

The Future of Capsule Endoscopy

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Small-bowel capsule endoscopy (SBCE) was introduced 11 years ago by Given Imaging and is becoming the gold standard for small-bowel examination. This major step in the field of digestive medicine has opened the possibility of promising non-invasive explorations of the esophagus, stomach, and colon. SBCE can be used to overcome the inherent limitations of enteroscopy, especially in the West, where the capsule has been available since 2001. Obscure gastrointestinal (GI) bleeding with normal findings on upper and lower endoscopy remains the most important indication, and suspected Crohn's disease is also a well-accepted indication. Findings from a capsule investigation may warrant therapeutic endoscopy, but in many cases, SBCE avoids this useful but time-consuming endoscopic procedure. The use of a colon capsule for colorectal cancer screening when traditional colonoscopy is contraindicated or impossible is undergoing clinical trials. Early results seem promising, but control of colonic motility is still cumbersome, and patient preparation remains the most important drawback. We performed the first clinical trial in humans of a magnetically guided gastric capsule that offers the possibility of investigation with a capsule that can be controlled spatially. To date, we have carried out procedures in more than 400 patients and volunteers, with impressive results compared with high-definition gastroscopy. Even though endoscopy remains the most important tool in the GI field, capsules offer promising new possibilities. (doi: 10.2302/kjm.2012-0011-RE; Keio J Med 62 (2) : 41–46, June 2013)

Keywords: capsule endoscopy, guided capsule, digestive endoscopy

Introduction

Small-bowel capsule endoscopy (SBCE) was introduced 11 years ago by Given Imaging and is becoming a gold standard for examination of the small bowel.¹ This major step in digestive medicine allowed promising non-invasive explorations of the esophagus, stomach, and colon.² The aim of this review is to highlight future improvements in SBCE and the potential clinical benefits of its use our patients.³

Small-bowel Capsule Endoscopy

SBCE can be used to overcome the inherent limitations of enteroscopy, especially in the West, where capsule endoscopy has been available since 2001; we have

been using the capsule device since 2004 (**Table 1**). The most important indication for the use of SBCE remains obscure gastrointestinal (GI) bleeding after upper and lower GI endoscopy have shown normal findings. Suspected Crohn's disease is also a well-accepted indication. Numerous findings relating to the small bowel have now been described, whereas, before the advent of SBCE, the small bowel was unable to be directly visualized and was considered the "black box" of the digestive tract (**Table 2**). In the near future, we will be able to improve the clinical application of SBCE in three major areas: handling of the equipment, optical performance, and reduction in reading time.

Handling of the equipment and most of the examination is carried out by a nurse or an assistant. The sensor array and the data recorder are built into a belt that was intro-

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Table 1 Number of examinations performed with different types of capsules at Institut Arnault Tzanck

	Given Imaging (PillCam SB)	MiroCam (SBCE)	Olympus (SBCE)	Olympus (MGCE)	Given Imaging (PillCam COLON 2)
2004	7	-	-	-	-
2005	15	-	26	-	-
2006	15	-	56	-	-
2007	24	-	94	-	-
2008	12	5	32	-	-
2009	18	-	57	-	2
2010	21	-	52	85	-
2011	23	-	59	290	-
2012	5	-	34	-	2
Total	140	5	410	375	4

SBCE, small-bowel capsule endoscopy; MGCE, magnetically guided capsule endoscopy.

Table 2 SBCE findings when investigating the causes of small-bowel bleeding (Reproduced from Pennazio M.)⁴

Vascular lesions	Tumors	Other causes
Angioectasia	Adenoma ^b	Crohn's disease
Dieulafoy lesion	Hamartoma ^c	Drug-induced small-bowel injury
Telangiectasia ^a	Lipoma	Ulcers in celiac disease
Varices	Adenocarcinoma	Chronic ulcerative jejunoileitis
Phlebectasia	Lymphoma	Vasculitis
Aorto-enteric fistula	Gastrointestinal stromal tumors (GISTs)	Radiation enteritis
Aneurysms	Carcinoid tumors	Ischemic injury
	Vascular tumors ^d	Meckel's diverticulum
	Neurofibroma ^e	Diverticulosis
	Metastases	Zollinger-Ellison syndrome
		Endometriosis
		Hemosuccus pancreaticus/hemobilia
		Infectious causes
		Von Willebrand disease

Associated syndromes: ^aOsler-Weber-Rendu disease, CREST syndrome, Turner's syndrome; ^bfamilial adenomatous polyposis; ^cPeutz-Jeghers syndrome; ^dblue rubber bleb nevus syndrome; Klippel-Trenaunay-Weber syndrome; ^eVon Recklinghausen's disease.

duced by Given Imaging for the SB2 model; in general, second-generation small-bowel capsules are less cumbersome and more reliable than first-generation devices. Most important is the inclusion of an external viewer, first introduced by Olympus. It facilitates accurate monitoring of the gastric passage of the capsule, thus informing decisions about the use of prokinetic agents, and allows cecal visualization as a marker of complete small-bowel examination. Expected improvements will allow direct monitoring of the image from the capsule and also access to video sequences if, for example, the capsule is blocked behind a fold or by a pathological stricture.

Image quality relies on multiple factors, such as the field of view, resolution, brightness, and automatic gain

control, as previously developed in high-definition endoscopy. Image quality is particularly improved with the SBCE Olympus capsule. Marked technical improvements are to be expected with the launch of each new generation of capsule. An improved field of view is a particularly important feature because it will allow a more extensive image of the lumen of the small bowel and could increase diagnostic yield.

The reading time of SBCE data is lengthy, which is a drawback for physicians. In addition, we have to bear in mind that capsule imaging does not comprehensively visualize the entire small bowel because of the local effects of motility, debris, bubbles, absence of insufflation, and presence of strictures. For example, the papilla of Vater,

Table 3 Six types of patient preparation for SBCE (Reproduced from Rey, et al.⁵)

1	Standard procedure as indicated by Given Imaging: clear fluid diet the day before the procedure, overnight fasting.
2	As above, plus simethicone 80 mg and metoclopramide 10 mL (0.1% solution) p.o. 20 min before the procedure.
3	Clear fluid diet the day before the procedure, 2 L of a PEG-based solution in the afternoon of the day before the procedure. Overnight fasting. Simethicone 80 mg 20 min before the procedure.
4	Clear fluid diet the day before the procedure, 4 L of a PEG-based solution (2L in the morning, 2L in the afternoon) the day before the procedure. Overnight fasting. Simethicone 80 mg 20 min before the procedure.
5	Clear fluid diet the day before the procedure, 2 L of a PEG-based solution in the afternoon of the day before the procedure. Overnight fasting. Metoclopramide 10 mL (0.1% solution) p.o. 20 min before the procedure. Simethicone 80 mg 20 min before the procedure.
6	Clear fluid diet the day before the procedure, 4 L of a PEG-based solution (2L in the morning, 2 L in the afternoon of the day before the procedure). Overnight fasting. Metoclopramide 10 mL (0.1% solution) p.o. 20 min before the procedure. Simethicone 80 mg 20 min before the procedure.

Table 4 The sensitivity and specificity of colon video capsule endoscopy (Reproduced from Van Gossum, et al.⁷)

Condition	Sensitivity	Specificity
Polyps > 6 mm	64%	84%
Advanced adenomas	73%	79%
Cancer	74%	-

Complete examination by colon video capsule endoscopy was possible in 92.8% of 328 patients. Five of 19 carcinomas were missed.

a constant feature of the second part of the duodenum, is seen only in 10% of investigations. Another problem is that some recorded images are difficult to interpret. New software technology includes multiple reading modes, e.g., “QuickView” for Given Imaging capsules, and “overview” or “skip” mode for Olympus capsules, and these can save up to 30% of reading time. Accurate detection of abnormally red areas could be an important advance for accurate diagnosis.

Finally, the anatomic locations of findings are still known only approximately, and three-dimensional localization needs to be developed. We may expect that in the near future most patient handling and image reading will be done by assistants; the physician will focus only on the final diagnosis from the information on selected images.

We should draw attention to the need for a clear protocol. SBCE was initially described as a patient-friendly examination for which no patient preparation was required; however, in 25% of examinations, the last part of the ileum is not clearly visible. We have shown, and this is now generally agreed, that patient preparation with polyethylene glycol (PEG)^{5,6} is required for a complete examination (**Table 3**). Prokinetics are only important when gastric passage is delayed.

Colon Capsule

The colon capsule is a serious contender for colorectal screening. The results to date are promising, but they need to be supported by larger studies. The reported miss rate of 25% for carcinomas⁷ is still a concern, even though this rate is much lower than that for the current fecal occult blood test (FOBT) (**Table 4**). From the diagnostic point of view, polyps smaller than 6 mm are an important issue. As is also the case for virtual colonoscopy, colon capsule endoscopy has a higher miss rate than high-definition colonoscopy for such lesions. The diagnostic yield is affected by two factors: bowel preparation and large-bowel motility. Currently, bowel preparation using the following protocol is very demanding for the patient, even more so than that for colonoscopy:

- 5 Days Before: Commence low-fiber diet.
- 2 Days Before: Commence clear fluid diet, 2 L and in the evening: sennoside (Pursennide) 2 × 20mg tablets.
- 1 Day Before: Morning: light breakfast.
 - o 12:00: pasta then clear liquid diet.
 - o 19:00–21:00: 2 L PEG.
- Day of Investigation: 06:00–7:00: 1 L PEG.
 - o 07:45: 20 mg domperidone.
 - o 08:00–09:00: when capsule is in the stomach, erythromycin 500 mg p.o. or i.v.
 - o Small-bowel detection: + 30 mL Fleet Phosphosoda + 1 L water (boost I).
 - o 3 h after boost I, or if capsule in cecum: + 15 mL Fleet + 1 L water (boost II).
 - o 2–4 h after boost II: suppository, Bisacodyl (10 mg) if capsule has not been eliminated.

It is important to note that, unlike colonoscopy, there is no possibility of intraprocedural cleaning and the capsule moves without guidance through the colon. Regarding colonic motility, the colon capsule might, for example, remain for several minutes in the cecal area or it might pass through the transverse colon in a few seconds, pushed on by strong colonic contractions. For these reasons, comparing the colon capsule with high-definition video colo-

Table 5 Diagnostic accuracy of colon capsule endoscopy for significant findings (polyps 6 mm in size or the presence of 3 or more polyps)(Reproduced from Spada C, Hassan C, Galmiche J. et al. Colon capsule endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy 2012; 44: 527-536 ⁸)

Author, year	Patients with significant findings, n (%)	Sensitivity	Specificity	PPV	NPV
Eliakim, 2006 [9] ^a	16 (19)	50%	82%	40%	88%
Schoofs, 2006 [10] ^a	13 (36)	77%	70%	59%	84%
Van Gossum, 2009 [7] ^a	87 (27)	64%	84%	60%	86%
Gay, 2010 [11] ^a	67 (53)	76%	76%	78%	74%
Sacher-Huvelin, 2010 [12] ^a	112 (21)	39%	88%	47%	85%
Pilz, 2010 [13] ^a	6 (10)	50%	75%	19%	93%
Spada, 2011 [14] ^a	13 (33)	62%	85%	67%	82%
Spada ; 2011 [15] ^a	7 (15)	100%	95%	78%	100%
Eliakim, 2009 [16] ^b	18 (19)	89%	76%	46%	97%
Spada, 2011 [17] ^b	45 (41)	84%	64%	62%	85%
All studies	384 (20)	63%	83%	57%	86%
CCE-1 studies	321 (19)	58%	85%	57%	86%
CCE-2 studies	63 (30)	86%	71%	56%	92%

PPV, positive predictive value; NPV, negative predictive value, ^aFirst-generation colon capsule endoscopy (CCE-1) studies, ^bSecond-generation (CCE-2) studies.

noscopy, the results from the colon capsule must still be improved (**Table 5**); however, in comparison with FOBT, the colon capsule gives acceptable results.^{8,18}

Based on this analysis, practitioners must accept the current indications for capsule colonoscopy, i.e., if colonoscopy is impossible for technical reasons, if there are temporary contraindications to colonoscopy, or if the patient is highly reluctant to undergo high-definition colonoscopy. With respect to the last indication, the patient should be aware of the necessity for colonoscopy if there are positive findings from the colon capsule. A final disadvantage to use of the colon capsule relates to cost: each colon capsule costs US\$700 plus the medical fee, and in most countries healthcare providers do not provide reimbursement. This is why, in our opinion, it seems too early to draw up official guidelines.

The Guided Gastric Capsule

Passive video capsule endoscopy is considered a gold standard for the small bowel, and it has been investigated clinically for use in the esophagus and colon; however, it was considered impossible to devise a clinical trial for gastric exploration because of the inherent technical limitations. To overcome some of the limitations of passive capsules, magnetically guided capsule endoscopy (MGCE) was developed jointly by Olympus Medical Systems Corporation and Siemens Healthcare. A comparative study between high-definition gastroscopy (Olympus Exera II 180) and MGCE was carried out in 85 patients with clinical indications for gastric examination. The guidance system, in which a capsule is steered by a low-

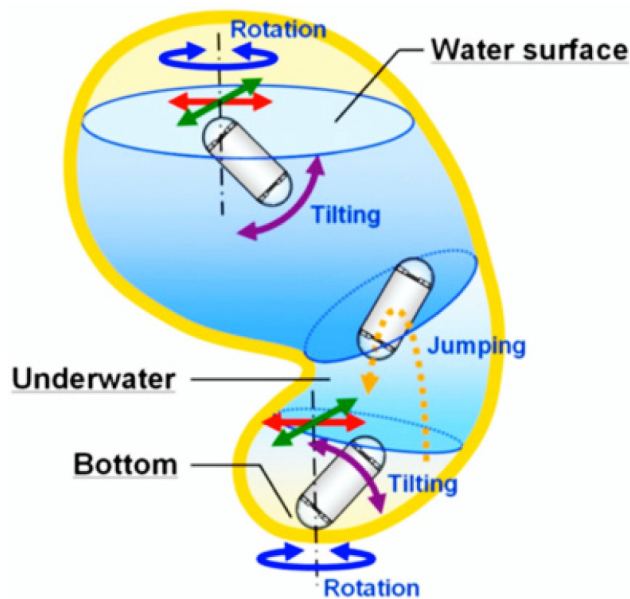


Fig. 1 Possible maneuvers of the video capsule using magnetic guidance.

level magnetic field, was designed by Siemens Healthcare, and images were obtained using a two-sensor video capsule built by Olympus Medical Systems Corporation (**Fig. 1**). The trial was carried out at the Institut Arnault Tzanck (St. Laurent du Var, France) with close cooperation with three Japanese universities: Keio University School of Medicine (Tokyo), Jikei University School of Medicine (Tokyo), and Showa University Northern Yo-

kohama Hospital (Yokohama). Japanese physicians performed capsule and endoscopy examinations on French patients.¹⁹ The Japanese physicians were included in the trial to develop the protocol and review the data.

The patients, who all gave their informed consent, underwent high-definition gastroscopy under propofol sedation and then underwent a capsule examination on the following day. A total of 97 patients were included, and 85 patients completed the trial. One patient had minor abdominal pain that resolved spontaneously.

Step 1, which involved the first 24 patients, was regarded as our learning-curve experience for capsule examination. Step 2 was the comparative study of the next 61 patients; comparative examinations were carried out blindly by two physicians by gastroscopy and then by capsule investigation. Using the guided gastric capsule, visualization of the gastric pylorus, antrum, body, fundus, and cardia was assessed as complete in 88.5, 86.9, 93.4, 85.2, and 88.5% of patients, respectively. In 12 patients, visualization was incomplete: in 4 patients this resulted from early pyloric passage of the capsule, and in the remaining 8 patients there were a variety of causes such as resistant mucus, excessive gastric motility, and incomplete gastric expansion. Visualization by guided gastric capsule was achieved in a mean total examination time of 17.4 min (range 9.9–26.4 min). The examination time became shorter with better understanding of navigation and with increasing familiarity with previously unseen perspectives of the stomach, such as panoramic views of the lesser curve and the appearance of the closed cardia. In total, 108 gastric findings (e.g., gastritis, angioma, polyp) were identified. Of these, 63 lesions were seen on both gastroscopy and capsule examination, 31 lesions were detected by capsule but were missed by conventional endoscopy, and 14 lesions were detected by gastroscopy but were missed by the capsule examination.²⁰

This first clinical trial raised some points about capsule navigation:

- Cleanliness of the stomach: Stomach lavage with 900 mL of mineral water ingested in two steps is required to obtain a clear view using MGCE. A clean gastric environment without bubbles, residue, or mucus is needed. Bile reflux can also impair gastric visibility.
- Expansion of the stomach: This is the main purpose of the final step in patient preparation, i.e., ingestion of 400 mL mineral water at 35°C, because an air–water interface is required for navigation of the capsule. This approach was effective in 84.2% of all patients; it was ineffective in 20% of male patients but in only 9.1% of female patients.
- Gastric motility: This could also impair navigation, especially in the antrum in the case of strong contractions. Antispasmodic drugs will be used in a further clinical trial on volunteers. In addition, MGCE could be a useful tool for assessing motility disorders in patients with

unexplained gastric pains.

Because these preliminary results were promising, a second study was carried out with 50 volunteers to improve the gastric lavage and distension protocol, and then a technical trial was carried out in 50 patients for training and to improve guidance. This was followed by a second scientific study in which the capsule examination was performed initially, and then a few hours later the findings were verified by high-definition endoscopy (214 patients).

Esophageal Capsule

The initial results for the esophageal capsule engendered an enthusiastic response,²¹ and a few months later, a well-known multinational pharmaceutical company exhibited a device at their booth devoted to proton pump inhibitors. However, a technical difficulty remains to be overcome, namely, the best way to steady the capsule in the Z line area. Appropriate positioning of patients and tethering of the capsule have been proposed, but results have not been reproducible. Currently, esophageal capsule endoscopy is not recommended by scientific societies, even for follow-up of varices or Barrett's esophagus.

Reimbursement

Although small-bowel capsule endoscopy is well accepted in the scientific community and is considered to be a major advance in small-bowel diagnosis, reimbursement is still an obstacle. Intensive marketing by the leading manufacturer has led to some reluctance to use the device in many countries, so that reimbursement for SBCE is limited, even though its clinical use in routine investigations is fully approved. Usually, obscure GI bleeding and suspected Crohn's disease are the only indications accepted for reimbursement. For other indications, the price of the device (about US\$700) and the medical fees must be borne by the patient.

The costs of newer capsule types have not yet been considered for reimbursement: the colon capsule is undergoing clinical trials, and the guided gastric and the esophageal capsules are still at the stage of preliminary research studies.

Conclusion

SBCE is a major advance in small-bowel exploration; in most cases it is performed before enteroscopy. It is the gold standard for small-bowel diagnosis. The colon capsule is still at the stage of clinical trials; in the near future it might be the first step in colorectal cancer screening, but bowel preparation and the use of prokinetics must be considered. Capsule endoscopy for the esophagus and stomach is still at the research stage. In the future, a magnetic guidance system could be included in all capsule designs.

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