Diagnostic value of OMOM capsule endoscopy for small bowel diseases in adults

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Received November 5, 2015; Accepted July 27, 2017

DOI: 10.3892/etm.2018.5864

Abstract. The present study aimed to determine the diagnostic yield of OMOM capsule endoscopy for small bowel diseases in adults. A total of 89 patients, including 45 cases of obscure abdominal pain, 22 of chronic diarrhea, 18 of obscure gastrointestinal bleeding and 4 of obscure anemia were enrolled in the present study. The transit time of the endoscopy capsule in the digestive tract was recorded and the testing results were analyzed. All detections were completed except for four capsule retentions and the completion rate was 95.51%. The average transit time of the endoscopy capsule in the esophagus, stomach and small intestine was 62.18±64.23 sec, 67.46±63.13 and 346.53±102.81 min, respectively. Of the 89 patients, 54 (60.67%) were found to have lesions, among which 19 had mucosal erosion (21.35%), 15 had anabrosis (16.85%), 9 were diagnosed with polyps (10.11%), 5 with angiodysplasia (5.62%); furthermore, tumors were identified in 5 patients (5.62%) and ancylostomiasis in 1 patient (1.12%). The results confirmed the feasibility and validity of OMOM capsule endoscopy for diagnosing small bowel diseases in adults.

Introduction

Patients with small bowel diseases usually present with abdominal pain, diarrhea, hematochezia, fever as well as weight loss. However, due to the length, tortuosity and location of the small bowel, its examination is technically difficult in previous times. Furthermore, conventional methods, such as X-ray analysis with barium enteroclysis, angiography, radioisotope scanning, computed tomography (CT) and magnetic resonance imaging are usually poorly tolerated or indirect, and have low diagnostic efficacy (1-3).

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Key words: capsule endoscopy, small bowel diseases, transit time, diagnostic efficiency

Since its implementation ~10 years ago, capsule endoscopy has become one of the most important tools for small bowel investigation (4). This non-invasive technology allows for direct and complete examination of the entire small bowel, and has been particularly used in patients with obscure gastrointestinal bleeding, mucosal lesions, chronic abdominal pain, chronic diarrhea and Crohn's disease (3,5-7). However, >50,000 images are reproduced during this endoscopy procedure and physicians are required to spend 50-120 min to completely review these images (8). It is undoubtedly difficult for physicians to concentrate for such a long time and misdiagnosis may occur. Thus, software-aided reading is urgently required to solve the time-consuming problem of traditional capsule endoscopy.

OMOM capsule endoscopy, developed by Jinshan Science & Technology Co. (Chongqing, China), has an added automatic mode and quickview mode, which functions through elimination of similar images as well as analyzing colors and patterns (9). This workstation is proved to be valuable for small bowel evaluation with a good overall diagnostic yield and to date, it has been widely used in >60 countries and regions, particularly in Asia and Europe (10). While previous studies have indicated the superiority of this innovative technique over conventional modalities, few published studies have reported on the experience of its clinical application (1,11,12). Therefore, the present study evaluated the feasibility and validity of OMOM capsule endoscopy for the diagnosis of small bowel diseases and reported on its rational application in practice.

Materials and methods

Patients. A total of 89 consecutive patients aged >20 years who underwent OMOM capsule endoscopy at the People's Hospital of Xinghua (Jiangsu, China) from March 2012 to September 2014 were recruited for the present study. These patients had small bowel diseases, including obscure abdominal pain, chronic diarrhea, gastrointestinal bleeding and anemia. Capsule endoscopy was not performed in patients who were unable to swallow, suffering from digestive tract stenosis or obstruction, acute ulcerative colitis, ischemic bowel diseases or radioactive colitis, suspected to have digestive tract stenosis and fistula and/or those with a cardiac pacemaker or other electro-medical device implanted.

The present study was approved by the Ethics Committee of Xinghua People's Hospital (Jiangsu, China). Written informed consent to undergo the entire procedure of capsule endoscopy and for the use of images/data for publication in the present study was obtained from each of the included patients.

Device description. The OMOM endoscopy capsule was purchased from Jinshan Science & Technology (Chongqing, China). This diagnostic system consisted of an OMOM capsule (13.0x27.9 mm), an image recorder and a workstation. Image features included a resolution of 0.1 mm and a 140˚ field of view. Images were first captured at a rate of two per second and the acquired images were then transmitted to the image recorder, which was later connected to the workstation. Images were finally processed in the workstation by a specifically designed software package.

Capsule endoscopy. Patients were instructed to follow a 1-day minimum-residue diet with an overnight fast prior to undergoing the procedure. At 3-4 h following dinner, each of them took polyethylene glycol electrolyte powder orally with 3-4 l drinking water for small-bowel cleansing and then took 100 mg simethicone to prevent bubbles in the small bowel half an hour prior to undergoing OMOM capsule endoscopy.

The procedure of capsule endoscopy was performed as previously described (13). The course was monitored through a computer station. If the OMOM capsule did not reach the duodenum within 2 h, a snare under gastroscopy was used to facilitate propulsion of the capsule. After 8-h ingestion, the recorded data were downloaded to the OMOM workstation and the capsule endoscopy video was reviewed by two physicians independently. The average transit time of the endoscopy capsule in the esophagus, stomach and small intestine was calculated, as well as the percentage of each type of small bowel disease.

Statistical analysis. Continuous and categorical variables were respectively presented as the mean ± standard deviation and frequency (%). All calculations and analyses were performed by SPSS 19.0 software (IBM Corp., Armonk, NY, USA). $P<0.05$ was considered to indicate a statistically significant difference.

Results

Demographic and clinical data of patients. A total of 89 patients, including 43 males and 46 females, were included in the present study. The age of the included patients ranged from 20 to 80 years and the median age was 53.41 years. Among these patients, 45 presented with obscure abdominal pain, 22 with chronic diarrhea, 18 with obscure gastrointestinal bleeding and 4 with anemia.

Transit time of capsule endoscopy in the digestive tract. As presented in Table I, the transit time of the capsules in the stomach was >90 min in 29 of the 89 patients. For 8 of the 29 patients, a snare under gastroscopy was used, as the endoscopy capsule was retained in the stomach for >120 min. However, capsule retention for >7 h occurred in 4 patients (4.49%), among which the capsules did not reach the colon in 2 of these patients. A further 2 patients presented with capsule retention in their small intestines. One of the capsule retention patients complained of abdominal pain and the other one developed diarrhea, the latter of which was diagnosed with Crohn's disease. Finally, all of the retention capsules were successfully removed. The completion rate of capsule endoscopy was 85/89 (95.51%). The average transit time of the endoscopy capsule in esophagus, stomach and small intestine was 62.18±64.23 sec, 67.46±63.13 min and 346.53±102.81 min, respectively.

Capsule endoscopy findings. On capsule endoscopy examination, small intestinal lesions were identified in 54 of 89 patients (60.67%), among which 19 (21.35%), 15 (16.85%), 9 (10.11%), 5 (5.62%), 5 (5.62%) and 1 (1.12%) were diagnosed with mucosal erosion, anabrosis, polypus, angiodysplasia, tumor and ancylostomiasis (Fig. 1 and Table II).

Specifically, of the 45 patients with obscure abdominal pain, 10 (22.22%) were diagnosed with mucosal erosion, 5 (11.11%) with anabrosis, 5 (11.11%) with polypus and 3 (6.67%) with tumors. Among the 22 chronic diarrhea patients, 5 (22.73%) had mucosal erosion, 5 (22.73%) had ulcers, 2 (9.09%) had polypus and 1 (4.55%) had one tumor. Of the 18 subjects with obscure gastrointestinal bleeding, 4 (22.22%) were diagnosed with mucosal erosion, 3 (16.67%) with anabrosis, 2 (11.11%) with polypus, 5 (27.78%) with angiodysplasia (3 (16.67%) with active bleeding and 2 (11.11%) with bleeding) and 1 (5.56%) with one tumor. Of the 4 anemia patients, 3 (75.00%) had anabrosis and 1 (25.00%) had ancylostomiasis.

Discussion

OMOM capsule endoscopy, a promising and innovative technique, has been widely used in China, Africa and Europe since its marketing from 2005 onwards. The present prospective study presented the diagnostic value of OMOM capsule endoscopy in practice. The results demonstrated that the average transit time of the endoscopy capsule in the esophagus, stomach and small intestine was 62.18±64.23 sec, 67.46±63.13 min and 346.53±102.81 min, respectively. In addition, OMOM capsule endoscopy identified 54 out of 89 patients (60.67%) with various types of small intestinal lesion, among which 19 (21.35%), 15 (16.85%), 9 (10.11%), 5 (5.62%), 5 (5.62%) and 1 (1.12%) were diagnosed with mucosal erosion, anabrosis, polypus, angiodysplasia, tumor and ancylostomiasis.

The small bowel is characterized by its considerable length, tortuosity and inaccessibility, which makes small bowel examinations a challenge for physicians. Conventional modalities for diagnosing suspected small bowel lesions have been reported to be low in sensitivity or invasive and difficult to tolerate for patients (14-16). Of note, the advent of capsule endoscopy has facilitated small bowel examination with high diagnostic efficiency and non-invasiveness with no pain. Several different types of capsule endoscopy system have emerged and the PillCam capsule endoscope, developed by Given Imaging (Yokne'am Illit, Israel), is the first and most widely used wireless endoscopy system worldwide. Although less well-known than the PillCam capsule endoscope, the diagnostic yield of OMOM capsule endoscopy has been proved to be similar (11). In the present study, visualization

Table I. Transit time of capsule endoscopy in the digestive tract of patients.

		Transit in stomach (min)			Transit in small intestine (min)			
	Transit in esophagus (sec)	<90	90-120	>120	120-240	240-360	360-420	420-480
Cases (n)	89	60	21	8	10	58	17	4
Transit time	62.18±64.23		67.46±63.13			346.53±102.81		

Table II. Capsule endoscopy results depending on different symptoms within the cohort (n=89).

Diagnosis	Abdominal pain	Diarrhea	Gastrointestinal bleeding	Anemia	Total, n (%)
Mucosal erosion	10	5	4	0	19 (21.35)
Anabrosis	5	5	2	3	15 (16.85)
Polypus	5	2	2	0	9 (10.11)
Angiodysplasia	0	0	5	0	5 (5.62)
Tumor	3	1	1	0	5 (5.62)
Ancylostomiasis	0	0	0	1	1 (1.12)
Total	23	13	14	4	54 (60.67)

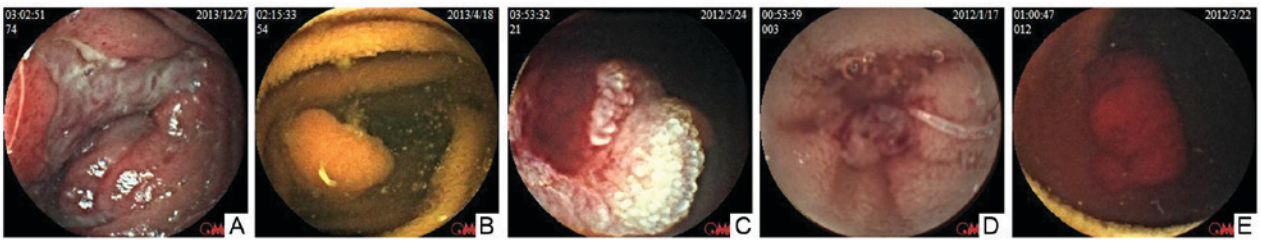

Figure 1. Capsule endoscopic images of small bowel lesions in patients. Representative images of (A) ulcer, (B) polypus, (C) bleeding, (D) ancylostomiasis and (E) tumor.

of the entire small bowel by OMOM capsule endoscopy was achieved in 85 of 89 patients (95.51%) and various distinct types of lesion were identified, including mucosal erosion, anabrosis, polypus, angiodysplasia, tumor and ancylostomiasis. Thus, OMOM capsule endoscopy is effective in diagnosing patients with suspected small bowel disease, particularly for those with pathologies that are difficult to detect by traditional methods.

The transit time in the digestive tract is a key parameter for successful completion of capsule endoscopy. A retrospective study demonstrated that a transit time of >45 min in the stomach is an independent risk factor for incomplete capsule endoscopy in the small bowel (17). The prolonged transfer may be associated with the positioning of patients and insufficient gastrointestinal motility in the resting state. In order to resolve limitations regarding incomplete small bowel capsule endoscopy, drugs such as domperidone have been used to improve the gastric dynamics and improve the diagnostic yield of endoscopy (18). In the present study, the first real-time observation was performed during the initial 90 min of capsule action. The second real-time observation was performed at 90-120 min. In 8 of the patients, gastroscopy intervention was performed, as the capsule retention in their stomach was >120 min. Finally, the capsules did not reach the colon in only 2 of the patients.

The diagnostic yield of capsule endoscopy varies among different studies. Mohan *et al* (1) reported that 36 out of 42 patients (85.71%) had abnormal findings on OMOM capsule endoscopy in their study, among which 26 patients exhibited obscure gastrointestinal bleeding and a further 10 patients exhibited abdominal pain and/or diarrhea. However, the diagnostic yield in another study using the PillCam patency capsule was 77.78% (14/18) (19). In the present study, various types of lesion were detected in 54 out of 89 patients (60.67%), which was lower than the rates in previous studies. This may be explained by the relatively small number of samples included in these studies. Although capsule endoscopy has the capacity of providing endoscopic imaging data of the entire small bowel, a miss rate of 10% has been reported for this method (20). In the present study, capsule retention occurred in four patients (4.49%); the capsules did not enter their small bowel at all and no detection was performed. Thus, endoscopy capsule retention may also be an explanation for the discrepancy in diagnostic yield.

As other capsules, the OMOM endoscopy capsule has several limitations. First, the diagnostic value for esophagus and colon lesions is limited due to the short transit time and battery life. Furthermore, there are blind areas and the capsule cannot accurately identify all lesions due to the small bowel residue, bleeding or peristalsis. Therefore, studies focusing on these limitations as well as those aiming to improve the diagnostic accuracy are required to realize the full potential of capsule endoscopy.

In conclusion, the present 2-year retrospective study confirmed the feasibility and validity of OMOM capsule endoscopy as a diagnostic tool for small bowel disease in adults. In China, OMOM capsule endoscopy may be a better choice for investigating the cause of obscure chronic abdominal pain, diarrhea and gastrointestinal bleeding, as it is relatively low-cost and while having an acceptable diagnostic value.

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