

## Retrospective Study

## Capsule endoscopy and single-balloon enteroscopy in small bowel diseases: Competing or complementary?

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Supported by the Key Medical Personnel of Jiangsu Province, No. RC2011063.

**Institutional review board statement:** This study was reviewed and approved by the institutional review board of the First Affiliated Hospital of Nanjing Medical University.

**Informed consent statement:** All patients, or their legal guardians, provided informed written consent prior to capsule endoscopy or single-balloon enteroscopy. Patients were not required to give informed consent for inclusion in the study, as the analysis used anonymous clinical data. Individuals cannot be identified according to the data presented.

**Conflict-of-interest statement:** There are no conflicts of interest to report.

**Data sharing statement:** No additional data are available.

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**Manuscript source:** Invited manuscript

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**Received:** August 21, 2016

**Peer-review started:** August 22, 2016

**First decision:** October 11, 2016

**Revised:** October 25, 2016

**Accepted:** November 14, 2016

**Article in press:** November 16, 2016

**Published online:** December 28, 2016

### Abstract

#### AIM

To evaluate diagnostic yields of capsule endoscopy (CE) and/or single-balloon enteroscopy (SBE) in patients with suspected small bowel diseases.

#### METHODS

We retrospectively analyzed 700 patients with suspected small bowel diseases from September 2010 to March 2016. CE, SBE, or SBE with prior CE was performed in 401, 353, and 47 patients, respectively. Data from clinical and endoscopy records were collected for analysis. Indications, procedure times, diagnostic yields, and complications were summarized and evaluated.

## RESULTS

The overall diagnostic yield for the CE group was 57.6%. The diagnostic yield of CE in patients with obscure gastrointestinal bleeding (OGIB) was significantly greater than that in patients with no bleeding (70.5% *vs* 43.8%,  $P < 0.01$ ). The overall diagnostic yield of SBE was 69.7%. There was no difference in the diagnostic yield of SBE between patients with OGIB and those with no bleeding (72.5% *vs* 68.9%,  $P = 0.534$ ). Forty-seven patients underwent CE prior to SBE. Among them, the diagnostic yield of SBE with positive findings on prior CE was 93.3%. In addition, SBE detected two cases with superficial ulcer and erosive lesions in the small bowel, which were missed by CE. However, one case with lymphoma and two with Crohn's disease were not confirmed by SBE. The rate of capsule retention was 2.0%. There were no significant complications during or after SBE examinations.

## CONCLUSION

SBE is a safe and effective technique for diagnosing small bowel diseases. SBE with prior CE seemed to improve the diagnostic yield of small bowel diseases.

**Key words:** Capsule endoscopy; Small bowel diseases; Single-balloon enteroscopy; Diagnosis; Balloon-assisted enteroscopy

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**Core tip:** The aims of this study were to evaluate diagnostic yields associated with capsule endoscopy (CE), single-balloon enteroscopy (SBE), or their combined use in patients with suspected small bowel diseases, as well as to demonstrate the appropriate diagnostic algorithms for diagnosing different small bowel diseases. This study revealed the diagnostic yield of SBE with positive findings on prior CE was high (93.3%). CE followed by SBE represents an especially effective strategy for determining the cause of small bowel disease when findings from an initial CE examination are indeterminate.

Ma JJ, Wang Y, Xu XM, Su JW, Jiang WY, Jiang JX, Lin L, Zhang DQ, Ding J, Chen L, Jiang T, Xu YH, Tao G, Zhang HJ. Capsule endoscopy and single-balloon enteroscopy in small bowel diseases: Competing or complementary? *World J Gastroenterol* 2016; 22(48): 10625-10630 Available from: URL: <http://www.wjgnet.com/1007-9327/full/v22/i48/10625.htm> DOI: <http://dx.doi.org/10.3748/wjg.v22.i48.10625>

## INTRODUCTION

The small bowel has long been considered by gastroenterologists as a "black box" due to its length and complex anatomy. Before 2000, it was not possible

to reach most of the small bowel using conventional endoscopic techniques, and thus the diagnosis of small bowel diseases has been a challenge for gastroenterologists. The development of capsule endoscopy (CE) and balloon-assisted enteroscopy (BAE) represents a decisive breakthrough in the field. CE is painless and can be used to explore the entire small bowel in a single examination, making it the best choice for an initial diagnostic examination when a patient is suspected of possessing small bowel disease<sup>[1-3]</sup>. However, CE has some technical limitations, including a lack of therapeutic capability and the risk of capsule retention.

BAE was introduced as a breakthrough technique for examining the deep small bowel, and comprises double-balloon endoscopy (DBE) and single-balloon enteroscopy (SBE). DBE was introduced in 2001 and is considered the standard technique of deep endoscopy for visualizing the small bowel and enabling endoscopists to perform therapeutic interventions; however, it must be noted that the preparation and handling of DBE is complex. SBE was introduced in 2008, which has a simpler and easier-to-handle small bowel endoscopy system. Although SBE may be less efficient in terms of depth of insertion and complete visualization of the small bowel when compared with DBE, some studies have shown that SBE is not inferior to DBE with respect to diagnostic yield<sup>[4]</sup>. Both CE and BAE are reported to have similarly high diagnostic yields for small bowel diseases<sup>[5,6]</sup>. DBE is considered an effective complementary technique which can be used after initial diagnostic CE examination<sup>[7]</sup>. However, there are comparatively limited data on the role of CE alone and in combination with SBE for assessment of small bowel diseases<sup>[8]</sup>.

We performed a retrospective study with the aim to: (1) compare the diagnostic yields of CE, SBE, or their combined use; (2) determine their performance characteristics in patients with suspected small bowel diseases; and (3) demonstrate the appropriate diagnostic algorithms for different small bowel diseases.

## MATERIALS AND METHODS

### Study design and patient selection

We retrospectively analyzed the records of 700 patients suspected of small bowel diseases who underwent CE and/or SBE between September 2010 and March 2016 at the First Affiliated Hospital of Nanjing Medical University. All patients underwent routine clinical examinations and laboratory tests (including hemoglobin level and stool tests), abdominal ultrasound or computed tomography (CT), upper gastrointestinal endoscopy, and colonoscopy. CE and SBE were performed after obtaining informed consent from the patients. Indications for the study included obscure gastrointestinal bleeding (OGIB), abdominal pain, diarrhea, or other symptoms. The characteristics of all patients and procedures were extracted from

**Table 1 Patient characteristics and indications for single-balloon enteroscopy and capsule endoscopy**

	CE	SBE	Both (CE prior to SBE)	<i>P</i> value (CE vs SBE)
No. of patients	401	353	47	
Age (yr)	49.4 ± 16.0	42.1 ± 15.8	45.3 ± 15.1	< 0.01
Mean (range)	(13-85)	(11-84)	(15-77)	
Male/female	248/153	235/118	38/9	0.177
Main indications, <i>n</i> (%)				
OGIB	207 (51.6)	80 (22.7)	30 (63.8)	
Abdominal pain	133 (31.2)	184 (52.1)	11 (23.4)	
Diarrhea	30 (7.5)	52 (14.7)	1 (2.1)	
Other	31 (7.7)	37 (10.5)	5 (10.6)	

CE: Capsule endoscopy; SBE: Single-balloon enteroscopy; OGIB: Obscure gastrointestinal bleeding.

electronic medical records and the endoscopy reporting system. Final diagnosis was based on SBE findings, CE findings, surgical pathology, and/or clinical follow-up. Diagnostic yield was calculated by dividing the total number of patients who underwent the procedure by the number of cases with positive findings that could explain the patient's symptoms. This study was approved by the Ethics Committee of the First Affiliated Hospital of Nanjing Medical University.

### CE procedure

CE studies were performed using the OMOM CE system (Jinshan Science and Technology Company, Chongqing, China) or MiroCam™ system (IntroMedic, Seoul, South Korea). Each patient underwent bowel preparation with 3 L polyethylene glycol solution the day before the procedure, and then fasted overnight. Collected CE data included gastric transit time (GTT), small bowel transit time (SBTT), abnormal findings during the procedure, total recording time, quality of bowel preparation, and complete visualization rate of the small bowel. The complete video of each CE examination was viewed by two independent and experienced gastroenterologists.

### SBE procedure

SBE procedures were performed using the SBE endoscope system (SIF-Q260; Olympus, Tokyo, Japan). For antegrade SBE, patients generally needed an overnight fast. For a retrograde approach, patients underwent bowel preparation with 3 L polyethylene glycol solution the day before the procedure, and then fasted overnight. The examination itself was carried out with conventional sedation with propofol and opioid. All procedures were performed by one of three experienced endoscopists, each of whom had previously conducted at least 50 SBE procedures. Procedures were carried out *via* the antegrade or retrograde approach, depending on whether the suspected pathology was in the proximal or distal small bowel.

### Statistical analysis

Continuous data are expressed as mean ± SD and range, and categorical data are showed as percentages. Student's *t* test was used to compare age

distributions between the CE and SBE groups. The  $\chi^2$  test was used to compare positive-detection rates and sex distribution between the CE and SBE groups. *P* < 0.05 was considered statistically significant. All statistical analyses were conducted using SPSS version 20.0 (SPSS Inc., Chicago, IL, United States).

## RESULTS

### Patient characteristics

Seven hundred patients who underwent CE and/or SBE were reviewed in the present study. Of these, 401 individuals (248 male, 153 female; mean age, 49.4 ± 16.0 years) underwent 404 CE procedures; 353 individuals (235 male, 118 female; mean age, 42.1 ± 15.8 years) underwent 419 SBE procedures; and 47 individuals (38 male, 9 female; mean age, 45.3 ± 15.1 years) underwent both CE and SBE (CE first) (Table 1). Main indications for CE and/or SBE were OGIB (37.1%, 243 with overt OGIB, and 17 with occult OGIB), chronic abdominal pain (42.6%), chronic diarrhea (11.3%), and other complaints (9.0%). The demographic data of these patients are shown in Table 1. The mean age of these patients was 46.1 ± 16.5 years (range, 11-85 years). There was no significant difference in sex distribution between the CE and SBE group (*P* = 0.177). The average age of the CE group was older compared with the SBE group (*P* < 0.01).

### CE

A total of 401 patients underwent 404 CE procedures. Complete visualization of the small bowel was achieved in 73.5% (297/404). The mean recording time was 555 min ± 115 min (192-721 min). Mean GTT was 51 min ± 62 min (range 1-565 min) and mean SBTT was 352 min ± 157 min (range 33-715 min). The overall diagnostic yield for small bowel disease by CE was 57.6% (231/401). The main findings included: mucosal erosion and superficial ulcer in 98 patients (42.4%), angiodysplasia in 67 (29.0%), Crohn's disease (CD) in 26 (11.3%), and masses (tumors and polyps) in 24 (10.4%). Other findings were parasites in 5.6% (13/231), diverticulum in 2.6% (6/231), and ongoing bleeding in 2.2% (5/231) (Table 2, Supplementary

**Table 2 Comparison of findings between single-balloon enteroscopy and capsule endoscopy *n* (%)**

Findings	CE ( <i>n</i> = 401)	SBE ( <i>n</i> = 353)
Overall detection rate	231 (57.6)	246 (69.7)
Superficial ulcer and erosion	98 (42.4)	111 (45.1)
Angiodysplasia	67 (29.0)	21 (8.5)
Mass	24 (10.4)	26 (10.6)
Crohn's disease	26 (11.3)	86 (35.0)
Parasites	13 (5.6)	1 (0.4)
Diverticulum	6 (2.6)	3 (1.2)
Bleeding	5 (2.2)	0

CE: Capsule endoscopy; SBE: Single-balloon enteroscopy.

Figure 1). The diagnostic yield of CE in patients with OGIB was greater than that in those with no bleeding (70.5% vs 43.8%, *P* < 0.01) (Table 3). For eight patients, capsules were retained at the lesion sites, leading to a capsule-retention rate of 2.0%. Five of these patients were diagnosed with CD, two were diagnosed with lymphoma, and another patient had diverticulum with ulceration. Retained capsules were subsequently removed *via* surgery. We also examined whether there was any difference between the OMOM system and MiroCam system. Complete visualization of the small bowel was achieved in 72.4% (197/272) with OMOM and 78.8% (104/132) with MiroCam (*P* = 0.169). The overall diagnostic yield for small bowel diseases was 57.2% (155/271) by OMOM CE and 60.8% (79/130) by MiroCam (*P* = 0.497). The results showed no significant difference with regards to the rates of complete small-bowel examination or diagnostic yields between MiroCam and OMOM capsule endoscopy (Supplementary Table 1).

**SBE**

A total of 419 SBE procedures were performed in 353 patients: 98 anterograde and 321 retrograde procedures were conducted, as well as 24 combined anterograde and retrograde SBEs. No adverse events occurred during or after these procedures. The mean examination time was 65.5 min ± 26.6 min (15-120 min). The overall diagnostic yield for small bowel disease by SBE was 69.7% (246/353). The main findings were as follows: mucosal erosion and superficial ulceration in 111 patients (45.1%), CD in 86 (35.0%), angiodysplasia in 21 (8.5%), and masses (tumors and polyps) in 26 (10.6%). Other findings were diverticulum (1.2%, 3/246) and parasites (0.4%, 1/246) (Table 2, Supplementary Figure 2). The diagnostic yield for small bowel diseases by SBE was greater than that by CE (69.7% vs 57.6%). There was no significant difference in the diagnostic yield of SBE between patients with OGIB and those with no bleeding (72.5% vs 68.9%, *P* = 0.534). In a subgroup analysis, the diagnostic yield for OGIB by SBE was similar to by CE (72.5% vs 70.5%). In addition, the diagnostic yield for small bowel diseases in patients with no bleeding

**Table 3 Subgroup analysis of the diagnostic yield of capsule endoscopy or single-balloon enteroscopy in patients with obscure gastrointestinal bleeding or non-bleeding patients**

	Diagnostic yield (%)		<i>P</i> value
	OGIB	Non-bleeding	
CE	70.5	43.8	< 0.01
SBE	72.5	68.9	0.534

OGIB: Obscure gastrointestinal bleeding; CE: Capsule endoscopy; SBE: Single-balloon enteroscopy.

tended to be greater using SBE compared with CE (68.9% vs 43.8%, *P* < 0.01) (Table 3).

**CE combined with SBE**

Forty-seven patients underwent CE (including 30 with OGIB, 11 with abdominal pain, 1 with diarrhea, and 5 with weight loss) and were subsequently subjected to SBE. The small intestinal findings on SBE in patients with negative evaluation or definite findings on CE are shown in Table 4. Of 47 patients, 45 had positive findings by CE examination followed by SBE and 42 had positive findings by SBE examination. The diagnostic yield of SBE with findings on prior CE was 93.3% (42/45), which was a high diagnostic yield. Two cases of superficial ulcer and mucosal erosion that were missed by CE were found by SBE. However, CE also detected one mass and two cases of CD that were not detected by SBE.

**DISCUSSION**

Current options for diagnosing small bowel diseases include push enteroscopy, CE, DBE, SBE, and intraoperative enteroscopy. Push enteroscopy has a limited depth of insertion. Intraoperative enteroscopy is the most invasive method and its use has diminished with the development of CE and BAE. CE is widely used to screen for various small bowel diseases, but is limited by a lack of therapeutic ability, as well as imprecise localization and the required collection of biopsy specimens. DBE is a deep enteroscopy technique that overcomes these shortcomings, but has the disadvantages of complex preparation and handling procedures. SBE was recently introduced as an alternative deep enteroscopy technique, with some studies demonstrating that it can provide a high diagnostic yield and enable therapeutic interventions<sup>[9-12]</sup>. In the present study, the diagnostic yield of SBE for small bowel diseases was 69.7%, which suggests that SBE has a high diagnostic yield. However, previous studies showed the complete visualization rate of the small bowel using SBE was lower than when using DBE; the rate of complete enteroscopy using DBE was 40%-80%, while using SBE was 0%-25%<sup>[13]</sup>. This indicated that CE, DBE, and SBE all have advantages and limitations. It is therefore important to select the

**Table 4 Identification of positive findings on prior capsule endoscopy or single-balloon enteroscopy**

Findings	CE: negative diagnosis	CE: definite diagnosis	CE: definite diagnosis
	SBE: definite diagnosis	SBE: definite diagnosis	SBE: negative diagnosis
Angiodysplasia		9	
Erosion and superficial ulcer	2	18	
Mass		3	1
Crohn's disease		11	2
Parasites		1	

CE: Capsule endoscopy; SBE: Single-balloon enteroscopy.

appropriate diagnostic algorithms when small bowel disease is suspected, and should be made on a case-by-case basis and dependent on clinical scenario, diagnostic yield, involved risks, availability, and patient preference.

In this study, OGIB was a common indication for small bowel endoscopy. Unless contraindicated, CE is recommended as the initial diagnostic test for patients with suspected OGIB<sup>[14]</sup>, as it is minimally invasive, easily tolerated, and can theoretically visualize the entire small bowel. Here, the diagnostic yield of CE for small bowel abnormalities in patients with OGIB was 70.5%, with this result being supported by previous studies<sup>[15,16]</sup>. CE and BAE are also considered complementary procedures for the evaluation and treatment of OGIB<sup>[17-20]</sup>. Previous studies have supported using the non-invasive CE technique for patients with OGIB, with a subsequent DBE examination if necessary<sup>[21]</sup>. In the present study, CE found small bowel lesions in 30 patients with OGIB who were subsequently subjected to SBE. Twenty-eight patients had confirmed diagnosis by SBE examination. If false-negative rates were considered, our data suggested that both SBE and CE did miss some lesions. This study supports the belief that CE evaluation should remain the preferred initial strategy for patients with OGIB because of its relative non-invasiveness and acceptable diagnostic yield. However, SBE is useful in cases in which the CE result is ambiguous and further examination or a biopsy is required. For patients with no bleeding, previous studies have not detected a difference between DBE and CE in identifying small bowel abnormalities<sup>[22]</sup>. However, we found that for identifying small bowel abnormalities in patients with no bleeding, the diagnostic yield of SBE was higher than that of CE (68.9% vs 43.8%).

SBE has the potential to become a useful technique for deep enteroscopy, as it has a reasonable depth of insertion, can be administered using standard conscious sedation, and can be used with existing endoscopy systems. In addition, the SBE technique is easy to learn and can be rapidly incorporated into an endoscopy unit<sup>[23,24]</sup>. In our study, SBE generated a high diagnostic yield for small bowel diseases (overall diagnostic yield, 69.7%), as well as for patients with OGIB and those without bleeding (72.5% vs 68.5%). A previous study recommended an initial CE examination that should be followed by DBE if necessary<sup>[7]</sup>. Here,

we combined CE and SBE techniques to detect small bowel diseases and found that 45 patients had positive findings by CE examination followed by SBE, and 42 patients had positive findings by SBE examination. The diagnostic yield of SBE with prior CE was 93.3% (42/45), which was a high diagnostic yield.

In summary, SBE appears to be a safe and effective method for diagnosing small bowel disease, especially for patients with OGIB. CE followed by SBE represents an especially effective strategy for determining the cause of small bowel disease when findings from initial CE examinations are indeterminate.

## COMMENTS

### Background

The diagnosis of small bowel diseases was difficult until the advent of capsule endoscopy (CE) and balloon-assisted enteroscopy (BAE). Both CE and BAE were reported to have similarly high diagnostic yields of small bowel disorders. Single balloon enteroscopy (SBE), which is an alternative technique of double balloon enteroscopy (DBE) for examining the deep small bowel, is simpler and easier to handle. There is limited data on the role of CE, both in comparison and combination with SBE, in the assessment of small bowel diseases.

### Research frontiers

In this study, the authors aimed to evaluate the diagnostic yields associated with CE, SBE, or their combined use in patients with suspected small bowel diseases, as well as demonstrate the appropriate selection for different small bowel diseases.

### Innovations and breakthroughs

This study was a single-center experience in China involving 700 patients who underwent CE and/or SBE. The diagnostic yield difference in detecting small bowel diseases between CE and SBE was evaluated. The diagnostic yields of different indications and findings of CE and/or SBE were analyzed in detail. At the same time, the advantage of SBE combined with prior CE was also evaluated.

### Applications

Both CE and SBE have high diagnostic yields of small bowel disorders. SBE has a similar diagnostic yield for patients with obscure gastrointestinal bleeding and a higher diagnostic yield with non-bleeding compared with CE. CE followed by SBE represents an especially effective strategy for determining small bowel disease.

### Terminology

CE refers to a miniature capsule-shaped camera that takes multiple pictures as it passes through the small intestine. SBE is a method of enteroscopy that can lead to the observation of the small intestine via the mouth or anus with the help of a balloon attached to the distal end of a soft overtube.

**Peer-review**

This is an interesting study that shows the role of small bowel evaluation in CE and SBE. It deserves to be published, as it will add to the literature on the subject. It shows very good language and presentation of data.

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**P- Reviewer:** Christodoulou DK, de'Angelis GL, Kawano S

**S- Editor:** Yu J **L- Editor:** Rutherford A **E- Editor:** Liu WX





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