NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of wireless capsule endoscopy

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2004.

Procedure name

- Wireless capsule endoscopy.
- Video capsule endocscopy.

Specialty societies

- British Society of Interventional Radiology.
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland.
- British Society of Gastroenterology.

Description

Indications

Gastrointestinal bleeding and suspected Crohn's disease

Obscure gastro-intestinal bleeding is defined as bleeding of unknown origin that persists or recurs after a negative initial or primary endoscopy (colonoscopy and/or upper endoscopy). Diagnosis may be difficult because often bleeding can be slow and/or intermittent. Patients may experience prolonged blood loss, leading to iron deficiency (anaemia) and a feeling of fatigue and or weariness.

A common source of gastrointestinal bleeding is the small intestine. This can result from several causes. The most common of these causes include vascular lesions (angioplasia), small bowel tumours, coeliac disease and Crohn's disease.

Crohn's disease is a chronic inflammatory disease of the intestine. It primarily causes ulceration (breaks in the lining) of the small and large intestines, but can affect the digestive system anywhere from the mouth to the anus. Common symptoms of Crohn's disease include abdominal pain, diarrhoea, and weight loss.

Current diagnostic tests and alternatives

The small bowel is the most likely source of blood loss in patients with obscure gastrointestinal bleeding. It is considered to be one of the most difficult sections of the gastrointestinal tract to examine because of its length and complicated configuration. There are several methods for the endoscopic evaluation of the small intestine, including push enteroscopy (a long tube which has a small video camera attached), intraoperative endoscopy and small bowel follow through. Push enteroscopy is the most commonly used of these methods because it is less invasive and has a relatively high diagnostic yield, although it is does not examine the whole bowel. For most of these methods the diagnostic accuracy (ability to correctly diagnose both positive and negative disease) is poor.

Crohn's disease may be suspected in patients who have had diarrhoea, abdominal pains and weight loss for an extended period of time. Small-bowel follow through (where the patient is required to drink barium and then have x-ray pictures taken of their abdomen at timed intervals) is the most commonly used diagnostic procedure and may be used to define the distribution, nature, and severity of the disease. Other tests include stool tests, blood tests, sigmoidoscopy (investigation of the lower bowel with a tube and light) and colonoscopy (investigation of the colon with a fibre optic telescope).

What the procedure involves

The patient swallows a small capsule, usually after an overnight fast. This capsule consists of a camera, a light source and a wireless circuit for the acquisition and transmission of signals. A small battery, which can last up to 8 hours, powers the capsule.

As the capsule moves trough the gastrointestinal tract, images are transmitted by the digital radiofrequency communication channel to a data recorder, worn on a belt outside the body. This data are transferred to a computer for interpretation. The capsule is then passed in the patient’s stool and discarded.

This procedure allows for the end-to-end exploration of the small bowel. However if a patient has a motility disorder or stricture this may preclude successful investigation.

Efficacy

Obscure gastrointestinal bleeding

The published evidence suggests that wireless capsule endoscopy can detect a bleeding source in 31–76% of patients with obscure gastrointestinal bleeding. In all studies, wireless capsule endoscopy had a higher diagnostic yield (proportion of patients identified with a lesion) than the comparator test. However, in most cases patients had undergone extensive prior investigations, which is likely to decrease the diagnostic yield for the comparator procedures. It is also not possible to determine the relative diagnostic performance (ability to correctly diagnose both positive and negative disease) of wireless capsule endoscopy compared with alternative conventional diagnostic tests. Several studies reported that capsule endoscopy

findings had changed patient management, but limited details were given as to whether change in management improved health outcomes.

Suspected Crohn's disease

The evidence indicates that wireless capsule endoscopy identifies small bowel lesions suggestive of Crohn's disease in 43–71% (9/21–12/17) patients with normal findings on conventional tests. Three studies reported that capsule endoscopy findings had changed patient management, with two studies reporting clinical improvement in 83–100% (10/12–9/9) of patients.

The available evidence, however, is not of sufficient quantity and quality to determine the relative diagnostic performance of wireless capsule endoscopy compared with alternative conventional diagnostic tests in diagnosing unselected patients with suspected Crohn's disease.

The Specialist Advisors noted a lack of comparative data in relation to existing technology. They also considered that the main indication for the procedure and its place in the diagnostic work-up of patients was still to be defined.

Safety

Obscure gastrointestinal bleeding/suspected Crohn's disease

No significant complications were reported in the studies. The most commonly reported adverse events associated with the procedure were abdominal pain, nausea, and vomiting. Delayed passage of the capsule was also reported in a number of studies and in the majority of cases was resolved without incident. In a study of 200 patients done to assess the complications associated with the use of capsule endoscopy, 6 (3%) patients had complications associated with the procedure. This included 1 patient who was unable to swallow the capsule, 1 patient who inadvertently aspirated the capsule and 2 patients who experienced delayed passage and had to have surgery to remove the capsule.

The Specialist Advisors considered that this was a safe procedure. They felt that the most likely adverse event was that the capsule might become lodged in narrowed areas of the small bowel, causing bowel obstruction. One Advisor commented that this complication was more likely in patients with suspected Crohn's disease rather than obscure gastrointestinal bleeding.

Literature reviews

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to wireless capsule endoscopy. Searches were conducted using the following databases: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index, and covered the period from their commencement to February 2003. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion and exclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good-quality published studies that reported on the diagnostic performance of the procedure. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study.
Patient	Patients with obscure gastrointestinal bleeding. Patients with suspected Crohn's disease.
Intervention/test	Wireless capsule endoscopy.
Outcome	Studies were required to report at least one of the following: diagnostic yield, diagnostic performance, effect on patient management, or effect on health outcomes for wireless capsule endoscopy in relation to diagnostic alternatives. Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

The evidence on wireless capsule endoscopy in patients with obscure gastrointestinal bleeding is based on a systematic review (health technology assessment) [1] and five studies published after the literature search date of the systematic review. [2-6]

The evidence on wireless capsule endoscopy in patients with suspected Crohn's disease in based on five studies. [7-11]

An additional three studies were included for the purpose of addressing complications associated with wireless capsule endoscopy. [12-14]

Existing reviews of the procedure

Three health technology assessment reports were identified relevant to this topic.

- Medical Services Advisory Committee *Wireless capsule endoscopy for patients with obscure digestive tract bleeding* (literature search date: October 2002, March 2003).
- Blue Cross Blue Shield Association *Wireless capsule endoscopy for obscure digestive tract bleeding* (literature search date:July 2002).
- Blue Cross Blue Shield Association *Wireless capsule endoscopy for small-bowel diseases other than obscure GI* bleeding (Literature search date: November 2003).

The findings of these reports are outlined in Appendix B.

Table 2 Summary of key efficacy and safety findings for obscure gastrointestinal bleeding

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
MSAC report (2003) [1] Systematic review Literature search date: October 2002 and March 2003 (Medline) **Comparative studies** (n = number of patients receiving capsule) • Costamagnata et al (2002)[15] 13 patients • Ell et al (2002)[16] 32 patients • Florent et al (2003)[17] 59 patients • Hartmann et al (2003)[18] 33 patients • Lewis & Swain (2002)[19] 21 patients • Selby and Desmond 2003[20] 40 patients **Abstracts – efficacy and safety** Gonzalez-Asanza et al (2002) 12 patients Lim et al (2003) [21] 29 patients Mylonaki et al (2002) [22] 38 patients **Abstracts – efficacy only** Demedts et al (2002) [23] 18 patients Hartmann et al (2003) [24] 21 patients Neu er al (2003) [25] 52 patients Nietsch et al [26] 27 patients Pennazio et al (2002) [27] 45 patients Toth et al (2003) [28] 28 patients Van Gossum et al (2002) [29] 21 patients **Non-comparative studies** – only reviewed for safety.	SBS PE PE PE PE PE PE PE PE PE Intraoperative PE PE PE PE PE	Diagnostic yield (percentage definite diagnosis) **Study** / **n** / **CE Definite** / **Comparator Definite** Costamagnata 13 31% 5% Ell 32 66 % 28 % Florent 59 56% 32% Hartmann 33 76% 21% Lewis & Swain 21 55 % 40% Selby & Desmond 73 73% 28% Gonzalez-Asanza 12 75% 56% Lim 29 72 % 34% Mylonaki 38 55% 33% Demedts 18 78% 56% Hartmann 21 81 % 81% Neu 52 71 % 29 % Nietsch 27 63 % 27 % Pennazio 45 73 % 42 % Toth 28 46 % 21 % Van Gossum 21 62 % 76 % Bayesian analysis results Diagnostic Test Capsule endoscopy / Small bowel series *Main analyses* Diagnostic yield 0.58 0.035 95% Credibility Interval 0.463-0.677 0.005-0 .120 Odds Ratio 37.3 37.3 95% Credibility Interval 9.43-270.97 9.43-270.97	**Adverse events** **Comparative data** (In 9 studies) No adverse events were reported in 7 studies 2 studies reported: • 5/59 patients – bleeding abdominal pain; abdominal pain with nausea; abdominal pain with nausea and vomiting • 2/41 patients – mild abdominal pain; death due to coronary occlusion. **Non-comparative data** (In 15 studies authors made comment on adverse events) No adverse events were reported in 9 studies 6 studies reported: • 1/1 capsule lodged in circopharyngeus • 2/35 mild abdominal pain • 1/4 abdominal pain • 1/259 obstructive symptoms • 1/1 capsule lodged in bronchus • 1/1 gastrointestinal	Systematic review provided an indirect comparison, that is, small bowel series versus push enteroscopy. Small bowel series was determined to be the main comparator. Studies varied in their definition of a positive diagnosis. Sensitivity analysis includes abstracts and unpublished studies. Trials with 10 or fewer patients were excluded from the efficacy evaluation. However, adverse events and safety outcome data from such trials were included. Trials were excluded where there was inadequate

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Fleischer et al (2003) [30] 1 patient Gay et al (2002) [31] 1 patient Hahne et al (2002) [32] 1 patient Hartmann et al (2003) 48 patients Hollerback er al (2003) [33] 2 patients Jonnalagadda and Prakash (2003) [34] 3 patients Mylonki et al (2002) [35] 1 patient Scapa et al (2002) [36] 35 patients Scapa et al (2002) [37] 1 patient Smith (2002) [38] 19 patients **Abstracts –safety only** The systematic review lists more than 60 abstracts reviewed for safety (for more detail see Appendix C of the Systematic Review) **Incomplete studies** CEDIT (2003)		Capsule endoscopy Small bowel series *Sensitivity analyses* Diagnostic yield 0.64 0.039 95% Credibility Interval 0.576-0 .698 0.006-0 .137 Odds Ratio 42.9 42.9 95% Credibility Interval 10.98-317.35 10.98-317.35 Change in management and health outcomes Limited information	obstruction **Delayed passage** 20 studies reported cases of delayed passage of the capsule endoscopy	separation of results on the basis of the patient population.
Pennazio et al (2004) [2] 100 consecutive patients January 2001 – March 2002 • 26 patients with ongoing obscure-overt bleeding • 31 patients with previous obscure-overt bleeding • 43 patients with obscure occult bleeding Push enteroscopy (PE) was performed in 51 patients shortly before or after capsule imaging. Mean age: 63 years (range 18–88 years)	PE (before and after capsule)	**Outcomes reported:** diagnostic yield, diagnostic accuracy, therapeutic management **Capsule** n = 100 Positive findings in 47 patients (47%; 95% CI 37–57%) Suspicious in 15 patients (15%; 95% CI 8–21%) Negative in 38 patients (38%; 95% CI 28–47%) **Diagnostic yield** n = 100 ongoing obscure-overt bleeding (92.3%; 95% CI 82–100%) previous obscure-overt bleeding (12.9%; 95% CI 1.2–25%) obscure occult bleeding (44.1%; 95% CI 29–59%) Capsule endoscopy found the source of bleeding in 18/36 patients with a negative push enteroscopy.	**Complications:** 5 (5%) patients had non-natural excretion of the capsule	Looks as though published results of [27] Diagnostic yield: defined as the frequency of detection of clinically relevant lesion. Sensitivity and specificity defined as: *True positive* – verification of capsule endoscopy by surgery, endoscopy or other alternative means (such as angiography).

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Median length of bleeding: 1– 195 months Patients had undergone a total of 620 diagnostic tests. Mean follow up: 18 months (range 5–25 moths) Follow up available on • 23 patients with ongoing obscure-overt bleeding • 29 patients with previous obscure-overt bleeding • 39 patients with obscure occult bleeding Follow up data not available for 9 patients		**Push enteroscopy n = 51** Identified bleeding source in 15 patients (29% 95% CI 23–36%) – 3 were not detected by capsule endoscopy **Combined findings** *Diagnostic yield* for the two techniques was 67% (33/51 patients) 95% CI: 54–80%. Lesions were identified by both techniques in 12 patients • by capsule endoscopy only in 18 patients • by push enteroscopy only in 3 patients *Diagnostic accuracy* 62 patients underwent further investigations with a final diagnosis in 56 patients. • 36 had positive diagnosis • 20 had negative diagnosis Capsule positive 32/36 patients (sensitivity of 88.9%) Capsule negative in 19/20 patients (specificity 95%) Positive predictive value was 97% Negative predictive value was 82.6% Overall accuracy was 91.1% False positives were in patients with previous obscure and occult bleeding *Therapeutic management* Capsule findings lead to changes in 86.9% of patients with ongoing obscure-overt bleeding and 69.2% and 41.4% of patients with previous obscure-overt bleeding or obscure occult bleeding respectively		*True negative* – negative capsule study and bleeding resolved with no further treatment. *False positive* – positive capsule study with a different lesion found on subsequent workup. *False negative* – negative capsule study with lesion diagnosed by other means. Can't really compare findings of capsule with PE because of timing. Greater proportion of patients with ongoing obscure bleeding underwent further investigations. Diagnostic accuracy based on only a small number of patients. 'Independent verification' not available for all patients.

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Saurin et al (2003) [3] 60 patients • 32 patients with occult obscure bleeding • 28 patients with overt obscure bleeding All patients had obscure digestive bleeding To be included patients had to have undergone at least one complete set of endoscopic examinations of the digestive tract the results of which were negative Mean age: 58 years (range 21–79 years) Mean duration of symptoms: 24.8 months. Follow up: not stated	PE (performed within 3 days)	**Outcomes reported**: diagnostic yield Lesions were classified into three categories P2 – high potential for bleeding P1 – uncertain hemorrhagic potential P0 – no potential for bleeding 15 patients had normal findings from capsule and push enteroscopy **Diagnosis** / **CE+/ PE+** / **CE+/ PE-** / **CE -/ PE+** / **Total** Anglomata 11 6 2 19 Mucosal red spots 2 10 1 13 Ulcerations 3 3 - 6 Erosions 1 1 - 2 Tumours 1 1 - 2 Intestinal varices 1 - - 1 Total 19 21 3 43 **Diagnostic yield** The additional diagnostic value of capsule enteroscopy was 36.2% (21/58) when looking at PI and P2 lesions and 17.2% (10/58) when just looking at P2 lesions. Increase in diagnostic yield was statistically significant p = 0.0396. Diagnostic yield capsule = 40/58 (69.0%) Diagnostic yield enteroscopy = 22/58 (37.9%)	**Complications**: Authors stated that no complication was observed during the study with either type of enteroscopy	Looks as though published results of [17] Patients were described as consecutive. Push enteroscopy carried out by an independent operator blinded to results. 2 patients capsule enteroscopy recordings could not be analysed. Lesions classified as PO and those outside the small intestine are not taken into account. Concordance between observers appeared to be good in patients with obvious bleeding and in negative studies – however in patients with less clinically relevant lesions the concordance decreased.

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Mylonaki et al (2003) [4] UK 52 patients (50 patients evaluable) • 11 patients with overt bleeding • 39 patients with occult bleeding In two patients data could not be analysed – these patients are not included in the analysis. To be included patients had to have a gastroscopy and colonoscopy which was negative. Number of investigations: 8 (3–17) Median age: 50.3 years (range 17–80 years) Median duration of bleeding: 4.2 years (0.5–20 years) Follow up: 2 weeks	PE (two weeks after capsule endoscopy)	**Outcomes reported:** diagnostic yield, therapeutic impact and patient satisfaction. **Diagnostic yield** *Capsule*: Identified a bleeding source in the small intestine in 34/50 patients (68%). Including diagnosis outside the small intestine 38/50 patients (76%) All gastric abnormalities were confirmed at subsequent push enteroscopy; the colonic abnormalities were confirmed and treated at subsequent colonoscopy *Push enteroscopy:* Identified a bleeding sources in the small bowel in 16/50 patients (32%) Following a second enteroscopy another source and including additional extraintestinal diagnoses diagnostic yield was 19/50 (38%) Wireless capsule endoscopy was significantly superior to push enteroscopy in the identification of bleeding sources $p < 0.05$ (both taking into account small intestine results and all results) **Therapeutic impact:** (denominator those with positive findings) Authors note that wireless capsule endoscopy led to alteration in therapy in 25/38 patients. Seven patients had surgery **Satisfaction** • 49/50 patients said they found the capsule preferable to push enteroscopy • 2/50 found the capsule to be uncomfortable but only at the time of swallowing • 34/50 found push enteroscopy to be painful	Complications: 1 patient delayed passage Other technical problems such as battery power expiring.	Results were reviewed by independent and blinded endoscopist. Not reported how patients had positive CE findings and positive PE findings. Unclear what a successful result means. In 2/38 patients there was disagreement on interpretation as to the source of the bleeding. Fourteen volunteers were also examined to acquire information n the normal appearance of the small bowel.

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Buchman et al (2003) [5] USA 20 patients with obscure bleeding • 9 men mean age: 54.8 years • 11 women mean age: 65.6 years Patients had been hospitalised on at least 1 occasion for gastrointestinal bleeding All had at least 1 negative esophogastroduodenoscopy (EDG), 1 negative colonoscopy and 1 negative small bowel barium contrast study Follow up: 1 week (unclear)	PE (1 week after capsule)	**Outcomes reported:** diagnostic yield, therapeutic impact **Diagnostic yield** *Capsule:* 12/20 (60%) patients had bleeding source successfully identified Normal findings were present in 7/20 patients and 1 patient had a poor prep *Push enteroscopy:* 7 patients refused enteroscopy. 4/7 patients that refused enteroscopy had normal capsule results 2/13 (15%) patients had bleeding source successfully identified by push enteroscopy Capsule found a bleeding source in 9/13 patients (p = 0.02) (unclear if this includes 2 patients identified by push enteroscopy) **Therapeutic impact** Capsule lead to successful surgical resection in 3 patients	**Complications** Capsule passed naturally by all subjects	Authors note patients were consecutive. Results read by an independent and blinded endoscopist. Unclear what is means by 'successful' in determining a bleeding source. Authors also note that they have examined an additional 16 patients using capsule endoscopy. Refusals in the push enteroscopy group means that results are based on small numbers.
Hara et al (2004) [6] USA Retrospective study September 2001– April 2002 52 patients (42 met the inclusion criteria unclear which patients) • 43 patients obscure gastrointestinal bleeding • 8 patients inflammatory bowel disease	Small bowel radiography (40 examinations) CT (19 examinations) Patients had to have undergone tests within 6 months of capsule	**Outcomes reported:** diagnostic yield, therapeutic impact **Diagnostic yield**: **capsule versus small bowel** *Capsule:* 19/40 (47.5%) patients had bleeding source identified Negative findings were present in 21/40 patients *Small bowel examination:* 1/40 (2.5%) patients had bleeding source identified Negative findings were present in 39/40 patients **Diagnostic yield**: c**apsule versus CT** *Capsule:* 12/19 (63%) patients had bleeding source identified		Demographic data presented on the 52 patients not the 42 patients. When available, image tests and capsule endoscopy results were also compared with endoscopy, surgical and biopsy results. Results were not reviewed

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
• 1 patient with chronic abdominal pain 33 patients were from one study institution 9 patients were from other institutions 31 patiens were men, mean age 64 years 21 were women, mean age 63 years Patients without a history of small bowel stricture or with a barium study negative for a stricture underwent capsule endoscopy	endoscopy	Negative findings were present in 7/19 patients *CT:* 4/19 (21%) patients had bleeding source identified Normal findings were present in 15/19 Surgical results available on some patients. Difficult to ascertain false positives and false negatives		blinded. 6 examinations were performed more than 3 months from capsule endoscopy. Heterogeneous group of patients.

Table 3 Summary of key efficacy and safety findings for patients with suspected Crohn's disease

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBFT – small bowel follow through; SBS – small bowel series

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Eliakim (2003) [7] 20 consecutive patients Patients had recurrent abdominal pain and/or chronic diarrhoea with or without weight loss Mean age was 30.8 years (20–57 years) Mean duration of symptoms: 8 months Follow up: not stated	Barium follow-through Entero-CT	**Outcomes reported**: diagnostic yield. **Diagnostic yield** *Capsule:* 'findings were medically significant' 14/20 patients Diagnostic yield = 70% *Comparative procedures* (barium/CT) Found abnormalities in 10/20 patients, and 'medically significant' in 7/20 patients. Diagnostic yield = 35% Colonsoscopy and ileoscopy with biopsy confirmed the capsule's findings in 8 patients in which there were controversial results between procedures	**Complications** Authors report no side effects during or after the procedure	Blinded interpretation. All three procedures were completed within 3 months. Noted that colonoscopy and ileoscopy was undertaken in most cases in which there was a discrepancy between tests. Patients had gone through 48 procedures before entry to this study. Unclear how many patients had 'controversial results'.
Fireman (2003) [8] 17 patients suspected Crohn's disease (originally 18; 1 patient was excluded) August 2000–December 2001 All patients had clinical symptoms Mean age: 40 (range 18–68 years) Mean duration of symptoms: 6.3 years Follow up: 4 months (1–8 months)	None	**Outcomes reported**: diagnostic yield, therapeutic management **Diagnostic yield**: 12/17 patients (70.6%) were diagnosed with suspected Crohn's disease 5/17 patients were assessed as having normal looking bowel **Therapeutic management:** 12 patients received medication for Crohn's disease. 10/12 patients showed good clinical improvement	**Complications** All capsules were passed without intervention	Six months prior to entry all patients had undergone conventional investigations – all revealing a normal bowel. (15/17 total colonoscopy; 16/17 oesophageal gastroduodenoscopy; 7/17 abdominal CT scans.) Not stated as consecutive. Two independent examiners blinded to clinical data.

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBFT – small bowel follow through; SBS – small bowel series

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Harrerias et al (2003) [9] 21 patients Patients presented with symptoms of Crohn's disease Mean age: 43 years Duration of symptoms: more than 6 months Follow up: unclear – 3 months?	None	**Outcomes reported**: diagnostic yield **Diagnostic yield:** 9/21 patients (43%) had 'medically significant' findings **Therapeutic management:** 9 patients received medication following diagnosis. All of the patients are in clinical remission at time of writing	**Complications** Authors note that there were no adverse effects caused by the technique	Conventional and radiological techniques had not identified pathological findings.
Chong (2003) [10] 9 patients – 7 patients known/ 2 suspected Crohn's disease (from a population of 60 consecutive patients) 4 July 2001 – 8 September 2002 Patients were required to have a small bowel barium study to exclude strictures Follow up: not stated	None	**Outcomes reported**: diagnostic yield, therapeutic management **Diagnostic yield:** 7/9 patients (78%) had findings that were medically significant 2 patients (1 with known and 1 with suspected Crohn's) had normal findings **Therapeutic management** : 5/9 patients had change of management 2 patients were lost to follow up; 2 patients had no change (including one patient with known Crohn's who had normal capsule findings)	**Complications** 1/60 patients had retention of the capsule	No comparator. Suspicion of Crohn's disease was based on a combination of clinical features. Capsule findings were reviewed by two gastroenterologists. Positive findings 'detected abdominalities that were potentially related to the presenting problem'. Limited information.

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBFT – small bowel follow through; SBS – small bowel series

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Bloom et al (2003) [11] 16 patients known or suspected Crohn's' disease without stricture	Small bowel follow through Ileoscopy (performed within a 6 week period prior to capsule)	**Outcomes:** diagnostic yield **Diagnostic yield:** 9/16 (56%) had small bowel findings diagnostic of Crohn's disease Proximal small bowel lesions seen in 7/16 (44%) 3/16 (19%) had SBFT findings diagnostic of Crohn's disease 7/16 (44%) has ileoscopy findings diagnostic of Crohn's disease No proximal lesions were identified by SBFT or ileoscopy	**Complications** Authors report no complications occurred.	Abstract. Limited information.

Table 4 Additional safety data for wireless capsule endoscopy

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series; SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Hutchinson et al (2003) [12] 200 patients 112 male, 88 female Indications included: • anemia 171 patients • evaluation of inflammatory bowel disease 16 patients • evaluation of malabsorption 13 patients Mean age 52 years (range 18–73 years)	None	None	**Complications** 6 patients (3%) had complications associated with the procedure • 1 patient was unable to swallow the capsule • 2 patients had battery failure • 1 patient aspirated the capsule into the trachea • 2 patients with bowel obstruction (one patient had strictures) – both patients underwent laporotomy for removal	Abstract. Limited information.
Barkin et al (2002) [13] 937 patients Patients are those included in capsule studies at different centres	None	None	**Complications** 7 patients (0.75%) required intervention for capsule removal • 6 patients for obstruction/stricture • 1 patient for bleeding ulcer All patients had resolution of their symptoms Non-natural passage revealed unsuspected pathology in 7 patients, which had not be revealed by other studies including small bowel	Abstract. Limited information. Only reports on the incidence and clinical features of those patients in whom the capsule become lodged in the small bowel and required removal – it does not report on delayed passage.

Abbreviations used: CE – capsule endoscopy; PE – push enteroscopy; SBS – small bowel series; SBFT – small bowel follow through

Study details	Comparator	Key efficacy findings	Key safety findings	Comments
Smith et al (2002) [14] October 2001–June 2002 71 patients (75 examinations): 33 women, 38 men Mean age was 63 years (range 27–87 years) Indications included: • Obscure GI bleeding 64 patients • abdominal pain 6 patients • suspected small bowel tumour in 1 patient	None	None	**Complications** • 3 capsule failures requiring repeat examination • 1 capsule had not passed beyond the pylorus • 1 capsule was retained • 5 examinations were compromised by transmission gaps • The colon could not be reached in 12/67 patients (18%) and passage of the IC valve could not be assessed in an additional 3 patients • 1 patients experienced capsule retention (surgery needed) • 1 patient delayed passage for 2 weeks (surgery needed)	Abstract. Limited information. All patients underwent EGD, colonscopy, and SBFT prior to CE.

Validity and generalisability of the studies

- Only one study reported on the diagnostic performance (sensitivity and specificity) of the procedure. Sensitivity and specificity were calculated using author defined definitions. Although a combination of tests (including push enteroscopy, which some patients had already undergone) was used to 'independently verify' results, this was not done using an accepted methodology such as the discrepant resolution method or a composite reference standard approach[39]. As such, sensitivity and specificity may be misleading and may not accurately reflect diagnostic performance of the procedure.
- In the majority of studies diagnostic yield (number of patients identified with a lesion/total number of patients assessed) was considered the most appropriate measure of diagnostic test performance.
- However, diagnostic yield cannot differentiate true positives from false positives or true negatives from false negatives.
- In most of the studies blinded independent assessment was undertaken in reviewing the test results.
- In all of the published studies patients had undergone extensive prior investigations, often including investigation with the comparator procedure – in some cases patients were those that had normal readings on other tests. This is therefore likely to decrease the apparent diagnostic yield for the comparator procedures.
- The timing of these comparator tests varied (from within 3 days of having a capsule endoscopy to 6 months). The longer the time between the two tests, the more likely that diagnostic yield will be over or under estimated.
- Studies had different definitions as to what constitutes a positive diagnosis, therefore limiting the comparisons that can be drawn among the studies in terms of diagnostic yield.
- Different studies also used different comparators – again limiting the comparisons that can be made.
- In general, the patients included in the studies are a heterogeneous group [2]. In some studies [6,15] patients other than those with obscure gastrointestinal bleeding were included in the study population. It is unclear what impact this has on overall diagnostic yield, particularly given there is some suggestion that there are particular patient groups who are the better candidates for this procedure [2].
- Follow up in most of the studies was short or in some cases unclear. This limits the ability to draw conclusions regarding the therapeutic impact of the test or the impact on health outcomes.

Specialist Advisor's opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- The main utility of capsule endoscopy will be in the diagnosis of obscure gastrointestinal bleeding however these patients present relatively infrequently.
- There are potential expansions for the role of the capsule in terms of screening and in the evaluation of inflammatory bowel disease, but these are by no means established at this point.
- Clinical follow up will be necessary to confirm value of findings.
- The experience in relation to the endoscopic capsule is that it performs at least as well as barium follow through and enteroscopy, but that these procedures are complementary and should not be regarded as competitors.

- There is a substantial interest worldwide in capsule endoscopy.

Issues for consideration by IPAC

The place of this procedure in the management of patients with obscure gastrointestinal bleeding and suspected Crohn's disease is still unclear i.e will it be used incrementally/triage or as a replacement test.

There appears to be a significant interest in the use of this procedure - further studies on this procedure are continually being published.

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28. Toth E, Fork FT, Almqvist P. *Capsule enteroscopy in obscure gastrointestinal bleeding: a prospective comparative study.* 2nd Conference on Capsule Endoscopy, Chaning Clinical Practice, Berlin. 2003. Abstract.

29. Van Gossum A, Francois E, Hittelet A, Schmit A, et al. A prospective, comparative study between push enteroscopy and wireless video capsule in patients with obscure digestive bleeding.[comment]. *Gastroenterology* 2003; 125(1):276.

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31. Gay G, Delvaux M, Fassler I, Laurent V, et al. Localization of colonic origin of obscure bleeding with the capsule endoscope: a case report. *Gastrointestinal Endoscopy* 2002; 56(5):758–62.

32. Hahne M, Adamek HE, Schilling D, Riemann JF. Wireless capsule endoscopy in a patient with obscure occult bleeding. *Endoscopy* 2002; 34(7):588–90.

33. Hollerbach S, Kraus K, Willert J, Schulmann K, et al. Endoscopically assisted video capsule endoscopy of the small bowel in patients with functional gastric outlet obstruction. *Endoscopy* 2003; 35(3):226–9.

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38. Smith J. The preliminary capsule endoscopy experience at Ochsner Clinic Foundation. *Ochsner Journal* 2002; 4(4) *Abstract*

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Appendix A: Additional studies not included in the summary tables

This is not an exhaustive list. As mentioned above the body of evidence is rapidly increasing in relation to this procedure – it should also be noted that given that Digestive Disease Week 2004 is in May a number of presentations on this procedure would be expected to be published.

Article	Patients/ follow up	Comments	Direction of the conclusions
Ang T-L, Fock K-M, Ng T-M, Teo E-K, et al. Clinical utility, safety and tolerability of capsule endoscopy in urban Southeast Asian population. *World Journal of Gastroenterology* 2003; . 9(10). 2313–6	16 patients with suspected small bowel pathology	Heterogeneous population No comparator	Capsule endoscopy is a useful tool
Ge ZZ, Hu YB, Gao YJ, Xiao SD. Clinical application of wireless capsule endoscopy. *Chinese Journal of Digestive Diseases* 2003; 4(2). 89–92	15 patients with suspected bowel disease	Heterogeneous population No comparator	Capsule endoscopy is a useful tool particularly in patients with obscure bleeding
Ciorba M, Prakash C, Jonnalagadda S, Stone C, et al. Diagnostic yield of capsule endoscopy is similar in obscure-occult and obscure-overt gastrointestinal bleeding but diagnoses vary. *The American Journal of Gastroenterology* 2002; 97(9, Supplement 1):S80.	45 patients with obscure bleeding	No comparator Abstract	Capsule endoscopy has a high diagnostic yield
Mele C, Infantolino A, Conn M, Kowalski T, et al. The diagnostic yield of wireless capsule endoscopy in patients with unexplained abdominal pain. *The American Journal of Gastroenterology* 2003; 98(9, Supplement 1):S298.	20 patients with unexplained pain	Heterogeneous population No comparator Abstract	Capsule endoscopy is a useful tool
Gross SA, Schmelikin IJ, Kwak GS. Capsule endoscopy in a private community practice: results of the first 178 patients. *The American Journal of Gastroenterology* 2003; 98(9, Supplement 1):S291.	178 patients with gastrointestinal complaints	Heterogeneous population No comparator Abstract	Capsule endoscopy is a useful tool
Riccioni ME, Foschia F, Shah SK, Mutignani M, et al. Diagnostic potential of the given M2A wireless video capsule endoscopy for obscure gastrointestinal (GI) bleeding. *Digestive and Liver Disease* 2001; 33(Supplement 1):A11.	13 patients obscure bleeding	No comparator Abstract	Capsule endoscopy is a useful tool
Mata AL. [Role of capsule endoscopy in patients with obscure digestive bleeding]. *Gastroenterologia y Hepatologia* 2003; 26(10):619-623. 619-23	21 patients obscure bleeding	Push enteroscopy Non-English	Higher diagnostic yield for capsule endoscopy
Leighton J, Sharma V, Malikowski M, Fleischer D. Long term clinical outcomes of capsule endoscopy (CE) in patients with obscure gastrointestinal bleeding (OGIB). *The American Journal of Gastroenterology* 2003; 98(9, Supplement 1):S300.	20 patients obscure bleeding 12 months	No comparator Abstract Lack of detail makes it difficult to	Procedure improves long term outcomes

Article	Patients/ follow up	Comments	Direction of the conclusions
		determine outcomes	
Mitchell SH, Schaefer DC, Komar MJ, Inverso NA, et al. Early findings of a new capsule endoscopy program. *The American Journal of Gastroenterology* 2002; 97(9, Supplement 1):S82.	16 patients	Abstract Unclear on patient population	Capsule endoscopy is a useful tool
Chutkan RK, Nader BH, Tonya AL, Marsha J. Video capsule endoscopy in the evaluation of obscure gastrointestinal bleeding. *The American Journal of Gastroenterology* 2002; 97(9, Supplement 1):S82.	70 patients with obscure bleeding	Abstract	High diagnostic yield
Marmo R. A prospective trial comparing small bowel radiographs and video capsule endoscopy for suspected small bowel disease. *Giornale Italiano di Endoscopia Digestiva* 2003; . 26(3). 207–10	20 patients	Non-English	Unclear
Liangpunsakul S, Chadalawada V, Maglinte D, Lappas J, et al. Wireless capsule endoscopy detects small bowel ulcers in patients with state of the art normal enteroclysis. *The American Journal of Gastroenterology* 2003; 98 6, 1295–8	40 patients	No comparator Limited information	Reports on the detection of small bowel ulcers
Raju GS, Abraham B, Shcreiber MH, Gomez G, et al. A prospective comparison of enteroclysis and capsule endoscopy in the diagnosis of obscure gastrointestinal bleeding. *The American Journal of Gastroenterology* 2003; 98(9, Supplement 1):S73.	20 patients	Enteroclysis Abstract	Capsule endoscopy is useful in the evaluation of patients with obscure bleeding
Voderholzer WA, Ortner M, Rogalla P, Beinholzl J, et al. Diagnostic yield of wireless capsule enteroscopy in comparison with computed tomography enteroclysis. *Endoscopy* 2003; . 35(12).1009–13	22 patients with suspected small bowel pathology	Heterogeneous population CT enteroclysis	Capsule endoscopy detects more small bowel lesions
Rossi S, Banwait KS, DiLisi J, Infantalino A, et al. Diagnostic Yield of M2A capsule endoscopy compared with sonde and push enteroscopy in patients with obscure gastrointestinal bleeding. *The American Journal of Gastroenterology* 2003; 98(9, Supplement 1):S294.	101 patients	Push enteroscopy Abstract Different population for capsule and comparator procedures	No difference in diagnostic yield – maybe an indicator of different populations

Appendix B: Existing reviews on the wireless capsule endoscopy

HTA Review: Medical Services Advisory Committee Wireless capsule endoscopy for patients with obscure digestive tract bleeding Literature search date: October 2002 and March 2003 (Medline)
Safety **Adverse events** The adverse events associated with the use of the capsule endoscopy in patients with obscure gastrointestinal (GI) bleeding appear to be infrequent and mild in nature. The most commonly reported adverse events associated with capsule endoscopy are abdominal pain, nausea, and vomiting. Delayed passage of the capsule has also been associated with abdominal pain and hospitalisation in a single patient. In another patient the retention of the capsule was associated with GI obstructive symptoms. In other isolated cases the capsule become lodged in a patient's bronchus and in a patient's throat. In both of these cases the capsule was removed without complication. **Delayed passage** In general, reported on the passage of the capsule in the available literature was poor. Delayed passage or lodgement of the capsule was reported in less than five per cent (27/581) of all patients included in studies systematically reported capsule passage data. Delayed passage or lodgement of the capsule was asymptomatic in all but one of these cases. In 37 per cent (10/27) of these events the capsule had to be surgically removed from the patient. In the majority of these cases (6/10) the capsule was removed at the time of planned surgical management. In practice, the delay of the capsule through the GI tract often aids the clinician in the diagnosis of previously undetected strictures.
Effectiveness Due to the lack of a suitable reference standard for capsule endoscopy, diagnostic yield (the number of patients with a pathological lesion identified/the total number of patients assessed) was used as the measure of diagnostic test performance. This measure are likely to overestimate the diagnostic capabilities of both the comparator and the procedure. At present due to the lack of a valid reference standard only level 3 and 4 evidence is available to describe the effectives of capsule endoscopy. 16 studies met the criteria for inclusion in the effectiveness review of capsule endoscopy. Only one small (13 patients) head-to-head trial comparing capsule endoscopy to small bowel series radiology (SBS) was identified at the time of assessment. Therefore a meta-analysis incorporating evidence from the head-to-head study of capsule endoscopy versus SBS, as well as indirect evidence from studies comparing capsule endoscopy to push enteroscopy and PE to SBS was undertaken. The summary point estimates of diagnostic yield for the two tests determined in the main analysis were: 58 per cent (CI 46.3-67.7%) for capsule endoscopy and 4 per cent (CI, 0.5-12.0%) for SBS. These point estimates of diagnostic yield were surrounded by wide credibility intervals due to the limited quantity of SBS data available. Despite this fact, the odds ratio of diagnostic yield of capsule endoscopy versus SBS was statistically significant (37.3 CI, 9.43-270.97) and favoured capsule endoscopy, In summary based on the available evidence capsule endoscopy has a significantly greater diagnostic yield compared with SBS radiology.

HTA Review: Blue Cross Blue Shield Association Wireless capsule endoscopy for obscure digestive tract bleeding.

Literature search date: July 2002

This review reports on three published studies including a total of 72 subjects. Two of these studies were conducted in patients with obscure digestive tract bleeding suspected to be of small bowel origin, and the third study was conducted in patients with suspected small-bowel disease, most of whom had obscure digestive tract bleeding.

Conclusions

The body of evidence is relatively small; however obscure digestive tract bleeding suspected to be of small-bowel origin is a relatively infrequent condition and thus the availability of subjects for investigation may be limited.

No significant complications from wireless capsule endoscopy were reported in these studies.

The findings of the two comparative studies illustrated that wireless capsule endoscopy demonstrates additional small bowel lesions generally beyond the reach of conventional push enteroscopy in 25–50% of cases studies. Wireless capsule endoscopy revealed additional suspicious or definite findings in 65–100% of cases when compared with small-bowel barium radiographic studies. In some cases, this additional information can lead to changes in management that would improve health outcomes.

HTA Review: Blue Cross Blue Shield Association Wireless capsule endoscopy for small-bowel diseases other than obscure GI bleeding.

Literature search date: November 2003 This review reports on three published studies, two abstracts and 9 relevant case reports included in 2 published case series.

Conclusions

For initial diagnosis of suspected Crohn's disease when all conventional diagnostic tests including SBFT have failed to reveal bowel lesions suggestive of Crohn's disease, the evidence suggests that wireless capsule endoscopy may demonstrate small-bowel lesions suggestive of Crohn's disease in a significant proportion of patients ranging from 43–71%. Furthermore, patients diagnosed with Crohn's disease by wireless capsule endoscopy were reported to improve after treatment for Crohn's disease, which represents an improvement in health outcomes.

However the available evidence is not of sufficient quantity and quality to determine the relative diagnostic performance of wireless capsule endoscopy compared with alternative conventional diagnostic tests in diagnosing unselected patients with suspected Crohn's disease. Thus no conclusions can be made as to whether wireless capsule endoscopy is an effective alternative to conventional tests.

Appendix C: Literature search

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PredMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

	Search history
1	wireless capsule endoscopy.mp.
2	capsule endoscopy.mp.
3	videocapsule endoscopy.mp.
4	(camera adj4 pill).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
5	Wireless capsule enteroscopy.mp.
6	WCE.tw.
7	(Given$ adj4 capsule).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]
8	or/1-7
9	exp CAPSULES/
10	exp Video-Assisted Surgery/
11	exp Endoscopy, Gastrointestinal/
12	9 or 10
13	12 and 11
14	8 or 13
15	14 not 6