ONE YEAR EXPERIENCE OF OMOM CAPSULE ENDOSCOPY FOR SUSPECTED SMALL INTESTINE LESIONS

Khadka Mohan, Tao Xiaohong, Chen Dao-Rong, Wang Shun-Wen and Gu Sai

Abstract:

Background: Capsule endoscopy (CE), is a superior non-invasive tool in the diagnosis of suspected small bowel lesions to conventional modalities. This study has been carried out with the aim to share the experience and to evaluate the efficacy of OMOM CE. The objectives have been set to find out and compare the diagnostic yields of the CE for obscure gastrointestinal bleeding (OGB) and unexplained abdominal pain and/or diarrhea and also to see the cost effectiveness and quality of the CE.

Methods: OMOM CE examination was conducted in consecutive 46 admitted patients presented with suspected small intestinal lesions over a period of one year. The indications were OGB, unexplained abdominal pain and diarrhea.

Results: Abnormal findings were revealed in 42 out of which 36 subjects revealed significant abnormal findings in small bowel. Overall diagnostic efficacy of the CE was 80% and Diagnostic yield was significantly higher for OGB (26/27) in comparison to unexplained abdominal pain and/or diarrhea (96.30% vs 55.55%, \(P < 0.001\)). Angioectasia was the major finding for OGB cases. No complications were observed with the CE examination.

Conclusion: OMOM CE has high diagnostic yield for OGB and unexplained abdominal pain or diarrhea and effectiveness is comparable with Pillcam CE.

Key Words: Angioectasia, Capsule endoscopy, Obscure gastrointestinal bleeding, Unexplained Abdominal pain or Diarrhea

Introduction:

Diagnosis of suspected small bowel lesions was always difficult due to their inaccessibility and poor compliance by conventional modalities. Conventional modalities like push enteroscopy, enteroclysis are having low diagnostic efficacy and associated with technical difficulty both for the doctors and patients. The novice non invasive technology used in our study allows us to reveal the whole small bowel more particularly mucosal lesions, which was comparatively not possible by the conventional invasive methods. According to Lewish BS and Swain CP1, 2, push enteroscopy has only the accessibility up to mid-jejunum so that lesions in the remaining part of small intestine can’t be visualized.

Endoscopic visualization of the entire small bowel can only be carried out with
sonde enteroscopy or intraoperative enteroscopy which are invasive and technically difficult modalities. Double balloon endoscopy (DBE) is also a new technology to explore lesions in suspicious small bowel lesions which can access to whole small intestine. Fukumoto A et al. found that the diagnostic ability of DBE is nearly equal to that of CE. However, in many suspected small-bowel bleeding lesions, CE should be selected for the initial diagnosis and DBE for the treatment or histopathological diagnosis after detection of the bleeding site on CE. DBE is an invasive and uncomfortable procedure whereas, video capsule endoscopy (CE) permits non-invasive way of capturing whole small bowel images with good compliance from the patients.

There are already ample of study results showing superiority of this innovative technique over the conventional modalities. From 2001 onwards, Pillcam CE (Given Imaging, Yoqneam, Israel) has been widely used around the world including Southeast Asia which costs around 1000$. But since marketing of OMOM CE (Jinshan Science and Technology Company, Chongqing, China) from 2005, the OMOM CE is replacing the use of Pillcam CE especially in Europe, Africa and China because of its easy availability and lower cost (less than half of Pillcam CE).

In our study, the aim was to find out the diagnostic yield of OMOM CE in various small bowel indications.

**Material and Method:**

All patients in the study were recruited from 1st December, 2008 to 20th January, 2010 at the Department of Gastroenterology of First Affiliated Hospital of Chongqing Medical University. The study was approved by the Ethics Committee of Chongqing Medical University’s First Affiliated Hospital and informed consent was taken from each patient.

The results of the findings in consecutive forty-six patients (24 males, 22 females) during the period of a year were retrospectively reviewed (Table 2). The mean age of the patients was 53.28±16.93 (range, 15-81 years). The indications for the study were obscure gastrointestinal bleeding i.e. OGB (28 patients), unexplained abdominal pain predominant (15 patients), unexplained persistent diarrhea predominant (3 patients). Before the CE examination, all patients were undergone routine blood test, stool test, urine test and upper gastrointestinal endoscopy and colonoscopy. In addition, particularly patients with abdominal pain were also undergone abdominal ultrasound and CT scan. A few cases of OGB also underwent small bowel barium follow-through to exclude structural lesions. Some patients were also undergone repeated conventional endoscopies two times or more.

**Technique used:**

All patients were kept on liquid diet on the day prior to the test. Magnesium hydroxide and Polyethylene glycol were
used as laxative preparations before the test. On the previous day of the test at 6:00 PM, 80 ml of 40% magnesium hydroxide was given orally. Then at the same day midnight, they were given Polyethylene Glycol (PEG; 137 gm) in 2 L of drinking water. On the day of the test at 6:00 AM, they were given Dimethicone powder (4.75 gm) as air bubbles removal and after half an hour sensors were attached to eight locations on the anterior abdominal wall. A belt containing data recorder set (Image 1) was positioned outside the anterior abdominal wall. Patients then swallowed the OMOM Capsule with a mouthful of water.

The course of the CE was monitored through computer station to make sure that it reached to the stomach and then asked the patient to lie in bed on right lateral side for an hour to facilitate the entry of the CE from stomach to duodenum. After an hour again the location of the CE was checked through a small screen monitor (new generation OMOM) which can detect the location of CE inside the body and in almost more than 90% cases, the CE successfully passed to duodenum but in few cases it still remained in the stomach for which gastroscope was used to transfer it into duodenum.

The patients were kept nil oral for 2 hours after intake of CE. Then they were allowed to drink clear fluid and after an additional 2 hours were permitted to walk around. As soon as the battery life was finished during the procedure, the recorder was removed and the data were transferred to the computer workstation through a high capacity digital link. After the examination was over, all patients were asked about complaints they feel related with the examination.

Interpretation of results and statistical analysis:

The images were reviewed by three gastroenterologists and final interpretation was made after having discussion among at least four gastroenterologists including one professor. Quantitative variables were expressed as mean±SD values, qualitative variables as percentages, and these variables were compared by means of a χ²-test. A P value<0.05 was considered significant

CE Image findings interpretation:

Currently there is no standard system of classification for CE image interpretation. The wide range of diagnostic yields reported in different studies partially reflects differences in image interpretation. We used the following criteria for image interpretation of CE findings:

Angioectasia: abnormally dilated blood vessels with or without oozing, a flat red mucosal lesion with visible border or legs

Chronic enteritis: signs of inflammation, erosions, ulcers

Inflammatory lesions: areas of redness, edema

Erosion: An interruption of the mucosal lining without visible depth

Ulcer: an interruption of the mucosa with visible depth.

Results:
The average gastric emptying time (based on 40 patients) was 57 ± 44 mins (range 1 to 165 mins). In 4 patients, gastroscope was used to shift the CE because of narrowing of lower part of esophagus possibly due to some mass compression from outside of esophagus. In 38 out of the 45 patients, the capsule passed the ileocecal valve within the duration of the examination. The mean small bowel transit time (based on 38 patients) was 341 ± 104 mins (range 80 to 540 mins). The average total operating time in 40 patients was 503±58 mins (range 300-590 mins). Total photos captured by CE in 32 patients recorded were 53,254 in averages until battery life was finished. The demographic variables of patients have been shown in table 1. CE examination was unsuccessful in one patient. In the patient of 59 year old female with overt OGB, the capsule did not pass through pylorus due to pyloric stenosis secondary to healed peptic ulcer. All patients said that the CE examination procedure was highly comfortable unlike invasive endoscopies and contrast radiological studies. No patients encountered any complaints related to the capsule used. In overall, significant findings were observed in 36 out of 45 patients accounting 80% as diagnostic yield of CE. Significant findings were identified in 26 out of 27 patients (96.30%) with OGB including active bleeding sites in 8 patients. CE didn’t reveal any abnormality in one patient of overt OGB. categorized here as non significant findings by CE in the sense of not revealing new lesions in suspected small intestine. No abnormal findings were observed in 2 patients of unexplained abdominal pain predominant. Among 3 patients of unexplained predominant chronic diarrhea, significant findings were revealed in all. Chronic enteritis was found in all three cases along with angioectasia too. In addition, lymphoectasia was uncovered in one case and enterointestinal fistula in one among them.
In 64% of cases, multiple types of lesions present.

Table 2: Comparison of CE findings* in small intestine, between OGB and abdominal pain and/or diarrhea

<table>
<thead>
<tr>
<th>Types of lesion</th>
<th>OGB (Percentage)</th>
<th>Abdominal pain/Diarrhea (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioectasia</td>
<td>16 (59.26%)</td>
<td>13 (72.22%) ‡</td>
</tr>
<tr>
<td>Chronic enteritis</td>
<td>6 (22.22%)</td>
<td>5 (27.78%) ‡</td>
</tr>
<tr>
<td>Parasites</td>
<td>6 (22.22%)</td>
<td>0</td>
</tr>
<tr>
<td>Ulcers†</td>
<td>5 (18.52%)</td>
<td>0</td>
</tr>
<tr>
<td>Polyp or polyp like lesion</td>
<td>3 (11.11%)</td>
<td>2 (11.11%) 3 (16.67%) ‡</td>
</tr>
<tr>
<td>Diverticulum</td>
<td>2 (7.40%)</td>
<td>0</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>1 (3.70%)</td>
<td>1 (3.70%)</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lymphoectasia</td>
<td>0</td>
<td>1 (5.56%)</td>
</tr>
<tr>
<td>Enterointestinal fistula</td>
<td>0</td>
<td>1 (5.56%)</td>
</tr>
</tbody>
</table>

*Including one case of CE examination failure

†One case is T.B. ulcer. ‡Non significant findings in case of abdominal pain or diarrhea
Repeat CE was performed in a female patient of 58 year old suffering from unexplained abdominal pain after 3 months of treatment in line of chronic enteritis (multiple erosions and ulcers). Her ulcers were almost recovered and still had some erosion and additionally some angioectasia were seen in repeat CE. A 63 year old female patient presented with overt OGB with history of cirrhosis and splenomegaly and therefore had splenectomy, found to have angioectasia mainly in the form of abnormally dilated blood vessels with oozing from some.

The diagnostic yield of OMOM CE for small bowel lesions was significantly higher in patients of OGB (96.30%) than in patients of unexplained abdominal pain and/or diarrhea (55.55%) ($\chi^2$=11.203, CI=99%, P<0.001).

**Discussion:**

In daily practice, available imaging techniques of the small intestine consists of push-endoscopy and X-Ray studies which include small bowel follow through, enteroclysis, CT enterography. For last few years double balloon endoscopy (DBE) is also in practice in few centers. According to literatures, usually DBE is helpful if it is performed in prior indeterminate or negative findings for OGB cases already done by CE9, 10, 11. In most cases, upper GI endoscopy can easily reach up to the second part of the duodenum. Push Enteroscopy can demonstrate sites of lesions up to mid jejunum 1, 2. Biopsy is also possible during enteroscopy. Push and sonde enteroscopies have been used for revealing the small intestinal lesions, but these techniques are not easy to neither carry out nor give a high diagnostic yield.

In radiological studies, diagnostic accuracy of any small bowel pathology is often low as well as uncomfortable. Overall visualization of the mid and distal portion of small bowel seems unsatisfactory with modality other than CE. Regarding the difficulty for evaluation of occult GI bleeding, which has often been attributed to a source in the small intestine, many patients finally undergo surgery without knowing the actual source of bleeding. CE has shown a good diagnostic tool in patients with obscure gastrointestinal bleeding12-19. Ell C et al. stated that CE can help reduce the number of diagnostic procedures and could become the initial diagnostic choice in patients with OGB20. In several clinical studies, it has been shown that this modality may be superior to push enteroscopy20-26, small bowel series12, 27, enteroclysis28 and CT scan29 in identifying small bowel lesions in obscure gastrointestinal bleeding.

According to Tang SJ et al., the diagnostic yield of CE for the suspected bleeding source in obscure GI bleeding has been reported from 38% up to 93%14. In our study, this modality demonstrated the source of bleeding in 26 out of 27 patients (96.30%) presented with OGB which is the highest yield till date in the literature. According to literature20, for patients suffering from OGB, CE revealed definitive diagnoses as follows: angioectasia 53%, tumor 6.3% and inflammatory lesions 6.3%. In our study, the findings for OGB patients (Table 2) came out as angioectasia (59.26%), chronic enteritis (22.22%), parasites (22.22%), and ulcer (22.22%) including one case of TB ulcer, polyp or polyp like
Small Intestine Lesions and OMOM Capsule Endoscopy

lesions (11.11%), diverticulum (7.40%), Crohn’s disease (3.70%), and GI stromal tumor (3.70%).

Parasites were also involved in causing OGB. Hookworms may cause overt intestinal bleeding as reported in few case reports30, 31, 32. Round worms i.e. Ascaris lumbricoides found by CE in intestine have also been reported to be the cause of overt OGB in few cases33. In our study, CE found parasites infestation in 6 cases of OGB with hookworms (Figure 1) in 4 and round worms in 2. Ascaris Lumbricoides often cause intestinal obstruction as recorded in the literature34; however our study showed that the round worms can also cause OGB. CE is a superior and more sensitive diagnostic tool than barium follow-through and entero-computerized tomography in patients with suspected Crohn’s disease29, 35. CE is effective in diagnosing patients with suspected Crohn’s disease undetected by using conventional diagnostic methods36-40. We had findings in favor of Crohn’s disease in two patients of overt OGB. However Tuberculosis (Figure 2) was diagnosed in one case later on by methodology of therapeutic trial and in another case same diagnosis of Crohn’s disease (Figure 3) was confirmed by further treatment trial in regard to clinical improvement with prednisolone.

According to literature, CE did not play an important role in the evaluation of patients with unexplained abdominal pain41, 42. In patients with undiagnosed abdominal pain, the yield of CE appears to be low43, 44. However May et al.45 disclosed relevant findings in 36% and 40% of patients by two investigators.

About chronic diarrhea of unknown origin, the diagnostic yield by CE was very low according to Fry LC and colleagues44. In other study, Li et al.46 recently discovered diagnostic yield of CE as 53.3% for abdominal pain and/or diarrhea case. In line with the study outcome45, 46, our study revealed significant findings in 10 patients out of 18 accounting 55.55% diagnostic yield in patients with unexplained abdominal pain and/or diarrhea. It has clearly shown the need of further large series of prospective study to show the possible high efficacy of CE for unexplained abdominal pain or chronic diarrhea too.

The clinical use of CE is rapidly expanding. Till date, the mostly used CE around the world since 2001 is the Pillcam CE from Israel. The cost of Pill CE examination in Southeast Asia is around 1000$ which is expensive in comparison to OMOM CE from Chongqing, China launched since 2005, which just costs approximately 500$. The structure and technical parameters of OMOM CE are similar to Pillcam CE. Moreover, real-time images can be viewed and capsule position inside the body can be estimated only by OMOM CE. Our hospital imported OMOM CE in November, 2008 and started clinical application in indicated patients.

According to Li et al.46 the overall diagnostic efficacy of OMOM CE for suspected small bowel lesions is 70.5% and our study showed it as 80%. The diagnostic yield of Pillcam CE is 68% in average according to published studies12-19. Therefore, OMOM CE seems to have comparable diagnostic yield with that of Pillcam CE.

Our study had few limitations such as we could not recruit all the patients in the
department who were clearly indicated for CE examination because of high examination cost, its limitation to only diagnostic role and lack of regular follow up in many cases.

A few interesting cases:
1. CE revealed a jejunal tumor [Figure 4] with active bleeding in an old patient suffering from anemia with overt OGB. Surgical biopsy report later disclosed the tumor as Adenocarcinoma.
2. A 15 year old female patient who presented with overt OGB had retention of CE for 17 days but remained asymptomatic during the period. In the beginning she was clinically suspected with tuberculosis but the CE examination later revealed only angioectasia.
3. A 19 year old boy presented with chief complaint of melena, was found to have diverticulum in ileum with outlet inflammation (Figure 5).
4. CE remained in small intestine for almost 3 months without any complication in a 43 year old man who was suspected with intestinal tuberculosis after the CE findings and got improved with ATT trial of one month and the therapy was further continued.
5. A 71 year old female patient who presented with chief complaint of chronic diarrhea, had history of resection and anastomosis of small intestine 20 years back for treatment of lower GI bleeding due to angioectasia. She was found to have enterointestinal fistula along with chronic enteritis.
6. Most of the patients who were found to have multiple erosions, ulcers in small intestine in addition to stomach had history of NSAIDs consumption for a long time period.

**Conclusion:**

In our relatively small pool of cases, we found that OMOM CE is highly diagnostic endoscopic technique particularly in diagnosing obscure GI bleeding and it also shows promising outcome in diagnosis of unexplained chronic abdominal pain and unexplained diarrhea. In Southeast Asia, OMOM CE may be better choice for indicated patients with regard to its relatively lower cost and presumably comparable with Pillcam CE for diagnostic yield and safety.

**Acknowledgement:**

The research was conducted by the authors in the Department of Gastroenterology, First Affiliated Hospital of Chongqing Medical University for their own Academic Interest without sponsorship from any person, institution or company. Therefore with the production of the paper, there is no conflict of interest. We would like to thank all the patients who took part in the examination.
References:

3. Lewis BS, Waye JD. *Total small bowel enteroscopy*. Gastrointest Endosc 1987; 33: 435-438
13. Lewis BS. and Swain P. *Capsule endoscopy in the evaluation of patients with suspected small intestinal bleeding: Results of a pilot study*. Gastrointest Endosc 2002; 56: 349-353

15. **Lewis BS.** The utility of capsule endoscopy in obscure gastrointestinal bleeding. Techniques in Gastrointestinal Endoscopy 2003; 5: 115-120


23. **Lim RM, O’Loughlin CJ, Barkin JS.** Comparison of wireless capsule endoscopy (M2A) with push enteroscopy in the evaluation of obscure gastrointestinal bleeding. Am J Gastroenterol 2002; 97: S31


45. May A, Manner H, Schneider M, Ipsen A, Ell C. Prospective multicenter trial of capsule endoscopy in patients with chronic abdominal pain, diarrhea and other signs and symptoms (CEDAP-Plus Study).


Mohan Khadka, Lecturer, Department of Internal Medicine, Nobel Medical College, Biratnagar. Dao- Rong Chen, Shun-Wen Wang, Sai Gu, and Xiaohong Tao; Department of Gastroenterology, First Affiliated Hospital of Chongqing Medical University, Yuanjiagang, Chongqing city, 400016, Chongqing Province, P.R. China. Correspondence address: Mohan Khadka: E-mail: kha_mohan620@yahoo.com or mohanakhadka@yahoo.com.