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Single Balloon Enteroscopy: Results from an initial experience at a U.S. tertiary care center

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Abstract

Background—Single Balloon Enteroscopy (SBE) is a novel deep enteroscopy modality for diagnosis and treatment of disorders of the small bowel.

Objective—The aim of the study was to examine the performance, yield and safety of SBE in the initial experience at a tertiary care center.

Design—Retrospective analysis of all SBEs during a 10 month period in 2008. Data was extracted from electronic clinical and endoscopy records.

Setting—U.S. tertiary care center.

Patients—All patients referred for SBE were included in the current analysis.

Intervention—SBE.

Main Outcome Measurements—Anterograde SBE procedure time, diagnostic yield, and complications.

Results—Thirty-eight anterograde SBEs were performed. The mean age was 62 (42% female). Patients (97%) were referred for gastrointestinal bleeding, Crohn's disease, suspected polyps or neoplasia, and abnormal capsule endoscopy. The mean procedure time was 49 ± 19 minutes. The estimated depth of insertion: proximal jejunum (34%), mid-jejunum (45%), distal jejunum (21%). The SBE diagnostic yield was 47%, with significant findings in 18 patients. Findings included: angiectasias, bleeding, abnormal mucosa, ulceration, polyps, and foreign body. The therapeutic yield was 42%, with lesion ablation performed in 24%. Diagnostic biopsies were performed in 24% of subjects, and tattooing in 52%. There were no significant complications.

Limitations—Single center retrospective study.

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Conclusions—Single balloon enteroscopy appears to be a safe and efficient method for examination of the mid-small bowel. The significant therapeutic yield (42%) suggests comparative studies with double balloon and spiral enteroscopy are warranted.

Keywords

Enteroscopy; balloon-assisted enteroscopy; endoscopy; outcomes

Introduction

The advent of capsule endoscopy (CE) has accelerated the need to directly access the small intestine for therapeutic purposes. Push enteroscopy has limited depth of insertion, Sonde enteroscopy is of historical interest only, and intra-operative enteroscopy carries significant comorbidities.[1, 2]

The first deep enteroscopy technique, developed in 2001 in parallel with CE, was double balloon enteroscopy (DBE) which allows for complete enteroscopy in some patients.[3] This technique has been disseminated among academic and high volume centers, yet remains limited by the following factors: the need for dedicated equipment, substantial operator learning curve, and prolonged procedure times.[4-7]

The single balloon enteroscope (SBE) was recently introduced as an additional method of examining the deep small bowel.[8, 9] The system consists of an enteroscope, a flexible overtube with a balloon at the tip, and a processing unit. Initial reports indicate that SBE may offer several advantages over DBE, including ease of use and improved procedure time. There are also reports of using SBE to perform ERCP in patients with post-surgical anatomy.[10] The purpose of this paper is to review our initial experience with SBE in a United States tertiary care center.

Methods

Patients

We performed a retrospective analysis of all SBEs performed at the University of North Carolina (UNC), a tertiary care referral center, during our initial experience with the device from February through December, 2008. Two reviewers independently identified cases. Patient and procedure characteristics were extracted from electronic medical records and the electronic endoscopy reporting system, ProVationMD®. Depth of insertion was based on the endoscopist report of the anatomic extent reached. We used anatomic regions because exact measurements were not consistently available. Any immediate complications were identified from the endoscopy report and nursing records, and admissions within 30 days of the procedure were reviewed for delayed complications. Recovery time was defined as interval between the time the procedure ended and the time the patient was discharged from the recovery area. This study was approved by the UNC IRB.

Single balloon enteroscopy

The SBE system consists of an enteroscope, overtube, and balloon pressure control unit (Figure 1). The enteroscope (SIF-180, Olympus Corporation, PA) has a working length of 200 cm, is 9.2 mm in diameter, and contains a 2.8 mm diameter working-channel. The disposable overtube (ST-SB1, Olympus Medical) is latex-free, hydrophobic, and has a balloon at the distal tip. The automatic pressure controlled inflation control unit (OBCU, Olympus Medical) allows on-demand inflation of the balloon. Endoscopes manufactured by other companies are compatible with the overtube, but the inflation control unit is required hardware.

SBE was performed by three endoscopists (DRM, ISG, ESD), who had no prior experience with DBE. Patients were placed in the left-lateral position and the SBE with overtube was introduced using standard technique.[8, 9] In iterative fashion with the system positioned in the small bowel, the overtube is advanced to the tip of the enteroscope and the balloon is inflated, the enteroscope is advanced as far as possible, and then the overtube and enteroscope are partially withdrawn to reduce the small bowel, with or without enteroscope suction applied to the small bowel. This procedure is repeated to advance the scope as far as possible.[11] In general, the procedure is a one physician procedure, with an endoscopy nurse or technician assisting with the overtube and balloon inflation. Conscious sedation with fentanyl and midazolam was used for the majority of cases.

Statistical analysis

Summary statistics were calculated using Stata version 9 (StataCorp, TX). Bivariate analysis was performed with either t-tests of chi-square, as appropriate.

Results

A total of 38 anterograde SBEs were performed during the study period. The mean age was 62 ± 17, 58% male, and mean BMI 26 ± 6 (Table 1). The clinical indication in nearly all patients (97%) was obscure GI bleeding (Table 2). Eleven patients had abnormal capsule endoscopy studies (AVM's (4), red spots (2), ulceration (3), denuded mucosa (1), subepithelial distortion (1), unspecified (1)). Other secondary indications included Crohn's disease (n=3); abdominal pain (n=2); and suspected neoplasia (n=3).

The mean procedure time was 49 ± 19 minutes (range 25-105 minutes) (Table 2). Procedural time did not substantially vary based upon the experience of the endoscopist over the study period. Depth of insertion, as recorded by the endoscopist, was to the proximal jejunum in 34% of procedures, to the mid-jejunum in 45%, and to the distal jejunum in 21%. Estimated distance past the ligament of Treitz was not routinely recorded. The mean medication doses used for conscious sedation were fentanyl 133 ± 59 mcg and midazolam 9 ± 4 mg. Adjuvant medications, when utilized, were promethazine (mean dose =16 ± 8 mg; n=8) and glucagon(mean dose = 0.3 ± 0.1 mg; n=16). General anesthesia was utilized in four cases (11%). The mean recovery time was 64 ± 44 minutes (range 29-230 minutes).

The overall SBE diagnostic yield was 47%, with significant findings in 18 patients (Figure 2). These included: angiectasias or bleeding (n=10), abnormal mucosa or ulceration (n=7),

polyps (n=1), and retained capsule (n=1). The therapeutic yield was 42%, similar to the diagnostic yield. Argon plasma coagulation (APC) was performed in 24% of patients. Additional therapeutic interventions included hemostasis with epinephrine and clip application (n=2), polypectomy (n=1), dilatation (n=1), and foreign body removal (n=1). Diagnostic biopsies were performed in 24% of subjects, and tattooing of the depth of maximal insertion in 52%. Three retrograde SBEs successfully evaluated the distal ileum (depth of insertion range: 50-70 cm), but there were no significant findings. Importantly, there were no recorded complications of perforation, pancreatitis, hospitalization, or death.

Of the 37 antegrade procedures that had at least one indication for obscure bleeding, there were seven patients (19%) who had a rebleeding event in a 12-24 month follow-up period which required either hospitalization or repeat endoscopic evaluation over a . Four of these patients were found to have recurrent AVM bleeding that was able to be treated with SBE. Two patients bled from a cause which remained obscure. One patient did not have repeat endoscopic evaluation due to medical instability.

Discussion

The advent of capsule endoscopy has triggered the development of deep enteroscopy methods. Single balloon enteroscopy represents one emerging technique for deep enteroscopy, in parallel with DBE and spiral enteroscopy (SpE). In our initial experience reported herein, the diagnostic and therapeutic yields (47% and 42%, respectively) and average procedure time (49 minutes) compare favorably with the initial experience published for double balloon enteroscopy.[7, 12] These results are also comparable to the initial reports of an SBE experience from Japan.[8, 9] Occult GI bleeding and abnormal video capsule endoscopy were the primary indications for the procedures, with vascular lesion ablation as the primary intervention. The procedure was safe and well-tolerated with the use of conscious sedation (fentanyl, midazolam) for the majority of cases.

The SBE program was seamlessly incorporated into the tertiary care endoscopy program, one without prior DBE services. We note the rapid transition to a single physician procedure technique. We would expect the diagnostic and therapeutic yields to further improve with experience, but we do qualify our observations as this study represents a retrospective, single center analysis. Because of this, we had to rely on the content of endoscopy notes for estimated depth of insertion. We followed the methodology described by May and colleagues for DBE,[13, 14] where after reaching maximal depth of insertion, serial 10 cm segments of small bowel are estimated on withdrawal until the angle of Treitz, and then summed to estimate of depth of insertion. However, since there was not consistent reporting of a measurement of depth of insertion in cm in our reports, we used the estimated anatomic region of depth reached which was present for all cases.

Another limitation of this report is that it focuses only on antegrade procedures. We had a limited preliminary experience with retrograde procedures (n = 3) during this time frame. All three cases were for occult bleeding with potential sources identified in the distal jejunum or ileum on prior CE; two patients had previously negative antegrade SpE. All three retrograde SBEs reached approximately 50-60 cm into the distal ileum, but there were no

definitive findings or therapeutic maneuvers. We felt that this approach proved more challenging, primarily due to traversal through the colon and the challenge of positioning the balloon and overtube in the terminal ileum, but are unable to draw conclusions with such a small sample size.

It is our belief that SBE has the potential to become a useful deep enteroscopy technique. Each of the three deep enteroscopy techniques feature advantages and disadvantages. SBE has reasonable depth of insertion, ability to use standard conscious sedation, use with existing endoscopy systems, and based on our experience, is easy to incorporate into an endoscopy unit and learn to use.[8, 9, 15] DBE offers probable maximal depth of insertion and extensive supporting literature, balanced by the significant time investment.[4, 7] Lastly, SpE is emerging in parallel with SBE, offering deep intubation with the efficient pleating approach, offset by the use of a larger overtube necessitating deeper sedation (e.g., propofol). [16, 17] The choice of which system to use will need to be individualized for each patient's small bowel findings, as well as tailored to local expertise.

In conclusion, our initial experience with SBE is encouraging and portends increasing use for therapeutic and diagnostic small bowel enteroscopy. The procedure appears to be safe and relatively efficient, particularly in comparison to DBE. The significant therapeutic yield suggests that comparative studies with DBE and spiral enteroscopy are warranted.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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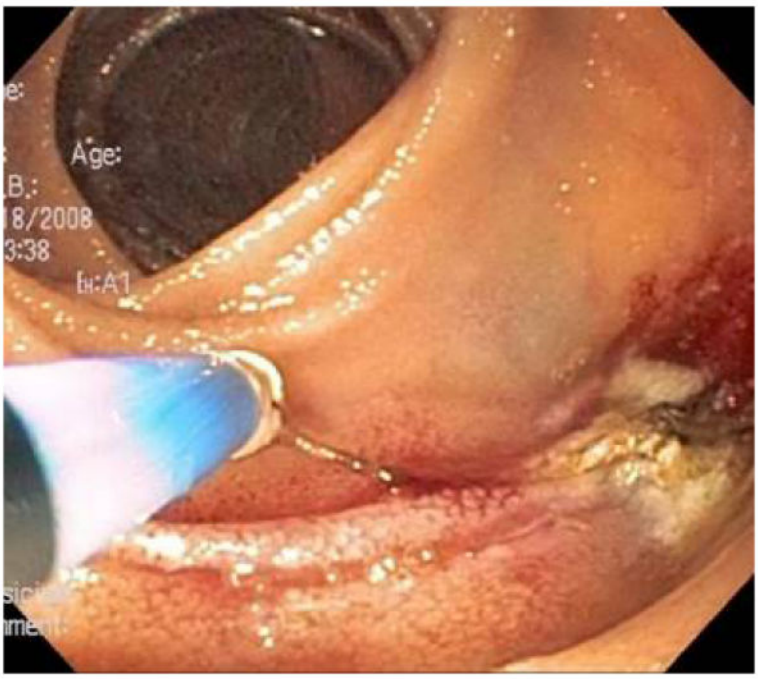
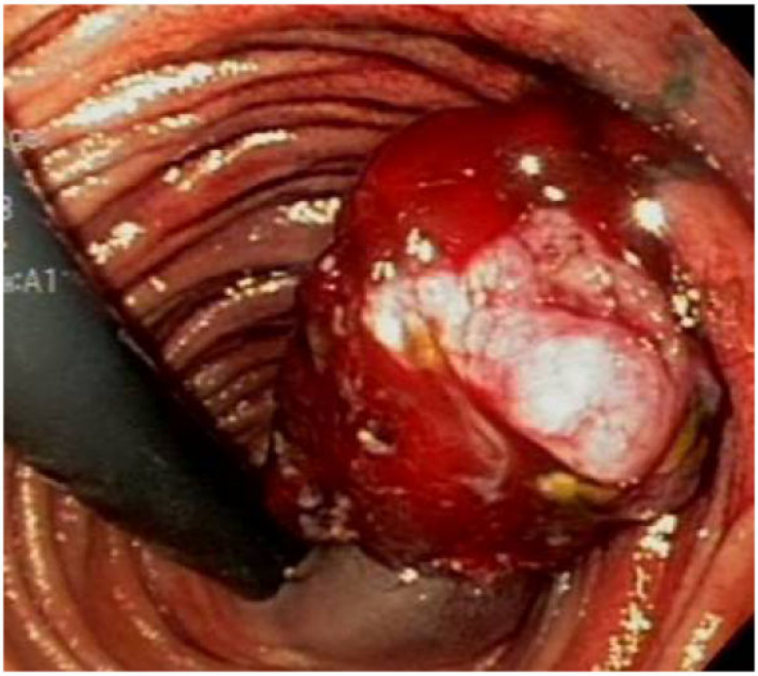
Figure 1.
Single balloon enteroscope (9.2 mm diameter, 2.8 mm working-channel, 200 cm working-length) and single balloon overtube (latex-free; deflated balloon seen here at the distal tip).





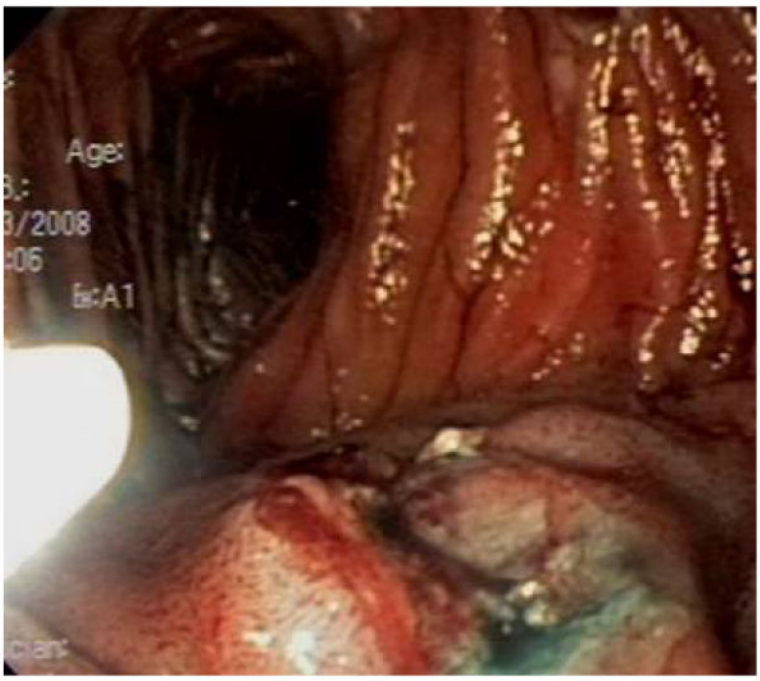


Figure 2.

Representative findings during SBE. (A) Telangiectasia > 75 cm from the ligament of Treitz, treated with argon plasma coagulation. (B) Polyp found > 90 cm from pylorus, treated by lift polypectomy. (C) Post-polypectomy view showing complete removal of polyp. Pathology revealed a hyperplastic polyp; the patient had known Peutz Jeghers Syndrome.

Table 1

Patient Characteristics

Patient characteristics (n =38)	**Number (%) or mean**
Mean age (years ± SD, range)	62 ± 17(19-85)
Median age	64
Sex:	
Female	16 (42)
Males	22 (58)
Body Mass Index (BMI)	26 ±6
American Society of Anesthesiologists Classification (ASA)	
I: Normal	3(8)
II: Mild Systemic Disease	24 (64)
III: Severe Systemic Disease	11 (28)

Table 2

Procedure Characteristics

Procedure Characteristics (n = 38)	Number (%) or mean (± SD)
Time (minutes)	
Mean procedure time	49 ± 19
Mean recovery time	64 ± 44
Estimated depth of insertion*	
Proximal jejunum	13 (34)
Mid jejunum	17 (45)
Distal jejunum	8 (21)
Conscious sedation mean doses†	
Fentanyl (mcg)	133 ± 59
Midazolam (mg)	9 ± 4
Promethazine (mg; used in 8 patients)	16 ± 8
Glucagon (mg; used in 11 patients)	0.3 ± 0.1
Indication‡	
Gastrointestinal bleeding	37 (97)
Nausea, vomiting, or weight loss	1 (3)
Abnormal capsule endoscopy	11 (29)
Suspected tumor	1 (3)
Abdominal pain	2 (6)
Crohn's disease	3 (8)
Celiac disease	1 (3)
Suspected abscess	1 (3)
Diagnostic yield (small bowel findings seen in 18 patients) ‡	
Angiectasias or bleeding	10 (56)
Abnormal mucosa or ulceration	7 (39)
Polyps	1 (6)
Foreign body	1 (6)
Stenosis	2 (12)
Therapeutic maneuvers (performed in 25 patients) ‡	
Argon plasma coagulation	11 (44)
Hemostasis (epinephrine or hemoclip)	2 (8)
Polypectomy	1 (4)
Dilation	1 (4)
Foreign body removal	1 (4)
Diagnostic biopsies	6 (24)
Tattooing	13 (52)
Immediate procedural complications#	0 (0%)

*Estimated depth of insertion was determined retrospectively from endoscopist report.

[†] Conscious sedation was administered to all patients except for 4 who received general anesthesia

[‡] Total to more than 100% as more than 1 category per patient was allowed

[#] Defined as respiratory depression, hypotension, cardiac arrhythmia, bleeding, pancreatitis, perforation, procedure-related hospitalizations, or death, as obtained from endoscopy reports and medical record review.