

NaviCam for diagnosing gastrointestinal tract conditions

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the NaviCam magnetically controlled capsule endoscopy system. It is used for diagnosing conditions of the upper gastrointestinal (GI) tract and small bowel.
- The **innovative aspects** are that unlike other capsule endoscopy systems, the capsule can be remotely controlled by the endoscopist, which may improve visualisation of the upper GI tract (including the stomach).
- The **intended place in therapy** would be for diagnostic purposes instead of conventional gastroscopy or device-assisted enteroscopy in people with suspected upper GI tract or small bowel disease.
- The **main points from the evidence** summarised in this briefing are from 5 studies involving 542 people including healthy volunteers, and adults and children from tertiary referral centres in China. They suggest that the NaviCam has similar diagnostic accuracy to conventional gastroscopy for diagnosing GI conditions, and is better tolerated.
- **Key uncertainties** around the evidence are that none of the published studies were done in the UK, so results may not be generalisable to NHS settings; and that some of the evidence is in healthy volunteers which may not reflect clinical situations.
- The **list price** of the NaviCam is £175,000 for the console and £400 per single-use capsule (exclusive of VAT). The **resource impact** may be greater than conventional gastroscopy or

enteroscopy because of the high costs of the equipment. This may be offset by reduced staff numbers or if the NaviCam improves diagnostic accuracy or delivers additional patient benefits, such as increased tolerability and convenience.

The technology

The NaviCam (ANKON) is a miniaturised wireless endoscope in a single-use capsule, which is remotely controlled by magnetic guidance hardware. This includes a magnetic guidance robot, computer workstation and software. The magnetically controlled endoscopy system is indicated for the diagnosis of upper gastrointestinal (GI) tract and small bowel disease.

To use NaviCam, the person having the procedure must fast overnight then drink about 1 litre of water and take simethicone (a defoaming agent). This reduces gastric mucus and distends the stomach, improving visualisation. During the procedure, a portable data recorder is worn outside the body, which is secured to the skin using adhesive pads before the person swallows the NaviCam capsule. The small capsule (12 mm x 28 mm) is made up of a camera, an LED light source, a magnet, a wireless circuit for sending and receiving signals, and a small battery that can last for more than 8 hours.

The person lies on a fixed bed, which is part of the magnetic guidance robot. The robot guides the capsule through the upper GI tract (including the stomach). This can be done in automatic mode, or in manual mode using a joystick guided by the endoscopist. Images are taken at 2 frames per second and sent wirelessly to the portable data recorder. The images are transferred to a computer for a clinician to examine, and can be stored in NHS IT systems (such as primary and acute care systems [PACS]). Once the upper GI tract examination is finished, the person can leave the endoscopy suite, while still wearing the portable data recorder. Magnetic control is not needed to guide the capsule through the small bowel so the recording can continue while the person is at home or on a ward. The location of the capsule can also be identified at any time using a handheld detector. The video recording will continue for about 8 hours. The capsule is then passed in the person's stool and discarded.

The NaviCam is contraindicated in pregnancy and for people with pacemakers, implantable electronic devices or implanted metal parts (similar exemption criteria to MRI scans).

Innovations

The NaviCam is less invasive than conventional gastroscopy, needing no intubation or sedation. Unlike other magnetic or passive wireless capsule endoscopy systems, the NaviCam capsule can be controlled remotely and guided through the upper GI tract using a magnetic guidance robot. This is

designed to improve manoeuvrability in the stomach and small bowel, aiming to improve gastric mucosal examination.

Current NHS pathway

Conventional gastroscopy is a routine test for identifying abnormalities in the upper GI tract. The procedure is usually done as an outpatient day case and involves an endoscope being passed through the mouth to examine the oesophagus, stomach and proximal small bowel (duodenum). Conventional gastroscopy can be used for diagnostic or therapeutic purposes; although it does not reach the distal small bowel, it enables tissue sampling and endoscopic treatments of the proximal jejunum.

To examine the entire length of the small bowel, device-assisted enteroscopy techniques (such as balloon or spiral enteroscopy) or wireless capsule endoscopy systems can be used. Device-assisted enteroscopy can be used for diagnosis and also for therapeutic endoscopic procedures and biopsies, which are not possible with wireless capsule endoscopy. Wireless capsule endoscopy systems currently used in the NHS use capsules which are not under magnetic control. The 2013 [NHS Atlas of Variation in Diagnostic Services](#) reported a 29-fold variation in wireless capsule endoscopy procedure rates across England.

NICE's guidance on the [management of acute upper gastrointestinal bleeding](#) recommends that people with severe acute upper GI tract bleeding who are haemodynamically unstable have an endoscopy within 2 hours. Those who are haemodynamically stable should be given an endoscopy within 24 hours, but there are no recommendations about the type of endoscopy that should be used.

NICE's interventional procedures guidance on [wireless capsule endoscopy for investigation of the small bowel](#) states that evidence on safety and efficacy is adequate to support its use; but recommends that other investigations should be used in people with suspected strictures, such as those with Crohn's disease.

The European Society of Gastrointestinal Endoscopy guideline for [small bowel capsule endoscopy and device-assisted enteroscopy for the diagnosis and treatment of small bowel disorders](#) states that capsule endoscopy should be used as a first-line investigation in people with overt GI bleeding of unknown origin. In people with suspected Crohn's disease, it should only be used when there are negative ileocolonoscopy findings without obstructive symptoms or known stenosis. In people with suspected coeliac disease, capsule endoscopy is not recommended unless they are unwilling or unable to have conventional endoscopy. For the detection of small bowel tumours, it is only

recommended if there is unexplained overt GI bleeding and iron-deficiency anaemia. If imaging tests suggest a tumour may be present, device-assisted enteroscopy is preferred.

NICE is aware of the following CE-marked device that appears to fulfil a similar function as the NaviCam, but this uses a handheld portable magnet to control the capsule, rather than a guidance robot:

- [MiroCam MC1000-WM](#) (IntroMedic, Korea).

Population, setting and intended user

The NaviCam is designed for use in the diagnosis of upper GI tract and small bowel disease, for people presenting with upper GI tract bleeding, suspected malignant disease or other suspected gastric disorders, such as Crohn's disease.

The technology is likely to be used in specialist endoscopy centres by trained clinicians, such as gastroenterologists and nurse endoscopists. Although the initial upper GI tract examination under magnetic control will be done in an endoscopy suite, the remaining 8 hour small bowel examination can be done in the ward or at home.

Costs

Technology costs

The costs of the NaviCam are shown in table 1. The company has estimated the cost of using the NaviCam to be about the same as standard gastroscopy (£418 per patient). This estimate is based on theoretical assumptions that the system is used for 500 patients per year or about 6 to 8 patients each day, and that the technology has a lifespan of 20 years. These assumptions have not been tested, and may be overestimates.

Table 1 NaviCam technology costs (excluding VAT)

Description	Cost	Additional information
NaviCam System	£175,000	Includes magnetic guidance robot, bed, workstation, 1 portable wearable data recorder, 1 capsule position detector, and clinician training

Single-use NaviCam capsule	£400 each	
Simethicone for gastric preparation	Less than £0.10 per dose	
Maintenance costs	£2,500 per year	

Costs of standard care

The NHS tariff for reimbursement for a standard diagnostic endoscopic procedure of the upper GI tract is £416 for adults (aged 19 years and over) and £869 for children and young people (aged between 2 and 18 years). For wireless endoscopy, the tariff is £734 for adults and £1,019 for children ([NHS reference costs 2015–16](#)). Specialist commentators estimated the costs of a standard reusable gastroscopy system to be between £30,000 and £100,000. Other wireless endoscopy systems were estimated to cost about £7,000 with single-use capsules costing about £500 each, with a lifespan of 5 years.

Resource consequences

A space measuring 3 m x 4 m is needed to install the NaviCam guidance equipment and 1 trained clinician is needed to use the device. If adopted, there may be a reduced need for staff compared with conventional gastroscopy, because only 1 operator is needed and no sedation or intubation is needed. A specialist commentator stated that in comparison, standard gastroscopy needs 1 expert medical endoscopist and 2 nurse assistants. The company states about 10 days' training is needed to operate the device and interpret images: 2 operators' training is provided with each system.

The NaviCam procedure takes 25 to 40 minutes from the person swallowing the capsule to the test result for the upper GI tract examination. This is made up of 15 to 30 minutes for the procedure and 10 minutes to interpret the images.

The NaviCam is currently being used in 1 UK centre as part of a research study.

Regulatory information

The NaviCam was CE marked as a class IIa device in August 2014.

A search of the Medicines and Healthcare Products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The NaviCam is contraindicated in pregnancy and for people with pacemakers, implantable electronic devices or implanted metal parts (similar exemption criteria to MRI scans). The technology may not be suitable for people who are obese as the bed under the guidance robot allows a maximum weight of 135 kg.

Clinical and technical evidence

A literature search was done for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five studies are summarised in this briefing, involving 542 people in China; a pilot study in 34 healthy volunteers ([Liao et al. 2012](#)), a non-blinded comparative study in 68 patients ([Zou et al. 2015](#)), a multicentre comparative study in 350 patients ([Liao et al. 2016](#)), a feasibility study in 30 patients and 30 healthy volunteers ([Qian et al. 2016](#)), and a poster presentation of a feasibility study in 30 children ([Tang et al. 2016](#)). Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence for the NaviCam is limited in quantity, and includes 4 published studies and 1 poster. Because all the studies were done in China, and some studies included healthy volunteers, this may

limit their relevance to the NHS care pathway. Randomised studies comparing the NaviCam with conventional gastroscopy or wireless capsule endoscopy done in a UK setting would be useful to confirm equivalence for diagnostic accuracy and any effect on patient outcomes.

Table 2 Summary of selected studies

<u>Liao et al. 2016</u>	
Study size, design and location	<p>Single-blind (investigator), single-arm diagnostic accuracy study in 350 patients with upper gastrointestinal (GI) tract complaints.</p> <p>Done in 7 tertiary referral centres in China.</p> <p>Patients were examined with the NaviCam first, followed by gastroscopy 2 hours later. Primary outcomes: sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) to detect gastric focal lesions (positive result defined as polyp, ulcers, submucosal tumour or other [such as xanthoma, diverticulum]), using gastroscopy as the reference standard.</p>
Intervention and comparator(s)	<p>The NaviCam (gastroscopy as the reference standard), gastroscopy for assessing patient preference.</p>
Key outcomes	<p>The NaviCam detected focal lesions in the upper and lower stomach with comparable accuracy using conventional gastroscopy as the reference standard. The NaviCam detected gastric focal lesions in the whole stomach with 90.4% sensitivity, 94.7% specificity, a PPV of 87.9%, a NPV of 95.9% and 93.4% accuracy. The NaviCam was preferred by almost all patients (95.7%), compared with gastroscopy. The authors concluded that the NaviCam can be used to screen gastric diseases without sedation.</p>
Strengths and limitations	<p>Authors had no reported conflicts of interest. Gastroscopy was done without sedation. Subjects were unblinded and had concurrent procedures, but investigators were blinded to the results from different procedures. People with overt GI bleeding were excluded. Oesophagus and small bowel were not assessed.</p>
<u>Zou et al. 2015</u>	

<p>Study size, design and location</p>	<p>Single-blind (investigator blinded to results), single-arm diagnostic accuracy study in 68 patients.</p> <p>Done in 2 tertiary centres in China.</p> <p>Patients were examined with the NaviCam first, followed by conventional gastroscopy 4 to 24 hours later. Primary outcome: degree of agreement between the NaviCam and gastroscopy for the diagnosis of gastric lesions.</p>
<p>Intervention and comparator(s)</p>	<p>The NaviCam Olympus gastroscopy.</p>
<p>Key outcomes</p>	<p>The NaviCam showed a diagnostic accuracy similar to standard gastroscopy: the positive percent agreement was 96.0%, and the negative percent agreement was 77.8%. The overall agreement was 91.2% with a κ value of 0.765 ($p < 0.001$). A total of 68 pathological findings were detected, of which 53 were identified by both methods. The NaviCam and gastroscopy missed 7 and 8 findings respectively.</p> <p>The NaviCam procedure time was longer than gastroscopy: 29.1 ± 8.5 minutes (range 8 to 53 minutes) compared with 5.0 ± 1.0 minutes (range 3.0 to 7.2 minutes) for gastroscopy ($p < 0.001$).</p> <p>There were 2 cases of temporary abdominal pain and 1 case of chronic diarrhoea with the NaviCam.</p>
<p>Strengths and limitations</p>	<p>No reported conflicts of interest. Subjects were unblinded and had concurrent procedures, but investigators were blinded.</p>
<p><u>Liao et al. 2012</u></p>	
<p>Study size, design and location</p>	<p>Feasibility and safety study in 34 healthy volunteers.</p> <p>Done at a single centre in China.</p> <p>Subjects were examined with NaviCam and were followed up for 14 days. Endpoints included adverse events, patient tolerability, overall manoeuvrability and visualisation of the gastric mucosa.</p>
<p>Intervention and comparator(s)</p>	<p>The NaviCam.</p>

Key outcomes	<p>The procedure took 43.8±10.0 minutes (range 27 to 60 minutes). Manoeuvrability was graded as good in 29 (85.3%) people and moderate in 5 (14.7%) people. More than 75% gastric mucosa was visualised in 27 (79.4%) people and 50% to 75% in 7 (20.6%) people. Visualisation of the gastric cardia, fundus, body, angulus, antrum and pylorus was subjectively assessed as complete in 82.4%, 85.3%, 100.0%, 100.0%, 100.0% and 100.0% respectively. Gastric preparation and examination was well tolerated and there were no adverse events.</p> <p>The authors concluded that the NaviCam used for examination of the stomach is feasible and safe.</p>
Strengths and limitations	Single-arm study in a small number of healthy people, not the indicated population.
<u>Tang et al. 2016</u>	
Study size, design and location	<p>Feasibility study in 30 children (aged 7 to 16 years). Done at a single centre in China.</p>
Intervention and comparator(s)	The NaviCam.
Key outcomes	No adverse events were reported. 4 children failed to swallow the capsule, but it was successfully delivered using a transparent hood-assisted endoscopic device applied to the top of the oesophagus. The authors concluded that the NaviCam is feasible and safe for the diagnosis of suspected gastric disease in children.
Strengths and limitations	Small feasibility single-centre study in children with no comparator. The authors' conflicts of interest are unknown. Poster presentation only.
<u>Qian et al. 2016</u>	
Study size, design and location	<p>Feasibility study in 30 healthy volunteers and 30 patients with GI complaints. Done at a single centre, China.</p> <p>Attempts to optimise the NaviCam visualisation by changing body position: patients were asked to adopt 5 body positions (left lateral, supine, right lateral, knee-chest, and sitting). In each position, the ability to visualise 6 gastric landmarks (cardia, fundus, body, angulus, antrum, and pylorus) was assessed.</p>

Intervention and comparator(s)	The NaviCam.
Key outcomes	A 5-position combination improved visualisation of gastric landmarks compared to the conventional 3-position combination (93.3%, $p < 0.001$). Supine position was the best for cardia and body visualisation (91.7% and 86.7% respectively, $p < 0.001$). Left lateral position was the best for fundus visualisation (91.7%, $p < 0.001$). Knee-chest position was the best for angulus observation (80.0%, $p < 0.001$). Right lateral and sitting positions were the best for antrum observation (88.3% and 90.0% respectively, $p < 0.001$). Right lateral position was the best for pylorus observation (81.7%, $p < 0.001$).
Strengths and limitations	Single-arm feasibility study. Adoption of all positions may not be possible by patients in clinical practice (for example older or very young people).
Abbreviations: N/PPV, negative/positive predictive value; GI, gastrointestinal.	

Recent and ongoing studies

- [The effectiveness of NaviCam magnetron capsule endoscopy in gastric lesions follow-up crowd: A multi-centre, self-controlled clinical trial](#). International Clinical Trials Registry identifier: ChiCTR-ODB-15007598. Status: recruiting. Location: China. Indication: gastric mucosal lesions. Devices: NaviCam, conventional gastroscopy.
- [Remote-controlled Capsule Endoscopy: a Feasibility Study](#). Clinicaltrials.gov identifier: NCT01946633. Status: unknown. Location: China. Indication: upper abdominal symptoms. Devices: NaviCam, conventional gastroscopy.
- [Gastric Capsule Examination for Iron Deficiency Anaemia](#). Clinicaltrials.gov identifier: NCT02282553. Status: recruiting. Location: UK. Indication: iron-deficiency anaemia. Devices: MiroCam Navi, NaviCam, conventional gastroscopy.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Four specialist commentators provided comments. One had used the NaviCam device as part of a research trial and 3 were familiar with the technology.

Level of innovation

Specialist commentators had mixed opinions on the novelty of the NaviCam. One commentator felt it was thoroughly novel, 1 thought it was a significant modification, whereas 2 thought it a minor variation of existing technology.

The MiroCam Navi was identified as a similar technology. It uses a handheld magnetic paddle that is operator-dependent, instead of a magnetic robot. One commentator stated that the MiroCam Navi handheld magnet allows some control, but the magnet is too weak to hold the capsule stationary against peristalsis. The NaviCam's robot magnet allows more control, which they felt was a significant advance. Another commentator stated that the results with MiroCam Navi and NaviCam were similar and that both technologies need further modifications to show their usefulness before they can replace gastroscopy.

One commentator stated the NaviCam allows the operator to steer the capsule, which could expand the indication of capsule endoscopy from the small bowel to the stomach and colon. A second commentator stated the NaviCam is a variation of the PillCam, but with real-time viewing; although another commentator stated the PillCam is not designed to image the upper GI tract. A third commentator thought that it allows upper GI tract and potentially small bowel endoscopy to be done 'all in one go' for people who cannot tolerate or are unwilling to have conventional gastroscopy.

Potential patient impact

Three commentators highlighted that the NaviCam is much less invasive and better tolerated than conventional gastroscopy. One commentator thought the NaviCam could improve the investigation of dyspepsia (upper abdominal discomfort or pain, including heartburn) and anaemia, because it is a simple, well tolerated, low risk procedure. In comparison, conventional upper GI tract endoscopy is uncomfortable, unpopular with patients and carries the small risks associated with intubation and sedation. This commentator highlighted that 2% of the population per year have a gastroscopy, but malignancy is found in less than 1%. If a patient-acceptable procedure could be done in the community to select the small proportion of people who need to go to hospital for gastroscopy (often with sedation) to have biopsy or therapy, this would be a major advance. Another commentator stated this technology could be useful in screening.

One commentator highlighted that this technology may be of particular benefit to people who are older or frail.

One commentator stated that the NaviCam would allow visualisation of the whole of the small bowel, as well as the oesophagus, stomach and duodenum. This commentator also stated there was no irradiation with the NaviCam compared with barium contrast studies.

One commentator thought there was no additional benefit compared with current technology, except that diagnosis may be able to be done on the same day as doing the procedure.

Potential system impact

Commentators thought that the NaviCam could replace standard gastroscopy as a diagnostic test, but not for therapy or biopsy, if it was shown that it was as accurate as other procedures.

One commentator thought the NaviCam could reduce costs by avoiding unnecessary biopsies and reducing the number of people with dyspepsia referred to secondary care for conventional endoscopy and biopsy. This commentator also thought the resource impact with the NaviCam could be less than standard gastroscopy as fewer trained staff are needed. One commentator stated that although there was a significant cost associated with the capsule, increasing its use could reduce costs if it replaced gastroscopy to any degree.

Two commentators stated the time needed to get images may be a limitation of the technology. One thought the NaviCam's real-time imaging may mean longer procedure times and another stated that conventional gastroscopy was quick in comparison. One commentator raised concerns that small bowel imaging may not be sufficient and a repeat endoscopy (with or without biopsy) may still be needed, however this is the case for all capsule procedures.

All commentators stated that special training would be needed to use the equipment and interpret images. One commentator highlighted that it takes between 1 and 2 years for a trainee to become competent in gastroscopy.

Two commentators stated that the NaviCam procedure could potentially be done in the community or primary care, in the same way as ultrasound scans. One commentator thought that access to a specialist endoscopy unit would still be needed for practitioner support.

General comments

Three commentators thought that evidence for the NaviCam was limited and more studies were needed to show any benefits. One commentator did not feel it was clinically valid for the NaviCam to replace gastroscopy, because the current studies do not show evidence of oesophageal and duodenal examination, and these are essential parts of routine gastroscopy examinations. Another commentator highlighted that the technology was in early development and large scale studies were needed to validate its use in the upper GI tract, and the feasibility of capsule control in the proximal small bowel. One commentator stated that more studies with the NaviCam are needed to improve visualisation of the whole upper GI tract and more randomised controlled studies are needed before it can be used for symptomatic patients.

Safety concerns with the NaviCam raised by commentators included its use in pregnancy (although the manufacturer has stated that this is a contraindication), the need for training in the event of complications (capsule inhalation or retention) and the need for pressure relieving equipment to prevent pressure sores while lying on the bed. Commentators also stated that the NaviCam may not be suitable for people with swallowing problems (including infants), GI strictures or pacemakers. One commentator raised concerns that the NaviCam procedure means the person has to drink a large amount of water, which may be a problem for some people. The person may need to change position, which may not be possible in older, frail people. Another commentator raised concerns about how the capsule would be removed if an oesophageal stricture was found.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Mark McAlindon, Consultant Gastroenterologist, Sheffield Teaching Hospitals. Received research funding from ANKON Technologies and financial support for a training course from Diagmed Healthcare, the UK distributors for PillCam. Received travel and accommodation funding to attend conferences from Given Imaging. Shareholder in Capsule Reader, a company that provides services for capsule endoscopy video reading.
- Dr Anastasios Koulaouzidis, Associate Specialist and Clinical Lead of capsule endoscopy service, Royal Infirmary of Edinburgh. Received research funding from SynMedUK (distributor of IntroMedic), Given Imaging and equipment support from Aquilant/OMOM.
- Ms Joanne Coyle, IBD/Nutrition Support and Capsule Endoscopy Clinical Nurse Specialist, George Eliot Hospital Nuneaton. No conflicts of interest declared.

- Dr Praful Patel, Consultant Gastroenterologist, University Hospital Southampton NHS Foundation Trust. Involved in completed studies with the MiroCam Navi device, but no funding received.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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