A Randomized Controlled Trial Comparing the Depth of Maximal Insertion Between Anterograde Single-Balloon Versus Spiral Enteroscopy

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ABSTRACT:

BACKGROUND: Three device-assisted deep endoscopic platforms presently exist and are available for clinical use: double-balloon enteroscopy, single-balloon enteroscopy (SBE), and spiral enteroscopy (SE). In a retrospective study, SE was associated with a greater depth of maximal insertion (DMI) with similar diagnostic yields and procedure time as compared with SBE.

AIMS: This was a prospective, randomized comparison of SE and SBE with respect to DMI, diagnostic yield, procedure time, and rate of adverse events.

METHODS: Patients were prospectively randomized to undergo either anterograde SE or SBE. Patient demographics, indication for procedure, DMI, procedure time, therapeutic procedure time, adverse event, diagnostic findings, and therapeutic interventions were prospectively recorded. The primary outcome was DMI. Secondary outcomes included: procedure time; diagnostic yield; therapeutic yield and adverse event rates.

RESULTS: During the study period, 30 patients underwent deep enteroscopy (SE 13, SBE 17). The most common indication was gastrointestinal bleeding in both groups. There was no significant difference in the DMI between SE and SBE (330.0 ± 88.2 cm vs 285.3 ± 80.8 cm, $P = .16$). There was no difference between SE and SBE in procedure time (37.0 ± 10.5 vs 38.3 ± 12.4, $P = .76$), diagnostic yield (SE = 9 [69%] vs SBE = 7 [41%], $P = .16$), or therapeutic yield (SE = 6 [46%] vs SBE = 4 [24%], $P = .26$). There were no major adverse events in either group.

CONCLUSIONS: Spiral enteroscopy and SBE are similar with respect to DMI, diagnostic yield, therapeutic yield, procedure time, and rate of adverse events. Small numbers prevent giving a definitive judgment and future adequately powered prospective study is required to confirm these findings.

KEYWORDS: Spiral, balloon, enteroscopy, randomized control trial, small bowel

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Introduction

Prior to the advent of device-assisted deep enteroscopy, the mainstay for navigating through the small bowel (SB) was surgically assisted enteroscopy or rope guide enteroscopy.[1,2] These were complex invasive procedures that for practical purposes left the SB inaccessible. Capsule endoscopy (CE) became available in 2000 and enabled physicians to better visualize the luminal aspect of the SB; however, it is limited by its inability to obtain diagnostic tissue and perform therapeutic interventions.[3] The development of device-assisted deep enteroscopy has provided us with a practical method to examine the SB and perform diagnostic and therapeutic interventions in real time.[4]

Three deep enteroscopy platforms exist: double-balloon enteroscopy (DBE), single-balloon enteroscopy (SBE), and spiral enteroscopy (SE). Double-balloon enteroscopy (FUJIFILM medical systems, Wayne, NJ, USA) was first described by Yamamoto in 2001.[4] It consists of an enteroscope and overtube with a balloon at the end of both the enteroscope and overtube. Single-balloon enteroscopy (Olympus America Inc., Center Valley, PA, USA) was first described in 2007 and consists of an enteroscope that is fitted with an overtube with a

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balloon on the tip.[5] The enteroscope and overtube are advanced into the SB, and on reaching depth of maximum insertion (DMI), the balloon is inflated and the overtube and enteroscope withdrawn, resulting in the SB being telescoped over the overtube. The enteroscope is then advanced with the overtube held in place by the inflated balloon and the procedure repeated. The most recent deep enteroscopy platform is SE (Spirus Medical Inc., Stoughton, MA, USA), first described in 2008.[6] This consists of a spiral overtube on an enteroscope that allows deep insertion into the SB by pleating the SB onto the overtube via rotation.

There have been multiple randomized controlled trials and prospective studies comparing DBE with both SBE and SE.[7–14] Double-balloon enteroscopy has been shown in some, but not all of these studies, to be superior to SBE and SE in terms of DMI and achieving total enteroscopy.[7,8,11,12,15,16] This potential advantage comes at the cost of an increased procedure time associated with DBE.[7,8,11,15] Despite the increased DMI, no difference has been found between diagnostic yield, therapeutic yield, or adverse events across these platforms. Khashab et al[17] published the only comparative study of SBE and SE. In this retrospective study, 105 deep enteroscopies were performed by a single experienced endoscopist. The DMI for SE was found to be superior, with no differences in procedure time and diagnostic yield observed between the 2 groups.

The literature to date suggests that a greater DMI does not correlate with a higher diagnostic or therapeutic yield. A consistent finding in the literature is the increased procedural time of DBE compared with both SE and SBE.[7,8,11,15] Given this, a comparison of these 2 newer platforms is appropriate. This is the first prospective randomized study to compare SBE and SE, with the primary aim being to compare the DMI between these 2 techniques. The secondary aims were to compare procedure time, diagnostic yield, therapeutic yield, and adverse event rate between SBE and SE.

Patients and Methods

The study was approved by the Johns Hopkins Institutional Review Board (IRB) for Human Research and complied with Health Insurance Portability and Accountability Act (HIPPA). The trial was registered at ClinicalTrials.gov with the identifier NCT01853241.

Patients

Patients were prospectively enrolled in the study between May 2010 and January 2011. Inclusion criteria were 18 years of age or older and need for an anterograde enteroscopy. Exclusion criteria were inability to give informed consent, pregnancy, uncorrected coagulopathy, cirrhosis, esophageal stricture, patients with prior SB surgery, primary anal approach, or inability to tolerate sedated endoscopy due to cardiopulmonary instability. Randomization was performed through a computer-generated sequence that was then sealed in an envelope and only revealed to the endoscopist prior to the procedure. The requirement for anterograde enteroscopy was based on the results of previous diagnostic studies when available. If a lesion detected on CE prior to deep enteroscopy was within the first 75% of SB transit time, an anterograde approach was chosen.[18] If no diagnostic studies were available, anterograde enteroscopy for evaluation of the midgut was performed based on the clinical information available.

Data collection

The following data were collected prospectively at the time of the procedure: Relevant demographic (age, sex) and clinical data including body mass index (BMI), presenting symptoms, indication for deep enteroscopy, prior radiologic and gastrointestinal (GI) investigations, and history of prior abdominal surgery (excluding appendectomy) were recorded. Procedural data including the type of anesthesia, diagnostic findings, therapeutic interventions, DMI, total procedure time, adjusted procedure time, and adverse event (including mucosal trauma) were recorded prospectively. All patients were contacted within 1 week of the procedure by telephone to assess for postprocedural adverse events.

In all patients undergoing enteroscopy for obscure GI bleeding (OGIB), the number and type of previous endoscopic and radiologic evaluations were noted. Obscure GI bleeding was defined as presumed midgut source of bleeding in patients with prior negative endoscopic and radiologic evaluations of the upper and lower GI tract or with evidence of SB bleeding on CE. Patients were documented to have either overt or occult OGIB based on clinical evidence of absence or presence of bleeding, respectively. Patients undergoing enteroscopy for causes other than OGIB also had documentation of the number of prior biochemical, endoscopic, and radiologic evaluations.

Deep enteroscopy technique

All procedures were performed by an experienced endoscopist (P.I.O.) with a second endoscopist assisting during SE procedures. P.I.O. had performed more than 110 SBE and 100 SE procedures prior to commencement of this study. All procedures were performed with carbon dioxide insufflation. Fluoroscopy was not used for any procedures. Procedures were performed under conscious sedation or general anesthesia with endotracheal intubation. The choice of sedation was determined by the anesthesiologist based on the patients' American Society of Anesthesiology (ASA) comorbidity status.

The SIF-Q180 high-resolution standard length (200 cm) enteroscope (Olympus America Inc.) was used in all procedures. The single-balloon overtube (ST-SB1; Olympus America) was used for SBE procedures and the Endo-Ease Discovery SB overtube (Spirus Medical Inc.) was used for SE procedures. For SBE, the enteroscope and SBE overtube were

inserted together through the mouth and passed into the duodenum. The enteroscope was advanced through the SB using a combination of push and pull technique, with sequential balloon inflation and deflation. For SE, the enteroscope and SE overtube were inserted through the mouth and advanced into the duodenum. The enteroscope was then advanced using a combination of spiral and pleating techniques as previously described.[6]

The depth of insertion was defined as the maximum distance the enteroscope was inserted past the pylorus. In SBE, the endoscopist estimated in 10-cm increments from 0 to 40 cm the length of SB released during each insertion of the overtube and pulling back of the enteroscope and overtube. The net advancement is defined as the point of maximal insertion for SBE.[19] To estimate the DMI for SE, the length of bowel examined in 10-cm increments during withdrawal was counted.[6] Total enteroscopy was defined as visualization of cecum during anterograde enteroscopy.

The total and therapeutic procedure times were recorded. The total procedure time was defined as the time from insertion to withdrawal of the enteroscope through the mouth. The therapeutic procedure time was the time spent for any therapeutic intervention (including tattooing, polypectomy, etc). The adjusted procedure time was calculated as the difference between total and therapeutic procedure times.

Procedure yield

Diagnostic yield was defined as the number of patients who had a diagnosis determined with enteroscopy. Therapeutic yield was defined as the number of patients who underwent an intervention at the time of enteroscopy. Biopsies were not included as a therapeutic intervention.

Adverse event

Adverse event were classified as immediate (ie, diagnosed during the procedure or in the immediate postprocedure period) or short-term (within 1 week of the procedure). A 5-point scoring system (0 = no trauma, 1 = edema/erythema, 2 = superficial hematoma/erosion, 3 = superficial laceration, 4 = deep laceration, and 5 = perforation) was used to document mucosal trauma which was determined by the endoscopist on withdrawal of the enteroscope.[20] Pain was assessed on a 10-point visual analog scale before and after the procedure. Major adverse event were defined as deep laceration, perforation, significant bleeding requiring blood products, pancreatitis, or hospital admission related to the procedure. Minor adverse event were defined as mild to moderate mucosal trauma (scores 1-3), sore throat less than 72 hours in duration, abdominal discomfort lasting less than 48 hours in duration, or mild nausea or vomiting. Patients were contacted by a study nurse, and the type and severity of any side effects and adverse event were recorded.

Statistical analysis

At the time of the study's IRB approval, there was no comparative evaluation between SBE and SE, based on expert opinion, a sample size of 70 (35 patients in each arm) was used to ensure adequate power to evaluate all primary and secondary end points. Based on the results from our prior retrospective study, published after the IRB was approved for this study, a new sample size of 24 (12 in each arm) was calculated to power the primary outcome.[17] This was based on the assumption of a mean (±SD) DMI for SBE and SE of 230(±60) and 300(±60) cm, respectively, with a power of 0.8 and a 2-sided α of .05. The characteristics of patients in each group (age, sex, prior abdominal surgeries, and prior capsule procedures) were compared based on type of deep enteroscopy arm to which the patient was randomized. Descriptive statistics were calculated for all demographic, clinical, and pathologic variables and reported as mean + SD or as a proportion.

Diagnostic yield, procedure time, DMI, and adverse event were compared. Continuous variables were analyzed using a *t* test. Categorical variables were analyzed using the Fisher exact test. All statistical analysis was performed using Stata, v. 12.0 (College Station, TX, USA). *P* values <.05 were considered statistically significant.

Results

Between the study period of May 2010 and January 2011, 32 patients were prospectively enrolled in the study. Enrollment ceased prior to reaching the required sample size due to SE being withdrawn from the market in 2011. When SE was reintroduced to the market, funding had lapsed for the study coordinators and it was elected not to restock the SE device, making it impracticable to restart the study. Two patients were excluded following enrollment due to prior SB surgery in 1 patient and a previously unrecognized esophageal stricture precluding passage of the spiral overtube in the second patient. Table 1 is the demographics of the 30 patients available for analysis (17 females; mean age: 54.6 ± 19.1 years). There were significantly more women in the SBE arm compared with the SE arm (14 vs 3, *P* = .01), with no difference between the 2 groups with respect to age, BMI, or history of abdominal surgery.

Procedure indications

Obscure GI bleeding was the most common indication for deep enteroscopy, present in 15 of the 30 patients (50%). In all, 6 (40.0%) were overt and 9 (60.0%) were occult. There were 17 patients (10 SBE; 7 SE) who underwent CE prior to enteroscopy. Evaluation for lesion found on CE (n = 6; 20%) and SB radiologic studies (n = 6; 20%) were the next most common indications for deep enteroscopy. There were 2 (6%) patients who required the procedure as part of an extensive evaluation at a tertiary referral motility clinic. Finally, 1 (3%) patient

Table 1. Patient demographics and indication for deep enteroscopy.

	SBE (N = 17)	SE (N = 13)	*P* VALUE
Patient factors			
Age, y (±SD)	55.8 (±20.3)	53.1 (±18.3)	.71
Female, No. (%)	14 (82.4)	3 (23.1)	.01
BMI (±SD)	25.1 (±6.7)	26.6 (±6.5)	.54
Prior abdominal/pelvic surgery, No. (%)	6 (37.5)	2 (15.4)	.24
Indication for deep enteroscopy			
OGIB	8 (47.1)	7 (53.8)	1
Occult, No. (%)	7 (41.2)	2 (15.4)	.23
Overt, No. (%)	1 (5.9)	5 (38.4)	.06
Other indications not OGIB	9 (52.9)	6 (46.2)	1
Lesion found on CE, No. (%)	4 (23.5)	2 (15.4)	.67
Lesion found on imaging, No. (%)	3 (17.6)	3 (23.1)	1
Evaluation for motility assessment, No. (%)	2 (11.8)	0 (0)	.43
Evaluation for celiac disease, No. (%)	0 (0)	1 (7.7)	.49

Abbreviations: BMI, body mass index; CE, capsule endoscopy; OGIB, obscure gastrointestinal bleeding; SBE, single-balloon enteroscopy; SE: spiral enteroscopy.

required deep enteroscopy due to suspected celiac disease who had positive serology but nondiagnostic duodenal biopsies (Table 1).

Prior investigations included esophagogastroduodenoscopy (n = 26, 87%), colonoscopy (n = 27, 90%), CE (n = 17, 57%), and computed tomography of the abdomen (n = 17, 57%). Of the patients who had CE prior to deep enteroscopy, 12 (70%) were found to have abnormal findings on CE.

The procedural data for each arm are shown in Table 2. A greater DMI was obtained with SE (330.0 ± 88.2 cm) than SBE (285.3 ± 80.8 cm) but this was not statistically significant (*P* = .16). There was no significant difference in the total procedure time between SBE and SE (37.0 ± 10.5 minutes vs 38.3 ± 12.4 minutes, *P* = .76) or adjusted procedure time (36.1 ± 11.4 minutes vs 34.8 ± 4.7 minutes, *P* = .75).

Diagnostic and therapeutic yield

Eighteen significant diagnostic findings were identified in 16 (53.3%) patients (Table 3). The most common diagnostic finding was a source of bleeding in 9 patients (30%), of which arteriovenous malformations were found in 7 patients and erosions or ulcers were found in 2 patients. The other diagnostic findings included stricture in 3 patients (9%), SB Crohn disease in 2 patients (7%), inflammatory changes not due to inflammatory bowel disease in 2 patients (7%), polyps in 1 patient (3%), midgut celiac disease (confirmed on histology) in 1 patient (3%), and prominent lymphoid tissue in 1 patient (3%). The diagnostic yield was higher in SE (69%) than SBE (41%) but did not reach statistical significance (*P* = .16). Eleven therapeutic interventions were performed during 10 procedures, including argon plasma coagulation in 7 patients, stricture dilation in 3 patients, and polypectomy in 1 patient. The overall therapeutic yield was 33% (n = 10 patients) with no statistically significant difference between SE (n = 4, 24%) and SBE (n = 6, 46%) (*P* = .26).

The diagnostic and therapeutic yields were examined based on the indication for SB enteroscopy (Table 3). The overall diagnostic yield was 53% (n = 16). It was the same in patients undergoing deep enteroscopy for OGIB (53%, n = 8) as for those with other indications for deep enteroscopy (53%, n = 8). There was also no difference in the diagnostic yield between the 2 arms (SBE and SE) when performed for evaluation of OGIB (SBE 53% vs SE 50%, *P* = 1) and for other indications (SBE 38% vs SE 57%, *P* = .11). The overall therapeutic yield was 33% (n = 10). It was highest in patients with OGIB (n = 7, 47%) as compared with other indications for deep enteroscopy (n = 4, 27%) but this was not statistically significant (*P* = .45). There was no difference in therapeutic yield between SBE and SE in cases of OGIB (*P* = .61) and other indications (*P* = .55).

Adverse events

Immediate follow-up was available in 28 patients: 16 patients who underwent SBE and 12 patients who underwent SE; 2 patients were lost to follow-up. Fifteen adverse events occurred in 14 patients (15 minor). There was no significant difference in adverse event rates between patients in the SBE

Table 2. Results and adverse events.

	SBE (N = 17)	SE (N = 13)	*P* VALUE
Procedural data			
Types of sedation			
General anesthesia, No. (%)	16 (94.1)	13 (100)	1
Conscious sedation, No. (%)	1 (5.9)	0 (0)	1
DMI, cm (±SD)[a]	285.3 (±80.8)	330.0 (±88.2)	.26
Mean procedural times			
Total procedural time, min (±SD)	37.0 (±10.5)	38.3 (±12.4)	.76
Adjusted procedure time, min (±SD)	36.1 (±11.4)	34.8 (±4.7)	.75
Adverse events			
No. of patients with adverse events, No. (%)	7/16 (44)[b]	7/12 (58)[b]	.82
No. of adverse events, No. (%)	8	7	
Types of adverse events			
Minor	8	7	.72
Mild mucosal trauma, No. (%)	6 (38)	4 (33)	
Sore throat, No. (%)	1 (6.3)	2 (17)	
Abdominal pain of <48 h, No. (%)	1 (6.3)	1 (8.3)	
Major			
Severe mucosal trauma, No. (%)	0	0	1

Abbreviations: DMI, depth of maximal insertion; SBE, single-balloon enteroscopy; SE, spiral enteroscopy.
[a]Adjusted for sex and prior abdominal surgery (excluding appendectomy).
[b]One patient in each study arm was lost to follow-up.

(n = 7) and SE (n = 7) (*P* = .71). The most common minor complication was minor mucosal trauma (score 1, n = 6; score 2, n = 4), followed by sore throat (n = 3) and abdominal pain for less than 48 hours (n = 2). There was one death in a patient who had an arrhythmia and subsequent pulseless electrical activity arrest 3 days after SBE. The postmortem examination revealed no evidence of an endoscopic complication. There were no major adverse events observed.

Discussion

This is the first prospective randomized study comparing SBE with SE. Diagnostic and therapeutic yields are influenced by the indication for enteroscopy and can be difficult to extrapolate into clinical practice. Depth of maximal insertion is an objective measurement that is independent of preprocedure indications, allowing direct comparison across enteroscopy platforms. In this study, we report a mean DMI in the range of 285 to 330 cm, which is at the higher end of previously published data.[6–15,20–22] The nonstatistically significant difference in DMI favoring SE (330.0 ± 88.2 vs 285.3 ± 80.8 cm, *P* = .16) is likely the result of a higher percentage of patients with female sex and a history of abdominal surgery in the SBE group, which both negatively affect DMI.[23] The presently reported DMI is greater than our previously published results; this may be accounted for by increased experience of the endoscopist performing the procedures and the use of carbon dioxide for insufflation, both of which are proven to increase the DMI.[17,22,24]

With the development of CE and improved radiologic imaging techniques, it has becoming evident that significant pathology can be harbored in the SB. Thus, evaluating diagnostic yield is critical for comparative studies between deep enteroscopy platforms. In this study, the diagnostic yield for SE was 28% higher than for SBE; however, this did not reach statistical significance (69% vs 41%, *P* = .16). The currently reported diagnostic yield is higher than that reported in early studies but in keeping with our previous study and other studies published over the past 5 years.[9,13–15] Diagnostic yield is heavily influenced by the indication for SB enteroscopy, with the literature supporting higher yields in the evaluation for OGIB.[25] Our results showed nonstatistically significant difference in diagnostic yield based on indication (OGIB vs non-OGIB), further supporting parity across these 2 platforms.

Therapeutic yield is considered a robust performance measure of device-assisted deep enteroscopy. In this study, there was

Table 3. Diagnostic and therapeutic yields.

	OVERALL (N = 30)	SBE (N = 17)	SE (N = 13)	*P* VALUE
Diagnostic yield				
Any diagnosis, No. (%)	16 (53.3)	7 (41.2)	9 (69.2)	.16
Source of bleeding, No. (%)	9 (30.0)	4 (23.5)	5 (38.5)	.44
AVM, No. (%)	7 (23.3)	3 (18)	4 (31)	
Erosions/ulcer, No. (%)	2 (6.7)	1 (6)	1 (8)	
Polyp, No. (%)	1 (3)	0	1 (8)	.43
Stricture, No. (%)	3 (9)	1 ()	2 (15)	.56
Other, No. (%)	6 (18)	3 (18)	3 (23)	1
Crohn disease, No. (%)	2 (7)	1 (6)	1 (8)	
Celiac disease, No. (%)	1 (3)	1 (6)	0	
Inflammation, No. (%)	2 (7)	1 (6)	1 (8)	
Lymphoid tissue, No. (%)	1 (3)	0	1 (8)	
Therapeutic yield				
Any therapy, No. (%)	10 (33)	4 (24)	6 (46)	.26
APC, No. (%)	7 (23)	3 (18)	4 (31)	.67
Stricture dilation, No. (%)	3 (10)	1 (6)	2 (15)	.57
Polypectomy, No. (%)	1 (3)	0	1 (8)	.43
Biopsy, No. (%)	19 (63)	10 (59)	9 (69)	.71
Diagnostic and therapeutic yield by indication				
OGIB, n	n = 15	n = 8	n = 7	
Diagnostic yield, No. (%)	8 (53)	4 (50)	4 (57)	1
Therapeutic yield, No. (%)	7 (47)	3 (38)	4 (57)	.61
Not OGIB, n	n = 15	n = 9	n = 6	
Diagnostic yield, No. (%)	8 (53)	3 (33)	5 (83)	.11
Therapeutic yield, No. (%)	4 (27)	1 (11)	2 (33)	.55

Abbreviations: APC, argon plasma coagulation; AVM, arteriovenous malformation; DMI, depth of maximal insertion; OGIB, obscure gastrointestinal bleeding; SBE, single-balloon enteroscopy; SE, spiral enteroscopy.

a 22% difference across the 2 platforms favoring SE; this was not statistically significant (SE = 46% vs SBE = 24%, *P* = .26) and is likely the result of the nonstatistically significant but higher diagnostic yield in the SE group. In patients with OGIB, overall therapeutic yield was 53% with no difference between the 2 arms (SE = 57% vs SBE = 38%, *P* = .61). There has been a suggestion that SE may offer a more stable platform to perform therapeutic interventions, although this has not been demonstrated in this study or the literature to date.[26]

Although DBE is the most established platform for deep enteroscopy, its main limitation in clinical practice is a prolonged procedure time as compared with both SBE and SE. Consistent with the previously published literature, the mean total procedure times were similar between the 2 devices in this study (SBE = 37.0 ± 10.5 minutes vs SE = 38.3 ± 12.4 minutes, *P* = .76) and were within the lower range of mean total procedure times reported in the literature for SBE and SE.[8,10,15] Adjusted procedure time, which eliminates the time for therapeutic interventions, may be a better reflection of the procedural time allotted to reaching the DMI and for adequate inspection of the SB. There was no difference in adjusted procedure time between these 2 platforms, with the results for SE being similar to that in the published literature.[20,27] This is the first study to document an adjusted procedural time for SBE.

The rate of adverse events from device-assisted deep enteroscopy is reported to be very low, with serious adverse events

being rare.[21,28] Mucosal trauma is one of the commonest adverse events to occur in deep enteroscopy. Although studies have evaluated this risk in SE, there are no studies examining this in SBE.[9,20,27] This study found that minor mucosal trauma was the most common adverse event, observed in over one-third of patients and most likely due to the passage of the overtube. No patient required intervention or extended observation for the management of minor mucosal trauma. Most importantly, no significant mucosal trauma (score ≥3) was observed with either device.

The main limitation of this study is that it failed to recruit sufficient numbers. This was due to the withdrawal of the SE system from the market. Spiral enteroscopy has since been reintroduced and is available for use in the United States, but the study was not restarted due to the previously stated reasons. Despite failing to reach its recruitment targets, the number of patients enrolled in this study is similar to some of the prior device-assisted enteroscopy comparative studies.[7,10,12] In addition, the procedures were performed by an experienced endoscopist at a tertiary referral center. Similar to other studies, 2 separate methods for measuring DMI were used.[17] An alternative approach which has recently been described is counting SB folds; this method can be deployed across all enteroscopy platforms, improving methodologic homology.[14]

Despite these limitations, the findings of this study are important. This is the first prospective, randomized study of SE and SBE and shows that there is no significant difference in DMI, diagnostic, or therapeutic yield between these 2 platforms. In comparison with SBE and SE, DBE offers superior DMI and total enteroscopy but suffers from a prolonged procedure time. Despite the differences across these platforms, they are all equal in terms of diagnostic and therapeutic yields. Thus, future studies should focus on differentiating what potential advantages exist between the SBE and SE platforms.

In conclusion, SBE and SE are safe and have comparable performance characteristics. Thus, the choice of deep enteroscopy platform should be guided by local expertise and experience. Small numbers prevent giving a definitive judgment, and future adequately powered prospective study is required to confirm these findings.

Author Contributions

RAM and SB were involved in data acquisition, wrote and edited the final manuscript. JKL, SKA, DR, VK, and EC performed the statistical analysis. VKS, ANK, MAK, AML, and PIO edited the final manuscript. VK was involved in data acquisition, and edited the final manuscript.

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