Fields of applications, diagnostic yields and findings of OMOM capsule endoscopy in 2400 Chinese patients

Zhuan Liao, Rui Gao, Feng Li, Can Xu, Yi Zhou, Jin-Shan Wang, Zhao-Shen Li

AIM: To retrospectively analyze the fields of application, diagnostic yields and findings of OMOM capsule endoscopy in Chinese patients.

METHODS: A database including 2400 Chinese patients who received OMOM capsule endoscopy in 27 endoscopy centers in China was retrieved from the Jianshan Science and Technology (Group) Co., Ltd., Chongqing 401120, China. The fields of application, potentially relevant findings, pyloric transit time (PTT), small bowel transit time (SBTT), and complete small-bowel examination rate (CSER) were recorded and analyzed.

RESULTS: Two thousand four hundred patients aged 9-91 years (mean, 49 years), of whom 1510 were males (62.9%), underwent 2400 OMOM capsule endoscopy procedures. One thousand two hundred and thirty two (51.3%) were referred with obscure gastrointestinal bleeding (OGIB), 642 (26.8%) with abdominal pain, and 223 (9.3%) with chronic diarrhea. The overall diagnostic yield was 47.7% (1144/2400). The diagnostic yield of OMOM capsule endoscopy in OGIB subgroup was much higher than in the non-OGIB subgroup (62.4% vs 32.1%, P < 0.001). The most common findings of the small bowel in Chinese patients with OGIB were arteriovenous malformation (28.1%) and tumors (18.9%). There was no significant difference in the diagnostic yield between the male and female patients with OGIB. However, the diagnostic yield in patients aged more than 60 was higher than in patients aged less than 60 (69.8% vs 58.9%, P < 0.001). The median PTT was 41 min (range: 1-544 min) and the mean SBTT was 247.2 ± 88.9 min. The overall CSER was 86.8%.

CONCLUSION: The OMOM capsule endoscopy is a valuable tool for small bowel evaluation with good overall diagnostic yield and CSER.

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Key words: OMOM capsule endoscopy; Obscure gastrointestinal bleeding; Small bowel

Peer reviewer: Sri P Misra, Professor, Gastroenterology, Moti Lal Nehru Medical College, Allahabad 211001, India
were introduced. On the other hand, radiologic techniques are relatively insensitive for diminutive, flat, infiltrative or inflammatory lesions of the small bowel. The capsule endoscope has been developed for direct and complete examination of the small bowel in a safe, non-invasive and well-tolerated manner and it has become the main method in the diagnosis of suspected diseases of the small bowel[1,2]. Today there are several different types of capsule endoscopy systems in use. The M2A or PillCam capsule endoscope (Given Imaging, Israel) is the first wireless endoscopy system, which was approved by the Food and Drug Administration in August 2001. It has been also the most widely used capsule endoscopy system with over 750 000 capsule ingestions worldwide[3]. Another less well known wireless capsule endoscopy system, the OMOM capsule endoscope, developed by Jiangshan Science and Technology (Group) Co., Ltd., Chongqing, China, has been widely used in China and some areas of Southeast Asian and European countries. It was approved by the State Food and Drug Administration of the People’s Republic of China in March, 2004. About 60 000 OMOM capsules have been ingested since 2004[4]. However, there are few published studies with large sample size that summarize the experience of its clinical application. In this study we reported the fields of application, diagnostic yields, findings, pyloric transit time (PTT), small bowel transit time (SBTT), and complete small-bowel examination rate (CSER) of OMOM capsule endoscopy in 2400 Chinese patients.

**MATERIALS AND METHODS**

**Database and patients**

A database including 2400 cases was retrospectively retrieved from the Jiangshan Science and Technology Ltd. OMOM capsule endoscopy database. The 2400 cases were performed at 27 endoscopy centers that used the OMOM capsule system in China.

Obscure gastrointestinal bleeding (OGIB) is defined as documented bleeding from the gastrointestinal tract with no etiology identified after upper endoscopy and colonoscopy. Each patient’s age, gender, filed date of application, the potentially relevant findings, PTT (defined as the recorded time of the first image of duodenum), and SBTT (defined as the time from the first duodenal image to the time of the first cecal image for patients in whom the capsule reached the cecum and the time from the first duodenal image to the time of the last small-bowel image for patients in whom the capsule did not reach the cecum) were recorded and analyzed. Complete small-bowel examination was considered when the cecum was visualized during capsule endoscopy. The CSER was defined as the percentage of patients with complete small-bowel examination.

**The OMOM imaging system**

The OMOM capsule endoscopy system consists of four main parts: a smart capsule, an image recorder jacket, a portable real-time monitor, and a computer workstation. The OMOM capsule has an outer diameter of 13 mm and length of 27.9 mm and it weighs 6 g. Pictures are generally taken at a rate of 2 frames/s, though the rate can be changed during the study, a unique feature of this capsule endoscope system. There are 14 receiver elements placed close to the surface of the abdomen and waist in the recorder jacket. The duration of the battery of the OMOM capsule is about 8 h, similar to the PillCam small bowel capsule. The OMOM capsule endoscope transmits the acquired images via a digital radio frequency communication channel to the recorder jacket. A real-time monitor allows the endoscopist to view progression of the capsule and even to send various commands to the OMOM capsule through the workstation. The image format (VGA: 640 × 480; QVGA: 320 × 240), sampling frequency (capture rate of 2 fps, 1 fps or 0.5 fps), flash intensity (1-31 levels), exposure controlling (auto or manual), white balance (auto or manual), and the conditions of capsule (sleep or wakeup) can be adjusted through these commands. The workstation reading can be done at 1, 2, 4, 6, 8, or 15 frames per screen.

**Statistical analysis**

Quantitative data were summarized by mean ± SD or as medians with ranges, and analyzed by the t-test if they were normally distributed, or by the Wilcoxon rank-sum test if they were not normally distributed. Categorical data were presented as a frequency (percentage) and analyzed by a χ² test. SPSS 13.0 software for Windows (SPSS Inc., Chicago, Illinois, USA) was used for the statistical analyses. A P value of < 0.05 was considered statistically significant.

**RESULTS**

**Age, gender and fields of application**

Two thousand four hundred patients aged 9 to 91 years (mean, 49 years), of whom 1510 were males (62.9%), underwent 2400 OMOM capsule endoscopy procedures. 1232 (51.3%) cases were performed for OGIB, 642 (26.8%) for abdominal pain, and 223 (9.3%) for chronic diarrhea. Other fields of application included health examination (103, 4.3%), suspected Crohn’s disease (52, 2.2%), and iron deficiency anemia (34, 1.4%) (Table 1).

**Diagnostic yields**

OMOM capsule endoscopies were negative in 1256 patients, and the overall diagnostic yield in the 2400 Chinese patients was 47.7%. OMOM capsule endoscopies were negative in 463 patients with OGIB and 793 patients with non-OGIB, respectively. The diagnostic yield of OMOM capsules in the OGIB subgroup was greater than in the non-OGIB subgroup (62.4% vs 32.1%, P < 0.001). In patients with abdominal pain and chronic diarrhea, the diagnostic yields were 39.4%, and 14.3%, respectively, and both were lower than that of patients with OGIB (both P < 0.001) (Table 2).

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Findings in small bowel

Arteriovenous malformations were the most common finding, comprising 28.1% of 1144 patients with positive capsule endoscopy. The other common findings in the small bowel included tumor (216, 18.9%), polyp (119, 10.4%) and Crohn’s disease (90, 7.9%). Small bowel parasites were also frequently found in 43 patients [hookworm, 26 (2.3%) and lumbricoides, 16 (1.4%)]. Celiac disease was rare in Chinese patients, accounting for only 0.6% (7) of the patients with positive capsule endoscopy (Figure 1).

In 1232 patients with OGIB, 769 potentially relevant lesions of the small bowel were seen on OMOM capsule endoscopy. The most common finding was arteriovenous malformations, which was seen in 313 patients (40.7%). The second most common finding in patients with OGIB was small intestinal tumors (201, 26.1%). The other common findings included small bowel ulcer (41, 5.3%), and polyps (24, 3.1%). Fifty seven patients (7.4%) had small intestinal active bleeding during the OMOM capsule endoscopy examinations. Hookworm and diverticulum were also causes for OGIB, and were seen in 26 (3.4%) and 18 (2.3%) patients. Interestingly,

Table 1  Fields of application for OMOM capsule endoscopy in Chinese patients

| Fields of application           | n (%) |
|--------------------------------|-------|
| Obscure gastrointestinal bleeding | 1232 (51.3) |
| Abdominal pain                | 642 (26.8) |
| Chronic diarrhea              | 223 (9.3) |
| Health examination            | 103 (4.3) |
| Suspected Crohn’s disease      | 52 (2.2) |
| Iron deficiency anemia        | 34 (1.4) |
| Suspected tumors              | 25 (1.0) |
| Unexplained weight loss        | 19 (0.8) |
| Small intestinal polyposis     | 10 (0.4) |
| Bleed                         | 10 (0.4) |
| Others                        | 50 (2.0) |
| Total                         | 2400 (100.0) |
finding was polyps (95, 25.3%). Other common findings in the small bowel included Crohn’s disease (67, 17.9%), mucosal erosions (63, 16.8%), and ulcer (48, 12.8%).

In 642 patients with abdominal pain, 253 small intestinal lesions were found. Polyps, mucosal erosions, and ulcers were the most common findings, and were seen in 66, 60, and 39 patients, respectively. Eighteen patients with duodenal ulcer were also diagnosed on capsule endoscopy. Only four small intestinal tumors were found in those patients. In 223 patients with chronic diarrhea, only 32 (14.3%) small intestinal lesions were found. Polyps, celiac disease, and Crohn’s disease were seen in 15, 6, and 4 patients, respectively. In 103 subjects who received capsule endoscopy for the purpose of health examination, only 27 lesions were found (23.6%). Moreover, 15 lesions outside the small bowel were found. Small bowel polyp, diverticulum, mucosal erosion, and tumor were found in 7, 2, 2, and 1 subjects, respectively (Tables 4 and 5). Figure 2 showed some representative small bowel images captured by the OMOM capsule endoscope.

**PTT, SBTT and CSER**

PTT and SBTT were recorded in 1876 and 1420 patients, respectively. The SBTT was normal distributed, while PTT was not. The median PTT was 41 min (ranging 1-544 min). The mean SBTT of the 1420 patients was 247.2 ± 88.9 min, ranging from 27 to 720 min. There was no statistically significant difference between the male and female patients in the median PTT [40 (1-544) min vs 41.5 (2-465) min, P = 0.155] and mean SBTT (246.6 ± 89.7 min vs 248.3 ± 87.5 min, P = 0.720). In the patients aged over 60, the median PTT was shorter, while mean SBTT was longer than patients aged less than 60 [32.5 (2-474) min vs 43.0 (1-544) min, P = 0.004; 258.9 ± 87.2 min vs 245.1 ± 89.1 min, P = 0.034]. PTT was shorter in patients with OGIB [40 (1-544) min vs 43 (1-544) min, P < 0.001], while SBTT was a little longer (252.9 ± 92.5 min vs 241.3 ± 84.8 min, P = 0.014) than patients without OGIB.
Two thousand and eighty-two capsules reached cecums, and 318 capsules failed to reach cecums during the entire recording procedure. The overall CSER was 86.8%. In 318 patients with incomplete small-bowel examination, capsule endoscopies were negative in 140 patients. Crohn’s disease (n = 41, 23.0%) and small bowel tumor (n = 40, 22.5%) were frequently found in the remaining 178 patients. Other findings included arteriovenous malformation and ulcer. CSER was not significantly different between males (1321/1510, 87.5%) and females (761/890, 85.5%) (P = 0.171). CSER in patients aged over 60 was significantly lower than patients aged less than 60 (81.1% vs 87.9%, P < 0.001).

**DISCUSSION**

This was the first large report on a new wireless capsule...
endoscopy system, OMOM, developed by Jianshan Science and Technology Ltd., Chongqing, China. Our study has shown that OMOM capsule endoscopy is a valuable tool for small bowel evaluation with good overall diagnostic yield and CSER. The diagnostic yield in the OGIB subgroup was much higher than in the non-OGIB subgroup. Arteriovenous malformations and tumors of the small bowel were the most common causes in Chinese patients with OGIB.

The OMOM capsule is widely used in China and some areas of Asian and European countries. The OMOM capsule is slightly larger and heavier than the Given Imaging PillCam small bowel capsule. The duration of the battery of the OMOM capsule is about 8 h, similar to the PillCam small bowel capsule. Two unique features of the OMOM capsule system are real-time viewing and workstation-to-capsule command controlling capabilities\(^\text{(1)}\). However, there has been no reported comparison in the literature of the diagnostic yields of the two different capsule endoscopy systems. The details and comparison with the available other capsule (i.e. PillCam), including the cost comparison, are shown in Table 6.

The most common applications for capsule endoscopy include evaluation for OGIB - including iron deficiency anemia, suspected Crohn's disease, suspected small intestinal tumors and surveillance in patients with polyposis syndromes, suspected or refractory malabsorptive syndromes (e.g. celiac disease)\(^\text{(12)}\). There is not yet consensus on indicated applications of capsule endoscopy from the Chinese Society of Digestive Endoscopy. In this study, though the most common indication for OMOM capsule endoscopy in Chinese patients was OGIB, many patients with abdominal pain and chronic diarrhea, even some healthy individuals, underwent OMOM capsule endoscopy. The study by Fry et al.\(^\text{(8)}\) suggested that capsule endoscopy had a low yield for evaluation of abdominal pain or chronic diarrhea and cannot be recommended as a first-line test without further study. Our study also found that the diagnostic yields by OMOM capsules in those patients were very low. Though the yields were a little higher than previous studies\(^\text{(8,9)}\), it is unknown whether the findings of the small bowel in those patients were the potential relevant causes of abdominal pain or chronic diarrhea. Moreover, in the 103 patients who underwent health examination by OMOM capsule endoscopy, only 12 lesions of the small bowel were found. Strict patient selection on the basis of such symptoms or signs was the key to increasing the yield of capsule endoscopy. Small bowel capsule endoscopy is not recommended as a tool for health examination.

The yield of capsule endoscopy in OGIB in published reports ranges from 30% to 92%, depending on the definition of positive findings and the type of bleeding investigated\(^\text{(10)}\). In our study with more than 2000 cases that underwent OMOM capsule endoscopy, the data showed that overall yield of the OMOM capsule was nearly 50% in this patient group. This yield was similar to previous studies on PillCam small bowel capsule endoscopy\(^\text{(11)}\). The yield of the OMOM capsule endoscopy in the OGIB subgroup was 62.4%, and was comparable with other published series using PillCam small bowel capsule endoscopy\(^\text{(12-15)}\). However, not all endoscopy centers in China had push enteroscopy and the database did not include the information on all investigations before capsule endoscopy. We also found the yield in the OGIB subgroup was greater than that in the non-OGIB subgroup, again suggesting that OGIB is the most important indication for capsule endoscopy and the OMOM capsule system probably has similar performance characteristics as those of the PillCam capsule system. Furthermore, we found that there was no significantly difference in the diagnostic yield between male and female patients with OGIB. We also found that the diagnostic yield in patients aged more than 60 was higher than patients aged less than 60. The proportions of arteriovenous malformations and small bowel tumors were not significantly different between young and old patients, which was different with the previous results by Papadopoulos et al\(^\text{(16)}\). Papadopoulos et al\(^\text{(16)}\) found that older patients had significantly less erosions and normal studies, but they had more angiodysplasias. Our study showed that, in Chinese patients, the causes of OGIB were not significantly different between male and female patients, and young and old patients.

It is reported that arteriovenous malformations of the small bowel comprise over 60% of the lesions found on capsule endoscopy\(^\text{(12)}\). However, the percentage of arteriovenous malformations in this study was much lower than previous studies\(^\text{(14,17)}\). The second most common finding in Chinese patients with OGIB was small bowel tumors. Another Chinese study on double balloon enteroscopy also showed that the most common abnormalities in Chinese patients with OGIB were small bowel tumors (39.1%) and angioectasia (30.4%)\(^\text{(18)}\). The data suggested that the spectrum of causes of small bowel bleeding might be different between Chinese people and...
Western countries populations. Interestingly, hookworm was seen in 26 Chinese patients with OGIB, comprising 3.4% of the positive findings in patients with OGIB. We also found that there were only six published case reports on hookworm-induced small intestinal bleeding on capsule endoscopy to date, and four out of six articles were from Asia. hookworm infestation rate in Asian patients is probably higher than Western patients, but to prove this, further larger study is needed.

The incidence of Crohn’s disease in Chinese population is increasing. A bibliometrics study also suggested that the incidence and prevalence rates of Crohn’s disease were still lower than those in Western and other industrialized Asian countries, but these rates have been increasing rapidly. In a prior study, capsule endoscopy yielded a diagnosis of Crohn’s disease only in a very small percentage of the patients (0% to 4%). In the present study, 90 patients with Crohn’s disease were diagnosed by OMOM capsule endoscopy, suggesting that this disease is probably no longer uncommon in Chinese people.

Celiac disease is a gluten-dependent enteropathy, characterized by chronic small bowel inflammation and mucosal atrophy. Celiac disease is a common medical condition with an estimated prevalence of 1:100 in the general Western population. Abdominal pain, chronic diarrhea, growth failure and malabsorption are its typical clinical presentation. Preliminary reports suggest that capsule endoscopy could represent an attractive and non-invasive diagnostic tool in patients with suspected celiac disease. However, our study showed that the prevalence of celiac disease in the Chinese patients who underwent capsule endoscopy was very low (7/2400, 0.3%). Up till now, there is no study which has reported on the prevalence of celiac disease in a general Eastern population.

Although the PTT and SBTT were not recorded in all 2400 patients, we found those values were similar to previous studies used Given Imaging capsule endoscopy. The overall CSER of OMOM capsule endoscopy was 86.8%, which was a little higher than Given Imaging capsule endoscopy (83.5%). Previous studies have shown that the real-time viewer of the Olympus EndoCapsule is very useful for determining a need for detecting gastric transit abnormalities and necessary intervention. The real-time viewer of OMOM capsule endoscopy may help to secure the passage of the capsule endoscope into the small bowel and hence increase the rate of complete small bowel examination. Many centers in China use the real-time viewer of the OMOM capsule endoscopy system and the CSER can be increased in some patients, but real-time viewing is sometime time-consuming, and some patients cannot wait for long in the endoscopy center.

Though the sample size was large, there were some limitations in our study. Firstly, many Chinese capsule endoscopists reported mucosal erosions of the small bowel, but further definitive categorization of such lesions was not clear. Secondly, the follow-up results of patients with positive findings by OMOM capsule were unknown; the positive findings of Crohn’s disease, celiac disease and tumor were not confirmed by biopsy, and the diagnostic yield may be overestimated.

In conclusion, this was the largest report on clinical application of the OMOM capsule endoscopy system in Chinese patients. OMOM capsule endoscopy is a valuable tool for small bowel evaluation with good overall diagnostic yield and CSER. The yield in OGIB subgroup was much higher than in the non-OGIB subgroup. Arteriovenous malformations and tumors of small bowel were the most common causes in Chinese patients with OGIB.

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