the Use of Artificial Intelligence: A Prospective Study in a Non-Academic Center in Latin America	Unnamed intervention
Cooper 2024[173]	Head-to-Head Comparison of Two Computer Aided Detection (CAD-e) Systems on Colonoscopy Performance Metrics	Non-randomised study and outcomes covered by randomised trials

Coron 2021[174]	Is artifical intelligence (CAD EYE) useful to not only detect but also to characterize small colorectal polyps? First results from a prospective french multicenter study	Abstract only and have full texts covering outcomes
Coronel 2022[175]	PHYSICIAN AND STAFF ATTITUDES TOWARDS IMPLEMENTATION OF ARTIFICIAL INTELLIGENCE-ASSISTED COLONOSCOPY	Limited usable data/no relevant outcomes
Correia 2021[176]	Artificial intelligence in the characterization of colorectal polyps: A prospective study in a clinical setting using cadeye	Abstract of full publication identified
de Castro 2023[177]	?EL EMPLEO DE UN DISPOSITIVO DE INTELIGENCIA ARTIFICIAL EN COLONOSCOPIAS DE CRIBADO DE CCR MEJORA LOS ESTANDARES DE CALIDAD DE LAS COLONOSCOPIAS? EXPERIENCIA EN UN HOSPITAL DE SEGUNDO NIVEL	Unnamed intervention
De Lange 2024[178]	Artificial intelligence for characterization of colorectal polyps: Prospective multicenter study.	Deprioritised as autonomous AI only
Deliwala 2020[179]	Artificial Intelligence (AI)-Guided vs Routine Colonoscopy for Colorectal Polyps: A Meta-Analysis of Recent Randomized Controlled Trials	Abstract of systematic review
Deliwala 2021[180]	Artificial intelligence (AI) real-time detection vs. routine colonoscopy for colorectal neoplasia: a meta-analysis and trial sequential analysis.	Systematic review used for reference checking

Desai 2024[181]	COMPUTER-AIDED POLYP DETECTION INCREASES ADENOMA DETECTION RATE IN A HIGH ADENOMA DETECTING GROUP: A MULTI-SITE COMMUNITY PRACTICE EXPERIENCE	Unnamed intervention
Djinbachian 2024[182]	COMPARING ENDOSCOPIST DIAGNOSIS OF COLORECTAL POLYPS ASSISTED BY ARTIFICIAL INTELLIGENCE (CADX) VS CADX WITHOUT ENDOSCOPIST INPUT: A RANDOMIZED CONTROLLED TRIAL	Unnamed intervention
Djinbachian 2024[183]	AUTONOMOUS ARTIFICIAL INTELLIGENCE VERSUS AI ASSISTED HUMAN OPTICAL DIAGNOSIS OF COLORECTAL POLYPS: A RANDOMIZED CONTROLLED TRIAL	Unnamed intervention
Djinbachian 2024[184]	OPTIMIZED COMPUTER ASSISTED TECHNIQUE FOR INCREASING ADENOMA DETECTION DURING COLONOSCOPY: A RANDOMIZED CONTROLLED TRIAL	Unnamed intervention
Djinbachian 2025[185]	Accuracy of histopathology evaluation in diminutive colonic polyps diagnosed as neoplastic by computer-aided characterisation	Full text not retrieved
Djinbachian 2024[186]	Autonomous Artificial Intelligence versus AI Assisted Human optical diagnosis of colorectal polyps: a randomized controlled trial	Unnamed intervention
Dominitz 2025[187]	DURABILITY OF THE IMPACT OF ARTIFICIAL INTELLIGENCE COMPUTER-AIDED DETECTION (CADE) ON THE ALL-INDICATION	Abstract only and have full texts covering outcomes

	ADENOMA DETECTION RATE (ADR) AND OTHER COLONOSCOPY QUALITY INDICATORS: A RANDOMIZED PRAGMATIC STUDY	
Dominitz 2024[188]	IMPACT OF ARTIFICIAL INTELLIGENCE COMPUTER-AIDED DETECTION (CADE) ON THE ALL-INDICATION ADENOMA DETECTION RATE (ADR): PRAGMATIC QUALITY IMPROVEMENT (QI) STUDY IN A NATIONAL HEALTHCARE SYSTEM	Non-randomised study and outcomes covered by randomised trials
Doring 2021[189]	Artificial intelligence in endoscopic screening for colorectal cancer-expensive add-on or cost saving	Health economic assessment only
Dos Santos 2023[190]	Performance of artificial intelligence in the characterization of colorectal lesions.	Deprioritised as autonomous AI only
DRKS00023157 2020[191]	Real-time use of artificial intelligence (CADEYE) in the colo-rectal cancer surveillance of Lynch syndrome patients (CADLY)	Trial record only
DRKS00024943 2021[192]	Computer-aided detection of polyps during colonoscopy - a prospective, controlled study	Trial record only
DRKS00026687 2021[193]	Artificial Intelligence in screening colonoscopy	Trial record only
DRKS00030695 2023[194]	Real-time use of artificial intelligence (CAD EYE) in the colorectal cancer surveillance of Lynch syndrome patients (CADLYII) - an international multicenter trial	Trial record only

Eelbode 2020[195]	879 A PROSPECTIVE MULTI-CENTER VALIDATION STUDY FOR AUTOMATED POLYP DETECTION AS A SECOND OBSERVER	Unnamed intervention
El Zoghbi 2023[196]	Artificial Intelligence-Assisted Optical Diagnosis: A Comprehensive Review of Its Role in Leave-In-Situ and Resect-and-Discard Strategies in Colonoscopy.	Systematic review used for reference checking
Elhadi 2024[197]	Using Artificial Intelligence-Enhanced White-Light Colonoscopy for Predicting Deeply Invasive Colorectal Cancer: A Diagnostic Accuracy Meta-Analysis	Abstract of systematic review
Ellison 2023[198]	Effect of Artificial Intelligence Polyp Detection in an Office-Based Endoscopy Practice	Non-randomised study and outcomes covered by randomised trials
Ellrichmann 2023[199]	THE USE OF ARTIFICIAL INTELLIGENCE IMPROVES QUALITY CRITERIA IN SCREENING COLONOSCOPY	Abstract only and have full texts covering outcomes
England 2024[200]	Artificial Intelligence And Health Technology Assessment: Playing Catch-Up	Abstract of systematic review
Foroutan 2025[201]	Computer aided detection and diagnosis of polyps in adult patients undergoing colonoscopy: a living clinical practice guideline	Systematic review used for reference checking

Fitting 2021[202]	Development and comparison of the polyp detection system endomind with a commercially available cade system	Non-randomised study and outcomes covered by randomised trials
Gach 2023[203]	Artificial Intelligence During Colonoscopy: The First Thousand Procedures	Unnamed intervention
Gallagher 2024[204]	AI in Action: Augmenting Adenoma Detection Rates in a Community-Based Gastroenterology Practice	Non-randomised study and outcomes covered by randomised trials
Gangwani 2023[205]	Comparing Adenoma Detection Rate (ADR) in Single vs Dual Observer vs Artificial Intelligence-Assisted Colonoscopy: A Network Analysis of Randomized Controlled Trials	Abstract of systematic review
Gangwani 2024[206]	Single Versus Second Observer vs Artificial Intelligence to Increase the ADENOMA Detection Rate of Colonoscopy-A Network Analysis.	Systematic review used for reference checking
Gross 2011[207]	Computer-based classification of small colorectal polyps by using narrow-band imaging with optical magnification.	Technology not relevant to review
Gu 2024[208]	Disconnect Between Perceptions of Artificial Intelligence and Adenoma Detection Rate at a Tertiary Center: Survey and Retrospective	Non-randomised study and outcomes covered by randomised trials
Guerrero 2022[209]	Computer-Aided Detection (CADe) and Its Effect on Adenoma Detection Rate (ADR) in a Single Tertiary Center	Unnamed intervention

Guerrero 2020[210]	Artificial intelligence for polyp detection during colonoscopy: A systematic review and meta-analysis	Abstract of systematic review
Halvorsen 2025[211]	Benefits, burden, and harms of computer aided polyp detection with artificial intelligence in colorectal cancer screening: microsimulation modelling study.	Health economic assessment only
Halvorsen 2025[212]	Cost-Effectiveness for Artificial Intelligence in Colonoscopy.	Study design - review not systematic
Hann 2021[213]	Current status and limitations of artificial intelligence in colonoscopy.	Study design - review not systematic
Hardy 2025[214]	Explainable endoscopic artificial intelligence method for real-time in situ significant rectal lesion characterization: a prospective cohort study	Technology not relevant to review
Hassan 2024[215]	Computer-aided diagnosis for the resect-and-discard strategy for colorectal polyps: a systematic review and meta-analysis	Systematic review used for reference checking
Hassan 2022[216]	ARTIFICIAL INTELLIGENCE FOR LEAVING-IN-SITU COLORECTAL POLYPS: RESULTS OF A REAL TIME CLINICAL TRIAL	Unnamed intervention
Hassan 2022[217]	ARTIFICIAL INTELLIGENCE FOR LEAVING-IN-SITU COLORECTAL POLYPS: RESULTS OF A CLINICAL TRIAL	Unnamed intervention

Hassan 2022[218]	CHARACTERIZATION COMPARISON BETWEEN TWO CAD SYSTEMS (COMBO CAD STUDY) IN REAL-LIFE ENDOSCOPY: AN INTERIM ANALYSIS	Abstract of full publication identified
Hassan 2022[219]	CHARACTERIZATION COMPARISON BETWEEN TWO CAD SYSTEMS (COMBO CAD STUDY) IN REAL- LIFE ENDOSCOPY: AN INTERIM ANALYSIS	Abstract of full publication identified
Hassan 2020[220]	Computer-aided detection-assisted colonoscopy: classification and relevance of false positives.	Limited usable data/no relevant outcomes
Hassan 2021[221]	Artificial intelligence for non-polypoid colorectal neoplasms.	Study design - review not systematic
Hassan 2024[222]	Computer-Aided Diagnosis for Leaving Colorectal Polyps In Situ : A Systematic Review and Meta-analysis.	Systematic review used for reference checking
Hassan 2023[223]	Cost-utility analysis of real-time artificial intelligence-assisted colonoscopy in Italy.	Health economic assessment only
Hassan 2023[224]	Comparative Performance of Artificial Intelligence Optical Diagnosis Systems for Leaving in Situ Colorectal Polyps.	Deprioritised as autonomous AI only
Hassan 2021[225]	Performance of artificial intelligence in colonoscopy for adenoma and polyp detection: a systematic review and meta-analysis.	Systematic review used for reference checking

Hassan 2023[226]	Real-Time Computer-Aided Detection of Colorectal Neoplasia During Colonoscopy : A Systematic Review and Meta-analysis.	Systematic review used for reference checking
Hassan 2020[227]	New artificial intelligence system: first validation study versus experienced endoscopists for colorectal polyp detection.	*Ex vivo* application of technology
Haviland 2025[228]	A RETROSPECTIVE ANALYSIS OF ADENOMA DETECTION WITH GI GENIUS, ENDOCUFF, THEIR COMBINATION, AND STANDARD COLONOSCOPY	Non-randomised study and outcomes covered by randomised trials
Herman 2024[229]	Time and Experience Do Not Lead to Improved Adenoma Detection Rate With Artificial Intelligence-Assisted Colonoscopy: An 11-Month Implementation Trial	Unnamed intervention
Herman 2024[230]	Artificial Intelligence-Assisted Colonoscopy Is Associated With Higher Conversions From Screening to Therapeutic Exams	Unnamed intervention
Herman 2024[231]	Head-to-Head Real World Comparative Analysis of Two Artificial Intelligence-Assisted Colonoscopy Systems	Unnamed intervention
Herman 2024[232]	699 ARTIFICIAL INTELLIGENCE-ASSISTED COLONOSCOPY FAILED TO INCREASE ADENOMA DETECTION RATE: AN IMPLEMENTATION STUDY	Unnamed intervention

Hocke 2022[233]	DISCOVERY AI COMBINATION WITH G-EYE COLONOSCOPY SIGNIFICANTLY INCREASES ADENOMA DETECTION RATE - RESULTS OF A MULTICENTER STUDY	Abstract only and have full texts covering outcomes
Holanda 2025[234]	COMPUTER-AIDED DETECTION WITH OR WITHOUT MUCOSAL-EXPOSURE DEVICES IN COLONOSCOPY: A SYSTEMATIC REVIEW AND META-ANALYSIS WITH TRIAL SEQUENTIAL ANALYSIS	Abstract of systematic review
Horiuchi 2019[235]	REAL-TIME COMPUTER-AIDED DIAGNOSIS OF DIMINUTIVE COLORECTAL POLYPS USING AN AUTOFLUORESCENCE IMAGING SYSTEM	Unnamed intervention
Horiuchi 2019[236]	Real-time computer-aided diagnosis of diminutive rectosigmoid polyps using an auto-fluorescence imaging system and novel color intensity analysis software.	Technology not relevant to review
Hsu 2023[237]	IMPLEMENTATION OF THE NOVEL AI-BASED CECAL RECOGNITION SYSTEM IMPROVED THE ADENOMA DETECTION RATE IN SCREENING COLONOSCOPY	Technology not relevant to review
Htet 2023[238]	TIME TO IMPLEMENT RESECT & DISCARD SERVICE INTO PRACTICE: TWO NOVEL WAYS OF POLYP SIZING AND OPTICAL DIAGNOSIS WITH CADX	Technology not relevant to review

Htet 2024[239]	REAL-TIME COMPARATIVE STUDY OF CADX AND SIZING DEVICES FOR COLORECTAL POLYPS DURING COLONOSCOPY: A SOLUTION TO IMPLEMENT RESECT & DISCARD?	Abstract only and have full texts covering outcomes
Htet 2025[240]	CADE RESULTS FROM A LARGE INTERNATIONAL, MULTI-CENTRE, RANDOMISED-CONTROLLED TRIAL: MORE ADENOMAS DETECTED, NO INCREASE IN UNNECESSARY POLYPECTOMIES	Technology not relevant to review
Huang 2023[241]	Artificial Intelligence-Assisted Colonoscopy Improves Adenoma Detection Rate (ADR) in Both Low and High ADR Endoscopists: A Meta-Analysis	Abstract of systematic review
Huang 2022[242]	Effect of artificial intelligence-aided colonoscopy for adenoma and polyp detection: a meta-analysis of randomized clinical trials.	Systematic review used for reference checking
Huneburg 2022[243]	Real-time use of artificial intelligence in colorectal cancer surveillance of patients with Lynch syndrome - a randomized controlled trial	Abstract of full publication identified
Ishiyama 2022[244]	Impact of the clinical use of artificial intelligence-assisted neoplasia detection for colonoscopy: a large-scale prospective, propensity score-matched study (with video).	Technology not relevant to review
ISRCTN15467766 2024[245]	Future of real time endoscopy, artificial intelligence	Trial record only

ISRCTN68236490 2023[246]	ColoVision: using computers to instantly find and describe colorectal polyps	Trial record only
Jabbal 2023[247]	Utilization of Endocuff-Assisted Colonoscopy and Computer-Aided Detection in Optimizing Colonoscopies in the Elderly	Abstract only and have full texts covering outcomes
Jaber 2024[248]	COMPARISON OF COLONOSCOPY QUALITY METRICS USING ARTIFICIAL INTELLIGENCE ASSISTED COLONOSCOPY VERSUS STANDARD COLONOSCOPY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS	Abstract of systematic review
James 2023[249]	REAL-WORLD VALIDATION OF A COMPUTER-AIDED DIAGNOSIS SYSTEM FOR CHARACTERIZATION OF POLYP HISTOLOGY IN COLONOSCOPY: A PROSPECTIVE MULTICENTER STUDY	Unnamed intervention
Jawwad 2025[250]	Novel Artificial Intelligence Systems in Detecting Adenomas in Colonoscopy: A Systemic Review and Network Meta-Analysis	Systematic review used for reference checking
Jimenez 2024[251]	ARTIFICIAL INTELLIGENCE ENHANCES ADENOMA DETECTION RATE IN LYNCH SYNDROME DURING COLONOSCOPY	Abstract only and have full texts covering outcomes
Jin 2024[252]	Effect of an artificial intelligence-assisted recognition system on colonoscopy quality	Full text not retrieved

Jin 2024[253]	Efficacy of artificial intelligence in reducing miss rates of GI adenomas, polyps, and sessile serrated lesions: a meta-analysis of randomized controlled trials	Systematic review used for reference checking
Jooton 2020[254]	PCN115 Economic Evaluation of Artificial Intelligence-Assisted Colonoscopy for Routine Screening of Low- to High-Risk Colorectal Cancer Patients in the United Kingdom	Health economic assessment only
Jooton 2020[255]	PCN99 Economic Evaluation of Artificial Intelligence-Assisted Colonoscopy for Routine Screening of High-Risk Colorectal Cancer Patients in Spain	Health economic assessment only
JPRN-jRCT1032230396 2023[256]	Clinical trial of colonoscopy using computer-aided detection systems in colorectal cancer screening	Trial record only
JPRN-UMIN000050685 2023[257]	The usefulness of computer-aided detection technologies based on artificial intelligence with image enhanced endoscopy for detecting colon adenoma; single center, randomized controlled trial	Trial record only
JPRN-UMIN000051437 2023[258]	A multicenter prospective randomized controlled trial evaluating the usefulness of a real-time colonoscopy diagnostic support system	Trial record only
JPRN-UMIN000053693 2024[259]	Influence of fatigue and stress on endoscopy accuracy and its relationship to AI colonoscopy: a multicenter clinical trial	Trial record only

JPRN-UMIN000053777 2024[260]	Randomised trial examining the sessile serrated lesion detection rate using linked color imaging in combination with an artificial intelligence assisted colonoscopy	Trial record only
jRCTs022190014 2019[261]	CAD for Polyp Detection Trial	Trial record only
jRCTs032190061 2019[262]	The validation study of detectability and diagnostic accuracy of AI-aided endoscopic diagnosis system for colonoscopy	Trial record only
Kader 2024[263]	RANDOMIZED CONTROLLED TRIAL OF A CLOUD-BASED ARTIFICIAL INTELLIGENCE (AI) COMPUTER-AIDED DIAGNOSIS (CADX) SYSTEM IN NON-EXPERT ENDOSCOPISTS	Abstract of full publication identified
Kader 2024[264]	RANDOMIZED CONTROLLED TRIAL OF A CLOUD-BASED ARTIFICIAL INTELLIGENCE POLYP DETECTION SYSTEM (CADDIE)	Abstract of full publication identified
Kader 2025[265]	CLOUD-BASED ARTIFICIAL INTELLIGENCE FOR DETECTION OF COLORECTAL NEOPLASIA - A RANDOMIZED CONTROLLED TRIAL (EAGLE TRIAL)	Abstract of full publication identified
Kader 2024[266]	RANDOMIZED CONTROLLED TRIAL (RCT) OF A CLOUDBASED ARTIFICIAL INTELLIGENCE (AI) COMPUTERAIDED DIAGNOSIS (CADX) SYSTEM INNON-EXPERT ENDOSCOPISTS	Abstract of full publication identified

Kader 2024[267]	Randomized controlled trial of a cloud-based artificial intelligence (AI) computer-aided diagnosis (CADx) system in non-expert endoscopists (CADDIE)	Abstract of full publication identified
Kader 2024[268]	Randomized controlled trial of a cloud-based artificial intelligence polyp detection system (CADDIE)	Abstract of full publication identified
Kader 2024[269]	RANDOMISED CONTROLLED TRIAL OF A CLOUD-BASED ARTIFICIAL INTELLIGENCE POLYP DETECTION SYSTEM (CADDIE)	Abstract of full publication identified
Kamba 2019[270]	The real-time detection and differential diagnosis of colorectal polyps in colonoscopy with an artificial intelligence algorithm; a prospective observational study	Unnamed intervention
Kamba 2021[271]	ID:3519580 A MULTICENTRE RANDOMIZED CONTROLLED TRIAL TO VERIFY THE REDUCIBILITY OF ADENOMA MISS RATE OF COLONOSCOPY ASSISTED WITH ARTIFICIAL INTELLIGENCE BASED SOFTWARE	Unnamed intervention
Kamba 2021[272]	Reducing adenoma miss rate of colonoscopy assisted by artificial intelligence: a multicenter randomized controlled trial.	Technology not relevant to review

Kandel 2024[273]	ARTIFICIAL INTELLIGENE AIDED COLONOSOCPY DOES NOT IMPROVE ENDOSCOPIST PERFORMACE IN COMMUNITY SETTINGS	Abstract only and have full texts covering outcomes
Kandel 2024[274]	Artificial Intelligence-Aided Colonoscopy Does Not Improve Endoscopist Performance in Community Settings	Non-randomised study and outcomes covered by randomised trials
Karthikeyan 2024[275]	COMPUTER-AIDED DETECTION OF POLYPS WITH ARTIFICIAL INTELLIGENCE DURING COLONOSCOPY IN THE HANDS OF AN EXPERIENCED COLORECTAL SURGEON	Non-randomised study and outcomes covered by randomised trials
Kawamoto 2022[276]	Systematic review of artificial intelligence-based image diagnosis for inflammatory bowel disease	Systematic review used for reference checking
Keshtkar 2023[277]	A Systematic Review and Meta-analysis of Convolutional Neural Network in the Diagnosis of Colorectal Polyps and Cancer.	Systematic review used for reference checking
Keswani 2023[278]	ADOPTION OF A COMPUTER-AIDED DETECTION SYSTEM SIGNIFICANTLY IMPROVES POLYP DETECTION IN ROUTINE CLINICAL PRACTICE	Abstract of full publication identified
Keswani 2024[279]	A Computer-Aided Detection (CADe) System Significantly Improves Polyp Detection in Routine Practice.	Non-randomised study and outcomes covered by randomised trials

Keswani 2024[280]	Adoption of a Computer-Aided Detection System May Improve Polyp Detection in Patients With Positive Stool-Based Testing	Non-randomised study and outcomes covered by randomised trials
Khatri 2023[281]	The Use of Artificial Intelligence to Improve Adenoma Detection Rate in a Community Practice	Non-randomised study and outcomes covered by randomised trials
Khouri 2024[282]	Effect of Computer-Aided Detection Device on the Adenoma Detection Rate and Serrated Detection Rate Among Trainee Fellows	Non-randomised study and outcomes covered by randomised trials
Kim 2025[283]	Role of Artificial Intelligence in Improving Quality of Colonoscopy	Systematic review used for reference checking
Kim 2025[284]	GI Genius increases small and right-sided adenoma and sessile serrated lesion detection rate when used with EndoCuff in a real-world setting: a retrospective United States study.	Non-randomised study and outcomes covered by randomised trials
Kim 2024[285]	The role of artificial intelligence in colonoscopy	Systematic review used for reference checking
Kim 2024[286]	EFFICACY OF COMPUTER-AIDED POLYP DETECTION WHEN USED ALONE AND IN CONJUNCTION WITH A MUCOSA-EXPOSURE DEVICE DURING COLONOSCOPY IN A REAL-WORLD SETTING	Non-randomised study and outcomes covered by randomised trials
Klare 2017[287]	Computer assisted detection of polyps during colonoscopy-results from an initial technical study	Unnamed intervention

Kliegis 2022[288]	Can a Polyp Detection and Characterization System Predict Complete Resection?	Limited usable data/no relevant outcomes
Kobayashi 2024[289]	Detailed Superiority of the CAD EYE Artificial Intelligence System over Endoscopists for Lesion Detection and Characterization Using Unique Movie Sets.	Endoscopists review of videos rather than live during colonoscopy
Kode 2024[290]	IMPACT OF ARTIFICIAL INTELLIGENCE ON ADENOMA DETECTION RATE OF GASTROENTEROLOGISTS AT A TERTIARY CARE ENDOSCOPY SUITE: A QUALITY IMPROVEMENT STUDY AND STATISTICAL ANALYSIS	Non-randomised study and outcomes covered by randomised trials
Koh 2023[291]	Real-time artificial intelligence (AI)-aided endoscopy improves adenoma detection rates even in experienced endoscopists: a cohort study in Singapore.	Non-randomised study and outcomes covered by randomised trials
Koleth 2022[292]	Artificial intelligence in gastroenterology: Where are we heading?.	Systematic review used for reference checking
Kominami 2016[293]	Computer-aided diagnosis of colorectal polyp histology by using a real-time image recognition system and narrow-band imaging magnifying colonoscopy.	Technology not relevant to review
Kudaravalli 2022[294]	Artificial Intelligence-Assisted Colon Polyp Detection: Initial Experience by Gastroenterology Fellows	Abstract only and have full texts covering outcomes

Kumar 2025[295]	Artificial intelligence breakthrough in diagnosis, treatment, and prevention of colorectal cancer - A comprehensive review	Systematic review used for reference checking
Kuo 2024[296]	META-ANALYSIS COMPARING ADVANCED ADENOMA DETECTION RATE OF WATER EXCHANGE AND COMPUTER-AIDED DETECTION COLONOSCOPY	Abstract of systematic review
Labaki 2024[297]	Artificial Intelligence in Gastrointestinal Endoscopy	Study design - review not systematic
Ladabaum 2023[298]	COMPUTER-AIDED DETECTION OF POLYPS DOES NOT IMPROVE COLONOSCOPIST PERFORMANCE IN A PRAGMATIC IMPLEMENTATION TRIAL	Non-randomised study and outcomes covered by randomised trials
Lam 2024[299]	LEVEL OF ACCEPTANCE AND TRUST OF ARTIFICIAL INTELLIGENCE AMONG GASTROENTEROLOGY NURSES	Technology not relevant to review
Lambin 2021[300]	Artificial intelligence for improving screening colonoscopies	Full text not retrieved
Lau 2023[301]	EFFECT of REAL-TIME COMPUTER-AIDED POLYP DETECTION SYSTEM (ENDOAID) on ADENOMA DETECTION in ENDOSCOPIST-IN-TRAINING: A SINGLE-BLIND RANDOMIZED CONTROLLED TRIAL (ENDOAID-TRAIN STUDY)	Abstract of full publication identified

Lau 2021[302]	New computer-aided polyp detection system (Endo-aid) increased the 5-10mm adenoma detection rate in junior endoscopists during colonoscopies-a pilot study	Non-randomised study and outcomes covered by randomised trials
Lee 2024[303]	EXPLORING ENDOSCOPIST PERCEPTIONS OF ARTIFICIAL INTELLIGENCE-AIDED COLONOSCOPY: A QUALITATIVE ANALYSIS	Limited usable data/no relevant outcomes
Lee 2023[304]	TANDEM STUDY DESIGN IS LESS LIKELY TO DEMONSTRATE IMPROVED ADENOMA DETECTION RATE THAN PARALLEL STUDY DESIGN IN THE ASSESSMENT OF ARTIFICIAL INTELLIGENCE-ASSISTED COLONOSCOPY	Abstract of systematic review
Lee 2024[305]	Impact of study design on adenoma detection in the evaluation of artificial intelligence-aided colonoscopy: a systematic review and meta-analysis.	Systematic review used for reference checking
Lee 2023[306]	Impact of Artificial Intelligence on Adenoma Detection Rate of Gastroenterologists at a Tertiary Care Endoscopy Suite: A Quality Improvement Study and Descriptive Analysis	Non-randomised study and outcomes covered by randomised trials
Lei 2020[307]	Adenoma detection rate is not influenced by the time of day in computer-aided detection colonoscopy.	Non-randomised study and outcomes covered by randomised trials

Levy 2022[308]	ARTIFICIAL INTELLIGENCE- AIDED COLONOSCOPY DOES NOT INCREASE ADENOMA DETECTION RATE IN ROUTINE CLINICAL PRACTICE	Abstract only and have full texts covering outcomes
Levy 2022[309]	Artificial Intelligence-Aided Colonoscopy Does Not Increase Adenoma Detection Rate in Routine Clinical Practice	Non-randomised study and outcomes covered by randomised trials
Li 2023[310]	Cost-effectiveness analysis of an artificial intelligence-assisted diagnosis and treatment system for gastrointestinal endoscopy	Health economic assessment only
Li 2022[311]	Real World Validation of an Artificial Intelligence Characterization Support System for Prediction of Polyp Histology in Colonoscopy: Interim Analysis of a Prospective Multicenter Study	Abstract only and have full texts covering outcomes
Li 2021[312]	Artificial intelligence can increase the detection rate of colorectal polyps and adenomas: a systematic review and meta-analysis.	Systematic review used for reference checking
Li 2022[313]	Performance and comparison of artificial intelligence and human experts in the detection and classification of colonic polyps.	Systematic review used for reference checking
Li 2025[314]	CAN ARTIFICIAL INTELLIGENCE ASSISTED COLONOSCOPY COMPENSATE FOR INADEQUATE BOWEL PREPARATION?	Non-randomised study and outcomes covered by randomised trials

Lin 2022[315]	COMPARISON OF COMPUTER-AIDED POLYP DETECTION (CADE) AND ENDOSCOPIC MECHANICAL ATTACHMENT ON ADENOMA DETECTION RATE: A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Linlawan 2024[316]	USING COMPUTER-AIDED POLYP DETECTION SYSTEM(CADE) TO MAINTAIN THE HIGH QUALITY IN ADENOMA RATE DURING COMMUNITY-BASED COLORECTAL CANCER SCREENING IN THAILAND: A RANDOMIZED TRIAL	Unnamed intervention
Liu 2023[317]	ENDOANGEL versus water exchange for the detection of colorectal adenomas	Non-randomised study and outcomes covered by randomised trials
Liu 2020[318]	Study on detection rate of polyps and adenomas in artificial-intelligence-aided colonoscopy	Technology not relevant to review
Lou 2023[319]	Artificial intelligence for colorectal neoplasia detection during colonoscopy: a systematic review and meta-analysis of randomized clinical trials.	Systematic review used for reference checking
Lu 2022[320]	LONG-TERM EFFECTIVENESS OF ARTIFICIAL INTELLIGENCE SYSTEM IN IMPROVING ADENOMA DETECTION RATE: A MULTICENTER SELF-CONTROLLED STUDY	Unnamed intervention

Lu 2022[321]	ARTIFICIAL INTELLIGENCE ASSISTANCE IMPROVES AS ENDOSCOPIST FATIGUE INCREASES: SECONDARY ANALYSIS OF TWO RANDOMIZED TRIALS	Limited usable data/no relevant outcomes
Lu 2023[322]	Assessment of the Role of Artificial Intelligence in the Association Between Time of Day and Colonoscopy Quality.	Limited usable data/no relevant outcomes
Lui 2020[323]	ACCURACY OF ARTIFICIAL INTELLIGENCE ON HISTOLOGICAL PREDICTION AND DETECTION OF COLORECTAL POLYPS: A SYSTEMATIC REVIEW AND METAANALYSIS	Abstract of systematic review
Lui 2024[324]	1246 FINDINGS AT SURVEILLANCE COLONOSCOPY IN HIGH-RISK PATIENTS WITH PRIOR COMPUTED-ASSISTED DETECTION DURING INDEX COLONOSCOPY: A PROPENSITY SCORE MATCHING ANALYSIS	Unnamed intervention
Lui 2022[325]	POTENTIAL IMPACTS OF COMPUTER-AIDED DETECTION OF COLORECTAL POLYPS ON COLONOSCOPY SURVEILLANCE INTERVALS	Non-randomised study and outcomes covered by randomised trials
Lui 2022[326]	COMPUTER-ASSISTED DETECTION VERSUS CONVENTIONAL COLONOSCOPY ON DETECTION AND MISS RATES OF PROXIMAL COLONIC LESIONS: A MULTI-CENTRE, RANDOMIZED, TANDEM COLONOSCOPY STUDY	Unnamed intervention

Lui 2023[327]	The Impacts of Computer-Aided Detection of Colorectal Polyps on Subsequent Colonoscopy Surveillance Intervals: Simulation Study.	Non-randomised study and outcomes covered by randomised trials
Lui 2020[323]	Accuracy of artificial intelligence on histology prediction and detection of colorectal polyps: a systematic review and meta-analysis.	Systematic review used for reference checking
Lui 2023[328]	Computer-assisted detection versus conventional colonoscopy for proximal colonic lesions: a multicenter, randomized, tandem-colonoscopy study.	Technology not relevant to review
Lui 2020[329]	ARTIFICIAL INTELLIGENCE-ASSISTED REAL-TIME DETECTION REDUCES MISSED LESIONS DURING COLONOSCOPY: A RETROSPECTIVE AND PROSPECTIVE STUDY	Unnamed intervention
Lui 2024[330]	ARTIFICIAL INTELLIGENCE ASSISTED MONITORING OF EFFECTIVE WITHDRAWAL TIME AND ADENOMA DETECTION RATE OF INDIVIDUAL ENDOSCOPIST	Non-randomised study and outcomes covered by randomised trials
Lui 2023[331]	COMPUTER-ASSISTED DETECTION WITH OR WITHOUR ENDOCUFF ON DETECTION OF COLORECTAL ADENOMA: A RANDOMIZED CONTROLLED TRIAL (INTERIM ANALYSIS)	Abstract only and have full texts covering outcomes
Lui 2025[332]	PROSPECTIVE EVALUATION OF ARTIFICIAL INTELLIGENCE-ASSISTED MONITORING OF EFFECTIVE WITHDRAWAL TIME	Study design - not assessing impact of intervention on outcomes

	VERSUS STANDARD WITHDRAWAL TIME ON ADENOMA PER COLONOSCOPY	
Lui 2025[333]	Surveillance findings in high-risk patients after baseline computer-assisted detection colonoscopy: a propensity score matching analysis	Non-randomised study and outcomes covered by randomised trials
Luo 2021[334]	Artificial Intelligence-Assisted Colonoscopy for Detection of Colon Polyps: a Prospective, Randomized Cohort Study.	Technology not relevant to review
Lwin 2025[335]	Clinical significance of computer-aided quality assessment systems in colonoscopy: a comprehensive review.	Systematic review used for reference checking
Ma 2024[336]	Efficacy and safety of computer-aided detection(CADe) in colonoscopy for colorectal neoplasia detection: A meta-analysis	Systematic review used for reference checking
Maan 2025[337]	Artificial Intelligence in Endoscopy Quality Measures	Study design - review not systematic
Maas 2023[338]	A NOVEL COMPUTER-AIDED POLYP DETECTION SYSTEM in DAILY CLINICAL CARE: AN INTERNATIONAL MULTICENTER, RANDOMIZED, TANDEM TRIAL	Abstract of full publication identified
Maida 2023[339]	EFFECTIVENESS OF ARTIFICIAL INTELLIGENCE FOR COLONOSCOPY ON ADENOMA AND POLYP MISS RATE: A METAANALYSIS OF TANDEM RCTS	Abstract of systematic review

Maida 2025[340]	Effectiveness of artificial intelligence assisted colonoscopy on adenoma and polyp miss rate: A meta-analysis of tandem RCTs	Systematic review used for reference checking
Makar 2024[341]	Use of Artificial Intelligence Improves Colonoscopy Performance in Adenoma Detection: A Systematic Review and Meta-Analysis.	Systematic review used for reference checking
Malik 2024[342]	Is Adenoma Detection Any Different From Polyp Detection With Artificial Intelligence in Colonoscopy? A Meta-Analysis of Randomized Controlled Data	Abstract of systematic review
Mangas-Sanjuan 2023[343]	ROLE OF ARTIFICIAL INTELLIGENCE IN COLONOSCOPY DETECTION OF ADVANCED LESIONS: A RANDOMIZED TRIAL	Unnamed intervention
Mangas-Sanjuan 2023[344]	ROLE of ARTIFICIAL INTELLIGENCE in COLONOSCOPY DETECTION of ADVANCED LESIONS	Abstract only and have full texts covering outcomes
Mansour 2023[345]	Artificial Intelligence in Colonoscopy	Systematic review used for reference checking
McGrath 2025[346]	DOES AI INFLUENCE ADENOMA DETECTION RATES IN FIT-POSITIVE PATIENTS	Unnamed intervention
Mehta 2023[347]	Effectiveness of artificial intelligence-assisted colonoscopy in early diagnosis of colorectal cancer: a systematic review	Systematic review used for reference checking

Mekritthikra 2022[348]	THE PERFORMANCE OF REAL-TIME COMPUTER-AIDED CHARACTERIZATION OF COLORECTAL NEOPLASIA IN SCREENING COLONOSCOPY: A PROSPECTIVE STUDY	Abstract only and have full texts covering outcomes
Melquist 2022[349]	CAUSES OF FALSE POSITIVE DETECTIONS BY CADE DURING REAL-TIME COLONOSCOPY AND ITS CLINICAL IMPACT: A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Milluzzo 2021[350]	ID: 3522041 INCREMENTAL YIELD OF ARTIFICIAL INTELLIGENCE IN FOLLOW-UP SCREENING COLONOSCOPIES - AN INTERIM ANALYSIS	Abstract only and have full texts covering outcomes
Milluzzo 2021[351]	Incremental Yield Of Artificial Intelligence In Followup Screening Colonoscopies: An Interim Analysis	Abstract only and have full texts covering outcomes
Milluzzo 2021[352]	Incremental yield of artificial intelligence in follow-up screening colonoscopies-an interim analysis on 432 patients	Abstract only and have full texts covering outcomes
Milluzzo 2021[353]	Incremental yield of artificial intelligence in follow-up screening colonoscopies-an interim analysis	Abstract only and have full texts covering outcomes
Minegishi 2022[354]	Comprehensive Diagnostic Performance of Real-Time Characterization of Colorectal Lesions Using an Artificial Intelligence-Assisted System: A Prospective Study.	Technology not relevant to review

Ming Yen Koh 2024[355]	REAL-WORLD ASSESSMENT OF THE EFFICACY OF COMPUTER-ASSISTED DIAGNOSIS (CADX) IN COLONOSCOPY - A COHORT STUDY IN SINGAPORE	Abstract only and have full texts covering outcomes
Misawa 2022[356]	A PROSPECTIVE STUDY OF REAL-TIME USE OF COMPUTER-AIDED CHARACTERIZATION FOR COLORECTAL LESIONS	Unnamed intervention
Misawa 2022[357]	A PROSPECTIVE STUDY OF REAL-TIME COMPUTER-AIDED CHARACTERIZATION OF COLORECTAL LESIONS: DIAGNOSTIC PERFORMANCE AND IMPACT ON HUMAN DIAGNOSIS	Technology not relevant to review
Miyaguchi 2024[358]	Artificial intelligence-assisted linked color imaging versus linked color imaging for colorectal adenoma detection: the first randomized controlled trial	Trial record only
Mizukami 2023[359]	Usefulness of AI-Equipped Endoscopy for Detecting Colorectal Adenoma during Colonoscopy Screening: Confirm That Colon Neoplasm Finely Can Be Identified by AI without Overlooking Study (Confidential Study).	Non-randomised study and outcomes covered by randomised trials
Mohan 2020[360]	Real-time computer aided colonoscopy versus standard colonoscopy for improving adenoma detection rate: A meta-analysis of randomized-controlled trials	Systematic review used for reference checking

Mohan 2020[361]	Accuracy of convolutional neural network-based artificial intelligence in diagnosis of gastrointestinal lesions based on endoscopic images: A systematic review and meta-analysis.	Systematic review used for reference checking
Moosvi 2020[362]	Computer-Aided Polyp Detection during Colonoscopy: A Systematic Review and Meta-Analysis	Abstract of systematic review
Mori 2022[363]	COST-EFFECTIVENESS OF ARTIFICIAL INTELLIGENCE FOR SCREENING COLONOSCOPY	Health economic assessment only
Mori 2020[364]	Cost savings in colonoscopy with artificial intelligence-aided polyp diagnosis: An add-on analysis of a clinical trial	Technology not relevant to review
Mori 2019[365]	482 PERFORMANCE OF NON-EXPERT ENDOSCOPISTS IN OPTICAL BIOPSY OF DIMINUTIVE COLORECTAL POLYPS WITH REAL-TIME USE OF ARTIFICIAL INTELLIGENCE	Unnamed intervention
Mori 2018[366]	Optical biopsy of diminutive colorectal polyps with real-time use of "artificial intelligence"-assisted endoscopy	Unnamed intervention
Mori 2017[367]	Diagnostic yield of "artificial intelligence"-assisted endocytoscopy for colorectal polyps: A prospective study	Unnamed intervention

Mori 2021[368]	Artificial intelligence-assisted colonoscopy for cancer recognition: A multicenter study designed to obtain regulatory approval	Unnamed intervention
Mori 2020[369]	Cost savings in colonoscopy with artificial intelligence-aided polyp diagnosis: an add-on analysis of a clinical trial (with video).	Technology not relevant to review
Mori 2018[370]	Real-Time Use of Artificial Intelligence in Identification of Diminutive Polyps During Colonoscopy: A Prospective Study.	Technology not relevant to review
Mori 2023[371]	Impact of Artificial Intelligence on Colonoscopy Surveillance After Polyp Removal: A Pooled Analysis of Randomized Trials.	Systematic review used for reference checking
Morimoto 2025[372]	DEVELOPMENT OF COMPUTER-AIDED DIAGNOSTIC SYSTEMS FOCUSED ON THE JNET CLASSIFICATIONS FOR COLORECTAL LESIONS	Unnamed intervention
Morimoto 2025[373]	Efficiency of Real-time Computer-aided Polyp Detection during Surveillance Colonoscopy: A Pilot Study.	Technology not relevant to review
Mwango 2024[374]	Effect of artificial intelligence-aided colonoscopy on the adenoma detection rate: A systematic review	Systematic review used for reference checking
Narimiti 2022[375]	AI Assisted Colonoscopy Does Not Affect Mental Workload in Gastroenterologists	Abstract only and have full texts covering outcomes

Nayar 2024[376]	The Impact of Real Time Artificial Intelligence Enhanced Colonoscopy: A One Year Performance Review	Unnamed intervention
Nazarian 2021[377]	Diagnostic Accuracy of Artificial Intelligence and Computer-Aided Diagnosis for the Detection and Characterization of Colorectal Polyps: Systematic Review and Meta-analysis.	Systematic review used for reference checking
NCT03622281 2018[378]	Quality Improvement Intervention in Colonoscopy Using Artificial Intelligence	Trial record only
NCT03925337 2019[379]	Computer Aided Detection of Polyps in the Colon	Trial record only
NCT03967756 2019[380]	Impact of Automatic Polyp Detection System on Adenoma Detection Rate	Trial record only
NCT04071678 2019[381]	A Randomized Controlled Multicenter Study of Artificial Intelligence Assisted Digestive Endoscopy	Trial record only
NCT04074577 2019[382]	Computer Aided Detection, Tandem Colonoscopy Study	Trial record only
NCT04102631 2019[383]	A Multicenter Study Evaluating the Effectiveness of Endo.Angel in Improving the Quality of Colonoscopy	Trial record only

NCT04126265 2019[384]	Artificial Intelligence-assisted Colonoscopy for Detection of Colon Polyps	Trial record only
NCT04294355 2020[385]	Artificial Intelligence-assisted Colonoscopy on Detection of Missed Proximal Lesions	Trial record only
NCT04325815 2020[386]	CADDIE Trial - Computer Aided Diagnosis and Detection for Intelligent Endoscopy	Trial record only
NCT04422548 2020[387]	Does AI-assisted Colonoscopy Improve Adenoma Detection in Screening Colonoscopy?	Trial record only
NCT04440865 2020[388]	Impact of Artificial Intelligence Genius® System-assisted Colonoscopy vs. Standard Colonoscopy (COLO-GENIUS)	Trial record only
NCT04441580 2020[389]	Assessing the Additional Neoplasia Yield of Computer-aided Colonoscopy in a Screening Setting	Trial record only
NCT04453956 2020[390]	A Single Center Study on Comparing the Different Function of EndoAngel in Improving the Quality of Colonscopy	Trial record only
NCT04485715 2020[391]	Application of AI in Polypectomy	Trial record only

NCT04640792 2020[392]	A Study to Evaluate the Safety and Efficacy of the Use of ME-APDS During Colonoscopy	Trial record only
NCT04673136 2020[393]	Usefulness of GI-GENIUS in FIT-based Colorectal Cancer Screening Program	Trial record only
NCT04691401 2020[394]	Impact of Artificial Intelligence (AI) on Adenoma Detection During Colonoscopy in FIT+ Patients	Trial record only
NCT04723758 2021[395]	COLO-DETECT: can an Artificial Intelligence Device Increase Detection of Polyps During Colonoscopy?	Trial record only
NCT04727814 2021[396]	Comparison of Polyp Detection and False Alarm Rates in Water Exchange and Air Insufflation Colonoscopy	Trial record only
NCT04837599 2021[397]	Artificial Intelligence Performance in Colonoscopy in Daily Practice	Trial record only
NCT04838951 2021[398]	Effect of Real-time Computer-aided System (ENDO-AID) on Adenoma Detection in Endoscopist-in-training	Trial record only
NCT04894708 2020[399]	Study on the Use of Artificial Intelligence (Fujifilm) for Polyp Detection in Colonoscopy	Trial record only

NCT04909671 2021[400]	Evaluation of ArTificial Intelligence System (Gi-Genius) for adenoMa dEtection in Lynch Syndrome	Trial record only
NCT04912037 2021[401]	A Study on the Effectiveness of AI-assisted Colonoscopy in Improving the Effect of Colonoscopy Training for Trainees	Trial record only
NCT04945044 2021[402]	Artificial Intelligence Aid Systems in Colorectal Adenoma Detection	Trial record only
NCT05013125 2021[403]	ENDO-AID Assisted Tandem Colonoscopy RCT	Trial record only
NCT05064124 2021[404]	Early diAgnosis Real-Time Healthcare System for CANcer Trial	Trial record only
NCT05133544 2021[405]	Endocuff With or Without AI-assisted Colonoscopy	Trial record only
NCT05139186 2021[406]	The EYE Study Enhancing the Diagnostic Yield of Standard Colonoscopy by Artificial Intelligence Aided Endoscopy	Trial record only
NCT05141773 2021[407]	Artificial Intelligence Aid Systems and Endocuff in Colorectal Adenoma Detection	Trial record only
NCT05158725 2021[408]	Comparison of Colonoscopy Adenoma Detection Yield	Trial record only
NCT05178095 2021[409]	Artificial Intelligence in Colonic Polyp Detection	Trial record only

NCT05237310 2022[410]	Comparing Detection of Standard Colonoscopy, CAD-EYE and Combined CAD-EYE and G-EYEÂ® Aided Colonoscopy	Trial record only
NCT05240625 2022[411]	Clinical Efficacy Evaluation of a Computer-aided Colonoscopy as Compared With the Standard Colonoscopy	Trial record only
NCT05275556 2022[412]	Gastroenterology Artificial INtelligence System for Detecting Colorectal Polyps (The GAIN Study)	Trial record only
NCT05317351 2022[413]	A Prospective Randomized Study Comparing the Adenoma Detection Yield of SC, AI and Combined AI and G-EYEÂ®	Trial record only
NCT05318495 2022[414]	A Dual Tandem Study - SC vs. CAD-EYE vs. CAD-EYE With G-EYE	Trial record only
NCT05323279 2022[415]	Evaluate the Effects of An AI System on Colonoscopy Quality of Novice Endoscopists	Trial record only
NCT05391477 2022[416]	Artificial Intelligence for Diminutive Polyp Characterization	Trial record only
NCT05414448 2022[417]	Combination of Artificial Intelligence and Mucosal Exposure Device to Enhance Colorectal Neoplasia Detection	Trial record only
NCT05423964 2022[418]	Impact of AI on Trainee ADR	Trial record only

NCT05448300 2022[419]	Adenoma Detection Rate in Water and Air Colonoscopy Using Computer-aided System	Trial record only
NCT05481632 2022[420]	Validating the Safety and Effectiveness of ENDOANGEL Lower Gastrointestinal Endoscope Image Auxiliary Diagnostic Software	Trial record only
NCT05500248 2022[421]	Artificial Intelligence for Leaving in Situ Colorectal Polyps	Trial record only
NCT05523271 2022[422]	A Multi Center Study Comparing the Efficacy of CAD EYE and the Standard of Care (White Light)	Trial record only
NCT05568992 2022[423]	Prospective, Randomized Controlled Study to Evaluate the Effect of Artificial Intelligence Assisted Optical Diagnosis of Advanced Adenomas	Trial record only
NCT05594576 2022[424]	Comparison of the ENDOCUFF VISION® Endoscopy Cap Coupled With GI GENIUS Artificial Intelligence Compared to Each Device Alone in Improving Colonic Adenoma Detection Rate During Colonoscopy	Trial record only
NCT05611151 2022[425]	Real-time Computer-Aided Detection of Colonic Adenomas With NEC WISE VISION Endoscopy	Trial record only
NCT05718193 2023[426]	Real-Time Artificial Intelligence Assissted Colonoscopy to Identify and Classify Polyps	Trial record only

NCT05730192 2023[427]	EAGLE Trial CADDIE Artificial Intelligence Endoscopy	Trial record only
NCT05740137 2023[428]	Adenoma Detection Rate in Artificial Intelligence-assisted Colonoscopy	Trial record only
NCT05829590 2023[429]	AI-assisted Colonoscopy Report System In Improving Reporting Quality	Trial record only
NCT05862948 2023[430]	Accuracy of Endo-aid in Consecutive Patients Referred for Colonoscopy	Trial record only
NCT05870332 2023[431]	Nationwide Study of Artificial Intelligence in Adenoma Detection for Colonoscopy	Trial record only
NCT05941689 2023[432]	Efficacy of Artificial Intelligence-assisted Colonic Polyp Detection System	Trial record only
NCT05943288 2023[433]	Safety and Efficacy of the Olympus CADe System in Real-time Colonoscopy	Trial record only
NCT05963191 2023[434]	CAD-EYE System for the Detection of Neoplastic Lesions in Patients With Lynch Syndrome	Trial record only
NCT05963724 2023[435]	Real-Time CAD for Colonic Neoplasia: a RCT	Trial record only
NCT05990218 2023[436]	Artificial Intelligence in the Detection of Right Sided Colonic Polyp in Different Operator Experience	Trial record only

NCT06041945 2023[437]	Artificial Intelligence to Implement Cost-saving Strategies for Colonoscopy Screening Based on in Vivo Prediction of Polyp Histology	Trial record only
NCT06062095 2023[438]	Computer Aided Diagnosis (CADx) for Colorectal Polyps Resect-and-Discard Strategy	Trial record only
NCT06077435 2023[439]	Comparing CADe Software for Enhanced Polyp Detection	Trial record only
NCT06160466 2023[440]	Assessing the Additional Neoplasia Yield of Computer-aided Colonoscopy in Follow-up Patients in a Screening Setting	Trial record only
NCT06173258 2023[441]	Water Exchange Colonoscopy With Artificial Intelligence-assisted Detection	Trial record only
NCT06216405 2024[442]	Performance of Artificial Intelligence in Colonoscopy for Right Colon Polyp Detection	Trial record only
NCT06251700 2024[443]	Longterm Effectiveness of Artificial Intelligence-assisted Colonoscopy on Adenoma Recurrence	Trial record only
NCT06281392 2023[444]	Artificial Intelligence and Dysplasia Detection in Inflammatory Bowel Disease (EIIDISIA Study)	Trial record only

NCT06469671 2024[445]	Effectiveness of Artificial Intelligence - Assisted Colonoscopy in Colorectal Neoplasms	Trial record only
NCT06543862 2024[446]	Autonomous Artificial Intelligence Versus AI Assisted Human Optical Diagnosis	Trial record only
NCT06617468 2024[447]	Effect of the Computer Aided Diagnosis with Explainable Artificial Intelligence for Colon Polyp on Optical Diagnosis and Acceptance of Technology	Trial record only
NCT06621225 2024[448]	Artificial Intelligence in Colonoscopy	Trial record only
NCT06654128 2024[449]	The Yield of Artificial Intelligence (GI Genius) in Lynch Syndrome - a Randomized Tandem-colonoscopy Trial	Trial record only
NCT06676930 2024[450]	Impact of Artificial Intelligence on Trainee Polyp Miss Rates	Trial record only
NCT06715384 2024[451]	Evaluation of a CAM System for Colorectal Polyp Size Measurement	Trial record only
NCT06786793 2025[452]	Artificial Intelligence in Colonoscopy	Trial record only
NCT06792292 2025[453]	Artificial Intelligence-Assisted Colonoscopy in Colorectal Cancer Screening in a General Hospital	Trial record only

NCT06799793 2024[454]	Artificial Intelligence-based Screening Models for Prevention and Early Detection of Colorectal Cancer	Trial record only
NCT06786793 2025[455]	Artificial Intelligence in Endoscopic Diagnosis of Colorectal Polyps: A Prospective Randomized Study	Trial record only
NCT06773832 2025[456]	Artificial Intelligence Predicts the Pathology and Endoscopic Classification of Colorectal Polyps During Colonoscopy	Trial record only
NCT06676930 2024[457]	Impact of Computer Aided Detection on Trainee Polyp Miss Rates Using a Tandem Colonoscopy Design	Trial record only
NCT06345105 2024[458]	A Prospective Evaluation of the Correlation Between Real Time Artificial Intelligence-derived Effective Withdrawal Time and Adenoma Detection Rate	Trial record only
NCT06469671 2024[459]	Artificial Intelligence - Assisted Colonoscopy in Diagnosis of Colorectal Neoplasms: Russian Multicenter Randomised Open - Label Trial	Trial record only
NCT06335654 2024[460]	Real-time Artificial Intelligence-based Endocytoscopic Diagnosis of Colorectal Neoplasms: a Single Center, Prospective Clinical Study	Trial record only

NCT06173258 2023[461]	Evaluation of Artificial Intelligence for Adenoma Detection in Water Exchange Colonoscopy: the WEAID Randomized Controlled Trial (Water Exchange With Artificial Intelligence-assisted Detection)	Trial record only
NCT05963191 2023[462]	Evaluation of the CAD-EYE System for the Detection of Colorectal Neoplastic Lesions in Patients With Lynch Syndrome	Trial record only
NCT05941689 2023[463]	Research on the Auxiliary Diagnosis and Treatment System of Digestive Endoscopy Based on Artificial Intelligence: An Efficacy Study of Artificial Intelligence-assisted Colonic Polyp Detection System	Trial record only
NCT06041945 2023[464]	Saving by Artificial Intelligence for Virtual Endoscopy Biopsy Artificial Intelligence to Implement Cost-saving Strategies for Colonoscopy Screening Based on in Vivo Prediction of Polyp Histology	Trial record only
NCT06077435 2023[465]	Comparing CADe Software for Enhanced Polyp Detection: A Randomized Controlled Trial	Trial record only
NCT06116864 2023[466]	Enhancing Polyp Detection: A Randomized Controlled Trial Comparing Combined Computer-Aid Detection and Polyp-Detecting Colonoscope Attachment to Computer-Aid Detection Alone in Patients Undergoing Colonoscopy	Trial record only

NCT05888623 2023[467]	Computer Assisted Detection of Neoplasia During Colonoscopy Evaluation (CADeNCE)	Trial record only
NCT05829590 2023[468]	Speech and Image Recognition Based System in Improving Reporting Quality During Colonoscopy	Trial record only
NCT05822895 2023[469]	A Comprehensive Review of the Impact of a COmPuter-aIded reaL-time pOlyp deTection System on Adult Colonoscopy (COPILOT Study) - a Single Institution Adoption Experience	Trial record only
NCT05730192 2023[470]	Evaluation of Artificial Intelligence for Detection of Gastrointestinal Lesions in Endoscopy (EAGLE)	Trial record only
NCT05829447 2023[471]	Impact on Polyp Detection of a Computer Aided Detection System (CADEYE) Combined With a Balloon Mucosal Exposure Device (G-EYE 760R) in Individuals Participating in a Organized Colorectal Cancer Screening Program	Trial record only
NCT05687318 2023[472]	A Clinical Trial of the Effectiveness and Safety of Software Assisting Diagnose the Intestinal Polyp Digestive Endoscopy by Analysis of Colonoscopy Medical Images From Electronic Digestive Endoscopy Equipment, a Prospective, Multicenter, Randomized Stratified Block, Incomplete Blind Setting, Para...	Trial record only

NCT05990218 2023[473]	Efficacy of Artificial Intelligence in the Detection of Right Sided Colonic Polyp in Operators with Different Endoscopic Experience: a Randomized Control Trial	Trial record only
NCT05734820 2023[474]	Real-time Computer-aided Polyp/Adenoma Detection During Screening Colonoscopy: a Single-center Crossover Trial	Trial record only
NCT06059378 2023[475]	Using Artificial Intelligence-assisted Optical Polyp Diagnosis for Diminutive Colorectal Polyps	Trial record only
NCT05754229 2023[476]	Accuracy of Real Time Characterization in Artificial Intelligence-assisted Colonoscopy - A Prospective Quality Assurance Study	Trial record only
NCT05942677 2023[477]	Comparison of Flat Colorectal Lesion Detection by Artificial Intelligence-assisted Colonoscopy Versus Endoscopists: AIChallenge - Medtronic	Trial record only
NCT05963724 2023[478]	Efficacy of Real-Time Computer Aided-Detected of Colonic Neoplasia in an Underserved Population, A Randomized Controlled Trial	Trial record only
NCT05943288 2023[479]	Safety and Efficacy of the Olympus Endoscopy Computer-Aided Detection (CADe) System in Detection of Colorectal Neoplasia's During Real-time Colonoscopy: A European Prospective, Multicenter, Randomized Controlled Trial (EuroCADe)	Trial record only

NCT06063720 2023[480]	A Prospective Evaluation of the Correlation Between Artificial Intelligence-derived Effective Withdrawal Time and Adenoma Detection Rate	Trial record only
NCT05619614 2022[481]	The Influence of Artificial Intelligence (AI) Assisted Polyp Detection (Discovery System) on Visual Gaze Patterns During Real-time Colonoscopy	Trial record only
NCT05542030 2022[482]	Accuracy of CAD Eye in the Detection of Colonic Remaining Lesions After Endoscopic Mucosal Resection: a Pilot Study	Trial record only
NCT05594576 2022[483]	Comparison of the ENDOCUFF VISION Endoscopy Cap Coupled with GI GENIUSTM Artificial Intelligence Compared to Each Device Alone in Improving Colonic Adenoma Detection Rate During Colonoscopy	Trial record only
NCT05523271 2022[484]	A Multi-center Control Study to Determine the Efficacy of CADEYE in Detecting Colon Polyps in Comparison to Standard of Care	Trial record only
NCT05414383 2022[485]	A Prospective Study to Evaluate the Diagnostic Accuracy of Computer-aided Diagnosis (CADx) System in Real-time Characterization of Colorectal Neoplasia	Trial record only
NCT05349110 2022[486]	Real Time Computer-aided Diagnosis (CADx) of Diminutive Colorectal Polyps Using Artificial Intelligence	Trial record only

NCT05318495 2022[487]	A Dual Tandem Study Comparing the Adenoma Detection and Miss-rate of SC to That of Artificial Intelligence (CAD-EYE) Aided Colonoscopy and to That of Artificial Intelligence (CAD-EYE) and G-EYE Aided Colonoscopy	Trial record only
NCT05423964 2022[488]	Impact of Artificial Intelligence on Trainee Adenoma Detection Rate	Trial record only
NCT05323279 2022[489]	Evaluate the Effects of An Artificial Intelligence System on Colonoscopy Quality of Novice Endoscopists: A Randomized Controlled Trial	Trial record only
NCT05500248 2022[490]	Impact of Computer-aided Optical Diagnosis (CADx) in Predicting Histology of Diminutive Rectosigmoid Polyps: a Multicenter Prospective Trial	Trial record only
NCT05236790 2022[491]	Performance Evaluation of CAD-EYE and SCALE-EYE for Detection, Classification, and Measurement of Colorectal Polyps: a Prospective Study	Trial record only
NCT05244278 2022[492]	Artificial Intelligence (AI) Assisted Real-time Adenoma Detection and Classification During Colonoscopies	Trial record only
NCT05237310 2022[493]	Dual Tandem Study Comparing the Adenoma Detection and Miss-rate of Standard Colonoscopy to That of Artificial Intelligence (CAD-EYE)	Trial record only

	and to That of Artificial Intelligence (CAD-EYE) and G-EYE Aided Colonoscopy	
NCT05220345 2022[494]	Synergistic Effect of G-Eye Balloon for Behind the Folds Visualization With Artificial Intelligence Assisted Polyp Detection (Discovery System) on Adenoma Detection Rate. 'Discovery III Study'	Trial record only
NCT05391477 2022[495]	Efficacy and Cost-effectiveness of an Artificial Intelligence System (GI-Genius) on the Characterization of Diminutive Colorectal Polyps Within a Colorectal Cancer Screening Program: a Multicenter Randomized Controlled Trial (ODDITY Trial)	Trial record only
NCT05214625 2022[496]	Questionnaire Study Concerning Artificial Intelligence and Its Application in (Gastrointestinal) Healthcare - Patients' and Physicians' Perspectives	Trial record only
NCT05611151 2022[497]	Real-time Computer-Aided Detection of Colonic Adenomas With NEC WISE VISION Endoscopy: Prospective, Randomized Clinical Performance Evaluation	Trial record only
NCT05492656 2022[498]	Accuracy and Feasibility of CADx System for White Light Colonic Polyp Characterization	Trial record only
NCT05448300 2022[499]	Adenoma Detection Using Real-Time Computer-Aided Colon Polyp Detection System to Compare Water Exchange and Air Insufflation - A Randomized Controlled Trial	Trial record only

NCT05414448 2022[500]	Combination of Artificial Intelligence (ENDOAID) and Mucosal Exposure Device (ENDOCUFF) to Enhance Colorectal Neoplasia Detection: a Randomized Controlled Trial	Trial record only
NCT05322993 2022[501]	Improving Polyp Detection Rate by Artificial Intelligence in Colonoscopy	Trial record only
NCT05034185 2021[502]	Real-World Validation of an Artificial Intelligence Characterization Support (CADx) System for Prediction of Polyp Histology in Colonoscopy: A Prospective Multicentre Study	Trial record only
NCT05141773 2021[503]	Computer-assisted Adenoma Detection Coloscopy With Endo-AID Artificial Intelligence System and Endocuff Versus Endocuff Assisted Colonoscopy: a Randomized Controlled Trial	Trial record only
NCT05171634 2021[504]	Impact of Artificial Intelligence in Dysplasia Detection During Colonoscopy in Patients With Long-data Ulcerative Colitis: a Crossover Study	Trial record only
NCT05178095 2021[505]	Artificial Intelligence in Colonic Polyp Detection	Trial record only
NCT05133544 2021[506]	Endocuff With or Without Artificial Intelligence-assisted Colonoscopy in Detection of Colorectal Adenoma: a Randomized Colonoscopy Trial	Trial record only

NCT05141409 2021[507]	The COMBO CAD Study: Characterization cOMparison Between twO CAD Systems	Trial record only
NCT05064124 2021[508]	Early DiAgnosis Real-Time Healthcare System for CANcer Trial	Trial record only
NCT04915833 2021[509]	Real-time Computer-aided Polyp Detection During Screening Colonoscopy Performed by Expert Endoscopists	Trial record only
NCT04945044 2021[510]	Usefulness of the Endo-AID Artificial Intelligence System in the Detection of Colorectal Adenomas. a Randomized Controlled Trial	Trial record only
NCT04979962 2021[511]	Colorectal Polyp Detection Comparing Computer Assisted Colonoscopy With Conventional Colonoscopy	Trial record only
NCT04921488 2021[512]	Cross-sectional, Multi-center Study Comparing Diagnostic Performance Between the CAD EYE System and the Physician on Histological Prediction of Colonic Polyps in Screening of Colorectal Cancer by Colonoscopy	Trial record only
NCT04884581 2021[513]	The CHANGE Study: Characterization Helping the Assessment of Colorectal Neoplasia in Gastrointestinal Endoscopy	Trial record only

NCT04749277 2021[514]	Artificial Intelligence in the Characterization of Small and Diminutive Colorectal Polyps: A Prospective Study in a Clinical Setting Using CAD EYE	Trial record only
NCT04777019 2021[515]	Computer Aided Polyp Detection (C3PO) Trial: A Multicenter International Trial Evaluating Diagnostic Accuracy of Artificial Intelligence System in Detecting Colon Polyps	Trial record only
NCT04723758 2021[516]	COLO-DETECT: A Randomised Controlled Trial of Lesion Detection at Colonoscopy Using the GI Genius Artificial Intelligence Platform	Trial record only
NCT04747665 2021[517]	Patient and Endoscopists' Experiences and Perceptions of Colonoscopy and New Technologies in Colonoscopy	Trial record only
NCT04727814 2021[518]	Polyp Detection and False Alarm Rates by Computer-Aided Analysis of Videos of Withdrawal Phase of Colonoscopy in a Randomized Controlled Trial of Water Exchange Versus Air Insufflation	Trial record only
NCT05080088 2021[519]	A Pilot Study: Retrospective Evaluation of 3 Colonic Adenoma Detection Strategies During a Colonoscopy: Endoscopy Cap Associated With the Artificial Intelligence GI GENIUS TM System, the Artificial Intelligence GI GENIUS TM Alone and Colonoscopy Alone	Trial record only

NCT05089071 2021[520]	Effect of Two Colonoscopy AI Systems for Colon Polyp Detection According to the False Positive Rates of the Systems: A Single-center Prospective Study	Trial record only
NCT05158725 2021[521]	Comparison of Colonoscopy Adenoma Detection Yield of Standard Colonoscopy, Discovery Aided Colonoscopy, and Discovery and G-EYE Aided Colonoscopy	Trial record only
NCT05013125 2021[522]	Assessment of Efficacy of ENDO-AID Assisted Colonoscopy in Adenoma Detection: a Single Centre Randomised Controlled Trial	Trial record only
NCT04912037 2021[523]	A Study on the Effectiveness of Artificial Intelligence-assisted Colonoscopy in Improving the Effect of Colonoscopy Training for Trainees	Trial record only
NCT04442607 2020[524]	Clinical vAliDation of ARTificial Intelligence in POlyp Detection	Trial record only
NCT04260321 2020[525]	The AID Study 2: Artificial Intelligence for Colorectal Adenoma Detection 2	Trial record only
NCT04607083 2020[526]	Impact of Computer-aided Optical Diagnosis (CAD) in Predicting Histology of Diminutive Rectosigmoid Polyps: a Multicenter Prospective Trial (Artificial Intelligence BLI Characterization - ABC Study)	Trial record only

NCT04453956 2020[527]	A Prospective, Randomized, Single-blind, 2 x 2 Factorial Design Single Center Study Evaluating the Polyp Detection and Quality Monitoring Function of EndoAngel in Improving the Quality of Colonoscopy	Trial record only
NCT04294355 2020[528]	Artificial Intelligence-assisted Colonoscopy Versus Conventional Colonoscopy for Missed Lesions in the Proximal Colon: A Prospective Multi-center Randomized Study in Asia	Trial record only
NCT04894708 2020[529]	Prospective Randomized Study on the Use of Artificial Intelligence (Fujifilm) for Polyp Detection in Colonoscopy	Trial record only
NCT04485715 2020[530]	Application of Artificial Intelligence in Colorectal Polypectomy	Trial record only
NCT04610177 2020[531]	Prospective Multicenter Study of Artificial Intelligence-assisted Quality Evaluation System for Colonoscopy	Trial record only
NCT04676308 2020[532]	The CERTAIN Study: Combining Endo-cuff in a Randomized Trial for Artificial Intelligence Navigation	Trial record only
NCT04640792 2020[533]	A Randomized Two Arm Multi-Center Study to Evaluate the Safety and Efficacy of the Use of Magentiq Eye's Automatic Polyp Detection System (ME-APDS) During Colonoscopy	Trial record only

NCT04586556 2020[534]	Artificial Intelligence for Real-time Detection and Monitoring of Colorectal Polyps	Trial record only
NCT04440865 2020[535]	Impact of Artificial Intelligence Genius System-assisted Colonoscopy vs. Standard Colonoscopy on Adenoma Detection Rate in Routine Practice: a Prospective Randomized Controlled Trial	Trial record only
NCT04399590 2020[536]	Comparing the Number of False Activations Between Two Artificial Intelligence CADe Systems: the NOISE Study	Trial record only
NCT04422548 2020[537]	Does AI-assisted Colonoscopy Improve Adenoma Detection in Screening Colonoscopy? A Multi-center Randomized Controlled	Trial record only
NCT04359355 2020[538]	Development and Validation of a New Artificial Intelligence System for Automated Detection of Colorectal Polyps During Colonoscopy	Trial record only
NCT04335318 2020[539]	Real Life AI in Polyp Detection	Trial record only
NCT04349787 2020[540]	Improving Optical Diagnosis of Colorectal Polyps Using Computer-aided Diagnosis (CADx) and the BLI Adenoma Serrated International Classification (BASIC)	Trial record only
NCT04378660 2020[541]	Artificial Intelligence Validation Trial for Polyp Detection: Pilot Study	Trial record only

NCT04227795 2020[542]	Artificial Intelligence-Assisted Real-time Detection of Missed Lesions During Colonoscopy: A Prospective Study	Trial record only
NCT04441580 2020[543]	Resa Diagnostica Aggiuntiva Dell'Intelligenza Artificiale Nella Colonscopia (GENIAL COLONOSCOPY), Per lo Screening Del Carcinoma Colorettale	Trial record only
NCT04589078 2020[544]	Polyp REcognition Assisted by a Device Interactive Characterization Tool - The PREDICT Study	Trial record only
NCT04325815 2020[545]	Multi-Centre, Open-label, Randomised, Prospective Trial to Assess Efficacy and Safety of the CADDIE Artificial Intelligence System for Improving Endoscopic Detection of Colonic Polyps in Real-time	Trial record only
NCT04216901 2019[546]	A Single Center Study on the Effectiveness and Safety of Polyp Detection and Polyp Classification With Artificial Intelligence	Trial record only
NCT04079478 2019[547]	The AID Study: Artificial Intelligence for Colorectal Adenoma Detection	Trial record only
NCT04102631 2019[548]	A Prospective, Randomized, Single-blind, Parallel-controlled Multicenter Study Evaluating the Effectiveness of Endo.Angel in Improving the Quality of Colonoscopy	Trial record only
NCT03925337 2019[549]	Computer Aided Detection of Polyps in the Colon	Trial record only

NCT04074577 2019[550]	Computer Aided Detection, Tandem Colonoscopy Study	Trial record only
NCT03954548 2019[551]	Prospective, Randomized, Multicenter, Tandem Study Evaluating the Safety and Effectiveness of the CB-17-08 Augmented Endoscopy System for the Detection of Mucosal Colorectal Polyps in Adult Patients Undergoing Screening or Surveillance Colonoscopy for CRC	Trial record only
NCT03842059 2019[552]	Computer-aided Detection With Deep Learning for Colorectal Adenoma During Colonoscopic Examination	Trial record only
NCT03775811 2018[553]	In Vivo Computer-aided Prediction of Polyp Histology on White Light Colonoscopy	Trial record only
NCT03637712 2018[554]	Deep-Learning for Automatic Polyp Detection During Colonoscopy	Trial record only
NCT03761771 2018[555]	Validating the Performance of Artificial Intelligence in Identifying Polyps in Real-world Colonoscopy	Trial record only
NCT03359343 2017[556]	Computer-aided Classification of Colorectal Polyp by Using Linked Colour Imaging	Trial record only
NCT03069833 2017[557]	Computer Aided Diagnosis of Colorectal Neoplasms During Colonoscopic Examination	Trial record only

NCT02838888 2016[558]	Computer-assisted Detection of Colonic Polyps	Trial record only
Nguyen 2024[559]	AI-Assisted Colonoscopy May Increase ADR in Right Side of Colon in Gastroenterology Fellows: A Randomized Control Trial	Abstract only and have full texts covering outcomes
Nguyen 2023[560]	Artificial Intelligence-Assisted Colonoscopy Improves ADR of Gastroenterology Fellows: Results of a Prospective Cohort Study	Non-randomised study and outcomes covered by randomised trials
NL-OMON22821 2020[561]	Discovery II Study	Trial record only
NL-OMON49600 2020[562]	Discovery: pentax* Computer-aided Detection to Improve Adenoma Detection in a Real-time Setting - The Discovery II Study. A randomized clinical trial	Trial record only
NL-OMON50965 2021[563]	Randomized Two Arm Multi-Center Study to Evaluate the Safety and Efficacy of the Use of Magentiq Eye's Automatic Polyp Detection System (ME-APDS) During Colonoscopy	Trial record only
NL-OMON51017 2021[564]	Effect of a computer-aided detection system (CAD EYE) on adenoma detection in patients with Lynch syndrome: an international, multicenter parallel randomized controlled trial	Trial record only

Norwood 2024[565]	LEAVING NO STONE UNTURNED - ROLE OF ARTIFICIAL INTELLIGENCE IN DETECTION OF SMALLER LESIONS DURING COLONOSCOPY	Unnamed intervention
Norwood 2024[566]	Performance of Computer-Aided Detection and Quality of Bowel Preparation: A Comprehensive Analysis of Colonoscopy Outcomes	Non-randomised study and outcomes covered by randomised trials
Okiye 2024[567]	A Comparison of Distal Attachment Devices, Artificial Intelligence, and Standard Colonoscopy for Adenoma Detection Rate and Withdrawal Times: Advantage or Hindrance	Unnamed intervention
Oleksiw 2025[568]	ARTIFICIAL INTELLIGENCE AND ENDOSCOPIST DIAGNOSTIC AGREEMENT AS A FRAMEWORK FOR COLORECTAL POLYP OPTICAL DIAGNOSIS IMPLEMENTATION	Unnamed intervention
Oleksiw 2025[569]	IMPLEMENTATION STRATEGIES TO OPTIMIZE DIAGNOSTIC ACCURACY OF COMPUTER-ASSISTED OPTICAL POLYP DIAGNOSIS	Unnamed intervention
O'Mara 2022[570]	Comparing the Adenoma Detection Rate of Endocuff-Assisted Colonoscopy (EAC) Against Combined Artificial Intelligence and Endocuff-Assisted Colonoscopy (AEAC)	Unnamed intervention

Okumura 2024[571]	Evaluating false-positive detection in a computer-aided detection system for colonoscopy.	Technology not relevant to review
Olabintan 2024[572]	ENVIRONMENTAL IMPACT OF OPTICAL DIAGNOSIS BY ARTIFICIAL INTELLIGENCE IN COLONOSCOPY: A PROSPECTIVE TRIAL	Unnamed intervention
Ortiz 2024[573]	EVALUATION OF ARTIFICIAL INTELLIGENCE-ASSISTED COLONOSCOPY FOR ADENOMA DETECTION IN LYNCH SYNDROME: A MULTICENTRE RANDOMIZED CONTROLLED TRIAL (TIMELY STUDY)	Abstract of full publication identified
Ortiz 2024[574]	Evaluation of Artificial Intelligence-Assisted Colonoscopy for Adenoma Detection in Lynch Syndrome: a multicentre randomized controlled trial (Timely study)	Abstract of full publication identified
Orzeszko 2024[575]	Effect of artificial intelligence implementation to the latest generation 4K colonoscopy	Non-randomised study and outcomes covered by randomised trials
Pagador 2025[576]	Identification of clinical needs for the improvement of ai-assisted colonoscopy cad systems	Limited usable data/no relevant outcomes
Pal 2024[577]	Artificial intelligence in endoscopy related to inflammatory bowel disease: A systematic review.	Systematic review used for reference checking

Pan 2021[578]	Artificial Intelligence-Aid Colonoscopy Vs. Conventional Colonoscopy for Polyp and Adenoma Detection: A Systematic Review of 7 Discordant Meta-Analyses.	Systematic review used for reference checking
Pannala 2020[579]	Artificial intelligence in gastrointestinal endoscopy.	Systematic review used for reference checking
Park 2024[580]	A prospective multicenter randomized controlled trial on artificial intelligence assisted colonoscopy for enhanced polyp detection	Technology not relevant to review
Pasam 2023[581]	ADENOMA DETECTION RATES WITH COMPUTER AIDED COLONOSCOPY AND DISTAL ATTACHMENT MUCOSAL EXPOSURE DEVICES - A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS	Abstract of systematic review
Patel 2024[582]	AI IN COLONOSCOPY FOR THE DETECTION OF COLORECTAL NEOPLASIA: A META-ANALYSIS OF RANDOMIZED AND NON-RANDOMIZED STUDIES	Abstract of systematic review
Patel 2024[583]	BENEFITS AND HARMS OF INCORPORATING AI DURING COLONOSCOPY FOR TRAINEES: A SYSTEMATIC REVIEW AND META-ANALYSIS OF PUBLISHED LITERATURE	Abstract of systematic review
Patel 2023[584]	COMPARISON OF MEAN ADENOMA PER COLONOSCOPY USING ARTIFICIAL INTELLIGENCE SYSTEMS VS STANDARD	Abstract of systematic review

	COLONOSCOPY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED STUDIES	
Patel 2023[585]	EXISTING ARTIFICIAL INTELLIGENCE SYSTEMS DO NOT IMPROVE SESSILE SERRATED LESION DETECTION: A META-ANALYSIS OF RANDOMIZED CONTROLLED STUDIES	Abstract of systematic review
Patel 2024[586]	AI IN COLONOSCOPY BENEFITS THOSE ENDOSCOPISTS WITH LOW BASELINE ADR: AN AGGREGATE META-ANALYSIS AND META-REGRESSION OF ENDOSCOPIST-LEVEL DATA	Abstract of systematic review
Patel 2023[587]	COMPARISON OF ADENOMA DETECTION RATE IN SCREENING OR SURVEILLANCE COLONOSCOPY USING ARTIFICIAL INTELLIGENCE VS STANDARD COLONOSCOPY: A META-ANALYSIS OF RANDOMIZED CONTROLLED STUDIES	Abstract of systematic review
Patel 2021[588]	Artificial intelligence increases adenoma detection even in 'high-detector' colonoscopy: Early evidence for human: machine interaction	Non-randomised study and outcomes covered by randomised trials
Patel 2024[589]	Lack of Effectiveness of Computer Aided Detection for Colorectal Neoplasia: A Systematic Review and Meta-Analysis of Nonrandomized Studies.	Systematic review used for reference checking
Patel 2025[590]	ROLE OF ENDOSCOPIST ON PERFORMANCE OF ARTIFICIAL INTELLIGENCE IN NEOPLASIA DETECTION DURING	Abstract of systematic review

	COLONOSCOPY: METAANALYSIS AND METAREGRESSION OF ENDOSCOPIST LEVEL DATA FROM 25 STUDIES	
Patel 2023[591]	Artificial Intelligence in Colonoscopy in the Community Setting	Unnamed intervention
Patel 2024[592]	Lack of Effectiveness of Computer Aided Detection for Colorectal Neoplasia: a Systematic Review and Meta-analysis of Non-Randomized Studies	Abstract of systematic review
Pecere 2022[593]	Endoscopists performance in optical diagnosis of colorectal polyps in artificial intelligence studies.	Systematic review used for reference checking
Pfeifer 2021[594]	Computer-aided detection of colorectal polyps using a newly generated deep convolutional neural network: from development to first clinical experience.	Non-randomised study and outcomes covered by randomised trials
Prijic 2022[595]	ARTIFICIAL INTELLIGENCE: A NEW TOOL IN ENDOSCOPIC SURVEILLANCE IN INFLAMMATORY BOWEL DISEASE PATIENTS	Limited usable data/no relevant outcomes
Putera 2024[596]	REAL-WORLD STUDY OF SEQUENTIAL IMPLEMENTATION OF PHYSICIAN ADR REPORTING AND CAD-E SYSTEM IN IMPROVING PRAGMATIC ADENOMA DETECTION RATE (ADR) IN ELECTIVE COLONOSCOPY IN A TERTIARY HOSPITAL IN SINGAPORE	Non-randomised study and outcomes covered by randomised trials

Quan 2019[597]	Artificial intelligence based computer aided detection system reliably detects polyps earlier than physicians during colonoscopy	Unnamed intervention
Quan 2021[598]	Increased Polyp Detection In A Western Population Using A Real-Time Artificial Intelligence-Based System During Colonoscopy: A Pilot Study	Unnamed intervention
Quan 2022[599]	Clinical evaluation of a real-time artificial intelligence-based polyp detection system: a US multi-center pilot study.	Technology not relevant to review
Qaqish 2024[600]	The Impact of Artificial Intelligence-Assisted Colonoscopy on Key Colonoscopy Quality Indicators in the Underserved Population	Unnamed intervention
Radadiya 2023[601]	ARE ALL COMPUTER-AIDED DETECTION SYSTEMS (CADE) CREATED EQUAL? - COMPARING ADENOMA DETECTION RATE OF DIFFERENT CADE SYSTEMS: NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS	Abstract of systematic review
Rath 2020[602]	Computer-aided detection of colorectal polyps using a newly generated deep convolutional neural network	Unnamed intervention
Renelus 2023[603]	AI ASSISTED COLONOSCOPY INCREASES ADENOMA DETECTION IN AVERAGE RISK SCREENING POPULATION	Unnamed intervention

Renelus 2023[604]	Computer-Aided Detection Device Increase Adenoma Detection in Anemic Patients Undergoing Diagnostic Colonoscopy	Unnamed intervention
Repici 2020[605]	876 REAL-TIME COMPUTER AIDED DIAGNOSIS FOR DETECTION OF COLORECTAL NEOPLASIA AT COLONOSCOPY	Abstract of full publication identified
Repici 2021[606]	Efficacy of real-time computer-aided detection of colorectal neoplasia in a non-expert setting: A randomized controlled trial	Abstract of full publication identified
Rex 2024[607]	Artificial Intelligence for Real-Time Prediction of the Histology of Colorectal Polyps by General Endoscopists.	Unnamed intervention
Rex 2022[608]	Strengths and Weaknesses of an Artificial Intelligence Polyp Detection Program as Assessed by a High-Detecting Endoscopist.	Limited usable data/no relevant outcomes
Rex 2025[609]	Detection of large flat colorectal lesions by artificial intelligence: a persistent weakness and blind spot	Full text not retrieved
Richter 2022[610]	INFLUENCE OF ARTIFICIAL INTELLIGENCE ON THE ADENOMA DETECTION RATE THROUGHOUT THE DAY	Non-randomised study and outcomes covered by randomised trials
Richter 2023[611]	Influence of Artificial Intelligence on the Adenoma Detection Rate throughout the Day.	Non-randomised study and outcomes covered by randomised trials

Rizkala 2024[612]	Accuracy of Computer-aided Diagnosis in Colonoscopy Varies according to Polyp Location. A Systematic Review and Meta-analysis.	Systematic review used for reference checking
Rizkala 2025[613]	Role of Artificial Intelligence for Colon Polyp Detection and Diagnosis and Colon Cancer.	Systematic review used for reference checking
Robles-Medranda 2023[614]	REAL-TIME COMPUTER-AIDED POLYP AND ADENOMA DETECTION DURING SCREENING COLONOSCOPY IN EXPERT AND NON-EXPERT ENDOSCOPISTS: A SINGLE CENTER STUDY	Unnamed intervention
Robles-Medranda 2022[615]	REAL-TIME COMPUTER-AIDED POLYP/ ADENOMA DETECTION DURING SCREENING COLONOSCOPY: A SINGLE-CENTER DIAGNOSTIC TRIAL	Non-randomised study and outcomes covered by randomised trials
Robles-Medranda 2022[616]	REAL-TIME COMPUTER-AIDED POLYP/ADENOMA DETECTION DURING SCREENING COLONOSCOPY: A SINGLE-CENTER DIAGNOSTIC TRIAL	Non-randomised study and outcomes covered by randomised trials
Roccato 2019[617]	Artificial intelligence-aided colonoscopy: A retrospective analysis of effect on procedure time	Unnamed intervention
Rocchetto 2024[618]	Combining a Computer Aided Detection system (CADe) and G-EYE balloon for adenoma detection in a FIT-based organized colorectal	Unnamed intervention

	cancer screening program: preliminary results of a randomized controlled trial	
Rodriguez-Diaz 2019[619]	ARTIFICIAL INTELLIGENCE AUGMENTS REAL-TIME HISTOLOGY OF COLON POLYPS USING COMBINED-MODALITY NARROW BAND IMAGE CLASSIFICATION AND ELASTIC-SCATTERING SPECTROSCOPY	Technology not relevant to review
Rodriguez-Diaz 2023[620]	REAL TIME CLINICAL VALIDATION OF COMPUTER AIDED DIAGNOSIS WITH AUGMENTED REALITY FOR HISTOLOGY ASSESSMENT OF COLORECTAL POLYPS	Unnamed intervention
Rodriguez-Diaz 2022[621]	EVALUATION OF REAL-TIME COLORECTAL POLYP HISTOLOGY ASSESSMENT USING COMPUTER AIDED DIAGNOSIS WITH AUGMENTED REALITY VISUALIZATION: PRELIMINARY RESULTS FROM PILOT STUDY	Unnamed intervention
Ronborg 2022[622]	Can artificial intelligence improve the quality of colonoscopy investigations? Evaluation of the GI genius endoscopy module in daily clinical practice	Abstract only and have full texts covering outcomes
Ronborg 2024[623]	Assessing the potential of artificial intelligence to enhance colonoscopy adenoma detection in clinical practice: a prospective observational trial.	Non-randomised study and outcomes covered by randomised trials

Rondonotti 2021[624]	COMPUTER-AIDED OPTICAL DIAGNOSIS OF DIMINUTIVE RECTOSIGMOID POLYPS IN CLINICAL PRACTICE: A MULTICENTER PROSPECTIVE STUDY	Abstract only and have full texts covering outcomes
Sabbagh 2024[625]	Ceiling Effect of CADe in Improving Detection Rates in FIT Positive Cases Among Gastroenterologists With High Baseline ADR	Non-randomised study and outcomes covered by randomised trials
Sabran 2024[626]	Artificial intelligence-assisted colonoscopy detection rate on colorectal neoplasia patient: a systematic review of RCTs	Abstract of systematic review
Saleepol 2024[627]	IMPACT OF A REAL-TIME COMPUTER-AIDED POLYP CHARACTERIZATION IN SCREENING COLONOSCOPY PERFORMED BY TRAINEES VERSUS EXPERIENCED ENDOSCOPISTS: A RANDOMIZED CONTROLLED TRIAL	Abstract only and have full texts covering outcomes
Salvi 2023[628]	BENEFITS FROM A COMPUTER-AIDED DETECTION DEVICE IN COLONOSCOPY (ACCENDO-COLO) - AN INTERIM ANALYSIS OF AN ITALIAN MULTICENTER RANDOMIZED CLINICAL TRIAL	Abstract only and have full texts covering outcomes
Samuel 2023[629]	Impact of AI-Assisted Colonoscopy on Sessile Serrated Adenoma Detection in a Community GI Practice Setting	Non-randomised study and outcomes covered by randomised trials
Sanchez-Peralta 2020[630]	Deep learning to find colorectal polyps in colonoscopy: A systematic literature review.	Systematic review used for reference checking

Satiya 2020[631]	Is Artificial Intelligence for Colonoscopy Ready for Prime-Time: A Systematic Review and Meta-Analysis of Randomized Controlled Trials	Abstract of systematic review
Sato 2024[632]	A MULTICENTER SINGLE-ARM PROSPECTIVE STUDY TO ASSESS THE PERFORMANCE OF AN ARTIFICIAL INTELLIGENCE TO SUPPORT CHARACTERIAZTION OF COLORECTAL POLYPS	Unnamed intervention
Scalvini 2025[633]	Strategies to Enhance the Adenoma Detection Rate (ADR) and the Serrated Polyp Detection Rate (SPDR) in Colonoscopy: A Comprehensive Review	Systematic review used for reference checking
Schacher 2024[634]	ARTIFICIAL INTELLIGENCE IN COLONOSCOPY: A REAL-WORLD EVALUATION	Abstract only and have full texts covering outcomes
Schauer 2022[635]	Artificial intelligence improves adenoma detection rate during colonoscopy.	Non-randomised study and outcomes covered by randomised trials
Schauer 2021[636]	Artificial intelligence for polyp detection during colonoscopy: A win for humans?	Non-randomised study and outcomes covered by randomised trials
Schmidt 2024[637]	PATIENT PERSPECTIVES AND ACCEPTABILITY OF ARTIFICIAL INTELLIGENCE USED DURING SCREENING COLONOSCOPY	Unnamed intervention
Schrader 2022[638]	Artificial intelligence in screening colonoscopy	Systematic review used for reference checking

Seager 2022[639]	Trial protocol for COLO-DETECT: A randomized controlled trial of lesion detection comparing colonoscopy assisted by the GI Genius TM artificial intelligence endoscopy module with standard colonoscopy.	Trial protocol only
Seager 2024[640]	THE EFFECT OF ENDOCUFF VISION ON POLYP DETECTION DURING COLONOSCOPY WITH THE GI GENIUS COMPUTER-AIDED DETECTION DEVICE	Post-hoc analysis of a trial included in the review with no relevant additional data
Seager 2024[641]	BMJ GUT BEST LABORATORY SCIENCE ABSTRACT: COLO-DETECT: A RANDOMISED CONTROLLED TRIAL OF THE GI GENIUS AI DEVICE FOR POLYP DETECTION DURING ROUTINE COLONOSCOPY	Abstract of full publication identified
Sekiguchi 2025[642]	Protocol for a multicenter randomized controlled trial to assess the usefulness of computer-aided detection systems for colonoscopy in colorectal cancer screening in the Asia-Pacific region (project CAD/NCCH2217)	Full text not retrieved
Sekiguchi 2023[643]	Cost-effectiveness analysis of computer-aided detection systems for colonoscopy in Japan.	Health economic assessment only
Shah 2022[644]	ARTIFICIAL INTELLIGENCE AND COMPUTER AIDED DETECTION (CADE) SYSTEMS IMPROVE ADENOMA MISS RATES, ADENOMA	Abstract of systematic review

	DETECTION RATES AND POLYP DETECTION RATES: A SYSTEMATIC REVIEW AND META-ANALYSIS	
Shah 2023[645]	Effect of computer-aided colonoscopy on adenoma miss rates and polyp detection: A systematic review and meta-analysis.	Systematic review used for reference checking
Shah 2025[646]	ASSESSING THE ECONOMIC IMPACT AND CLINICAL BENEFITS OF ARTIFICAL INTELLIGENCE (AI)- ASSISTED COLONOSCOPY USING SIMULATION MODELS: IS AI WORTH THE HYPE? - A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Shao 2023[647]	Comparing Sessile Serrated Adenoma/Polyp Detection Rate Between Water Exchange and Computer-Aided Detection Colonoscopy Using Pooled Data From Randomized Controlled Trials	Abstract of systematic review
Shao 2023[648]	Comparing Advanced Adenoma Detection Rate Between Water Exchange and Computer-Aided Colonoscopy Using Pooled Data From Randomized Controlled Trials	Abstract of systematic review
Shao 2023[649]	Comparing Adenoma Detection Rate Between Computer-Aided Detection and Water Exchange Colonoscopy Using Pooled RCTs Data - An Interim Report	Abstract of systematic review

Shao 2024[650]	WATER EXCHANGE AND COMPUTER-AIDED DETECTION IMPROVED ADENOMA DETECTION RATE - A META-ANALYSIS OF POOLED DATA FROM RANDOMIZED CONTROLLED TRIALS	Abstract of systematic review
Shao 2024[651]	WATER EXCHANGE IS SUPERIOR TO COMPUTER-AIDED DETECTION IN DETECTING SESSILE SERRATED ADENOMA/POLYP	Abstract of systematic review
Shao 2022[652]	Effects of ai-assisted colonoscopy on adenoma miss rate/adenoma detection rate: A protocol for systematic review and meta-analysis.	Systematic review used for reference checking
Sharma 2024[653]	393 ARTIFICIAL INTELLIGENCE ASSISTED COLONOSCOPY IMPROVES PDR AND ADR IN RIGHT COLON IN PATIENTS WITH IBD: A COHORT STUDY IN A HIGH-VOLUME CENTER	Unnamed intervention
Shaukat 2021[654]	ID: 3526633 THE EFFECT OF CHANGING THE SPECIFICITY OF AN ARTIFICIAL INTELLIGENCE-AIDED POLYP DETECTION DEVICE AND ITS IMPACT ON CLINICAL PERFORMANCE	Unnamed intervention
Shaukat 2022[655]	Computer-Aided Detection Improves Adenomas per Colonoscopy for Screening and Surveillance Colonoscopy: A Randomized Trial.	Technology not relevant to review
Shen 2021[656]	Real-time use of a computer-aided system for polyp detection during colonoscopy, an ambispective study.	Technology not relevant to review

Shinozaki 2025[657]	Computer-aided diagnosis for colorectal polyp in comparison with endoscopists: Systematic review and meta-analysis	Systematic review used for reference checking
Siggens 2024[658]	THE FIRST EVER REAL-TIME EVALUATION OF A NOVEL CADE-IBD ALGORITHM FOR DETECTION OF NEOPLASIA DURING SURVEILLANCE COLONOSCOPY IN COLITIS PATIENTS	Technology not relevant to review
Siggens 2025[659]	A VALIDATION STUDY EVALUATING THE ADDED VALUE OF A NOVEL COMPUTER AIDED DETECTION SYSTEM FOR NEOPLASIA DETECTION IN INFLAMMATORY BOWEL DISEASE (CADE-IBD)	Technology not relevant to review
Siggens 2023[660]	VALIDATION AND REAL-TIME PERFORMANCE OF A NOVEL CAD-X ALGORITHM FOR CHARACTERISATION AND SIZING OF COLORECTAL POLYPS	Unnamed intervention
Siggens 2023[661]	VALIDATION OF A NOVEL CADE ALGORITHM FOR DETECTION OF NEOPLASIA IN IBD: DATA FROM IMAGE BASED AND REAL-TIME EVALUATION	Technology not relevant to review
Siggens 2023[662]	A NOVEL CADX ALGORITHM FOR CHARACTERISATION AND SIZING OF COLORECTAL POLYPS MEETS PIVI 1 AND PIVI 2 THRESHOLD	Technology not relevant to review

Singh 2019[663]	Artificial Intelligence for Colon Polyp Detection: Get a Machine for Your Unit Now!	Abstract only and have full texts covering outcomes
Sinonquel 2025[664]	THE CLINICAL VALIDATION OF A COMPUTER-ADIDE POLYP DETECTION MODEL INTEGRATED AS A PLUG-AND-PLAY ENDOSCOPY DEVICE (ALTER-EGO TRIAL)	Unnamed intervention
Sinonquel 2025[665]	CLINICAL IMPACT OF THE MISMATCH BETWEEN OPTICAL DIAGNOSIS AND HISTOLOGY: A POST- HOC SUB-ANALYSIS OF THE CAD-ARTIPOD TRIAL	Technology not relevant to review
Sinonquel 2020[666]	Artificial intelligence for colorectal polyp detection: A validation trial with real-time unblinding	Unnamed intervention
Sinonquel 2023[667]	CLINICAL VALIDATION OF A COMPUTER-AIDED DETECTION MODEL FOR COLORECTAL POLYP DETECTION (CAD-ARTIPOD) TRIAL USING A SECOND OBSERVER AND REAL-TIME UNBLINDING	Unnamed intervention
Sinonquel 2021[668]	Real-time unblinding for validation of a new CADe tool for colorectal polyp detection.	Technology not relevant to review
Sinonquel 2024[669]	Clinical consequences of computer-aided colorectal polyp detection.	Unnamed intervention

Sivananthan 2021[670]	ID: 3525827 PERFORMANCE OF COMPUTER AIDED DETECTION SYSTEMS IN FLAT, SESSILE AND DIMINUITIVE ADENOMAS: A META-ANALYSIS	Abstract of systematic review
Sivananthan 2022[671]	Does computer-aided diagnostic endoscopy improve the detection of commonly missed polyps? A meta-analysis.	Systematic review used for reference checking
Soleymanjahi 2023[672]	PERFORMANCE OF ARTIFICIAL INTELLIGENCE ASSISTED COLONOSCOPY VS CONVENTIONAL COLONOSCOPY: A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Soleymanjahi 2024[673]	DOES COMPUTER-AIDED DETECTION (CADE) OFFER ANY ADVANTAGE TO CONVENTIONAL COLONOSCOPY: A COMPREHENSIVE COMPARISON OF EFFICACY AND SAFETY MEASURES?	Abstract of systematic review
Soleymanjahi 2024[674]	PERFORMANCE OF DIFFERENT COMPUTER-AIDED DETECTION (CADE) PLATFORMS COMPARED TO CONVENTIONAL COLONOSCOPY: A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Soleymanjahi 2024[675]	PROVIDER TRUST TOWARDS ADOPTING REAL TIME ARTIFICIAL INTELLIGENCE IN COLONOSCOPY: A SYSTEMATIC REVIEW	Abstract of systematic review
Soleymanjahi 2024[676]	Artificial Intelligence-Assisted Colonoscopy for Polyp Detection	Systematic review used for reference checking

Soleymanjahi 2024[677]	Perceived Advantages and Disadvantages of Adopting Real Time Artificial Intelligence in Colonoscopy by Providers: A Systematic Review	Abstract of systematic review
Soo 2024[678]	Detection of sessile serrated adenoma using artificial intelligence-enhanced endoscopy: an Asian perspective.	Limited usable data/no relevant outcomes
Soons 2022[679]	Real-time colorectal polyp detection using a novel computer-aided detection system (CADe): a feasibility study.	Non-randomised study and outcomes covered by randomised trials
Spadaccini 2022[680]	COMPARING NUMBER AND RELEVANCE OF FALSE ACTIVATIONS BETWEEN TWO ARTIFICIAL INTELLIGENCE CADE SYSTEMS: THE NOISE STUDY	Unnamed intervention
Spadaccini 2022[681]	COMPARING NUMBER AND RELEVANCE OF FALSE ACTIVATIONS BETWEEN TWO ARTIFICIAL INTELLIGENCE CADE SYSTEMS: THE NOISE STUDY	Unnamed intervention
Spadaccini 2023[682]	REAL-TIME COMPUTER-AIDED DETECTION OF COLORECTAL NEOPLASIA DURING COLONOSCOPY: SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Spadaccini 2022[683]	PERFORMANCE OF AI-AIDED COLONOSCOPY FOR THE DETECTION OF HIGH-RISK COLORECTAL CANCER PRECURSORS: A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review

Spadaccini 2024[684]	VARIABILITY IN COMPUTER-AIDED DETECTION EFFECT ON ADENOMA DETECTION RATE IN RANDOMIZED CONTROLLED TRIALS: A META-REGRESSION ANALYSIS	Abstract of systematic review
Spadaccini 2024[685]	ARTIFICIAL INTELLIGENCE AND COLORECTAL NEOPLASIA DETECTION PERFORMANCES IN FIT+ PATIENTS: A META-ANALYSIS AND SYSTEMATIC REVIEW	Abstract of systematic review
Spadaccini 2023[686]	IN VIVO CONCORDANCE BETWEEN TWO ARTIFICIAL INTELLIGENCE SYSTEMS FOR LEAVING IN SITU COLORECTAL POLYPS	Abstract only and have full texts covering outcomes
Spadaccini 2021[687]	ARTIFICIAL INTELLIGENCE VERSUS ADVANCED IMAGING FOR DETECTION OF COLORECTAL NEOPLASIA: A NETWORK METAANALYSIS	Systematic review used for reference checking
Spadaccini 2022[688]	Comparing the number and relevance of false activations between 2 artificial intelligence computer-aided detection systems: the NOISE study.	Non-randomised study and outcomes covered by randomised trials
Spadaccini 2023[689]	Combination of Mucosa-Exposure Device and Computer-Aided Detection for Adenoma Detection During Colonoscopy: A Randomized Trial.	Comparator not relevant to review

Spadaccini 2021[690]	Computer-aided detection versus advanced imaging for detection of colorectal neoplasia: a systematic review and network meta-analysis.	Systematic review used for reference checking
Spadaccini 2025[691]	Artificial intelligence and colorectal neoplasia detection performances in patients with positive fecal immunochemical test: Meta-analysis and systematic review	Systematic review used for reference checking
Spadaccini 2025[692]	Variability in computer-aided detection effect on adenoma detection rate in randomized controlled trials: A meta-regression analysis	Systematic review used for reference checking
Su 2020[693]	Impact of a real-time automatic quality control system on colorectal polyp and adenoma detection: a prospective randomized controlled study (with videos).	Technology not relevant to review
Sultan 2025[694]	AGA Living Clinical Practice Guideline on Computer-Aided Detection-Assisted Colonoscopy	Systematic review used for reference checking
Syed 2023[695]	Artificial Intelligence (CAD-E)-Assisted Colonoscopy Helps Increase Adenoma Detection Rate (ADR) in the Afternoon Session	Duplicate of abstract already included in review
Taghiakbari 2025[696]	PRAGMATIC IMPLEMENTATION OF RESECT AND DISCARD AND DIAGNOSE AND LEAVE STRATEGIES USING AUTONOMOUS COMPUTER-ASSISTED OPTICAL POLYP DIAGNOSIS	Abstract only and have full texts covering outcomes

Takasu 2025[697]	IMPACT OF INTRODUCING ARTIFICIAL INTELLIGENCE ON COLONOSCOPY IN REAL-WORLD CLINICAL PRACTICE	Non-randomised study and outcomes covered by randomised trials
Tanaka 2021[698]	Evaluation of cad eyeTM based on artificial intelligence technology for detection and characterization of colorectal neoplasia in a clinical setting	Abstract only and have full texts covering outcomes
Tang 2021[699]	Comparing polyp detection rate between water exchange and air insufflation by a computeraided detection algorithm: An analysis of withdrawal phase videos from a randomized controlled trial	Unnamed intervention
Tang 2022[700]	ADENOMA DETECTION USING REAL-TIME COMPUTER-AIDED COLON POLYP DETECTION SYSTEM TO COMPARE WATER EXCHANGE AND AIR INSUFFLATION - A PILOT CONTROLLED STUDY	Unnamed intervention
Tang 2022[701]	Polyp detection and false-positive rates by computer-aided analysis of withdrawal-phase videos of colonoscopy of the right-sided colon segment in a randomized controlled trial comparing water exchange and air insufflation.	Technology not relevant to review
Tang 2021[702]	A review of water exchange and artificial intelligence in improving adenoma detection.	Study design - review not systematic
Tang 2025[703]	REAL-TIME COMPUTER-AIDED SYSTEM TO COMPARE RIGHT COLON ADENOMA DETECTION AND ADENOMA PER	Unnamed intervention

	COLONOSCOPY RATES IN WATER EXCHANGE AND AIR INSUFFLATION - A RANDOMIZED CONTROLLED STUDY	
Tariq 2025[704]	Perception and Understanding of Artificial Intelligence Among Gastroenterology Fellows and Early Career Gastroenterologists: A Nationwide Cross-Sectional Survey Study	Mixed colonoscopy and other gastroenterology population
TCTR20200929003 2020[705]	Comparison of computer-aided diagnosis colonoscopy, Endocuff-Assisted Colonoscopy, combination of computer-aided diagnosis colonoscopy and Endocuff-Assisted Colonoscopy and High-definition Colonoscopy for Adenomas Detection in Colorectal Cancer Screening	Trial record only
TCTR20220826004 2022[706]	Comparison between two computer-aided diagnosis colonoscopy systems (Deep GI system and CAD EYE system) and High-definition Colonoscopy for Adenomas Detection in Colorectal Cancer Screening: a randomized control Trial	Trial record only
TCTR20230504002 2023[707]	Adenoma Miss rate in Artificial Intelligence-Based versus Conventional Colonoscopy, A Prospective Randomized Trial	Trial record only
TCTR20230706006 2023[708]	Comparison between two computer-aided polyp detection colonoscopy systems and High-definition Colonoscopy for Adenomas Detection in Colorectal Cancer Screening: a multi-center randomized control Trial	Trial record only

TCTR20240710001 2024[709]	Using Computer-Aided polyp detection system (CADe) to maintain the high quality in adenoma detection rate during community-based colorectal cancer screening in Thailand: a randomized trial	Trial record only
Tham 2023[710]	Knowledge, perceptions and behaviours of endoscopists towards the use of artificial intelligence-aided colonoscopy.	Full text not retrieved
Thijssen 2024[711]	Improving the endoscopic recognition of early colorectal carcinoma using artificial intelligence: current evidence and future directions	Systematic review used for reference checking
Thiruvengadam 2023[712]	THE IMPACT OF COMPUTER-AIDED DETECTION ON PATIENTS UNDERGOING SCREENING COLONOSCOPY PERFORMED BY LOW- AND HIGH-DETECTOR ENDOSCOPISTS: A MICROSIMULATION ANALYSIS	Unnamed intervention
Thiruvengadam 2022[713]	COST-EFFECTIVENESS OF THE ADDITION OF REAL-TIME COMPUTER-AIDED DETECTION OF ADENOMAS TO SCREENING COLONOSCOPY IN COLORECTAL CANCER SCREENING OF AVERAGE-RISK PERSONS AT 45 YEARS OF AGE	Health economic assessment only
Thiruvengadam 2023[714]	EFFICACY OF REAL-TIME COMPUTER AIDED-DETECTED OF COLONIC NEOPLASIA IN AN UNDERSERVED POPULATION, A RANDOMIZED CONTROLLED TRIAL	Abstract of full publication identified

Thiruvengadam 2023[715]	An Evaluation of Critical Factors for the Cost-Effectiveness of Real-Time Computer-Aided Detection: Sensitivity and Threshold Analyses Using a Microsimulation Model.	Health economic assessment only
Thomas 2023[716]	Advancing Colorectal Cancer Screening: A Comprehensive Systematic Review of Artificial Intelligence (AI)-Assisted Versus Routine Colonoscopy.	Systematic review used for reference checking
Tiankanon 2023[717]	THE IMPROVEMENT ON ADENOMA DETECTION RATE AND OTHER SECONDARY INDICATORS OF THE TWO REAL-TIME ARTIFICIAL INTELLIGENCES IN HIGH ADENOMA DETECTORS: A RANDOMIZED MUTI-CENTER TRIAL	Abstract of full publication identified
Tolosa 2023[718]	REDUCTION OF ADENOMA MISS RATE WITH ARTIFICIAL INTELLIGENCE (AI): A META-ANALYSIS OF RANDOMIZED TANDEM TRIALS OF AI-ASSISTED COLONOSCOPY	Abstract of systematic review
UMIN000013917 2014[719]	Prospective study for endocytoscopy-based computer-aided diagnosis system for small colorectal lesions	Trial record only
UMIN000044031 2021[720]	Evaluation of the impact of CAD EYE on the quality of colonoscopy and the learning curve of gastroenterology fellows	Trial record only

UMIN000044748 2021[721]	Artificial Intelligence in Colonoscopy for Cancer Prevention -a Randomized Health Service Implementation Trial-	Trial record only
UMIN000046361 2021[722]	A randomized control trial of adenoma detection rate in artificial intelligence-assisted colonoscopy using linked color imaging	Trial record only
UMIN000046502 2022[723]	Examination of detection ability of colorectal polyps with AI colonoscopy	Trial record only
UMIN000047666 2022[724]	Veridation research of colonoscopy using artificial intelligence	Trial record only
Vadhwana 2023[725]	The Role of Artificial Intelligence in Prospective Real-Time Histological Prediction of Colorectal Lesions during Colonoscopy: A Systematic Review and Meta-Analysis.	Systematic review used for reference checking
van der Zander 2022[726]	REAL-TIME CLASSIFICATION OF COLORECTAL POLYPS USING ARTIFICIAL INTELLIGENCE - A PROSPECTIVE PILOT STUDY COMPARING TWO COMPUTER-AIDED DIAGNOSIS SYSTEMS AND ONE EXPERT ENDOSCOPIST	Abstract only and have full texts covering outcomes
Van Langendonc 2021[727]	Computer aided detection (CADE) in colonoscopy: an end-user experience using two systems	Abstract only and have full texts covering outcomes
Vinsard 2025[728]	IMPACT OF ARTIFICIAL INTELLIGENCE ON RIGHT COLONIC ADENOMA MISS RATE: A PRAGMATIC QUASI-RANDOMIZED TRIAL	Unnamed intervention

Wadhwa 2023[729]	Diagnostic Accuracy of Artificial Intelligence in Classification of Colonic Polyps - A Real World Prospective Study	Abstract only and have full texts covering outcomes
Wallace 2022[730]	IMPACT OF ARTIFICIAL INTELLIGENCE ON MISS RATE OF COLORECTAL NEOPLASIA: A RANDOMIZED TANDEM CLINICAL TRIAL	Unnamed intervention
Wang 2021[731]	Artificial intelligence-assisted detection and classification of colorectal polyps under colonoscopy: A systematic review and meta-analysis	Systematic review used for reference checking
Wang 2022[732]	Artificial Intelligence - based Colorectal Polyp Diagnostic System Can Increase the Detection Rate of Polyps: A Prospective Randomized Controlled Study	Full text not retrieved
Wang 2018[733]	Assistance of a real-time automatic colon polyp detection system increases polyp and adenoma detection during colonoscopy: A prospective randomized controlled study	Unnamed intervention
Wang 2018[734]	Automatic polyp detection during colonoscopy increases adenoma detection: An interim analysis of a prospective randomized control study	Unnamed intervention
Wang 2024[735]	A retrospective study of computer-aided detection system for detection improvement of adenomas	Full text not retrieved

Wang 2019[736]	Colonoscopy with embedded deep learning computer-aided detection system improves adenoma detection without increasing physician fatigue: A prospective randomized study	Abstract only and have full texts covering outcomes
Wang 2020[737]	859 COMPUTER-AIDED-DETECTION EMBEDDED COLONOSCOPY VERSUS ROUTINE COLONOSCOPY: A PROSPECTIVE, RANDOMIZED TANDEM TRIAL	Abstract of full publication identified
Wang 2021[738]	Artificial intelligence-assisted detection and classification of colorectal polyps under colonoscopy: a systematic review and meta-analysis.	Systematic review used for reference checking
Wang 2024[739]	ENDOANGEL improves detection of missed colorectal adenomas in second colonoscopy: A retrospective study.	Non-randomised study and outcomes covered by randomised trials
Wang 2024[740]	AI Assisted Colonoscopy Improves Polyp Detection in Obese Patients	Unnamed intervention
Wang 2024[741]	Artificial Intelligence-Assisted Colonoscopy Improves PDR in Patients With IBD: A Cohort Study in a High Volume Center	Unnamed intervention
Warman 2024[742]	Non-Neoplastic Polyp Detection Using AI, GI Genius, With Experienced Endoscopist - Pilot Study	Non-randomised study and outcomes covered by randomised trials
Wei 2023[743]	Artificial Intelligence-Assisted Colonoscopy in Real World Clinical Practice: A Systematic Review and Meta-Analysis	Abstract of systematic review

Wei 2023[744]	EVALUATION OF ARTIFICIAL INTELLIGENCE ENABLED COMPUTER AIDED DETECTION ASSISTANCE IN DETECTING COLON POLYPS IN THE COMMUNITY (AI-SEE): A MULTICENTER RANDOMIZED CLINICAL TRIAL	Technology not relevant to review
Wei 2024[745]	Artificial Intelligence-Assisted Colonoscopy in Real-World Clinical Practice: A Systematic Review and Meta-Analysis.	Systematic review used for reference checking
Wenderott 2024[746]	Effects of artificial intelligence implementation on efficiency in medical imaging-a systematic literature review and meta-analysis	Systematic review used for reference checking
Wong 2021[747]	The study on artificial intelligence (AI) colonoscopy in affecting the rate of polyp detection in colonoscopy - A single center retrospective study	Abstract of full publication identified
Wong 2022[748]	The study on artificial intelligence (AI) colonoscopy in affecting the rate of polyp detection in colonoscopy: A single centre retrospective study	Non-randomised study and outcomes covered by randomised trials
Wong 2022[749]	The study on artificial intelligence (AI) colonoscopy in affecting the rate of polyp detection in colonoscopy - a single center retrospective study	Abstract of full publication identified
Wong 2021[750]	The study on artificial intelligence (ai) colonoscopy in affecting the rate of polyp detection in colonoscopy - a single-center retrospective study	Abstract of full publication identified

Wu 2023[751]	Efficacy of Water Exchange vs Computer-Aided Detection: A Bayesian Network Meta-Analysis of Randomized Controlled Trials	Abstract of systematic review
Xu 2023[752]	Implementation of Artificial Intelligence Device for Polyp Detection During Colonoscopy at an Academic County Hospital System	Non-randomised study and outcomes covered by randomised trials
Xu 2025[753]	Artificial intelligence system improves the quality of digestive endoscopy: A prospective pretest and post-test single-center clinical trial	Non-colonoscopy population
Xu 2021[754]	Artificial intelligence-assisted colonoscopy: A prospective, multicenter, randomized controlled trial of polyp detection.	Technology not relevant to review
Xu 2021[755]	Comparison of diagnostic performance between convolutional neural networks and human endoscopists for diagnosis of colorectal polyp: A systematic review and meta-analysis.	Abstract of systematic review
Yamada 2019[756]	Development of a real-time endoscopic image diagnosis support system using deep learning technology in colonoscopy.	*Ex vivo* application of technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Yamada 2021[757]	Detection of flat colorectal neoplasia by artificial intelligence: A systematic review.	Systematic review used for reference checking

Yamaguchi 2023[758]	EVALUATION OF THE IMPACT OF AN AI-AIDED ENDOSCOPIC DIAGNOSIS SYSTEM ON IMPROVING ENDOSCOPY QUALITY AND INCREASING THE LEARNING CURVE FOR BEGINNING COLONOSCOPY TRAINEES: A PROSPECTIVE RANDOMIZED MULTI-CENTER STUDY	Abstract of full publication identified
Yang 2022[759]	Clinical application and diagnostic accuracy of artificial intelligence in colonoscopy for inflammatory bowel disease: systematic review.	Systematic review used for reference checking
Yi 2024[760]	REAL-TIME USE OF ARTIFICIAL INTELLIGENCE IN CHARACTERIZATION OF DIMINUTIVE POLYPS DURING COLONOSCOPY: A SYSTEMATIC REVIEW AND META-ANALYSIS	Abstract of systematic review
Yu 2019[761]	Improved adenoma detection with ENDOANGEL: A randomized controlled trial	Abstract only and have full texts covering outcomes
Yu 2024[762]	ASSESSMENT OF THE ROLE OF FALSE-POSITIVE ALERTS IN COMPUTER-AIDED POLYP DETECTION FOR ASSISTANCE CAPABILITIES: A SECONDARY ANALYSIS OF RANDOMIZED CLINICAL TRIAL	Limited usable data/no relevant outcomes
Zha 2024[763]	Diagnostic Accuracy of Artificial Intelligence in Endoscopy: Umbrella Review.	Systematic review used for reference checking

Zhang 2021[764]	An artificial intelligence-based quality improvement system significantly improved the efficacy of computer-aided detection system in colonoscopy: A 2*2 factorial analysis	Abstract of full publication identified
Zhang 2024[765]	Assessment of the role of false-positive alerts in computer-aided polyp detection for assistance capabilities.	Limited usable data/no relevant outcomes
Zhang 2021[766]	Artificial Intelligence-Aided Colonoscopy for Polyp Detection: A Systematic Review and Meta-Analysis of Randomized Clinical Trials.	Systematic review used for reference checking
Zhang 2025[767]	The Effect of Computer-Aided Device on Adenoma Detection Rate in Different Implement Scenarios: A Real-World Study	Technology not relevant to review
Zhao 2025[768]	Artificial intelligence in colorectal sessile serrated lesion: recent progress	Systematic review used for reference checking
Zhao 2021[769]	Influence of artificial intelligence on colonoscopy in different examination periods	Unnamed intervention
Zhao 2022[770]	CLINICAL STUDY OF ARTIFICIAL INTELLIGENCE ASSISTED COLONOSCOPY IN DETECTING COLORECTAL POLYPS	Unnamed intervention
Zhao 2021[771]	Establishment and validation of a computer-assisted colonic polyp localization system based on deep learning.	Technology not relevant to review

Zhou 2019[772]	A REAL-TIME AUTOMATIC DEEP LEARNING POLYP DETECTION SYSTEM INCREASES POLYP AND ADENOMA DETECTION DURING COLONOSCOPY: A PROSPECTIVE DOUBLE-BLIND RANDOMIZED STUDY	Unnamed intervention
Zippelius 2021[773]	Prospective evaluation of a new artificial intelligence system for detection of colonpolyps	Abstract only and have full texts covering outcomes
Zippelius 2022[774]	Diagnostic accuracy of a novel artificial intelligence system for adenoma detection in daily practice: a prospective nonrandomized comparative study.	Full text not retrieved

Table 75. Table of notable studies excluded - mentioned in manufacturer submissions, AI used autonomously or WISE VISION® studies originally included in the report

Study	Title	Reason for exclusion
Abdelrahim 2022 – WISE VISION®[775]	Automated sizing of colorectal polyps using computer vision	*Ex vivo* application of technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Abdelrahim 2022 – WISE VISION®[776]	O29 Expected value of AI-assisted polyp detection, sizing and characterisation by non-expert endoscopists, a prospective multicentre international trial	*Ex vivo* application of technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Abdelrahim 2024 – WISE VISION®[74]	New AI model for neoplasia detection and characterisation in inflammatory bowel disease	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Akanbi 2022 – Argus®[777]	ARTIFICIAL INTELLIGENCE FOR POLYP SIZE IN COLONOSCOPY: FELLOWS VERSUS FACULTY	Study design – assessment using artificial polyps
Bechtold 2021 – Argus®[778]	S312 USING ARTIFICIAL INTELLIGENCE FOR POLYP SIZE IN COLONOSCOPY: A PHANTOM STUDY	Study design – assessment using artificial polyps
Biffi 2022 – GI Genius™[779]	A novel AI device for real-time optical characterization of colorectal polyps.	Excluded at title and abstract stage of review – appears to be *ex vivo* application of technology

Bustamante-Balén 2024 – GI Genius™[780]	Artificial intelligence-aided colonoscopy for adenoma detection and characterization. A cost-effectiveness analysis in the Spanish setting.	Abstract only of health economic assessment
Bustamante-Balen 2025 – GI Genius™[125]	Cost-effectiveness analysis of artificial intelligence-aided colonoscopy for adenoma detection and characterization in Spain	Health economic assessment only
Cherubini 2023 – GI Genius™[781]	A Review of the Technology, Training, and Assessment Methods for the First Real-Time AI-Enhanced Medical Device for Endoscopy.	Study design - review not systematic
De Lange 2024 – CAD EYE®[178]	Artificial intelligence for characterization of colorectal polyps: Prospective multicenter study.	Deprioritised as autonomous AI only
Dos Santos 2023 – CAD EYE®[190]	Performance of artificial intelligence in the characterization of colorectal lesions.	Deprioritised as autonomous AI only
Hassan 2020 – GI Genius™[220]	Computer-aided detection-assisted colonoscopy: classification and relevance of false positives.	Limited usable data/no relevant outcomes
Hassan 2020 – GI Genius™[227]	New artificial intelligence system: first validation study versus experienced endoscopists for colorectal polyp detection.	*Ex vivo* application of technology

Hassan 2023 (COMBO-CAD) – CAD EYE® and GI Genius™[224]	Comparative Performance of Artificial Intelligence Optical Diagnosis Systems for Leaving in Situ Colorectal Polyps	Deprioritised as autonomous AI only. CADx-assisted data is based on combination of CAD EYE® and GI Genius™
Hassan 2023 – GI Genius™[223]	Cost-utility analysis of real-time artificial intelligence-assisted colonoscopy in Italy.	Health economic assessment only
Htet 2023 – WISE VISION®[238]	O14 Time to implement resect & discard service into practice: two novel ways of polyp sizing and optical diagnosis with CADx	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Htet 2023 – WISE VISION®[782]	O49 Can artificial intelligence (AI) aid in sizing of colorectal polyps in real-time?	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Htet 2023 – WISE VISION®[783]	eP576 A real-time comparative study of CADx and sizing devices for colorectal polyps during colonoscopy: A total solution to implement resect and discard strategy?	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Htet 2023 – WISE VISION®[784]	P160 Real-time comparative study of CADx and sizing devices for colorectal polyps during colonoscopy: a solution to implement resect & discard?	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Htet 2025 – WISE VISION®[240]	CADE RESULTS FROM A LARGE INTERNATIONAL, MULTI-CENTRE, RANDOMISED-CONTROLLED TRIAL: MORE	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)

	ADENOMAS DETECTED, NO INCREASE IN UNNECESSARY POLYPECTOMIES	
Hossain 2022 – WISE VISION®[785]	Performance of a novel computer-aided diagnosis system in the characterization of colorectal polyps, and its role in meeting Preservation and Incorporation of Valuable Endoscopic Innovations	*Ex vivo* application of technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Pfeifer 2021 – Discovery™[594]	Computer-aided detection of colorectal polyps using a newly generated deep convolutional neural network: from development to first clinical experience	Non-randomised study and outcomes covered by randomised trials
Prijic 2022 – CAD EYE®[786]	VALIDATION OF REAL-TIME CAD SYSTEM FOR COLORECTAL POLYP DETECTION AND CHARACTERIZATION DURING COLONOSCOPY IN CROATIAN COHORT OF PATIENTS – PRELIMINARY DATA	Abstract only and have full texts covering outcomes
Reverberi 2022 – GI Genius™[787]	Experimental evidence of effective human–AI collaboration in medical decision-making.	Excluded at title and abstract stage of review – appears to be *ex vivo* application of technology
Salvi 2023 – ENDO-AID™[628]	BENEFITS FROM A COMPUTER-AIDED DETECTION DEVICE IN COLONOSCOPY (ACCENDO-COLO) – AN INTERIM ANALYSIS OF AN ITALIAN MULTICENTER RANDOMIZED CLINICAL TRIAL	Abstract only and have full texts covering outcomes

Schauer 2022 – ENDO-AID™[635]	Artificial intelligence improves adenoma detection rate during colonoscopy	Non-randomised study and outcomes covered by randomised trials
Siggens 2023 – WISE VISION®[788]	CADE-IBD: A reality or a dream? Prospective evaluation of a novel neural network for detection of neoplasia in IBD colon	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Siggens 2023 – WISE VISION®[662]	P178 A NOVEL CADX ALGORITHM FOR CHARACTERISATION AND SIZING OF COLORECTAL POLYPS MEETS PIVI 1 AND PIVI 2 THRESHOLD.	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Siggens 2023 – WISE VISION®[661]	Validation of a novel CADe algorithm for detection of neoplasia in IBD: data from image based and real-time evaluation	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Siggens 2023 – WISE VISION®[789]	PP0676 NEOPLASIA CHARACTERISATION IN IBD COLON: AN INTERNATIONAL MULTI-CENTRE STUDY OF ENDOSCOPIST PERFORMANCE AND A GENERIC COLON CADX ALGORITHM PERFORMANCE	Technology not relevant to review – CADx-IBD algorithm not part of current technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Siggens 2023 – WISE VISION®[790]	PP1194 RESECT AND DISCARD IN THE ERA OF ARTIFICIAL INTELLIGENCE: A NOVEL CADX ALGORITHM FOR CHARACTERISATION AND SIZING OF POLYPS MEETS PIVI THRESHOLDS.	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)

Siggens 2024 – WISE VISION®[791]	P208 The added value of novel CADe-IBD algorithm for neoplasia detection in IBD for expert and non-expert endoscopists: a pilot study	*Ex vivo* application of technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Siggens 2024 – WISE VISION®[792]	SAY GOODBYE TO THE CHROMOSCOPY BLUES: DEVLEOPMENT, VALIDATION AND PROSPECTIVE EVALUATION OF A NOVEL COMPUTER AIDED DETECTION ALGORITHM FOR DETECTION OF NEOPLASIA IN INFLAMMATORY BOWEL DISEASE PATIENTS	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Siggens 2024 – WISE VISION®[793]	O32 The first ever real-time evaluation of a novel CADe-IBD algorithm for detection of neoplasia during surveillance colonoscopy in colitis patients	As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)
Soons 2022 – Discovery™[679]	Real-time colorectal polyp detection using a novel computer-aided detection system (CADe): a feasibility study	Non-randomised study and outcomes covered by randomised trials
Spadaccini 2022 – GI Genius™[688]	Comparing the number and relevance of false activations between 2 artificial intelligence computer-aided detection systems: the NOISE study.	Non-randomised study and outcomes covered by randomised trials

Spadaccini 2023 – GI Genius™[689]	Combination of Mucosa-Exposure Device and Computer-Aided Detection for Adenoma Detection During Colonoscopy: A Randomized Trial.	Comparator not relevant to review
Troya 2024 – ENDO-AID™[794]	Direct comparison of multiple computer-aided polyp detection systems.	*Ex vivo* application of technology
Wong 2022 – ENDO-AID™[748]	The study on artificial intelligence (AI) colonoscopy in affecting the rate of polyp detection in colonoscopy: A single centre retrospective study.	Non-randomised study and outcomes covered by randomised trials
Yamada 2019 – WISE VISION®[756]	Development of a real-time endoscopic image diagnosis support system using deep learning technology in colonoscopy.	*Ex vivo* application of technology. As of February 2025, WISE VISION® not available to the NHS (see Section 1.3.1 of the main report)

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Artificial intelligence software to help detect and characterise colorectal polyps

External Assessment Report - Comments collated table

Any confidential sections of the information provided should be underlined and highlighted. Please underline all confidential information, and separately highlight information that is [redacted] in blue and all that is [redacted] in yellow

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
1	UK National Screening Committee	38	1	It states that "colonoscopies can be scheduled if indicated based on patient signs or symptoms, or as part of national screening or surveillance programmes regardless of signs or symptoms" and screening should be for those without symptoms, not whether they have symptoms or not.	The wording has been changed here as suggested.
2	UK National Screening Committee	39	1	"National screening programmes such as the one in the UK, which screen people above a certain age for bowel cancer (between age 50 and 74 years in the UK)" – this is the case for England, Scotland and Wales but not Northern Ireland (60 – 74).	The wording has been updated to reflect this difference in Northern Ireland.
3	UK National Screening Committee	45	1.2.1	"For England, the screening programme applied to those aged between 50 and 74 years from 2021, with a threshold of 120 µg of haemoglobin/g of faeces" – may be worth adding that a FIT threshold of 80 is currently being piloted in some parts of England.	The information about the pilot of a lower threshold in England has been added.
4	UK National Screening Committee	146	3.2.2.1.1.13	Sensitivity, false positive and false negative study info not available for all the AI tech options. This would be needed for screening evidence.	The EAG notes that diagnostic accuracy data are available from studies of the CADx functionality for applicable technologies. However, diagnostic accuracy data are not readily available for studies of the CADe functionality, which is consistent across the literature for all technologies, with outcomes

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					focusing on detection rates and other procedural outcomes.
5	Magentiq Eye	102 213 252 300	Table 4 Table 24 Table 43 Table 44	In addition to its CADe functionality, MAGENTIQ-COLO™ also provides CADx capabilities, including polyp characterization and size categorization. These features were discussed with NICE's representative, Anam Khan, during our feedback on the Scoping Workshop presentation (see email dated August 29, 2024). If still possible, we would be happy to provide supplementary statistical data that we have in test reports to support these claims; however, even if it is too late now to supply this data, we believe this should be noted in the report, to reflect the actual version of the systems in the field	Tables 4, 24 and 44 have been updated in line with this information on functionality, although the EAG notes that the sizing functionality has less relevance to the scope of this review. No updates to Table 43 have been made given no changes to the scenarios run have been made. To be eligible for inclusion, any statistical data on the CADx functionality would need to be from application during real-time (*in vivo*) colonoscopies, rather than *ex vivo* application to photos or videos. Unfortunately, consideration of additional data will not be possible prior to the first committee meeting.
6	Magentiq Eye	114	3.2.1.10	It is stated in this section that the Magentiq-COLO study was considered to have "some concerns" in terms of risk of bias While it is correct that to the date of data submitted, MAGENTIQ-COLO™ have been evaluated in a single study, we would like to emphasize the robustness of this trial. The study was conducted across 10 academic and ambulatory centres in four countries, spanning three territories (Europe, the US, and Israel). It included a large cohort of 952 patients and involved 31 practicing endoscopists. To our knowledge, this is the only study to date that incorporated both a randomized controlled trial (RCT) design and a tandem colonoscopy protocol. These characteristics strengthen the reliability and generalizability of the results and, in our view, mitigate the concern of risk of bias.	The EAG considers that consistent wording has been used throughout the report to describe risk of bias for studies of all technologies. Therefore, additional details have not been added to the report.
7	Magentiq Eye	125 127 133	Table 6 Table 7 Table 10	The review indicates missing information (e.g., advanced and non-advanced ADR across interventions, PDR, etc). These parameters have already been evaluated for the system and are included in the clinical study report of the	Unfortunately, consideration of additional data will not be possible prior to the first committee meeting. If these data are required after the committee meeting, the EAG will assess the

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				pivotal study of the Magentiq-Colo.We will be happy to provide the supporting data as needed.	importance of considering them in the report and economic model.
8	Medtronic	71	3.1.5.2	Medtronic would like to thank NICE for the opportunity to comment on the External Assessment Report (EAR) and economic model. Furthermore, Medtronic would like to publicly state we have consistently and will continue to support the approach that NICE in all its forms takes in the evaluation of technologies and its place in ensuring best value for the NHS. However, related to this assessment and the related process, we do feel it necessary to raise some legitimate methodological concerns on what we believe to be a key element to the decision-making. To maintain consistency in the methodology undertaken for this analysis other real-world data (RWD) from other AI technologies should be included in the economic modelling as a scenario analysis. We are concerned that NICE continues to show limited consideration of RWD within its appraisals, even when high-quality RCT data are available. For AI-assisted colonoscopy, RWD is usefulto understand performance in routine clinical practice, including operator variability and implementation effects that RCTs cannot fully capture. We ask that the NAIAD be incorporated into the economic modelling, at minimum as a scenario analysis. To ensure the appraisal reflects both controlled trial efficacy and real-world effectiveness in the NHS setting. We note that in other NICE diagnostic appraisals, such as the evaluation of heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices (DG61) with TriageHF Plus, RWD was included within the economic analysis to better reflect clinical practice. To maintain methodological consistency across the programme, we propose that RWD from NAIAD and other relevant AI technologies such as CADDIE with the	RCTs were prioritised in the review protocol for this assessment for technologies where these were available. The NAIAD trial has been included in the report based on data provided to the EAG given it is a fairly large UK-based assessment of GI Genius™ in the NHS setting; given [redacted] including this as an additional scenario in the economic analysis was not considered to be valuable. Furthermore, data from the FORE AI trial were not provided in time for formal consideration in the report, but the information provided did not raise concerns about its omission from the economic analysis.

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				FORE AI trial be similarly integrated into this assessment through scenario analyses, in adherence with NICE RWE framework recommendations (Assessing data suitability section).	
9	Medtronic	75	3.2	The source used for the detection accuracy, IBD sensitivity for colonoscopy without AI (Pera et al. 1987) is outdated and unlikely to reflect modern endoscopic practice. Advances in technology, training, and quality standards mean that sensitivity estimates from this paper are likely not representative. A more appropriate and up-to-date source would be the following: Frazzoni L, La Marca M, Radaelli F, et al. Systematic review with meta-analysis: the appropriateness of colonoscopy increases the probability of relevant findings and cancer while reducing unnecessary exams. Aliment Pharmacol Ther. 2021; 53: 22–32. https://doi.org/10.1111/apt.16144 This is a meta-analysis which provides pooled estimates of colonoscopy sensitivity. We recommend that this meta-analysis is considered as a replacement source, or at minimum tested in sensitivity analysis, to ensure the model reflects current evidence. Alternatively, can commentary be provided as to why this is not an appropriate source for this parameter?	The input for sensitivity of colonoscopy in the IBD population was sourced from Pera *et al.* 1987 as this aligns with the approach used the recent diagnostic review for the PillCam COLON 2 technology (DG10083). The EAG notes that the sensitivity of colonoscopy for detecting IBD reported in the study cited by the company appears to be extremely close to the value used in the model (89% compared to 89.2% in the model). Therefore, further changes have not been made to the model or report.

10	Medtronic	202	4.1.2.2	The model's use of the MiMiC-Bowel model as a source of long-term costs and QALY payoffs presents several limitations. First, because the MiMiC-Bowel outputs are not publicly available, the baseline characteristics and lifetime payoffs applied in this model cannot be validated against the source data. This reduces transparency and limits our ability to confirm whether these inputs are appropriate for the evaluated population. This is particularly relevant when the long-term payoffs are key drivers of the overall results (see model comment 14) Second, the implementation assumes that long-term payoffs are static between populations, which restricts the functionality of the model and may introduce bias. Specifically, the model applies the same lifetime costs and QALYs to both the symptomatic and screening populations. Similarly, it is assumed that the Lynch syndrome population have the same long-term payoffs as the surveillance population. Checks of the model results indicate that only the proportion of LRAs that are missed/detected change between the screening and symptomatic populations, and that only the proportion of AAs and LRAs change when lynch syndrome and surveillance populations are changed. We feel there are likely to be key differences in outcomes between these various populations, as highlighted below: Lynch syndrome and surveillance populations: ● Individuals with Lynch syndrome tend to have a much higher lifetime risk of CRC (up to 80%, according to Bowel Cancer UK) and these cancers can progress faster. While those on surveillance protocols do also have an inflated risk of CRC, this is unlikely to align with the Lynch syndrome population. ● As a result of the above, people with Lynch syndrome are usually subject to more intensive surveillance (including via colonoscopy) which, if	The EAG acknowledges that the MiMiC-Bowel model is not publicly available, and outputs from the MiMiC-Bowel model used in the economic analysis have not been published in a peer-reviewed journal. However, the inputs used in this appraisal were also used in DG10083, and similar inputs were used in DG56 and the Health Technology Wales 2024 appraisal. The MiMiC-Bowel model itself has also been extensively validated. Therefore, the EAG considers that these inputs are appropriate for use in the economic analysis. The MiMiC-Bowel model was not rerun to derive results for specific populations beyond those considered in the appraisal for the PillCam COLON2 technology (DG10083), since the MiMiC-Bowel model is not publicly available, and changing the patient population would require extensive reparametrisation of the MiMiC-Bowel model. Furthermore, the EAG considers that it is broadly appropriate to use the same long-term outcomes for the symptomatic and screening populations, as subsequent follow-up is likely to be similar for these populations. The EAG acknowledges the limitations of assuming similar outcomes for different patient populations, but this limitation only affects the subgroup analyses, which are in general informed only by limited clinical data. Similarly, the MiMiC-Bowel model does not report estimates of uncertainty in results; producing such estimates would require many reruns of the MiMiC-Bowel model with different input values. Both of these were beyond the scope of the current project.

				explicitly modelled, may lead to a change in incremental outcomes. ● Given that individuals with Lynch syndrome are known to progress faster, any diagnostic delay may have a greater impact on QALY outcomes if adenomas are initially missed. Symptomatic and screening populations: ● Screening populations comprise of people who have been referred for follow-up colonoscopy due to a positive FIT, but who do not necessarily have symptoms. This population may potentially be more likely to present with earlier stage conditions compared with symptomatic populations, who have presented due to symptoms (often as a result of existing progressed disease). If it is not possible to re-run the MiMiC bowel model to generate more accurate long-term outcomes, could further justification be provided as to why these populations were assumed to have the same long-term outcomes? An additional limitation of the use of the MiMiC-Bowel model payoffs is that, although sensitivity analysis has been conducted, this was implemented by applying standard errors equal to 20% of the mean. This approach does not necessarily capture the true differences that would be expected between symptomatic, screening, Lynch syndrome, and surveillance populations. Could clarification be provided as to whether alternative approaches to test these assumptions were considered, and if so, why these were not used? Please also refer to report comment 3 regarding the assumed SE values used in the model	

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11	Medtronic	204	4.1.2.4	Could some further insight / discussion be provided as to the likely driver of the differences in incremental QALYs vary between this evaluation and other cost-effectiveness evaluations identified? Other modelling suggests variation in QALY gain (Barkun et al. = 0.024; Hassan et. al 0.027; HTW = 0.0007; Sekiguchi = 0.001). We appreciate that these are minimal in size, relative to an individual's lifetime but also note that that given their size, any small variation in QALYs has a significant impact on the ICER so we feel this is an important matter to discuss in additional detail.	The EAG is unable to comment definitively on the reason for the variation between QALY gains between existing economic appraisals, given that none of the other economic models are publicly available, and only limited details are generally reported in publications. It is likely that the following factors may contribute to variation in observed QALY gains: • Different country contexts leading to differences in population characteristics (e.g. age at baseline) and approaches to implementing CRC screening/surveillance; • Different interventions are considered in different studies, leading to differences in clinical accuracy; • Differences in approaches to parametrising clinical accuracy (for example, using the IRR for APC rather than the RR for ADR).
12	Medtronic	215	4.2.1.4.2	While we acknowledge that, for most technologies included in this evaluation, there is limited or no evidence relating to the CADx functionality of the devices, we strongly consider that, in the case of GI Genius, there is a substantially higher level of evidence to support a more rigorous analysis of the resect-and-discard and diagnose-and-leave scenarios. In particular, the Antonelli et al. (2025) study published in *The Lancet Gastroenterology & Hepatology* represents the first randomised controlled trial (RCT) evaluating the use of CADx in real-world colonoscopy practice. The study demonstrated that the leave-in-situ strategy using CADx for diminutive rectosigmoid polyps was both safe and effective, supporting its potential as a viable and cost-saving	The EAG disagrees with the company's characterisation of the diagnose-and-leave scenario. In fact, in the model base case, 100% of patients in the NSBP health state are assumed to undergo unnecessary polypectomy and incur costs for a therapeutic colonoscopy, whereas in the diagnose-and-leave scenario, a large proportion of patients do not undergo unnecessary polyp removal, and incur costs for a diagnostic colonoscopy instead. The histopathology cost used in the economic analysis is discussed in the EAG's response to Question 19.

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				approach in clinical practice. Accordingly, we request that justification be provided for why the evaluation of CADx functionalities has been characterised and conducted as exploratory, given the strength of the available evidence for GI Genius. Notably where we feel this evaluation lacks in this regard is: ● The model does not appropriately capture the additional cost savings of CADx in the diagnose-and-leave scenarios. For polyps that are identified in this scenario, a therapeutic colonoscopy is assumed to occur, which does not reflect the nature of this assumption (i.e., we feel that this should be a diagnostic colonoscopy). The histopathology cost saving is also not applied (also see comment 12) ● For the resect-and-discard scenario, the cost savings associated with histopathology resource use appears low. (see report comment 12) ● Lifetime payoffs do not capture any downstream impacts of the use of CADx associated with additional reduction in subsequent histopathology tests. The additional cost savings from unnecessary histopathology tests should be acknowledged. We appreciate that it may not be feasible to update the model to incorporate the impact of CADe/CADx in the long-term payoffs at this stage (see comment 6). However, we kindly ask to update the decision tree calculations to more accurately capture the short-term impacts of CADx, such as avoided polypectomies, biopsies, and associated histopathology costs within the diagnose-and-leave and resect-and-discard scenarios, following a similar methodological approach to that employed by Bustamante	The EAG acknowledges the limitation of not reflecting the use of CADx in downstream colonoscopies. This is an unavoidable consequence of using outputs from the MiMiC-Bowel model. This issue is discussed further in the EAG's responses to Question 10 and Question 13. However, the EAG would like to reiterate that the analyses including CADx should be considered to be exploratory, given the limited availability of robust clinical evidence.

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				et al., who modelled these outcomes to quantify the economic benefits of incorporating CADx.	
13	Medtronic	227	4.2.1.9	The justification for assuming that CADe/CADx with AI was applied only to the index colonoscopy is unclear. Further clarification is requested regarding why additional iterations of the MiMiC bowel model could not be undertaken to simulate the lifetime use of the AI technology. In practice, if adopted, the AI system would be expected to be used for all subsequent colonoscopies. It is therefore essential that the model either captures or explicitly acknowledges that these additional potential benefits have not been incorporated into the current analysis. Furthermore, as one of the primary drivers of incremental cost is likely to be the cost of the AI technology itself, the effective "cost per colonoscopy" would be expected to change if the utilisation of the technology across multiple years and procedures were taken into account.	The EAG considers that the approach of including costs and benefits only for the index colonoscopy is reasonable, as it considers the impact of a single use of the technology. If it were assumed that the same AI technology would be used indefinitely, this would lead to higher total estimated costs and increased total QALYs/LYs than the EAG's approach. This is an unavoidable consequence of using outputs from the MiMiC-Bowel model to generate long-term outputs; the MiMiC-Bowel model could not be rerun to generate outcomes for individual interventions with and without CADx, as this would have necessitated a very large number of additional model runs. The EAG also notes that a similar approach was accepted in DG10083. The cost per colonoscopy is not affected by this approach, since this is calculated based on a separate input for the average number of colonoscopies per centre per year, rather than estimates generated by the economic model or the MiMiC-Bowel model.
14	Medtronic	235	4.2.1.12	The report states that a SE of 10% was used where confidence intervals could not be derived, but the model used SEs of 20%. This should be corrected in the report or model. Can justification please be provided as to why the selected value was used?	The EAG apologises for the discrepancy; in the absence of confidence intervals, the SE was assumed to be 20% of the mean value in the economic analysis. The report has been updated accordingly.
15	Medtronic	251	4.2.2.4	We notice that all diagnose-and-leave scenarios are associated with a negative NHB. This is unexpected, given we do not anticipate a situation where a diagnose-and-leave strategy, under currently modelling assumption, would lead to such a significant result. We believe that this	This question is no longer relevant given the EAG's updates to the economic model; please refer to the EAG's response to Question 15 in Section B.

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				result is caused by an error on the decision tree, which is discussed in modelling comment 15	
16	Medtronic	256	4.2.3.1	Additional economic and clinical evidence on the CADx functionality of GI Genius has been excluded from this analysis and report. Namely, the following: ● Antonelli et al. (2025). Safety of artificial intelligence-assisted optical diagnosis for leaving colorectal polyps in situ during colonoscopy (PRACTICE): a non-inferiority, randomised controlled trial ● Bustamante-Balén (2025). Cost-effectiveness analysis of artificial intelligence-aided colonoscopy for adenoma detection and characterization in Spain In particular, we consider that the Antonelli paper provides important and relevant evidence regarding the benefits of CADx and should be included in this assessment, given that it represents the only randomised controlled trial (RCT) currently available for CADx. We would appreciate clarification regarding the rationale for the exclusion of these papers. Furthermore, we believe that the Antonelli paper offers sufficient evidence to inform the CADx scenario analysis. Although this study does not incorporate a reference standard, we respectfully request that it be reviewed and considered for inclusion within the economic modelling. In addition, the Bustamante et al. paper is the only published cost-effectiveness analysis to date that includes CADx and demonstrates clear additional benefits associated with its use. The study found that incorporating CADx with CADe (using GI Genius) was a dominant strategy, delivering both improved health outcomes and overall cost savings compared with standard colonoscopy. These findings further support the inclusion and consideration of CADx within the economic evaluation.	With regards to the clinical assessment, a confidential version of the Antonelli *et al.* 2025 study was provided to the EAG but was not considered relevant to the review given the main aim was to compare a leave-in-situ approach with a resect-all approach; comparing different management strategies in terms of polyp resection is not within the scope of the clinical review. Furthermore, the GI Genius™ CADe/CADx system was used in both of these groups, so data comparing between use and no use of CADe/CADx is also not available from this study. The results for Antonelli *et al.* 2025 were not incorporated into the economic analysis as the reported outcomes were not appropriate for use within the current model structure (in particular, direct comparison against colonoscopy without AI was not possible, as GI Genius™ was used in both trial arms). The EAG notes that Bustamante-Balén *et al.* 2025 was not included in the report, since this study was published after the economic SLR was conducted. Unfortunately, consideration of additional economic evaluations will not be possible prior to the first committee meeting. If it is deemed important by committee, the EAG will assess the relevance of any new data after that meeting.

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17	Medtronic	267	6.2	It is important to note that we have consistently maintained full transparency regarding the data used to train the algorithms for GI Genius. Furthermore, this report underscores that the previous pooling of AI technologies in other evaluations represents a methodological limitation, as it fails to account for the distinct features, training data, and supporting evidence unique to individual technologies such as GI Genius. We wish to highlight and fully align with your observation in Section 3.3.2 (pages 185–186) that *"it is plausible that effects could be different across the technologies"* due to differences in their algorithms and underlying training datasets. Accordingly, any assessment or recommendation should be based on the individual clinical and economic evidence for each technology, rather than on the assumption of homogeneity across all AI systems. GI Genius is supported by a comprehensive and robust evidence base, including multiple randomised controlled trials (RCTs) and real-world NHS data, which together justify its evaluation and consideration on its own merits.	The EAG acknowledges this comment, with no changes to the report required.
18	Medtronic	357, 210	9.1.10, 4.2.1.2	To the comment below (12), the diagnose-and-leave scenarios appears to apply therapeutic colonoscopy costs to all diagnosed polyps, and it is not clear how the anticipated reduction in cost (associated with fewer therapeutic procedures) is taken into consideration. Can clarification be provided as to why these cost savings are captured?	The EAG does not agree with this characterisation of the diagnose-and-leave scenarios. Please refer to the response to Question 12 for further details.
19	Medtronic	361	9.10.3	The histopathology cost currently used in the model represent the cost savings associated with a resect-and-discard approach. This value (£8) appears relatively small, and the sourcing is unclear. Existing cost collection data (2023-2024) indicate the national weighted average value	The histopathology cost used in the economic analysis was aligned with the NHS reference costs at the time of model development, but these costs appear to have been updated subsequently. The EAG agree that the current

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				to be £36. NHS Cost Collection data from 2022-2023 provide a range of values from £7-£200+ while data from 2021-2022 puts this value at £44 per specimen. What was the justification for using £8 for this input? Please also refer to model comment 10 Furthermore, this cost saving is only applied to the resect-and-discard scenario, although it seems plausible that this cost saving would also be incurred for the diagnose-and-leave scenarios. Could some commentary please be made as to why this was not the case?	costs are potentially more representative, and has conducted a scenario analysis using the updated model cost, which is presented in an addendum to the report. Since data reporting in the 2023/24 reference costs appears to have been inconsistent across services for histopathology and histology (PATH02), with the majority of values 'unknown', the weighted average cost across all histopathology and histology categories was used (£36). For the diagnose-and-leave scenario, the cost saving arising from avoided histopathological tests was assumed to be reflected in the use of a diagnostic colonoscopy cost rather than a therapeutic colonoscopy cost for some patients.

Section B Economic model - Comments

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Medtronic	1	Parameters AB107	Outdated costs.	We acknowledge that the NHS Cost Collection 2023/24 from which these costs are sourced is updated frequently and as such variation in these costs is expected.	Moderate Impact – Inaccurate costing	The EAG do not consider this to be an error; the costs used in the model are in line with the NHS Cost Collection as of 01/10/2025.
Medtronic	2	Parameters AB108				
Medtronic	3	Parameters AB111				
Medtronic	4	Parameters AB112				
Medtronic	5	Parameters AB31	The current waiting times (2.9) are only sampled from a single month. Could the justification for this be provided?	We would recommend an average wait time across a longer period of time should be conducted (up to one year recommended due to seasonal variation in NHS demand)	Moderate Impact – Inaccurate predicted waiting time	The EAG acknowledges that the company's suggestion is more appropriate, and has updated the report accordingly. However, no changes have been made to the model as the current input value is approximately equal to the mean waiting time for the months April 2024-May 2025.
Medtronic	6	Parameters AB64 (recurs across all devices)	Alternative polyp management scenario.	We recommend that this calculation be reviewed and, if necessary, updated accordingly.	Moderate Impact – SD error	The EAG apologises for the error; the model has been updated accordingly. The results presented for the relevant analyses

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			Inputs: No CADx specificity (high-confidence). We believe the standard deviation used to calculate the standard error should be 0.76 as provided in the input source.			(diagnose-and-leave [high confidence] scenario, with and without CADx) have also been updated in the report.
Medtronic	7	Parameters AB58	Alternative polyp management scenario. Input: COLAI APC mean diff of the Argus device. We believe this is potentially entered incorrectly. Only an abstract was publicly available and therefore it is plausible that the full text contains information to validate this which we were unable to access.	Unless this has been calculated using data not available from abstract alone, the value of the mean should be adjusted to 0.12. The SE should also be adjusted as appropriate.	Moderate Impact – Incorrect inputs	The EAG notes that the value of 0.12 reported in the Strapko *et al.* 2023 abstract refers to the outcome of ADR, not APC. The EAG obtained APC data from this trial from additional material provided by the manufacturer (instructions for use document from 2023), which has been included in the report and economic model. Table 68 of the report has been updated to clarify the source for this input.
Medtronic	8	Parameters AH60	Alternative polyp management scenario Inputs: CADx prop low confidence diagnoses for the CAD EYE device It was not possible to validate this as we could not identify this from the	Please provide commentary as to how this value was obtained.	Moderate Impact – Inappropriate validation	The CAD EYE® value for proportion of low confidence diagnoses was taken from Rondonotti *et al* 2023 (ABC trial). Of 596 diminutive rectosigmoid polyps, a high confidence assessment was possible for AI-assisted endoscopist diagnosis in 550 polyps, leading to a proportion of 0.07 for low-confidence

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			reference source. Could this please be provided?			assessments (information available from the first paragraph underneath “Accuracy of the optical diagnosis process” heading).
Medtronic	9	Parameters AH65	The input for CADx sensitivity appears to use a value for sensitivity of endoscopist diagnosis rather than the AI + endoscopist diagnosis.	If our understanding is correct, please adjust the value of the mean to 0.943 and also adjust the corresponding SEs.	Moderate Impact – Incorrect mean and SE values	The EAG has been unable to identify an error here; the input value specified in the model already aligns with the company’s suggested value.
Medtronic	10	Parameters AB110	The source of the histopathology cost (£8) is unclear where this is sourced from. Existing cost collection data: 2023-2024: National weighted average value to be £36. 2022-2023: A range of values from £7-£200+ 2021-2022: £44 per specimen. In reality, this cost is likely to vary significantly depending on multiple factors such as whether the sample is sent to an external site for testing, or if it is tested on site. In any case, we believe	Please review this figure or provide justification for why £8 was used. Additionally, scenario analysis could be conducted where this value is varied between more plausible ranges. We anticipate that this would be particularly impactful to the resect-and-discard and diagnose-and-leave scenario analyses.	High impact to the resect-and-discard and diagnose-and-leave scenarios.	The EAG agrees that the currently available NHS reference costs for histopathology are potentially more appropriate, and has presented a scenario analysis using the cost suggested by the company in an addendum to the report. Further details are given in the response to Question 19 in Section A.

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			the existing value to be an underestimation			
Medtronic	11	Parameters AB26-30	Page 216 of the report states that 10.6% of colonoscopies are due to screening, which is in contradiction to another section of the report (page 349), which states that the Turvill data is used to inform both screening and symptomatic subgroups. In the model, for the full population analysis, the underlying distribution of disease and long-term payoffs is taken from Turvill et al for screening (10.6%, in line with page 216) and from Crispin et al for surveillance, symptomatic, and lynch syndrome.	Justification should be provided as to why only the screening population was informed by Turvill in the full population analysis or update the weighting of data taken from Turvill and Crispin data in the "Full population" analysis for the underlying characteristics (profile 1) and long-term payoffs (profile 5)	Moderate Impact – may influence the incremental outcomes and the level of uncertainty observed in the PSA results.	The EAG acknowledges that the approach taken in parametrising the subgroup analysis was not ideal; however, the EAG was only able to identify true disease prevalence data for the symptomatic and surveillance populations. The EAG notes that the subgroup analyses are all informed by limited clinical data, and as a result, fully robust subgroup analyses cannot be conducted regardless of the population prevalence inputs used.
Medtronic	12	Parameters G73-74	In the base case, the subscription purchase option for GIG is applied. However, only one purchase method is used for	Analysis where the upfront cost of each technology should be included in the base case results, with subscription pricing used as part of a scenario analysis	High impact to incremental costs – Flawed costing methodology and incorrect cost comparison and	The cost inputs for GI Genius™ used in the economic model were informed by the RFI provided by GI Genius™ for this project; in particular, the subscription cost was used as this was given as an

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			each technology, and this differs across technologies. We consider the current approach to costing inappropriate, as the model currently applies only the subscription-based costing method. Furthermore, we request clarification as to why, when the upfront cost is implemented in the model, this cost is distributed over a four-year period, given that the expected lifetime of the technology is greater than this. It is also important to note that a comparative table of AI technologies is only meaningful when a consistent costing methodology is applied across all devices. Using differing approaches for different technologies effectively results in non-comparable outcomes and risks producing a misleading representation of relative cost-effectiveness. Finally, the structure of the current model combines the	where applicable. This will allow the impact of a variety of procurement options to be evaluated.	cost per colonoscopy [redacted]	option for NHS use in the RFI. However, the EAG has provided additional analyses using the updated cost provided by Medtronic in an addendum to the report. The EAG does not agree that it is inappropriate to use different pricing structures for different technologies, or that costs are not comparable when different pricing structures are used. The majority of technologies only provide one pricing structure option, but where multiple options were available, the EAG has used a subscription option since this avoids any assumptions around the longevity of the technology. When only an upfront cost is used, it is assumed that the technology is used for four years, as the longevity of the technology is not known *a priori*; this was varied in scenario analyses and found to have a negligible effect on results. The annual costs applied alongside the upfront cost corresponds to the annual maintenance cost reported by the relevant manufacturer; maintenance costs have been

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			annual subscription costs and upfront costs, which are often provided as two independent costing structures and therefore risks overestimating device costs. We recommend applying a consistent costing method across all technologies using only the upfront purchase structure, to ensure comparability and avoid double counting. Additionally, from experience with the NHS, there has been no instance of a subscription model used in this setting as of date. We ask that the EAG reflect the true four-year cost of GI Genius to align with the current business model used in the NHS with a value of [redacted], which includes the cost of the maintenance for four years. The annual maintenance cost is [redacted]. Both excluding VAT. All costs listed above includes hardware,			excluded from the upfront cost to avoid issues with double-counting.

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			software, upgrades, installation, training, and education.			
	13	Decision Tree	In the diagnose-and-leave scenarios, the cost of a therapeutic colonoscopy is still applied to all detected polyps. We believe that this overestimates the cost of colonoscopies for which polys are detected but not removed and sent for histopathological testing. We ask that calculations be updated accordingly.	Calculation update required.	Moderate Impact – inappropriate calculations impacting the diagnose-and-leave results	The EAG does not agree that this is an error; further details are given in the response to Question 12 in Section A.
	14	Parameters – Profile 1 and 5	This comment is a follow on from report comment 1 Long-term payoff calculations weigh the long-term outcomes by population (where screening + symptomatic populations assume screening long-term payoffs, and surveillance + lynch syndrome surveillance use surveillance long-term payoffs). In reality, it is highly likely that the underlying	Given that the MiMiC bowel model is routinely reused across multiple evaluations, there should be sufficient flexibility to adapt it for this analysis. If the model has the functionality to do so, it would be valuable to run it specifically for each population to derive accurate SE values across these groups. In addition, conducting a scenario analysis in which long-term payoffs are excluded from	Moderate Impact - The outcomes of the symptomatic and Lynch syndrome populations are currently less representative and the uncertainty of the results across all populations and scenarios are potentially inflated.	The EAG is unable to include additional analyses based on the MiMiC-Bowel model; further details are given in the response to Question 12 in Section A.

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			characteristics (presence of polyps, age, likelihood of progression) will vary significantly between these populations. Furthermore, while page 247 of the report implies these SEs are representative of the 95% confidence intervals, in the model they are assumed to be 20% of the mean. The impact of long-term payoffs on the overall model results can be important, particularly for costs, and particularly given how small the incremental results of this analysis are. Is it possible to use the MiMiC bowel model to calculate more accurate long-term payoffs for each population, and for more robust SEs to be identified? The DSA indicated that the highest driver of outcomes stem from the long-term payoffs (specifically, for people with LRA and AAs) so it will be important to ensure these are modelled as accurately as possible,	the PSA may also provide useful insights.		

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			again, particularly given the PSA indicates only minor incremental costs and QALYs An example of how these assumed SE values impact the results can be shown in the PSA iterations, where in approximately 15% of simulations, life years are smaller than QALYs for both the intervention and comparator (incremental life years are lower than QALYs in around 8% of simulations). This is not clinically plausible and seems to be primarily driven by the large assumption-based SE values for long-term payoffs. Furthermore, in the PSA, the long-term QALY payoffs for objectively less severe disease states may fall below those for more severe conditions, a result that lacks face validity. There is a case to be made that including wide and assumption-based SEs			

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			introduced additional uncertainty. There could be some benefit to running a scenario where long-term payoff inputs are excluded from the PSA and included in the results section of the report.			
	15	Decision Tree AK28	This cell is set to 0, meaning that for both of the diagnose-and-leave scenarios, the sum of all decision tree branch populations does not sum to 1, and so some individuals are not being included in the analysis. This appears to be an error in the model, and likely significantly skews the results in this scenario in favour of the comparator as it is essentially assuming that a significant proportion of the population have died at the index text (approximately 2.8% and 1.9% of the diagnose and leave and diagnose-and-	This calculation should be rectified and the results and accompanying discussion should be updated	Very high impact to the incremental QALYs and subsequent ICER in the diagnose-and-leave scenario results	The EAG apologises for this error, and thanks Medtronic for drawing attention to it. The error has been corrected in the model, and relevant analyses (i.e. scenarios including the diagnose-and-leave polyp management strategy) have been rerun. The results and conclusions presented in the report have also been updated accordingly.

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			leave (high confidence) scenarios respectively.			
	16	Decision tree AQ-AR	For people who die at colonoscopy, their “lost” life years are directly subtracted from the long-term payoffs. It is unclear if this is double counting as the long-term payoffs may already incorporate the proportion of those who die during the initial diagnostic period. Similarly, QALY losses associated with adverse events are also subtracted from long-term payoffs, which may already incorporate this. Whether this is the case is uncertain given the MiMiC bowel model is not available for scrutiny. Can you please confirm whether this is the case and provide clarification either way in the report?	The MiMiC bowel model should be reviewed to identify whether life year and QALY losses are incorporated in the long-term payoffs.	Moderate impact due to the how rare colonoscopy-associated adverse events and deaths are.	The lifetime payoffs sourced from the MiMiC-Bowel model do not cover the ‘pre-diagnosis’ period for patients, which includes deaths due to the index colonoscopy. Therefore, no changes are required.
	17	Decision tree AT	The model incorporates repeat (failed)	Provide justification as to why this value was used	Moderate impact on results	The value used in the model is informed by the proportion of

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			colonoscopies; however, the proportion of colonoscopies that are repeated seems low (1.1%) compared with other data. Reported failure rates in other trials and data can be considerably higher. For example, the Bowel cancer screening standards data report 2023-24 demonstrated there was a 95.9% caecal intubation rate, implying a 4.1% failure rate. Were any other data sourced for this input considered?			patients observed to receive a repeat colonoscopy after an incomplete initial colonoscopy in a five-year audit of colonoscopies conducted at the Royal Liverpool University Hospital, which is considered likely to be reflective of UK clinical practice. This source was also used in the diagnostic appraisal for PillCam COLON 2 (DG10083). The EAG has conducted a scenario analysis to use the input value suggested by Medtronic; the impact on results is minimal. The results for this scenario are presented in an addendum to the report.
	18	Decision tree AW	The rate of death from therapeutic colonoscopy is incorporated into this calculation but the justification for this is unclear – could this please be provided? Data to inform the proportion of individuals who will go on to receive a second therapeutic colonoscopy is an	Review this element of the model structure	Moderate impact on results	This calculation is structured so that the proportion of patients who undergo a secondary therapeutic colonoscopy is applied only to patients who do not die after the first colonoscopy. It is unclear whether the original source includes patients who died as a result of an initial colonoscopy in the denominator of the calculation. However, the EAG notes that the approach used has a

Stakeholder	Comment	Cell reference	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	EAG response
			assumption and may have already accounted for this.			minimal impact on results, as the proportion of patients expected to die as a result of colonoscopy is extremely small.
	19	Intermediate results	The calculation for the total number of therapeutic colonoscopies does not include secondary colonoscopies. Equally, the number of diagnostic colonoscopies does not include failed ones. This means that the probabilistic and deterministic colonoscopies results are incorrect (cells F16:G17 on both respective results sheets). What is the justification for excluding these from the results?	Review this element of the model calculations or provide justification as to its exclusion	Moderate impact to the number of reported colonoscopies	The EAG does not agree that secondary colonoscopies were excluded from the number of therapeutic colonoscopies. Failed colonoscopies were not counted as diagnostic colonoscopies, as only completed colonoscopies were counted in this category; while failed colonoscopies were costed using the diagnostic colonoscopy cost. In theory, some failed colonoscopies would have been therapeutic colonoscopies if they had been completed.
	20	Results (probabilistic and deterministic)	We believe that the total waiting time (weeks) is calculated incorrectly and that it should be the total difference in the number of colonoscopies multiplied by the mean/median waiting time.	Review this element of the model calculations	Moderate impact to the total average waiting time	The EAG does not consider this to be an error. The company's suggested approach does not align with the EAG's stated approach to estimating waiting time, as outlined in Section 4.2.1.11 of the report.

Artificial intelligence software to help detect and characterise colorectal polyps [GID-DG10118]

Diagnostics Assessment Report Addendum

October 2025

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Produced by:	BMJ Technology Assessment Group (BMJ-TAG)
Authors:	Steve Edwards, Director of Health Technology Assessment, BMJ-TAG, London Nicole Downes, Senior Clinical Evidence Analyst, BMJ-TAG, London Sophie Ip, Senior Health Economist, BMJ-TAG, London Victoria Wakefield, Principal Clinical Evidence Analyst, BMJ-TAG, London Clare Dadswell, Clinical Evidence Manager, BMJ-TAG, London Isaac Mackenzie, Health Economist, BMJ-TAG, London Tracey Jhita, Health Economics Manager, BMJ-TAG, London
Correspondence to:	Steve Edwards, BMJ TAG, BMJ Group, 5th Floor, 90 Whitfield Street, London W1T 4EZ, UK.
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This review has been registered on PROSPERO under registration number CRD42024586541.

All commercial in confidence data and information are highlighted in [redacted].

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List of Abbreviations

AA	Advanced adenoma
ADR	Adenoma detection rate
AE	Adverse event
AI	Artificial intelligence
AMR	Adenoma miss rate
APC	Adenomas per colonoscopy
CADe	Computer-aided detection
CADx	Computer-aided diagnosis
CEAC	Cost-effectiveness acceptability curve
CI	Confidence interval
CRC	Colorectal cancer
EAG	External assessment group
EMIS™	Endoscopic Multimedia Information System
IBD	Inflammatory bowel disease
ICER	Incremental cost-effectiveness ratio
LRA	Low-risk adenoma
LT	Long-term
LYG	Life years gained
NHB	Net health benefit
NHS	National Health Service
NSBP	No significant bowel pathology
QALY	Quality-adjusted life year
RFI	Request for information
RR	Risk ratio
WTP	Willingness-to-pay

1 Results with updated cost for GI Genius™

The cost used for GI Genius™ in the economic analysis presented in the main report is informed by the request for information (RFI) provided by Medtronic. However, in a stakeholder comment on the report, Medtronic noted that this cost is no longer reflective of the expected cost for National Health Service (NHS) use, and requested an updated analysis using a new cost ([redacted] upfront cost, including four years of maintenance, and [redacted] maintenance cost per year thereafter). Using the costing assumptions detailed in Section 4.2.1.10.2 of the main report, this results in an average cost of [redacted] per colonoscopy for the technology.

Updated results are presented below. The results related to the number of procedures are not affected by the change in cost, so are not presented here. Subgroup analyses and scenario analyses have been presented deterministically, due to time constraints; however, for the base case, the probabilistic results are generally closely aligned with the deterministic results, and the same is expected to be true of the subgroup and scenario analyses. The scenario analyses presented in Table 4 are aligned with the scenario analyses presented in the main report with the exception of scenarios 10, 11, 14a, 14b and 14c, which are excluded as these scenarios are not relevant to GI Genius™; detailed descriptions of each scenario are given in Section 4.2.1.15 of the main report. Additional scenarios performed after the stakeholder consultation are detailed in Section 2 of this addendum.

In general, the results are still dominant in the base case when using the updated cost, and the incremental net health benefit (NHB) is very slightly increased. However, the overall magnitude of the differences in results compared to the results for the original cost is negligible.

Table 1. Probabilistic cost-effectiveness results for GI Genius™

Technology	Total Costs	Total QALYs	Total LYG	Incremental costs vs colonoscopy without AI	Incremental QALYs vs colonoscopy without AI	Incremental LYG vs colonoscopy without AI *	ICER vs colonoscopy without AI (£/QALY)	Incremental NHB vs colonoscopy without AI
Colonoscopy without AI	£3,171.62	10.981	14.061					
GI Genius™ (original cost)	£3,126.46	10.982	14.065	-£45.16	0.002	0.004	Dominant	0.003
GI Genius™ (updated cost)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dominant	0.004

Footnote: * Undiscounted total and incremental LYG is presented to aid interpretability; all other results are discounted at a rate of 3.5% per year.

Abbreviations: AI, artificial intelligence; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year.

Table 2. Deterministic cost-effectiveness results for GI Genius™

Technology	Total Costs	Total QALYs	Total LYG	Incremental costs vs colonoscopy without AI	Incremental QALYs vs colonoscopy without AI	Incremental LYG vs colonoscopy without AI *	ICER vs colonoscopy without AI (£/QALY)	Incremental NHB vs colonoscopy without AI
Colonoscopy without AI	£3,164.39	10.932	14.042					
GI Genius™ (original cost)	£3,116.16	10.934	14.045	-£48.23	0.003	0.003	Dominant	0.004
GI Genius™ (updated cost)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Dominant	0.004

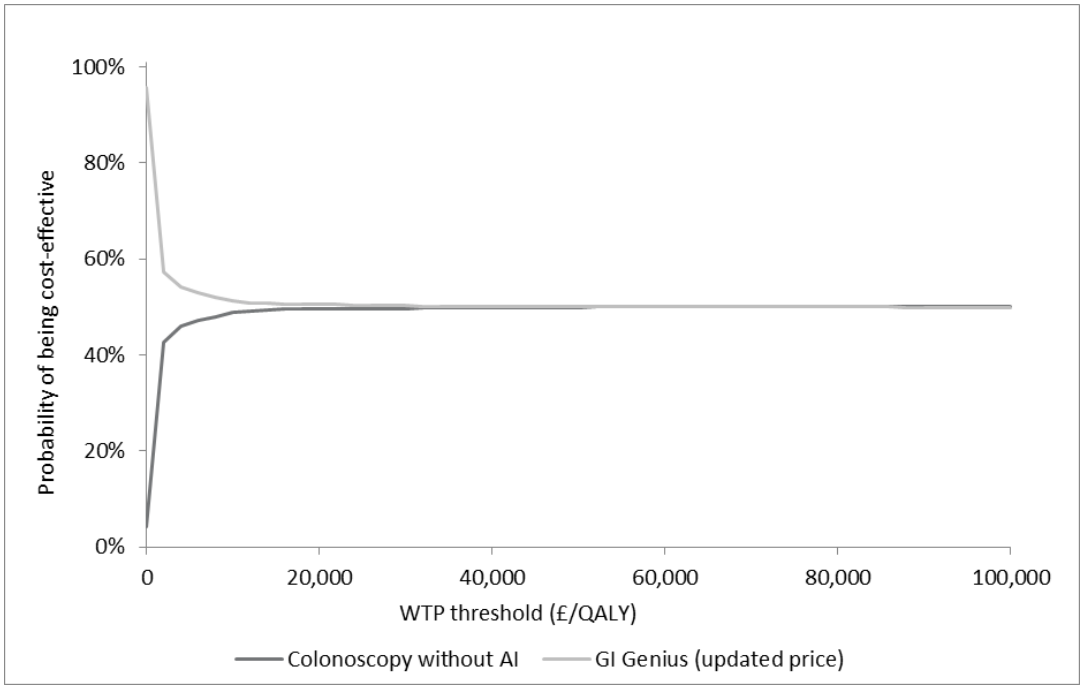
Footnote: * Undiscounted total and incremental LYG is presented to aid interpretability; all other results are discounted at a rate of 3.5% per year.

Abbreviations: AI, artificial intelligence; ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year.

Figure 1. GI Genius™ (updated cost) vs colonoscopy without AI cost-effectiveness plane

Abbreviations: AI, artificial intelligence; QALY, quality-adjusted life year; WTP, willingness-to-pay.

Figure 2. GI Genius™ (updated cost) vs colonoscopy without AI CEAC



Abbreviations: AI, artificial intelligence; CEAC, cost-effectiveness acceptability curve; QALY, quality-adjusted life year.

Figure 3. GI Genius™ (updated cost) vs colonoscopy without AI incremental NHB convergence plot

Abbreviations: AI, artificial intelligence; CI, confidence interval; NHB, net health benefit.

Figure 4. GI Genius™ (updated cost) vs colonoscopy without AI incremental NHB tornado plot

Footnote: the lower and upper bounds used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; NHB, net health benefit; QALY, quality-adjusted life year; RR, risk ratio.

Figure 5. GI Genius™ (updated cost) vs colonoscopy without AI incremental costs tornado plot

Footnote: the lower and upper bounds used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; NSBP, no significant bowel pathology; RR, risk ratio.

Figure 6. GI Genius™ (updated cost) vs colonoscopy without AI incremental QALYs tornado plot

Footnote: the lower and upper bounds used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; NSBP, no significant bowel pathology; QALY, quality-adjusted life year; RR, risk ratio.

Figure 7. GI Genius™ (updated cost) vs colonoscopy without AI incremental LYG tornado plot

Footnote: the lower and upper bounds used to generate results were aligned with the endpoints of the 95% confidence interval, where available; otherwise, a 95% confidence interval was estimated by assuming a standard error of 20% of the mean value.

Abbreviations: AA, advanced adenoma; AI, artificial intelligence; CRC, colorectal cancer; LRA, low-risk adenoma; LT, long-term; LYG, life years gained; NSBP, no significant bowel pathology; RR, risk ratio.

Table 3. Deterministic subgroup analyses: cost-effectiveness results vs colonoscopy without AI for GI Genius™

Subgroup	GI Genius™ Cost	Incremental costs (£)	Incremental QALYs	Incremental LYG*	ICER (£/QALY)	Incremental NHB
Full population	Original	-£48.23	0.003	0.003	Dominant	0.004
	Updated	[redacted]	[redacted]	[redacted]	Dominant	0.005
Screening	Original	-£34.40	0.001	0.000	Dominant	0.002
	Updated	[redacted]	[redacted]	[redacted]	Dominant	0.003
Symptomatic/ diagnostic	Original	-£38.66	0.001	0.000	Dominant	0.003
	Updated	[redacted]	[redacted]	[redacted]	Dominant	0.003
Lynch syndrome surveillance	Original	£908.99	-0.067	-0.076	Dominated	-0.097
	Updated	[redacted]	[redacted]	[redacted]	Dominated	-0.095
Surveillance	Original	-£458.70	0.049	0.056	Dominant	0.064
	Updated	[redacted]	[redacted]	[redacted]	Dominant	0.065

Abbreviations: ICER, incremental cost-effectiveness ratio; LYG, life years gained; NHB, net health benefit; QALY, quality-adjusted life year.

Table 4. Deterministic scenario analysis results for GI Genius™

Scenario	Incremental NHB vs colonoscopy without AI		ICER vs colonoscopy without AI	
	GI Genius™ (original cost)	GI Genius™ (updated cost)	GI Genius™ (original cost)	GI Genius™ (updated cost)
Base case	0.004	0.005	Dominant	Dominant
1a. Diagnose-and-leave polyp management strategy	0.003	0.004	Dominant	Dominant

1b. Diagnose-and-leave (high-confidence) polyp management strategy	0.004	0.004	Dominant	Dominant
2. Resect-and-discard polyp management strategy	0.004	0.005	Dominant	Dominant
*3a. Diagnose-and-leave polyp management strategy with CADx**	*-0.011*	*-0.011*	*Dominated*	*Dominated*
*3b. Diagnose-and-leave (high-confidence) polyp management strategy with CADx**	*-0.015*	*-0.015*	*Dominated*	*Dominated*
*4. Resect-and-discard polyp management strategy with CADx**	*0.004*	*0.005*	*Dominant*	*Dominant*
5. Alternative values for sensitivity of detection for colonoscopy without AI	0.005	0.005	Dominant	Dominant
6. CADe sensitivity of interventions calculated using AMR	0.005	0.005	Dominant	Dominant
7. CADe sensitivity of interventions calculated using APC	0.012	0.012	Dominant	Dominant
8a. Alternative rate of CRC detection: 100% for all technologies	0.004	0.005	Dominant	Dominant
8b. Alternative rate of CRC detection: 90% for all technologies	0.004	0.005	Dominant	Dominant
8c. Alternative rate of CRC detection: informed by ADR RR	0.004	0.005	Dominant	Dominant
9a. Alternative rate of IBD detection: 100% for all technologies	0.004	0.005	Dominant	Dominant
9b. Alternative rate of IBD detection: 80% for all technologies	0.004	0.005	Dominant	Dominant
12. Alternative costing for failed initial colonoscopies: 0% of diagnostic colonoscopy cost	0.004	0.005	Dominant	Dominant
13a. Alternative proportion of patients receiving secondary therapeutic colonoscopies: 0%	0.004	0.004	Dominant	Dominant
13b. Alternative proportion of patients receiving secondary therapeutic colonoscopies: 50%	0.005	0.005	Dominant	Dominant
13c. Alternative proportion of patients receiving secondary therapeutic colonoscopies: informed by ADR RR	0.004	0.004	Dominant	Dominant
15. AE costs removed for patients who die	0.004	0.005	Dominant	Dominant

Footnote: *These analyses should be considered to be exploratory.

Abbreviations: ADR, adenoma detection rate; AE, adverse event; AI, artificial intelligence; AMR, adenoma miss rate; APC, adenomas per colonoscopy; CADe, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; IBD, inflammatory bowel disease; N/A, not applicable; NHB, net health benefit.

2 Additional scenario analyses

The External Assessment Group (EAG) performed additional scenario analyses based on stakeholder comments, as follows:

- The NHS National Cost Collection for 2023-2024 has been updated since the model was developed; in particular, the histopathology reference costs as of 01/10/2025 appear to be more appropriate than the cost used in the original version of the model.[6] In particular, the original histopathology cost was £8 based on reference cost DAPS02. The updated version of the NHS National Cost Collection for 2023-2024 has used a different structure for directly accessed pathology services, with histopathology and histology costs reported under the code PATH02, separated by service. Since data reporting appears to have been inconsistent across services, with the majority of datapoints assigned to the 'unknown' category, the weighted average cost across all PATH02 services was considered appropriate, giving a value of £36. Since this change is only relevant to the resect-and-discard polyp management strategy, the EAG implemented an additional version of this scenario using the updated version of this cost.
- The EAG also implemented an updated version of the resect-and-discard scenario with computer-aided detection (CADx) with the alternative histopathology cost, for the two interventions for which data are available (CAD EYE® and GI Genius™). As for the original version of this scenario, this analysis should be considered to be exploratory, due to the uncertainty in the clinical parameters informing the scenario.
- The base case of the model assumes that 1.1% of colonoscopies initially failed and necessitated a second colonoscopy; this input value was informed by Britton *et al.* 2015.[7] An alternative input value of 4.1% was proposed in a stakeholder comment, informed by the Bowel Cancer Screening Standards Data Report for 2023-2024.[8] The EAG implemented a scenario using this alternative input value.

Results for these scenarios are presented below (including results with both the original and updated prices for GI Genius™). Results have been presented deterministically rather than probabilistically, due to time constraints; however, for the base case, the probabilistic results are generally closely aligned with the deterministic results (see Section 4.2.2.1 of the main report), and the same is expected to be true of the scenario analyses.

The results of the additional analysis consistently show a negligible deviation from base case results. Therefore, the conclusions drawn in the main report are still considered to be valid.

Table 5. Deterministic results for additional scenarios: NHB

Scenario	Incremental NHB vs colonoscopy without AI								
	Argus®	CAD EYE®	Discovery™	EMIS™	ENDO-AID™	EndoScreener®	GI Genius™ (original price)	GI Genius™ (updated price)	MAGENTIQ-COLO™
Base case	0.007	0.008	0.001	0.003	0.011	0.009	0.004	0.005	0.010
16. Resect-and-discard polyp management strategy with updated histopathology cost	0.007	0.008	0.001	0.003	0.011	0.009	0.004	0.005	0.010
*17. Resect-and-discard polyp management strategy with CADx, and updated histopathology cost**	*N/A*	*0.008*	*N/A*	*N/A*	*N/A*	*N/A*	*0.004*	*0.005*	*N/A*
18. Alternative failure rate for index colonoscopy	0.007	0.008	0.001	0.003	0.011	0.009	0.004	0.005	0.010

Abbreviations: AI, artificial intelligence; CADx, computer-aided diagnosis; EMIS™, Endoscopic Multimedia Information System; N/A, not applicable; NHB, net health benefit.

Table 6. Deterministic results for additional scenarios: ICER

Scenario	ICER vs colonoscopy without AI								
	Argus®	CAD EYE®	Discovery™	EMIS™	ENDO-AID™	EndoScreener®	GI Genius™ (original price)	GI Genius™ (updated price)	MAGENTIQ-COLO™
Base case	Dominant	Dominant	£606.67	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
16. Resect-and-discard polyp management strategy with updated histopathology cost	Dominant	Dominant	£606.67	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
*17. Resect-and-discard polyp management strategy with CADx, and updated histopathology cost**	*N/A*	*Dominant*	*N/A*	*N/A*	*N/A*	*N/A*	*Dominant*	*Dominant*	*N/A*
18. Alternative failure rate for index colonoscopy	Dominant	Dominant	£925.60	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant

Abbreviations: AI, artificial intelligence; CADx, computer-aided diagnosis; EMIS™, Endoscopic Multimedia Information System; N/A, not applicable; ICER, incremental cost-effectiveness ratio.

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