Spiral enteroscopy with the new DSB overtube: a novel technique for deep peroral small-bowel intubation

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Background and study aims: Spiral enteroscopy is a new technique for deep small-bowel intubation that uses a special overtube (Discovery Small Bowel, DSB) to pleat small bowel. The aims of this prospective study were to evaluate the use of a new-design DSB over new, longer and smaller-diameter enteroscopes, the Fujinon EN-450T5 and the Olympus SIF-Q180.
Patients and methods: This is a prospective study of 75 patients at two referral centers. All enteroscopies were performed by two experienced endoscopists. Patients underwent spiral enteroscopy perorally with the DSB and either the Fujinon EN-450T5 or the Olympus SIF-Q180 enteroscope. Procedure time and depth of insertion past the ligament of Treitz were determined for all patients.
Results: Peroral spiral enteroscopy with DSB was performed in 50 patients with the Fujinon enteroscope and in 25 patients with the Olympus. Average estimated depth of insertion was 243 cm (range 50 – 380 cm) vs. 256 cm (range 50 – 400 cm) and the average time to reach this depth was 18.7 minutes (range 7 – 52 minutes) vs. 16.2 minutes (range 7 – 33 minutes) in the Fujinon and the Olympus groups respectively. Overall findings were 10 angiodysplasias, 2 small-bowel tumors, 1 Peutz–Jeghers polyp, 1 case of celiac sprue, 2 of small-bowel strongyloidiasis, and 2 small-bowel ulcers. All angiodysplasias were treated with bipolar cauterization. Biopsies were taken from the small-bowel tumors. There were no major complications.
Conclusions: The new DSB is a means of rapid, safe, and effective deep small-bowel intubation. Depth of insertion into the small bowel and total procedure time compare favorably with other deep enteroscopy techniques. The DSB performed equally well with both enteroscopes.

Introduction

The small bowel is poorly suited to standard endoscopy techniques due to its anatomical differences from the colon and the upper gastrointestinal tract. The small bowel has an average length of 6.7 m, with a free mesentery that resists standard "push to advance" techniques [1]. Push enteroscopy, therefore, can visualize only a small portion of the small bowel, but in the absence of reasonable alternatives it remains the most commonly performed endoscopic procedure for visualization of small bowel [2 – 4]. The performance of the first total enteroscopy using the double-balloon technique demonstrated the principle of pleating small bowel so that the entire length of the small bowel could be traversed with an enteroscope [5].

An alternative method to pleat the small bowel is spiral enteroscopy [6]. In this method, a special overtube called the Discovery Small Bowel (DSB) (Spirus Medical Inc., Stoughton, Massachusetts, USA) is used with the endoscope. The DSB has raised helices at the distal end, and clockwise rotation of the DSB pleats the small bowel on to the overtube. The prototype DSB overtube was 130 cm in length, with an outer diameter of 17.5 mm and a helical thread height of 5 mm. It was used over a pediatric colonoscope (length 168 cm, outer diameter 11.3 mm). The recent development of 200-cm slim enteroscopes, the Fujinon EN-450T5 (Fujinon Inc., Saitama, Japan) with an outer diameter of 9.4 mm and the Olympus SIF-Q180 (Olympus America Inc., Center Valley, Pennsylvania, USA) with an outer diameter of 9.2 mm, enabled the development of the new DSB with a smaller outer diameter of 16 mm. In this study, we report our experiences of peroral spiral enteroscopy with these new devices.

Patients and methods

Patient population

Between December 2006 and November 2007, 75 patients underwent peroral enteroscopy at two referral centers, Hospital Privado Frances, Asunción, Paraguay, and Clinica de Diagnosticos, Pangtay, Tampico, Mexico. All the patients were recruited from the clinics of the authors of the respective institutions. The study was approved by the institutional review boards at the respective hospitals, and written informed consent was obtained from all patients. The indications for enteroscopy were obscure gastrointestinal bleeding or unexplained anemia in 58 patients, chronic diarrhea in 12 patients, and abdominal pain in 5 patients. Obscure gastrointestinal bleeding was defined as blood in stool with no bleeding source identified on upper endoscopy and colonoscopy. None of the patients had capsule endoscopy studies prior to their enteroscopy. The patients were nonrandomly assigned to undergo spiral enteroscopy with the DSB and either the Fujinon EN-450T5 enteroscope or the Olympus SIF-Q180 enteroscope, depending on enteroscope availability at the time of the procedure. Exclusion criteria included surgically altered gastric anatomy, esophageal strictures, age less than 18 years, pregnancy, and inability to give informed consent.

Instruments

The new DSB is an overtube 118 cm long, 16 mm outer diameter, 9.8 mm internal diameter, made of polyvinyl chloride (**Fig. 1**). It has a raised hollow spiral 5.5 mm high on the distal 21 cm and a soft, tapered tip (**Fig. 2**). The device has two handles for manual rotation, a locking device at the proximal end that allows attachment to the enteroscope with free rotation of the DSB, an injection port for injection of lubricant, and a seal at the distal end to limit backflow of air and fluid (**Fig. 3**). The device is FDA-cleared in the United States and has the CE (Conformité Européenne) mark for use in Europe.

The enteroscopes used were the Olympus SIF-Q180 with working length 200 cm, outer diameter 9.2 mm, and forceps channel diameter 2.8 mm, and the Fujinon EN-450T5 with working length 200 cm, outer diameter 9.4 mm, and forceps channel diameter 2.8 mm. The Olympus enteroscope was used without the single-balloon overtube. The Fujinon enteroscope was used without the distal balloon on the enteroscope.

Fig. 1 Discovery Small Bowel (DSB) overtube over the enteroscope.

Fig. 2 Tip of the DSB showing helices and soft tapered tip.

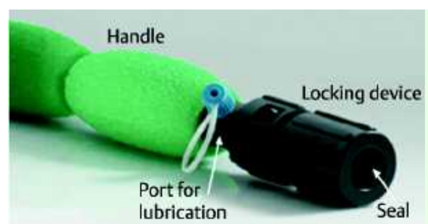

Fig. 3 Proximal end of the DSB.

Endoscopy protocol

The patients were placed in left lateral decubitus position for the procedure and received monitored anesthesia using propofol, midazolam, and fentanyl. The inside of the DSB overtube was well lubricated with the proprietary lubricant and the DSB was then placed over the enteroscope. The distal end of the DSB was positioned 25 cm from the tip of the enteroscope and locked into place using the DSB proximal collar. The enteroscope and DSB were well lubricated on the outside with water-soluble lubricant jelly and advanced through the mouth into the stomach. The DSB overtube was then unlocked and advanced to just proximal to the bending section of the endoscope, about 12 cm from its tip, and locked again. The overtube and enteroscope were then advanced as one unit with gentle push and rotation until they were past the ligament of Treitz. The DSB was then advanced in the small bowel with clockwise rotation and small bowel was pleated on to the enteroscope and overtube. The DSB was advanced until the maximal depth of insertion was reached. We considered maximal depth of insertion as the point when rotation of the overtube was no longer effective in advancing the enteroscope through the small bowel or the rotation of the overtube became difficult. The DSB was then unlocked from the enteroscope and the enteroscope was advanced through the overtube. The enteroscope was then withdrawn while rotating the DSB and attempting to "hook and suction" to pleat more small bowel on the DSB. This maneuver was done three or more times depending on whether successively deeper small-bowel intubations were successful. The DSB was then gradually withdrawn using anticlockwise rotation of the DSB and the small-bowel mucosa examined. To perform interventions or take biopsies, the rotation of the DSB was discontinued and the instruments inserted through the accessory channel of the enteroscope. The depth of insertion was estimated on withdrawal. Fluoroscopy was used in only one case. All the procedures were done on an outpatient basis and patients discharged the same day.

Data collection

During endoscopy, the following data were collected: the time taken to reach maximal depth of insertion, total procedure time, endoscopic findings, and maximal depth of insertion. Maximal depth of insertion was estimated by endoscopic criteria and was defined as the number of centimeters past the ligament of Treitz. In an ex vivo benchtop model, one gastroenterologist (P.A.A.) was trained to estimate the depth of insertion in a porcine small bowel [7]. The gastroenterologist was present for all the procedures and estimated all depths of insertion. Estimation of insertion depth was performed on withdrawal [8]. Immediate (i. e., during endoscopy) and short-term (i. e., within 3 days of endoscopy) complications were recorded in this study. Major complications were defined as perforation, significant bleeding requiring blood products, pancreatitis, or any hospital admission related to the procedure. Minor complications were defined as mild to moderate esophageal trauma, sore throat less than 72 hours in duration, abdominal discomfort lasting less than 48 hours in duration, or mild nausea or vomiting. In estimating the degree of esophageal trauma, isolated or confluent subepithelial petechial-like lesions were considered mild trauma; superficial disruption of the mucosa, submucosal blebs, and hematomas were considered moderate trauma; esophageal tears and perforations were considered severe trauma. For short-term follow-up, all the patients undergoing the procedure were called by their gastroenterologist after 48 – 72 hours and asked questions about pain, discomfort, swallowing difficulties, nausea, vomiting, fevers, appetite, and changes in color and consistency of stool.

Statistical analysis

The distribution of continuous variables was tested for violation of the assumption of normality based on the coefficient of skewness. Samples were compared using two-tailed unpaired *t*-tests assuming unequal variance. The differences in gender between the two groups were tested using the χ^2 test. α was set to 0.05 for all comparisons.

Results

Clinical characteristics

Peroral spiral enteroscopy was performed on 50 patients using the Fujinon enteroscope and on 25 patients using the Olympus enteroscope. The Fujinon and the Olympus groups were similar with respect to clinical characteristics (**Table 1**). The overall average age was 45.7 years, height 164.7 cm, and weight 71 kg. Seventeen patients had had prior abdominal surgery, but none had surgically altered anatomy. The overall indications for enteroscopy were obscure gastrointestinal bleeding or unexplained anemia in 58 patients, chronic diarrhea in 12 patients, and abdominal pain in 5 patients.

Outcome

The average depth of insertion past the ligament of Treitz, average time for maximal depth of insertion, and average total procedure time for both groups are shown in **Table 2**. There was no statistically significant difference in any of the measured criteria for the two groups. The overall average maximal depth of insertion past the ligament of Treitz for all the patients in the study was 247.7 ± 83.2 cm (range 50 – 400 cm) and the average time taken to reach this distance was 17.8 ± 8.4 minutes (range 7 – 52 minutes).

The diagnostic yield of spiral enteroscopy in the Fujinon group was 22 % and the findings were 5 angiodysplasias, 1 small-bowel tumor, 2 small-bowel ulcers, 1 case of small-bowel strongyloidiasis, and 1 Peutz–Jeghers polyp. The diagnostic yield in the Olympus group was 32 % and the findings were 5 angiodysplasias, 1 small-bowel tumor, 1 small-bowel strongyloidiasis, and 1 case of celiac sprue **Fig. 4** and **5**). All angiodysplasias were

Table 1 Clinical characteristics of the study patients.

Clinical characteristics	Fujinon group, n = 50	Olympus group, n = 25	*P* value
Age, years, mean ± SD (range)	46.2 ± 14.7 (19 – 78)	45 ± 13.2 (25 – 68)	0.66
Gender, m/ f	23/27	15/10	0.25
Height, cm, mean ± SD (range)	164.4 ± 10.3 (145 – 180)	165.8 ± 9.1 (148 – 180)	0.52
Weight, kg, mean ± SD (range)	72.4 ± 72.4 (49 – 118)	69.3 ± 16.1 (43 – 100)	0.44
Prior abdominal surgery, n (%)	11 (22)	6 (24)	

Table 2 Measured outcomes in the study patients.

Outcomes	Fujinon group, n = 50	Olympus group, n = 25	*P* value
Depth of insertion, cm, mean ± SD (range)	243.4 ± 78.6 (50 – 380)	256.4 ± 92.9 (50 – 400)	0.55
Time to reach maximal depth of insertion, min, mean ± SD (range)	18.7 ± 9.3 (7 – 52)	16.2 ± 5.9 (7 – 33)	0.17
Total procedure time, min, mean ± SD (range)	29 ± 12.1 (12 – 64)	26.1 ± 6.7 (10 – 41)	0.18

Fig. 4 Jejunal arteriovenous malformation.

Fig. 5 Stricture from small bowel tumor.

treated with bipolar cauterization. The two tumors were biopsied with standard biopsy forceps; 4 – 6 biopsies were obtained. The small-bowel tumors were confirmed on surgical resection to be gastrointestinal stromal tumor and lymphoma.

Three patients underwent surgery after spiral enteroscopy. Two patients with findings of small-bowel tumors subsequently underwent surgery. One patient needed surgery for unrelated reasons. The distance of the tumor tattoo past the ligament of Treitz was measured at the time of surgery was comparable to the endoscopic estimation during spiral enteroscopy. These distances measured surgically versus endoscopically in the first two patients were 100 cm versus 75 cm and 260 cm versus 240 cm. In the third patient, the area of maximal insertion was marked with a tattoo at 300 cm and the corresponding distance measured during surgery was 260 cm.

Complications

All 75 patients were contacted 48 – 72 hours after the procedure by their gastroenterologist. There were no major complications in this series. Nine patients had a sore throat lasting less than 72 hours. Twenty patients had superficial mucosal trauma, which occurred primarily at the upper or lower esophageal sphincter, pylorus, and ligament of Treitz. Five patients had moderate esophageal trauma that did not require any intervention. One patient had a large duodenal ulcer that was noted during insertion of the enteroscope. The enteroscopy was completed and no trauma was noted over the ulcer during withdrawal.

Discussion

Recently, small-bowel visualization and therapy have undergone considerable advancements. These can be divided into nontherapeutic techniques such as capsule endoscopy, magnetic resonance enteroscopy, CT enteroscopy, enteroclysis, and therapeutic techniques such as double-balloon and single-balloon enteroscopy. The newer nontherapeutic techniques have stimulated considerable interest and demand for therapeutic intervention and diagnosis of small-bowel pathology. The currently available therapeutic techniques are effective but have limitations [9,10]. Development of a rapid and deep small-bowel intubation technique that provides an excellent platform for therapeutic intervention would be of great clinical utility.

We have earlier described peroral spiral enteroscopy, which uses a specialized overtube (DSB) with helices at the distal end for deep intubation of the small bowel [6]. The clockwise rotation of the DSB mimics the motion of a corkscrew and pleats the small bowel onto the overtube. In this study, we report our experience of peroral spiral enteroscopy using the new DSB over thinner, longer enteroscopes. Compared to our prototype device, the new DSB has several design improvements including decreased outer and inner diameter, soft compressible spirals, variable flexibility and decreased length of the overtube, flush port, and improved inner liner. These design changes were made to improve performance and safety while taking advantage of the decreased diameter and increased length of the enteroscopes. Procedure time, maximal depth of insertion, and complication rates all improved with this new design compared to the prototype device [6].

During spiral enteroscopy it is sometimes hard to determine when the limit of advancement is reached. We considered the maximal depth of insertion to be reached when rotation of the overtube was no longer effective in advancing the enteroscope through the small bowel or when the rotation of the overtube became difficult. Resistance to rotation of the DSB was considered to be primarily due to creation of loops and due to pleating of small bowel. Assessment of the degree of resistance to rotation was somewhat subjective, although torque-induced changes in the DSB were considered objective signs and rotation was halted if increased resistance could not be relieved by reducing loops. The depth of insertion into the small bowel as described in this study is probably limited by the design of the DSB. At maximal depth of insertion, the tip of the 118-cm-long DSB is limited to about 90 cm due to the handles and locking device on the proximal end. This leaves a relatively short length of DSB to pleat a significant amount of small bowel. Lengthening the DSB would allow more room for pleating small bowel but would lead to more loop formation and limit the amount of enteroscope that can be pushed through the small bowel. In theory a device that only rotated the spiral at the distal end would not be limited by these considerations and would continue advancement through the small bowel.

Determination of the distance of small bowel traversed during enteroscopy is more difficult than in the colon and upper gastrointestinal tract because of the unique anatomy of the small bowel, which is on a floppy mesentery and therefore subjected to considerable distortion by stretching and compacting during endoscopy. Earlier attempts at estimating the depth of small-bowel intubation have been accurate to a reasonable degree [8]. The distance of small bowel traversed can be estimated upon intubation or withdrawal from the small bowel. In this study, the distance of small bowel traversed was estimated upon withdrawal. One of the authors (P.A.A.) trained on a model to estimate the distance of small bowel intubated [7]. The mean estimated depth of insertion past the ligament of Treitz was 243 cm (range 50 – 380 cm), and this compares favorably with both double-balloon and single-balloon enteroscopy [11 – 15]. Three patients subsequently underwent surgery, and in these patients the distance to the lesions past the ligament of Treitz was measured intraoperatively. The measured distances were within 15 % of the distances estimated during spiral enteroscopy, suggesting that our methods of estimating depth of insertion were reasonably accurate.

The diagnostic yield of spiral enteroscopy in this study was 22 % overall in the Fujinon group and 32 % in the Olympus group. The diagnostic yield of push enteroscopy in cases of obscure gastrointestinal bleeding reportedly is around 30 %–44 % [11,16] and that of double-balloon enteroscopy varies from 40 % to 100 % [12 – 14]. This range is wide because the chances of finding a bleeding source are much higher in patients with overt obscure bleeding than occult obscure bleeding and also when patients have been "screened" with capsule endoscopy prior to enteroscopy [14 – 16]. In our study, the patients were relatively younger and had not undergone capsule endoscopy. In addition, we did not make the distinction between occult and overt obscure gastrointestinal bleeding.

There were no major complications in our study. Specifically, there were no cases of pancreatitis or small-bowel perforation, which have been reported with double-balloon enteroscopy [10,20]. The rate of serious complications appears to be higher when therapeutic interventions are performed [10]. The small number of patients in our study and relatively low rate of therapeutic interventions may explain the low major complication rate in our series. Thirty-three percent of patients had minor complications in the form of mild and moderate esophageal trauma seen during withdrawal of the enteroscope. The areas of mucosal damage were primarily limited to the areas of relative stenosis (upper and lower esophageal sphincters and pylorus) and the area of fixation of the small bowel (ligament of Treitz). Interestingly, one patient had a large duodenal ulcer, and after completed spiral enteroscopy no additional trauma around the ulcer was noted.

Mucosal trauma is a concern with the use of any overtube. Earlier studies have shown that the most common cause of severe esophageal trauma with overtubes is "pinch" entrapment of mucosa between the endoscope and the overtube during the process of sliding the overtube over the endoscope during its insertion [22, 23]. The current design of the DSB limits this possibility with a tight-fitting gasket at its distal end. No evidence of severe entrapment injury was seen in this study. The trauma seen to the esophagus is probably due to friction injury from the spirals. One of the design modifications of the new DSB was soft, compressible spirals replacing the noncompressible spirals of the prototype DSB. The possibility of an inflatable spiral is currently being explored. Reduction in diameter of the overtube would in theory further reduce the possibility of esophageal trauma. Liberal use of water-soluble lubricant over the DSB is recommended.

In this study, all patients received monitored airway control anesthesia with propofol, midazolam, and fentanyl. Some patients also received atropine to reduce secretions. None of the patients in this study were intubated. There were no sedation-related complications. Had the need arisen for rapid withdrawal of the endoscope and overtube, the overtube could have been rapidly removed by counterclockwise rotation of the DSB.

This study demonstrates the safety and efficacy of peroral spiral enteroscopy using the DSB with the Fujinon EN450-T5 and Olympus SIF-180 200-cm enteroscopes. By all measured criteria there were no performance differences between the two enteroscopes. The technique of spiral enteroscopy may have advantages over other deep small-bowel techniques in terms of speed of advancement through the small bowel and controlled withdrawal. The rapidity of advancement of the enteroscope during spiral enteroscopy was superior to that of other deep small-bowel intubation techniques with similar estimated depths of insertion. To the extent that this and other studies can accurately estimate the depth of intubation, this study would suggest that spiral enteroscopy is a more rapid way to advance through the small bowel. With spiral enteroscopy, excellent control of withdrawal from the maximal depth of insertion is seen. Using this technique, withdrawal is accomplished by counterclockwise rotation of the overtube, allowing careful and very controlled withdrawal of the enteroscope. Endoscopic therapeutic procedures are easy to perform during spiral enteroscopy. The configuration of the enteroscope and the DSB is relatively straight, which permits easy passage of the accessories. We also feel it is easier to maintain a stable position during interventions. We have also successfully used DSB in visualizing the small bowel using the retrograde approach [24]. This has the potential of achieving total enteroscopy. Our experience with the retrograde approach is limited and further refinements in technique and design of the overtube are currently being evaluated.

In conclusion, peroral spiral enteroscopy is a safe, effective method for deep intubation of the small bowel. The introduction of longer, slimmer endoscopes by Fujinon and Olympus enabled us to construct an improved, smaller-diameter DSB overtube. This DSB overtube is safe and showed better performance than the prototype. Further comparative studies will help establish the role of spiral enteroscopy in evaluation and treatment of the small bowel.

Competing interests: P. Akerman, D. Cantero, and J. Pangtay have stocks of and are paid consultants for Spirus Medical Inc., Stoughton, Massachusetts, USA. D. Agrawal has no conflict of interest.

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