

# Capsule endoscopy: A single-centre experience with the first 226 capsules

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**BACKGROUND:** Capsule endoscopy (CE) refers to a novel diagnostic method of imaging the gastrointestinal tract using a wireless capsule that transmits images to a data recorder while the device traverses the small intestine.

**OBJECTIVE:** To review the authors' experience with CE to determine the indications, outcomes and management of positive findings.

**METHODS:** Patients were prepared for CE with a single dose of magnesium citrate. Following an 8 h fast, a sensor array system was applied to the abdomen, the capsule was swallowed and the images were transmitted to a data recorder worn on the patient's side. Typically, the battery life of the capsule is 8 h, following which the data recorder is returned, downloaded to a computer workstation and reviewed.

**RESULTS:** To date, 226 capsule studies have been performed in 209 patients. The indications included obscure bleeding (167 studies: 88 overt, 79 occult), anemia (14 studies), evaluation for inflammatory bowel disease (12 studies), screening for polyps (10 studies), pain (19 studies) and abnormal radiological imaging (4 studies). In the setting of obscure bleeding, a definitive source of bleeding was discovered in 85 studies. This included angiodysplasia (52 studies), mitotic lesions (10 studies) and ulcers (23 studies). A probable source of bleeding was found in another 10 capsule studies. In the setting of anemia without evidence of bleeding, the definitive findings included ulcers (three studies), angiodysplasia (two studies), mitotic lesions (one study) and celiac disease (one study). Of four patients with abnormal radiological imaging, CE demonstrated lesions in two. The results of 35 capsule studies led to laparotomy with curative surgical resection. In eight studies, the capsules became lodged within a stricture; none led to obstruction and three were managed endoscopically.

**CONCLUSION:** The yield of CE in carefully selected patients with obscure bleeding approximates 51%. There appear to be few complications, and patient satisfaction appears high. Cost analysis and further studies of clinical outcomes are required to elucidate appropriate indications for this device.

**Key Words:** *Capsule endoscopy; Endoscopy; Gastrointestinal bleeding; Obscure bleeding; Small intestine*

Capsule endoscopy (CE) is a novel noninvasive technique used to image the gastrointestinal (GI) tract (1-5). Based on several studies, the Food and Drug Administration in the United States approved CE in October 2001; since this time, it has quickly gained acceptance as a new gold standard for assessing disorders of the small intestine (6,7).

CE has demonstrated superior imaging capabilities to push enteroscopy (7-13), small bowel barium studies (both

## L'endoscopie vasculaire : Une expérience unicentrique avec les 226 premières capsules

**HISTORIQUE :** L'endoscopie capsulaire (EC) désigne une nouvelle méthode diagnostique d'imagerie du tractus gastro-intestinal faisant appel à une capsule sans fil qui transmet des images à un enregistreur de données tandis que la capsule traverse l'intestin grêle.

**OBJECTIF :** Analyser l'expérience des auteurs avec l'EC pour établir les indications, les issues et la prise en charge des observations positives.

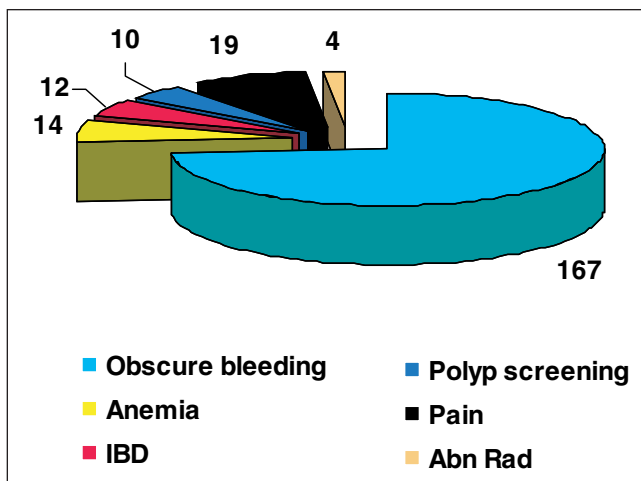
**MÉTHODOLOGIE :** Les patients prenaient une unidose de citrate de magnésium pour se préparer à l'EC. Après un jeûne de huit heures, une mosaïque de capteurs était appliquée à l'abdomen, la capsule était ingérée et les images transmises à un enregistreur de données porté sur la hanche. D'ordinaire, la vie utile de la pile de la capsule est de huit heures. L'enregistreur de données est ensuite rendu, téléchargé dans un poste de travail et analysé.

**RÉSULTATS :** Jusqu'à présent, 226 études capsulaires ont été effectuées chez 209 patients. Les indications incluaient un saignement occulte (167 études : 88 cas de saignement apparent, 79 cas de saignement occulte), de l'anémie (14 études), une évaluation de maladie inflammatoire de l'intestin (12 études), un dépistage de polypes (10 études), de douleur (19 études) et une radiologie anormale (quatre études). En cas de saignement occulte, une source établie de saignement a été découverte dans 85 études. Il s'agissait de cas d'angiodysplasie (52 études), de lésions mitotiques (10 études) et d'ulcères (23 études). Une source probable de saignement a été décelée dans 10 autres études capsulaires. En cas d'anémie sans trace de saignement, les découvertes établies incluaient des ulcères (trois études), une angiodysplasie (deux études), des lésions mitotiques (une étude) et une maladie cœliaque (une étude). On a découvert des lésions par EC chez deux des quatre patients pour qui l'imagerie radiologique était anormale. Les résultats de 35 études capsulaires ont donné lieu à une laparotomie associée à une résection chirurgicale curative. Dans huit études, la capsule s'est coincée dans un rétrécissement. Aucune n'a entraîné d'obstruction, et trois ont été réglées par voie endoscopique.

**CONCLUSION :** Le rendement de l'EC chez des patients soigneusement sélectionnés présentant un saignement occulte avoisine les 51 %. Les complications semblent rares, et la satisfaction des patients, élevée. Une analyse des coûts et des études plus approfondies des issues cliniques s'imposent pour déterminer les indications pertinentes de l'EC.

enteroclysis and small bowel follow through), angiography and computed tomography (CT) enteroscopy (6,14-17). Most of the present published studies have been used in clinical trials under careful scrutiny and specially designed protocols. When new technology is developed, the initial enthusiasm in clinical trials is often tempered by subsequent declining yields once the device is released into routine clinical practice.

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**Figure 1**) Indications for capsule endoscopy (CE) studies (total of 226 CE studies). Abn rad Radiological abnormalities; IBD Inflammatory bowel disease

We have been using CE in St Paul's Hospital, Vancouver, British Columbia since December 2001. Initially, its use was restricted to patients with severe refractory bleeding. However, as time passed, the indications for this procedure have expanded, and our threshold for performing the test decreased. We reviewed our first 226 capsule studies to determine the indications, outcomes, complications and management of positive findings. These studies were all used in a 'real-life' setting outside of clinical trials; however, data were collected prospectively in a number of areas for planned assessment of our results.

## METHODS

All capsules were purchased through Southmedic, the distributor for GIVEN Imaging, Canada. The structure of the capsule has been previously described (1). In Canada, capsules are purchased in sets of 10, and because their function may decline with time, they are used relatively quickly. All patients were prepared with a single 300 mL bottle of magnesium citrate the evening before the test and took nothing by mouth after midnight. The capsule was ingested at 07:30 and patients returned approximately 8 h later to have their data recorder removed and downloaded. Motility agents were not routinely used for the procedure; however, if the patient was taking these agents (eg, erythromycin or domperidone) as part of their routine care, they were not discontinued. Patients were permitted to drink liquids within 2 h of ingestion of the capsule and could eat 4 h later. Ambulation was encouraged because it was thought this would enhance peristalsis and improve complete visualization of the small intestine. Studies were typically reviewed within 24 h.

Because there have been few definitions in CE regarding what constitutes a positive or negative study, some aspects were defined to aid in future evaluations. A positive result was defined as the presence of active bleeding, definite ulceration or other finding that was unequivocally the etiology of the problem. Mitotic lesions included all mass lesions, benign or malignant. Because strictures can be difficult to assess with capsule studies (unless there is nonspontaneous excretion) and because most strictures arise from an inflammatory process (eg, ulceration), the category of strictures was included within the subheading 'mucosal breaks'. The following disorders were included within the category of diarrhea as the indication for the procedure: Crohn's disease,

celiac disease, protein-losing enteropathy and radiation enteritis. Capsule failure was defined as any procedure with less than 20 min of transmission.

Patients with obscure bleeding had all been previously evaluated with at least one upper endoscopy, colonoscopy and/or small bowel examination. Most patients were also evaluated with an enteroscopy using an Olympus SIF-100 enteroscope (Olympus, Japan). Most patients had multiple endoscopic and radiological studies. It was left to the discretion of the investigator whether studies were repeated before CE. A consultation was always performed before CE to ensure that an adequate endoscopic and radiological evaluation had already been performed.

## RESULTS

Between December 2001 and February 2004, 226 CE studies had been performed in 209 patients (17 patients had more than one CE). All patients were evaluated by one investigator (RE) before their study. Additionally, the same investigator interpreted the results of the CE. Where controversy existed, consultation with other capsule endoscopists led to consensus of opinion. The reviewing speed varied depending on the preparation, abnormal findings and the location of the capsule within the GI tract. Review times were not always recorded, but were usually between 30 min and 45 min.

### Indications

The indications for the studies were grouped as per Figure 1. All capsule studies were performed for the assessment of small intestinal pathology. The most common indication for CE was obscure GI bleeding, which included 167 studies (74%). Obscure GI bleeding was classified into overt (88 studies [53%]) and occult (79 studies [47%]) bleeding. At times, it was difficult to classify patients into these two categories because some patients fit into both. If the patient fit both categories, the category most often deemed responsible for bleeding was selected.

The second most common indication for CE was abdominal pain (19 studies [8.4%]). These were patients without evidence of bleeding, anemia or any radiological abnormalities, but typically had chronic debilitating abdominal pain severely inhibiting their lifestyles. There were 14 patients without any evidence of bleeding who underwent CE for anemia. Ten patients (4%) with polyposis syndromes (familial adenomatous polyposis, Peutz-Jeghers syndrome), 12 patients (5%) with suspected inflammatory bowel disease (IBD) and four patients (2%) with isolated radiological abnormalities (eg, CT demonstrating abnormality in the terminal ileum) completed the CE indication group.

### Yield

Of 167 CE studies performed for obscure GI bleeding, four studies were incomplete (limited to esophagus/stomach and less than 20 min of small intestine), two studies had poor preparation which limited visibility and one capsule failed to transmit (Table 1). Of the remaining studies, 85 (51%) revealed abnormalities that were believed to be the site of bleeding. Of these 85 studies, 52 (61%) were vascular lesions, 10 (12%) were mitotic lesions and 23 (27%) were mucosal breaks/ulcerations. Thirty-five (42%) of these patients underwent surgical intervention (laparotomy). If the surgeon could not locate the lesion, an intraoperative enteroscopy was performed. One patient had a negative laparotomy (no intraoperative enteroscopy performed) and one patient had a

**TABLE 1**  
Yield in obscure gastrointestinal bleeding: Individual capsule studies

Study outcome	n
Failed to transmit	1
Poor visualization	2
Incomplete*	4
Positive studies†	85
Vascular lesions	52
Mitotic lesions	10
Mucosal breaks/ulceration	23
Negative studies	75
Total	167

\*Limited to esophagus, stomach; †Of these 85, 35 (42%) eventually underwent surgical correction

lesion that required a second laparotomy and intraoperative enteroscopy to locate the lesion. All other patients had curative resections performed.

Of the 19 patients who underwent CE for abdominal pain, the yield of positive findings was 32% (six patients) (Table 2). Of these, three had angiodysplastic lesions, one had a mitotic lesion and two other had ulcerative lesions (one suspected IBD and the other from nonsteroidal anti-inflammatory drugs [NSAIDs]). Of the 14 patients with anemia and no evidence of bleeding there was a 50% yield: one patient had a mitotic lesion, two had ulcerative lesions, three had numerous angiodysplastic lesions and one had villous atrophy.

Of the 12 patients assessed with suspected IBD, four (33%) had evidence of ulcerative lesions within the small intestine. There were 10 patients evaluated for polyposis, of whom five had small intestinal polyps not visualized by other methods. Four patients had CE for clarification of their radiological imaging results where a suspicion of small intestinal pathology was raised on CT or abdominal ultrasound. Of these, two patients had abnormalities (one had angiodysplasia and one had small bowel ulcerations).

### Complications

There were no capsules that resulted in intestinal obstruction. Eight capsules, however, did become lodged within a stricture. Three of these strictures were within reach of an endoscopic examination but had previously been unrecognized by the referring physician. Two capsules were removed endoscopically and one was removed surgically (surgery was indicated for the lesion, not the obstruction). There were two additional capsules that were removed at the time of surgery, which was remote (more than six weeks) from the capsule study. Two other capsules were passed over the next few weeks (one patient was treated with corticosteroids for an inflammatory stricture). One patient still has a capsule lodged within a stricture, but remains asymptomatic and is being treated supportively.

## DISCUSSION

CE is a new method of assessing the small intestine. Two early studies (6,7) led the way for Food and Drug Administration Approval in 2001; however, there is still much to study with this new technology. We have assessed our data in regard to how CE is used in clinical practice. We have used slightly more stringent criteria for defining positive findings, and this may explain why our results are slightly lower than earlier studies

**TABLE 2**  
Yield and findings in indications other than obscure gastrointestinal bleeding

Indications	n	Yield (%)	Findings			
			Angiodysplasia	Mitotic lesions	Ulcers	Celiac disease
Pain	19	32	3	1	2	0
Anemia	14	50	2	1	3	1
IBD	12	33	0	0	4	0
Polyposis screening	10	50	0	5	0	0
Abnormal imaging	4	50	1	0	1	0

IBD Inflammatory bowel disease

(5,6,10,13,15,17,18). On the other hand, as technology tends to be more accessible, it is logical to assume that a lower threshold for performing the test may occur, possibly leading to the assessment of patients with milder disease who might have negative studies.

The most common indication for CE is obscure GI bleeding. We divided our patients into categories of occult and overt; however, these definitions are sometimes relatively arbitrary. Some patients have both, and in others, it may be difficult to determine whether the patient is truly having melena. Additionally, when we assessed our data, there did not seem to be any differences in yield whether GI bleeding was classified as obscure or overt. Definitive yields of over 50% appears to be an impressive result, particularly because these patients had all been assessed with endoscopic and radiological exams with negative results. Recent reports (19) have suggested that early CE in patients with overt bleeding may enhance the diagnostic yield; however, some of these lesions were managed endoscopically, and raised concerns about the evaluation before CE. In many centres, the use of push enteroscopy may now be limited to after the capsule study, whereas in our assessments it was typically performed before CE. If a patient has a thorough endoscopic assessment, the yield of lesions within reach of a standard endoscopy should be very low. On the other hand, even with our own data, we found that up to 30% of lesions were within reach of an endoscope (including enteroscopy). This raises the question of whether CE is being used to assess the small intestine, or alternatively, to double-check the previous endoscopic examination. It is likely, if a thorough endoscopic exam is performed (including enteroscopy), that yields may decrease because many positive findings reported that have been within the reach of a standard endoscope. However, even with these limitations, CE clearly has benefits. Even in the setting of abdominal pain a small, yet significant, yield was accomplished in the present study.

The treatment of lesions found on CE must always be considered. In our patient group of obscure GI bleeding, 42% of those with positive findings were managed surgically, most with curative results. The goal of this technology in this setting is a curative result. Other therapies must, however, also be considered. For those with ulcerative lesions of the small intestine, the altering of NSAIDs or escalation of therapy for Crohn's disease are clear medical therapies that these positive studies promote. Additionally, several vascular lesions of the cecum have been demonstrated, which has encouraged further endoscopic therapy resulting in the cessation of bleeding. 'Physiological' CE study is without insufflation or hypotension (as may occur with narcotic

sedation and endoscopic exams) and some lesions (particularly those in the cecum) may be easier to visualize with CE than during an endoscopic examination.

We have concentrated on the positive findings and found that CE was a very useful diagnostic test that often led to alterations of therapy. The applications for this technology are expanding and hopefully, clearer guidelines for its use will gradually develop as more data become available. Already, new applications include assessing patients with polyposis syndromes. A patency capsule has been developed and is undergoing early testing (20-22), as is a capsule assessment of the gastroesophageal junction for Barrett's esophagus (23,24). Additionally, future studies assessing mucosal healing will likely incorporate this technology into both NSAID and Crohn's disease medical therapies. It would seem logical that in future studies (of both NSAIDs and Crohn's disease) the mucosa would be evaluated, in part, by CE (25,26).

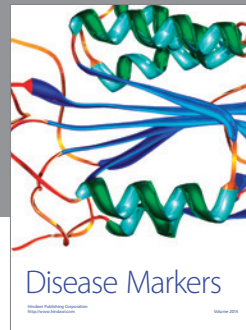
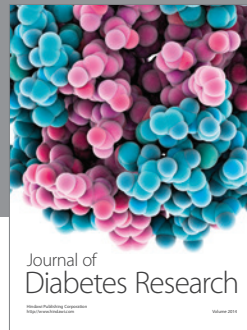
The issues of reading the capsule studies have been a point of considerable debate. Some centres prefer to have assistants read

the entire 'video' and 'thumbnail' appropriate abnormalities. Physician extenders include technicians, nurses, physicians' assistants, trainees (eg, Fellows in gastroenterology) and/or junior staff. There is considerable ongoing debate regarding this topic, and more study is required in this area. Inter- and intra-observer variability has not been fully assessed among these different groups, although some studies are currently underway.

The use of CE in patients with positive results does appear to change patient management. The cost-effectiveness of this new technology is not well-defined. It has the potential to decrease resource use; however, the addition of costly interventions (eg, laparotomy) may well offset the cost savings. The true benefit of this device is in the endoscopic visualization of a small intestinal lesion. The improved streamlined care of patients is of benefit to both the patient and the physician. Although many more studies are required, we strongly advocate the use of this test and believe that it is the new gold standard for the visualization of small intestinal disorders.

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