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Report:

OMOM capsule endoscopy in diagnosis of small bowel disease

Chen-yi LI, Bing-ling ZHANG, Chun-xiao CHEN[†‡], You-ming LI

(*Department of Gastroenterology, the First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou 310003, China*)

[†]E-mail: 56622000@163.com

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Abstract: Objective: To assess the diagnostic efficiency of OMOM capsule endoscopy (CE) in a group of patients with different indications. Methods: Data from 89 consecutive patients (49 males, 40 females) with suspected small bowel disease who underwent OMOM CE (Jinshan Science and Technology Company, Chongqing, China) examination were obtained by retrospective review. The patients' indications of the disease consisted of the following: obscure gastrointestinal bleeding (OGIB), abdominal pain or diarrhea, partial intestinal obstruction, suspected inflammatory bowel disease, tumor of unknown origin, hypoproteinemia, constipation, weight loss, and elevated tumor markers. Results: CE failed in one patient. Visualization of the entire small bowel was achieved in 75.0%. Capsules were naturally excreted by all patients. The detection rate of abnormalities was 70.5% for patients with suspected small bowel disease, and the diagnostic yield for patients with OGIB was higher than that for patients with abdominal pain or diarrhea (85.7% vs 53.3%, $P<0.005$). Angiodysplasia was the most common small bowel finding. Active bleeding sites were noted in the small intestine in 11 cases. Conclusion: OMOM CE is a useful diagnostic tool for the diagnosis of variably suspected small bowel disease, whose diagnostic efficiency is similar to that of the Pillcam SB (small bowel) CE (Given Imaging, Yoqneam, Israel).

Key words: OMOM capsule endoscopy (CE), Small bowel disease, Obscure gastrointestinal bleeding (OGIB), Diagnosis
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INTRODUCTION

Historically the small bowel was considered technically difficult to examine because of its length, location, and tortuosity. Since capsule endoscopy (CE) was approved by the Food and Drug Administration (FDA) in August 2001, the small bowel no longer appears mysterious territory. Currently this technique is generally utilized because it is non-invasive and painless. Until now, CE has been shown to be successful in many cases, providing better results than traditional techniques, especially in the diagnosis of obscure gastrointestinal bleeding (OGIB), which is defined as recurrent or persistent bleeding or iron deficiency anemia after a negative initial evaluation (AGA, 2000). Its superior diagnostic yield is up to 92% (Pennazio *et al*., 2004). In China the application of Pillcam SB (small bowel) CE (Given Imaging, Yoqneam, Israel) is limited by its cost, more than RMB 6000 Yuan, which is too expensive for most people. In March 2005, OMOM CE (Jinshan Science and Technology Company, Chongqing, China) went on the market, and its cost is only approximately half that of Pillcam SB CE.

In this study our aim was to describe the diagnostic efficiency of OMOM CE in different small bowel pathologies in which conventional modalities failed to find the organic lesions.

MATERIALS AND METHODS

Patients

A total of 89 patients (61 inpatients, 28 outpatients), mean age (54±18) years (range 16~84 years), were evaluated by OMOM CE at the Department of Gastroenterology, the First Affiliated Hospital, School of Medicine, Zhejiang University, China, from September 2006 to June 2007. Forty-nine subjects, mean age (52±18) years (range 16~82 years), were male

‡ Corresponding author

and 40, mean age (56±19) years (range 19~84 years), were female. The indications for the study were OGIB, abdominal pain or diarrhea, partial intestinal obstruction, suspected inflammatory bowel disease, tumor of unknown origin, hypoproteinemia, constipation, weight loss, and elevated tumor markers (Table 1). All patients had undergone upper and lower gastrointestinal endoscopies. Most of them had undergone other investigations, such as small bowel follow through, computed tomography, magnetic resonance imaging. These methods are common now in detecting small bowel lesions. All of the findings were negative or did not significantly explain the clinical picture. Two patients had undergone gastrectomy, one of them with suspected inflammatory bowel disease, and the other with OGIB.

Table 1 Indications for capsule endoscopy (CE)

Indication of patients for CE	Number
Obscure gastrointestinal bleeding (OGIB)	42
Abdominal pain or diarrhea	30
Partial intestinal obstruction	5
Suspected inflammatory bowel disease	4
Weight loss	3
Hypoproteinemia	2
Constipation	1
Tumor of unknown origin	1
Elevated tumor markers	1
Total patients	89

Equipment

The OMOM CE (Jinshan Science and Technology Company, Chongqing, China) was used in all patients. This system is made up of three parts: a disposable CE, an image recorder and an image workstation. The pill measures 13 mm×27.9 mm, and weighs <6 g. Image features include a 140° field of view and a resolution of 0.1 mm. CE has a battery life of approximately 6~8 h, and is propelled by peristalsis. The pictures are taken at a rate of two per second. The acquired images are transmited to the image recorder. The recorder is later connected to the workstation, in which the images are processed using a specifically designed software package. The trait of OMOM CE is similar to that of Pillcam SB CE.

Methods

All examinations were carried out according to the following rules: a clear semi-liquid diet on the day prior to CE; fasting for 12 h; drinking 200 g/L mannitol 250 ml and 50 g/L glucose saline 1 L 4 h before the examination. Prokinetic drugs were not used. After the examination, patients were allowed to drink 2 h later and to eat a light snack 4 h later, while continuing their usual activities. The recorder was disconnected approximately 8 h after the start of the exploration. All patients were interviewed after completing the study to evaluate their tolerance or complications.

Interpretation of results and statistical analysis

The acquired images were reviewed by two gastroenterologists. Quantitative variables were expressed as mean±*SD* values, qualitative variables as percentages, and these variables were compared by means of a χ^2-test. A P value <0.05 was considered significant.

RESULTS

The recording time was 367 to 540 min. All of the patients said that the pill was easy to swallow, painless and preferable to conventional endoscopy, and no complications were observed. The capsules were spontaneously excreted by all patients.

CE examination was unsuccessful in one patient with abdominal pain. The capsule transited repeatedly between stomach and duodenum until the end of the examination. Eventually 88 explorations were used for statistical evaluation. The average gastric emptying time (based on 88 patients) was (59±72) min (range 2~434 min). In 22 cases (25%), the capsule failed to pass the ileocecal valve within the duration of the examination. The mean small bowel transit time (based on 66 patients) was (248±91) min (range 65~421 min). The most common causes for not passing the ileocecal valve during the recording time were prolonged permanence of the capsule in the stomach (>60 min, 11 patients, 50%), and impact of lesions (6 patients, 27.3%).

CE identified small bowel lesions in 62 patients (70.5%), mostly represented by angiodysplasia, tumors, ulcers, lymphangiectasia, etc. (Table 2). Several patients had more than one type of lesion. Angiodysplasia was the most common small bowel finding and was seen in 34 cases (54.8%). An ulcer with or without stenosis was seen in 9 cases, of which

3 were suggestive of Crohn's disease, confirmed by history and pathology. In 7 of the cases of a tumor, 3 cases underwent surgery, 2 of them being a stromal tumor and the third a lymphoma; in another case the tumor was found in the proximal intestine. Following double balloon enteroscopy, a long strip of neoplasm (7~8 cm) in the descendant duodenum was found, which was endoscopically removed and eventually diagnosed as duodenal Brunner's gland adenoma. Ancylostomes were seen in 4 cases. Additionally, no pathological findings were found in 24 patients (27.3%). In another 2 patients, no lesions but a gastric ulcer and a duodenal ulcer were found.

Table 2 Type of lesions in small bowel detected by CE*

Findings	Number	Findings	Number
Total	62	Ancylostome	4 (6.5%)
Angiodysplasia	34 (54.8%)	Crohn's disease	3 (4.8%)
Tumor	7 (11.3%)	Inflammatory	3 (4.8%)
Ulcer#	6 (9.7%)	Diverticulum	2 (3.2%)
Lymphangiectasia	6 (9.7%)	Polyps	1 (1.6%)

*Several patients had more than one type of lesion; #Ulcer except for Crohn's disease

Of 42 patients with OGIB, small bowel lesions were detected in 36 patients (85.7%), in which angiodysplasia was also the most frequent lesion in small bowel (27 patients, 75.0%). In 11 cases, active bleeding sites were noted in the small intestine. The sources of the bleeding were found to be angiodysplasia (5 patients), tumor (2 patients), ulcer (1 patient), while in another 3 patients the sources were not clearly seen. Of 30 patients with abdominal pain or diarrhea, small bowel lesions were detected in 16 patients (53.3%). The types of small bowel lesions in the group with OGIB and with abdominal pain or diarrhea are shown in Table 3. The detection rate of small bowel disease in the patients with OGIB was superior to that in the patients with abdominal pain or diarrhea (χ^2=9.15, P<0.005).

Table 3 Comparison of lesions between OGIB and abdominal pain or diarrhea

Findings	Number	
	OGIB	Abdominal pain or diarrhea
Total	42	30
Positive case	36 (85.7%)	16 (53.3%)
Type of lesions		
Angiodysplasia	27 (75.0%)	6 (37.5%)
Tumor	5 (13.9%)	1 (6.3%)
Lymphangiectasia	0	4 (25.0%)
Polyps	1 (2.8%)	0
Ancylostome	2 (5.6%)	0
Crohn's disease	0	3 (18.8%)
Ulcer	1 (2.8%)	2 (12.5%)

In this study, there were 5 patients with partial intestinal obstruction undergoing CE, one of them with lymphangiectasia and the other four being negative. All of capsules were naturally excreted. There were no capsule retensions.

In addition to lesions of the small bowel, CE could find lesions of other parts of the gastrointestinal tract. In the study a gastric ulcer was seen in 2 patients, while there were 5 with gastric erosions, 2 with duodenal ulcers and 1 with colonic ulcer. But in almost all cases the colon was difficult to see because of residuals.

DISCUSSION

The characteristics of the small bowel make its evaluation by conventional examination difficult. In daily practice the methods for examining the small bowel consist of double balloon enteroscopy, push enteroscopy, and indirect methods such as the small bowel X-ray series and enteroclysis, radioisotope bleeding scans, angiography, computed tomography, and so on. These indirect methods had proved low in sensitivity (Ell *et al*., 2002; Costamagna *et al*., 2002; Hara *et al*., 2004). The double balloon enteroscopy and push enteroscopy are invasive and difficult to tolerate for patients. The advent of CE is well known on account of its non-invasiveness with no pain and a high detection rate. Recently Li *et al*.(2007) showed that CE should be selected as the first diagnostic approach for suspected small bowel disease after comparing it with double balloon enteroscopy, especially for OGIB. Patients may soon be able to opt for CE as their first line of investigation instead of conventional endoscopy.

The clinical use of CE is rapidly expanding. Until now the most commonly used CE around the world is the Pillcam SB CE. But in China the price of Pillcam SB CE examination, more than RMB 6000 Yuan, is too costly to permit wider use. A number of patients give up this examination only on account of the cost. In 2005 OMOM CE made in China was launched, and its price is RMB 3000 Yuan, only half that of Pillcam SB CE. The structure and technical

parameters of OMOM CE are similar to those of Pillcam SB CE. Moreover, thanks to the Real Time Viewer, physicians can view real-time images and estimate the capsule position. Our hospital imported OMOM CE in September 2006. Up until June 2007, there were 89 patients undergoing OMOM CE.

CE has been shown to have a superior ratio of positive findings, ranging from 45%~76% for the recognition of small bowel pathology (Sidhu *et al*., 2006). In this study, the ratio of small bowel positive findings was 70.5% (62/88), which is in the range of results published by others (Sidhu *et al*., 2006).

The most obvious and the first indicator to be tested by CE was OGIB, which occurred in 5%~10% of patients with any type of gastrointestinal bleeding. The yield of CE in published reports ranges from 30% to 92%, depending on the definition of positive findings and the type of bleeding investigated (Carey *et al*., 2007). Commonly detected abnormalities include angiodysplasia, tumors, varices, and ulcers (Pennazio *et al*., 2004). In this study, the detection rate of OGIB was 85.7% (36/42), and the definitive diagnoses included angiodysplasia 75.0% (27/36), tumors 13.9% (5/36), ancylostome 5.6% (2/36), polyps 2.8% (1/36). Angiodysplasia was the most frequent finding in this study, which is coincident to other studies (Pennazio *et al*., 2004; Matas *et al*., 2006). In the patients with OGIB, active bleeding was found in 11 patients, but the lesions could not be found in 3 patients because of the presence of abundant fresh blood. It is considered that timing when using the procedure is a crucial and definite influence on the diagnostic efficacy. Sturniolo *et al*.(2006) believed that a satisfactory diagnostic yield can be obtained if the procedure is performed within a month of the bleeding episode.

It was reported that CE did not play an important role in the evaluation of patients with chronic abdominal pain of unknown origin, and that in patients with undiagnosed abdominal pain, the yield of CE appeared to be low (Ersoy *et al*., 2006). But in this study, the detection rate of small bowel lesions in patients with abdominal pain or diarrhea was up to 53.3% (16/30), and the most common finding was also angiodysplasia, followed by lymphangiectasia, Crohn's disease and ulcers. Though the detection rate of abdominal pain or diarrhea is lower than that of OGIB, it is also the indication for CE. But some lesions, such as angiodysplasia, cannot explain the clinical symptoms. So the diagnostic yield of patients with abdominal pain or diarrhea is also low.

Tumors of the small bowel account for less than 6% of all gastrointestinal neoplasms and 1%~2% of gastrointestinal malignancies. Because of the difficulty of diagnosis and lack of symptoms in the initial phase, malignant small bowel tumors are often diagnosed late. By that time almost 50% have metastasized (Bailey *et al*., 2006). Several studies confirmed the importance of CE in the diagnosis of small bowel tumors. It was reported that tumors could be found anywhere along the small intestine in 3%~9% of patients undergoing CE for OGIB or with some other suspicion of small bowel disease (de Franchis *et al*., 2004). In this study, 7 patients (8.0%, 7/88) were found to have a small bowel tumor, and in 4 patients of them, this was confirmed by an operation. The other 3 patients rejected further management. The indications from these 7 patients were OGIB (6 patients) and abdominal pain (1 patient). The majority of patients with a tumor were referred for OGIB, which was coincident with others (Schwartz and Barkin, 2007).

The initial experiences showed that the cecum could not be viewed in approximately 20% (17.9%~26.0%) of the study population on account of the short battery life, because the capsule had remained in the stomach for more than 60 min (Mylonaki *et al*., 2003; Fireman *et al*., 2005; Carey *et al*., 2007), and for a variety of other reasons. In this study the capsule failed to pass the ileocecal valve within the duration of the examination in 22 cases (25%, 22/88), and half of these cases were due to the prolonged gastric emptying time (>60 min). In particular, there were 2 cases whose gastric emptying time was more than 400 min, to be exact 416 min and 434 min, which made the average gastric emptying time long. There are many researchers looking at the best way to prepare patients for the CE study, and achieve a shorter transit time, but still with no definite answer. Some of the published studies considered that use of oral erythromycin significantly reduced the gastric transit time of CE (Fireman *et al*., 2005; Leung *et al*., 2005). In future we can utilize the function of a real time display of OMOM CE. If the capsule is detained in the stomach too long, we can impel it to pass the pylorus with an upper gastrointestinal endoscope.

A serious concern is represented by capsule

retention, which may lead to acute small bowel obstruction, and in some cases surgery may be required to remove it. In the case of OGIB the most quoted retention rate is 0.75%. For patients with Crohn's disease, retention may happen in 6.7% of cases (Moglia *et al*., 2007). Intestinal obstruction or known stricture was thought to be a primary contraindication for CE. Nevertheless, several studies showed capsule retention was not always an adverse event. Capsule retention in the small intestine could help a pre-decided operation by guiding the surgeons to clearly identify the site of obstruction in patients with suspected small bowel obstruction (Cheifetz and Lewis, 2006; Kalantzis *et al*., 2007). In our study, 5 patients with a diagnosed partial intestinal obstruction by X-ray examination were included. Eventually capsules were spontaneously excreted by all patients and no significant lesions were found. The dimension of OMOM CE is similar to that of Pillcam SB CE. It is thought that intestinal obstruction is not an absolute contraindication.

In this study, we conclude that OMOM CE is a useful endoscopic technique in the evaluation of small bowel disorders, particularly in diagnosing OGIB. We presume that the diagnostic efficiency of OMOM CE made in China is similar to that of Pillcam SB CE with reference to the published studies. For the Chinese, OMOM CE has a higher performance-price ratio.

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