The clinical utility of single-balloon enteroscopy: a single-center experience of 172 procedures

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Background: Single-balloon enteroscopy (SBE) is a novel endoscopic technique designed to evaluate and treat small-bowel disease. Although there is substantial literature addressing double-balloon enteroscopy and its impact on the diagnosis and management of small-bowel disease, there are limited data available on the clinical utility of SBE.

Objectives: To evaluate the clinical utility and diagnostic impact of SBE in a large cohort of patients at a single tertiary center.

Design: Single-center, retrospective study.

Setting: Digestive Disease Institute, Cleveland Clinic, Cleveland, Ohio.

Patients: A total of 161 patients were referred for SBE from January 2006 to August 2008.

Main Outcome Measurements: Demographic, clinical, procedural, and outcome data were collected and analyzed.

Results: A total of 161 patients underwent a total of 172 procedures. Antegrade and retrograde approaches were used in 83% and 17% of subjects, respectively. The average insertion depth using the antegrade approach was 132 cm beyond the ligament of Treitz (range 20-400 cm). The average insertion depth using the retrograde approach was 73 cm above the ileocecal valve (range 10-160 cm). The average procedure time was 40 minutes overall, 38 minutes (range 12-90) antegrade and 48 minutes (range 28-89) retrograde. Fluoroscopy was used in 20 cases (12%). Diagnostic yield was 58% (99/172); 42% (72/172) were therapeutic cases. There were no significant complications.

Limitations: Single-center, retrospective study.

Conclusions: SBE demonstrated a high diagnostic yield and frequently provided useful therapeutic intervention. It seems to be a safe and effective method for performing deep enteroscopy. (Gastrointest Endosc 2010;71:1218-23.)

Until the advent of capsule endoscopy and balloon-assisted enteroscopy, the nonsurgical management of suspected small-bowel disease had been limited.[1] Traditional approaches using conventional endoscopic techniques such as push enteroscopy and imaging techniques such as barium small-bowel series and enteroclysis have had low yield. Even more specialized studies such as intraoperative enteroscopy, diagnostic CT enterography, magnetic resonance angiography, and interventional angiography have all had substantially greater invasiveness, cost, and morbidity without a significantly increased yield.[2-5] Capsule endoscopy has provided the diagnostic capability to visualize the small bowel far beyond the aforementioned modalities, but offers no therapeutic capability to date. The superior diagnostic and therapeutic impact of double-balloon enteroscopy (DBE) has, along with capsule en-

Abbreviations: DBE, double-balloon enteroscopy; SBE, single-balloon enteroscopy.

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doscopy, ushered in a new era in small-bowel endoscopy. Numerous studies attest to the clinical impact of DBE and capsule endoscopy.[6-14]

Limitations of DBE reported by some authors include a significant learning curve, increased expense, long procedure times, inability to use in patients with latex allergy, and the cumbersome nature of the procedure. The more recently developed single-balloon enteroscopy (SBE) system by Olympus (Olympus Inc, Tokyo, Japan) has been proposed to be more intuitive, to be easier to set up and use, to offer more compatibility with existing endoscopy systems, and to offer abilities similar to those of the double-balloon system to address small-bowel pathology. There are limited data available on SBE, and there are no published direct comparison studies of the 2 platforms. The primary aim of this retrospective study was to evaluate the clinical utility of SBE in patients referred to our facility with suspected small-bowel pathology.

Take-home Message

- Single-balloon enteroscopy seems to have clinical utility similar to that of double-balloon enteroscopy in this large cohort of patients with small-bowel disease in a single-center referral practice.

PATIENTS AND METHODS

Chart reviews were conducted on patients referred to our hospital for enteroscopy from January 2006 to August 2008. Demographic, clinical, and procedural data; findings; and complications were collected. Limited outcome data were obtained because of the nature of the referral practice. All patients were required to provide informed consent. The study was approved by the Cleveland Clinic Institutional Review Board. Inclusion criteria specified were suspected small-bowel disease after negative EGD and colonoscopy and/or localization of small-bowel pathology by capsule endoscopy or other imaging studies. Exclusion criteria included known large esophageal varices, severe active Crohn's disease, fresh surgical stoma, severe ulcerative esophagitis, medical instability, and inability to provide informed consent. All patients referred for enteroscopy during this period who met inclusion and exclusion criteria were included in the study.

All procedures were performed by 1 of 4 experienced endoscopists who had previous experience with DBE and/or advanced therapeutic endoscopy training. Our analysis of this experience began with the first SBE at our institution. Office consultation or a history and physical examination with supporting laboratory studies were generally obtained before the procedure and assessed by the endoscopist to determine the appropriateness of enteroscopy as the standard of care. Urine pregnancy tests were performed before the procedure in women of childbearing potential. All patients and their drivers were given standard discharge instructions and numbers to call to report any postprocedure problems or suspected complications.

Antegrade procedures (per oral) for inpatients were performed after 2-L polyethylene glycol preparation. Outpatient antegrade procedures required no specific preparation except for continuing to receive nothing by mouth for 8 hours. Retrograde procedures (per rectum) were performed after 4-L polyethylene glycol preparation in all patients. Patients were sedated with moderate sedation including meperidine, fentanyl, and midazolam or with monitored anesthesia using propofol by an anesthesia provider. Fluoroscopy was used in selected cases depending on the preference of the endoscopist, technical difficulty, and anatomic approach (antegrade vs retrograde). Total procedure time was defined as the period from the insertion to withdrawal of the enteroscope. Estimated maximal depth of insertion with the antegrade approach was defined as number of centimeters beyond the ligament of Treitz when no further advancement was possible. From the retrograde approach, this represented the number of centimeters passed into the small bowel beyond the ileocecal valve. Depth was measured in centimeters using the total number of 40-cm push and pull cycles on insertion, as defined by May et al[15,16] or by simply counting the amount of small bowel traversed on withdrawal in 5- or 10-cm increments. At the point of maximal insertion, a tattoo could be placed using SPOT ink (GI Supply, Camp Hill, Pa). Total enteroscopy was defined as visualizing the entire small bowel when the tattoo left by the previous examination was reached in the subsequent examination initiated from the opposite insertion route or if the ileocecal valve was reached from the antegrade route. Enteroscopy failure was defined as an inability to pass beyond 60 cm from the ligament of Treitz with the antegrade approach or 20 cm above the ileocecal valve with the retrograde approach, based on recognized typical limits of push enteroscopy and colonoscopy with ileal intubation, respectively.[9,17-21] Therapeutic cases were defined as those that involved endoscopic intervention such as polypectomy, stricture dilation, foreign-body removal, and hemostasis procedures. Tissue sampling was performed as clinically appropriate.

The decision to use an antegrade or retrograde initial approach was primarily determined by clinical presentation. If the patient presented with melena or if upper small-bowel pathology was suggested on imaging or capsule endoscopy, then an antegrade approach was used for the study. If the patient presented with frank hematochezia or if localization suggested a more distal small-bowel lesion, then the study was performed with the retrograde approach. The default approach was to use the antegrade approach for the examination if no clinical features were available to guide the decision, keeping in mind the con-

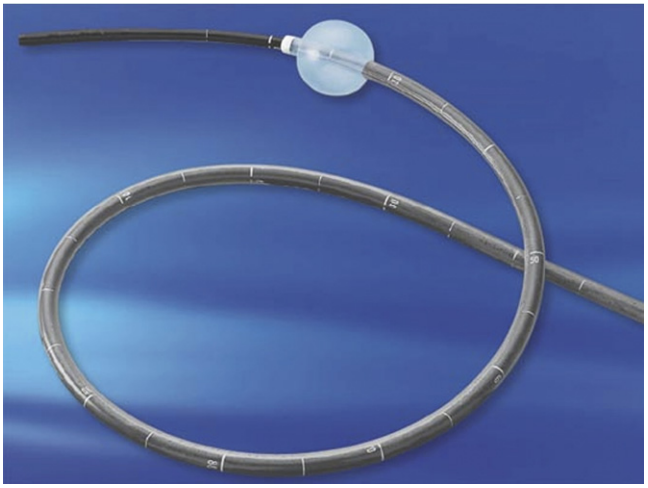

Figure 1. Single-balloon enteroscope. (Courtesy of Olympus America Inc, Center Valley, Pa.)

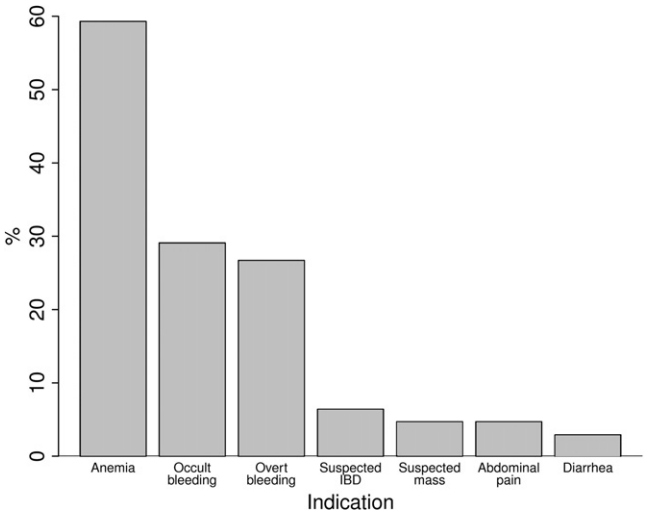

Figure 2. Indication for SBE. Nonexclusive; patients with anemia included 26% overt and 29% occult bleeding.

clusion of some authors in DBE that antegrade procedures may traverse twice the distance into the small bowel as that of retrograde examinations.[18-20,22-24] If pathology was not reached with the initial insertion route, a tattoo was placed and the opposite anatomic approach was performed, as deemed clinically appropriate.

Single-balloon system

The Olympus SIF–Q180 is a 200-cm high-resolution enteroscope with a 2.8-mm working channel that uses a 140-cm long × 13.2-mm outer diameter flexible overtube (Fig. 1). The silicone balloon at the tip of the overtube can be inflated and deflated by the balloon control module, with a pressure range of 6 to 16 kPa. This pressure allows atraumatic traction on the small-bowel mucosa. The tip of the endoscope is angled and hooked behind a fold, if possible, to achieve the same stabilizing effect of the endoscope tip balloon of the double-balloon system. Then, in a very similar fashion to the double-balloon technique, the overtube balloon is used to pleat the small bowel onto the overtube. With serial inflations and deflations of the overtube balloon and hooking and grasping with the endoscope tip, the endoscope is advanced deep into the small bowel with the push-and-pull technique.[23,25] Ideally, as in DBE, the balloon is not inflated in the area of the proximal duodenum to avoid trauma to the papilla and lessen the risk of pancreatitis. Early reports with this enteroscopy system have shown favorable outcomes, both diagnostically and therapeutically, with similar utility to that of the double-balloon technique.[5,21-23,25-34]

Statistical analysis

Data are presented as mean (range) for continuous variables and percentages for categorical factors. Student *t* test for continuous variables and the χ^2 and Fisher exact tests for categorical factors were used to compare the 2 SBE approaches. $P < .05$ was considered statistically significant. SAS version 9.2 software (SAS Institute, Cary, NC) and R 2.9.1 (The R Foundation for Statistical Computing, Vienna, Austria) were used for all analyses.

RESULTS

A total of 172 procedures were performed in 161 patients. There were 83 women and 78 men studied. The mean age was 64 years, and the range was 23 to 88 years. The most common indication was anemia, with 59% (102/172) patients referred; 45% (46/102) of these patients had overt bleeding and 50% (51/102) had occult GI bleeding. In 4% (5/102) of the patients referred for anemia, the nature of the bleeding was undetermined. Six percent (11/172) of patients were referred for suspected inflammatory bowel disease, 4% (8/172) of patients were referred for abdominal pain, 4% (8/172) of patients were referred for a suspected small-bowel mass, and 2% (5/172) of patients were referred for chronic diarrhea (Fig. 2).

We performed a total of 143 antegrade procedures and 29 retrograde procedures. Conscious sedation was used in 85% (146/172) of procedures. Propofol-based monitored anesthesia care was provided by an anesthesia team when indicated. The average depth of insertion from the antegrade approach was 133 cm beyond the ligament of Treitz (range 20-400 cm). The average depth of insertion from the retrograde approach was 73 cm above the ileocecal valve (range 10-160 cm). The average procedure time for an antegrade approach was 38 minutes (range 12-90 minutes). The average procedure time for a retrograde procedure was 48 minutes (range 24-89 minutes). Overall, the average procedure time was 40 minutes (standard deviation 17.1). Fluoroscopy was used in 20 (12%) cases, and the average time used

TABLE 1. SBE Indications, procedural factors and findings.

Factor	All (n = 172)	Antegrade (n = 143)	Retrograde (n = 29)	*P* value
Indication (nonexclusive)				
Anemia	102 (59.3)	86 (60.1)	16 (55.2)	.62
Overt bleeding	46 (26.7)	41 (28.7)	5 (17.2)	.2
Occult bleeding	50 (29.1)	38 (26.6)	12 (41.4)	.11
Suspected IBD	11 (6.4)	7 (4.9)	4 (13.8)	.092
Suspected mass	8 (4.7)	7 (4.9)	1 (3.5)	.99
Abdominal pain	8 (4.7)	6 (4.2)	2 (6.9)	.62
Diarrhea	5 (2.9)	3 (2.1)	2 (6.9)	.2
Procedure time (min)	40.2 (17.1)	38.2 (17.1)	47.7 (15.0)	.008
Insertion depth (cm)	121.9 (80.2)	132.8 (82.9)	73.3 (40.2)	<.001
Fluoroscopy time (min)	4.1 (4.0)	3.7 (3.0)	4.6 (5.1)	.67
Conscious sedation	146 (84.9)	122 (85.3)	24 (82.8)	.78
Interventional BAE	77 (45.0)	68 (47.9)	9 (31.0)	.097
Any BAE finding*	106 (62.0)	87 (61.3)	19 (65.5)	.67
Findings* (nonexclusive)				
Angioectasia/telangiectasia	73 (42.7)	65 (45.8)	8 (27.6)	.071
Erosions	2 (1.2)	2 (1.4)	0 (0.0)	.99
Ulcers	8 (4.7)	5 (3.5)	3 (10.3)	.14
Strictures	3 (1.8)	1 (0.7)	2 (6.9)	.075
Polyps	10 (5.9)	6 (4.2)	4 (13.8)	.068
Blood in lumen	4 (2.3)	2 (1.4)	2 (6.9)	.13
Acid hematin	3 (1.8)	3 (2.1)	0 (0.0)	.99
Failure	18 (10.5)	15 (10.5)	3 (10.3)	.99

IBD, Inflammatory bowel disease; *BAE*, balloon assisted Enteroscopy.
Values presented as mean (SD) for time and depth and no. (%) otherwise. *P* values correspond to Student *t* test for time and depth and Pearson's χ^2 or the Fisher exact test otherwise.
*1 subject with unknown finding.

per case was 4 minutes (range 12 seconds to 14 minutes). The first 15 retrograde cases had an average insertion depth of 85 cm and an average procedure time of 46 minutes; in the 3 cases in which fluoroscopy was used, the fluoroscopy time was 3.6 minutes (range 1.2-8.2 minutes). The next 14 retrograde cases had an average insertion depth of 61 cm and average procedure time of 47 minutes; in the 4 cases in which fluoroscopy was used, the fluoroscopy time was 6.5 minutes (range 32 seconds to 14 minutes) (Table 1).

Findings

The abnormalities detected at enteroscopy were angioectasia or telangiectasia in 73 (44%) procedures, 10 with polyps, 8 with ulcers, 6 with small-bowel diverticula, 4 with blood in the lumen, 3 with acid hematin seen, 2 with strictures, and 2 with erosions. There were normal findings (no pathology detected) in 65 procedures (37%). One subject had an unknown finding at enteroscopy (Table 1).

Diagnostic yield

Diagnostic yield was 58% (99/172), representing enteroscopy findings deemed significant enough to explain symptoms or the source of bleeding. In the 7 cases in which acid hematin or blood in the lumen was found, but the source of bleeding not identified, we excluded these when determining our diagnostic yield. Forty-two percent (72/172) were therapeutic cases. Arteriovenous malforma-

tions or telangiectasias were treated in 66 cases, 5 polyps were removed, and 1 stricture was dilated. The failure rate in the retrograde procedures was 10% (3/29) and 10% (15/149) in antegrade procedures. A total of 135 (78%) patients had capsule studies done before the enteroscopy. In 70 (40%) cases, the capsule findings were confirmed by the enteroscopy. A new diagnosis was found on enteroscopy in 17.4% (30/172).

Complications

No serious complications occurred that were deemed related to the enteroscopy. One patient had a self-limited cardiac arrhythmia after the procedure. He had a history of cardiac arrhythmias, and the event resolved spontaneously without the need for intervention. Another patient reported postprocedure abdominal pain that required an emergency department visit, without the need for intervention.

DISCUSSION

SBE has emerged as a viable alternative to DBE in the evaluation of small-bowel diseases. There are limited data available to fully ascertain the exact role of the SBE system if DBE is available, and comparison studies are needed. This retrospective study of our initial experience with SBE demonstrates the abilities of the SBE system to provide a diagnostic yield similar to that of DBE, particularly in patients presenting with obscure GI bleeding.[5,21-23,25-37] Attributes of SBE proposed by other investigators have included the ease of setup; the intuitive nature of the technique; shorter procedure time, perhaps with or without a corresponding decrease in the depth of insertion; a similar diagnostic yield; and potentially lower costs.[25,28-33]

In our experience, SBE demonstrated a yield of 58%, which compares favorably with that of published studies in both SBE and DBE.[5,21-39] Of 172 cases, 72 (42%) were therapeutic, primarily being the treatment of vascular lesions with argon plasma coagulation in 66 cases. The concordance with capsule findings and enteroscopy findings was 40%, with vascular lesions having the highest correlation. Erosions on capsule studies correlated poorly with enteroscopy findings. Polypectomy was safely performed in the small bowel in 5 cases. In a patient with Crohn's ileitis, an ileal stricture was dilated from the retrograde approach, after a failed attempt to reach the area with colonoscopy.

Postprocedure abdominal pain has been reported in a small percentage of patients after SBE and DBE. Adhesions have been suggested to play a role in postprocedure pain by some.[38] The use of CO_2 for insufflation may reduce postprocedure pain, as suggested by some authors.[19,39] This complication was not reported in our series for those individuals who did not report pain that persisted to or beyond the time that they met discharge parameters from endoscopy.

The estimation of insertion depth has for some time been one of the more controversial aspects of the performance of balloon-assisted enteroscopy. Our initial approach was to count the centimeters of small bowel traversed on withdrawal. To move toward a more consistent standard and in preparation for an eventual comparison study, the trend was to record single-balloon insertion depth in the same 40-cm push-pull cycles as traditionally used for DBE.[16] Although this study does not serve as a comparison of SBE and DBE, some early observations can be made. The average procedure time for SBE was shorter than that for DBE. The insertion depth for SBE averaged less than that of DBE. Nevertheless, the overall yield for SBE did not differ greatly from that of published studies in DBE.[18,19,25,29,38] Although not quantitatively measured, the perceived setup time and ease of use of the SBE system were favored among our endoscopists and staff over that of the DBE.

There did not seem to be a significant learning curve with SBE for our group of endoscopists in terms of the technical difficulty of the procedure, reduction in fluoroscopy or procedure time, or insertion depth. It should be noted, however, that there were no total enteroscopies achieved in this early experience in patients with nonsurgically altered small bowel. In other reports of SBE in the West, the total enteroscopy rates also range from 0% to 5%.[25,28,29] The vast majority of our cases were antegrade based on capsule findings, clinical presentation, or imaging, without total enteroscopy being intended. With good yield on the first procedure, most of these individuals who underwent antegrade procedures initially did not require retrograde procedures. Additionally, there was a very low failure rate (10%) in retrograde examinations in contrast to DBE.[18-20]

The limitations of this study include the single-center retrospective setting and the absence of long-term follow-up data. Larger prospective studies are needed to further assess the diagnostic and therapeutic potential of the SBE system and its role relative to other modalities available for investigation of the small bowel.

In conclusion, our early SBE experience represents the largest cohort of patients in a single center reported to date. It suggests that the SBE platform is safe and offers a diagnostic and therapeutic yield in the management of small-bowel disease similar to that of DBE.

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