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Spiral enteroscopy: prospective U.S. multicenter study in patients with small-bowel disorders

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Abstract

Background—The performance characteristics of spiral enteroscopy have not been well-described.

Objective—To determine the technical performance, diagnostic and therapeutic yields, and safety of oral spiral enteroscopy in patients with suspected or established small-bowel pathology.

Design—Prospective, multicenter, cohort study, with centralized database.

Setting—Ten U.S. tertiary-care medical centers.

Patients—This study involved 148 participants, of whom 101 were referred for obscure bleeding. All participants referred for antegrade deep enteroscopy were considered eligible.

Intervention—Spiral enteroscopy.

Main Outcome Measurements—Examination duration, depth of insertion, spiral enteroscopy findings, mucosal assessment upon withdrawal, and patient symptom assessment (day 1 and day 7 after the procedure).

Results—Spiral enteroscopy was successful in 93% of patients, with a median depth of insertion beyond the angle of Treitz of 250 cm (range 10–600 cm). The mean (± standard deviation) total procedure time was 45.0 ± 16.2 minutes for all procedures, and 35.4 minutes for diagnostic procedures. The diagnostic yield was 65%, of which 48% revealed more than one abnormality. The most common findings were angiectasias (61.5%), inflammation (7.5%), and neoplasia (6.8%). Argon plasma coagulation ablation accounted for 64% of therapeutic interventions.

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Limitations—This was not a randomized, controlled trial of deep enteroscopy modalities.

Conclusion—Spiral enteroscopy appears to be safe and effective for evaluation of the small bowel. The procedure duration, depth of insertion, and diagnostic and therapeutic yields compare favorably with previously published data on other deep enteroscopy techniques such as single-balloon and double-balloon enteroscopy. Comparative studies are warranted. (Gastrointest Endosc 2010;72:992–8.)

The advent of deep enteroscopy has revolutionized the management of patients with mid-small–bowel diseases. Since the introduction of double-balloon enteroscopy by Yamamoto in 2001, two additional techniques have become available, single-balloon enteroscopy and spiral enteroscopy.[1–3] Double-balloon enteroscopy and single-balloon enteroscopy entail a similar mechanism of advancement consisting of sequential bowel pleating by a push-pull technique that uses a balloon-fitted overtube with or without a second balloon inserted over the tip of a dedicated enteroscope.

In contrast, spiral enteroscopy, or rotational enteroscopy, uses a spiral or raised helix–fitted overtube coupled with the enteroscope, advanced as a unit into the small bowel by continuous rotation of the overtube in a manner similar to use of a corkscrew. An inner sleeve allows the independent motion of the overtube from the enteroscope during advancement and withdrawal. The main difference between balloon enteroscopy and spiral enteroscopy is that the latter uses a more or less continuous pleating of the small bowel by a clockwise rotation of the overtube rather than the push-pull technique of the former two methods.[4] Previous small studies have suggested that spiral enteroscopy allows advancement into the small bowel more efficiently than do techniques using balloon-assisted devices.[5] The technical performance of spiral enteroscopy as well as the diagnostic and therapeutic yields have not been rigorously studied.

The aims of the present study were to determine the performance, yield, and safety of oral spiral enteroscopy in patients with suspected or established small-bowel pathology within the framework of a prospective, multicenter study in the United States.

MATERIALS AND METHODS

Study design

The study design consisted of a prospective, multicenter investigation of antegrade spiral enteroscopy yield and efficacy. A centralized database was used to collect data from patients evaluated at participating U.S. centers with experience in balloon enteroscopy. Patients with suspected or established small-bowel disorders referred for anterograde deep enteroscopy were considered eligible for the study if they had a previous nondiagnostic upper and lower endoscopy or if they had other objective evidence of small-bowel disease based on prior capsule endoscopy or small-bowel radiological studies. Patients with histories of esophageal stricture, varices, advanced cirrhosis, or coagulopathy were excluded. Per study protocol, centers with an enrollment of fewer than 10 participants were not included in the analysis. Research informed consent was obtained from all patients before the procedure.

Procedure and instruments

The spiral enteroscopy technique has been described.[4] Each procedure was performed by a two-physician team, consisting of two experienced gastroenterologists or one faculty gastroenterologist and one gastroenterology fellow. One physician guided the enteroscope while the other operated the overtube. All investigators had participated in or observed at least 20 spiral enteroscopy procedures before the current investigation.

The Discovery small-bowel overtube (DSB; Spirus Medical, Inc, Stoughton, Mass) was used for all study procedures. The use of the DSB standard profile or DSB low-profile system was determined based upon patient characteristics and physician preference. The choice of enteroscope was made based upon site availability, including the Fujinon diagnostic double-balloon enteroscope (EN-450TS; Fujinon, Inc, Saitama, Japan) or the Olympus single-balloon enteroscope (SIF-Q180; Olympus Corporation, Tokyo, Japan).

All sites chose procedure sedation according to local standards and anesthesia guidelines for individual patients. Mallampati scores were assessed by the anesthesia or gastroenterology attending physician. The use of fluoroscopy was allowed at the discretion of the site gastroenterologist.

Study endpoints

Procedure times—Study times were recorded by the study staff during each procedure, with the total procedure time (enteroscope insertion to enteroscope removal) as the primary time endpoint. The following time milestones were also measured: helix engagement of the pylorus and duodenum, maximum overtube insertion, maximum enteroscope insertion, and procedure termination. The times of each therapeutic intervention were recorded and summed to facilitate calculation of the total therapy time. Interventions included vascular lesion ablation, polypectomy, stricture dilation, and solution injection (eg, India ink). The procedure-adjusted diagnostic time was defined as the total procedure time minus the total therapy time, which was calculated on a per-participant basis.

Depth of insertion and procedure yields—The depth of maximum enteroscope insertion was estimated for each case, based upon withdrawal or bowel unpleating in sequential 10-cm increments, a variation on the technique described by May et al,[6] and estimated as total centimeters beyond the angle of Treitz. The overtube external helix facilitates controlled advancement and withdrawal of the enteroscope, such that the bowel slippage observed with balloon enteroscopy was not a factor in depth estimations. Procedure success was defined as enteroscope advancement beyond the angle of Treitz.

The procedure diagnostic and therapeutic yields were calculated based upon procedure findings and therapeutic interventions. Correlation with capsule endoscopy findings was graded as definite, probable, or negative.

Safety and tolerance—The evaluation of mucosal changes was systematically performed upon enteroscope and overtube withdrawal. Assessment of the mucosa upon withdrawal of the enteroscope is standard, but for the most part, other studies have not commented on the spectrum of iatrogenic mucosal or bowel-wall damage. Specific evaluation focused upon the following anatomic regions: proximal and distal esophagus, gastric lesser curve, pylorus, second duodenum, angle of Treitz, and small bowel. Enteroscopy-related trauma was graded as none/mild, moderate, and mucosal disruption. The type and severity of side effects and complications were assessed during and after the procedure as well as at postprocedure days 1 and 7 by telephone interview. Patients were specifically queried about throat discomfort, difficult or painful swallowing, abdominal discomfort or distention, and ability to resume normal activities after the procedure. Preprocedure assessment of chronic abdominal symptoms by Rome III or other criteria was not performed.[7]

A centralized, standard database, with Web-based data entry was used. The database included 185 fields within the categories of demographics, medical history, enteroscopy indications, procedure efficacy, therapeutic interventions, mucosal trauma, patient follow-up, physician experience, and impressions. Statistical analysis was performed with STATA

9 (Stata Corporation, College Station, Tex). The study was approved by the institutional review boards of each center.

RESULTS

A total of 149 participants with suspected or established small-bowel disorders were enrolled at 10 U.S. centers from April 2008 through October 2008. The median age was 68.0 years (range 20–88 years), and 40% were male (n = 57). The current analysis included 141 patients who had complete data. In agreement with the study protocol, centers with an enrollment of fewer than 10 participants at the time of study closure were not included in the analysis; 3 participants (two centers) were thereby excluded, each of whom had an uncomplicated study and usual procedure time (37, 45, and 51 minutes). Five procedures were aborted before initiation or completion—two for medical indications and two in patients with obstructive sleep apnea (the anesthesiologist recommended intubation, but the participants declined). One case was instructive, wherein a previously undiagnosed, subtle cervical web was encountered; the spiraling of the overtube helix did not facilitate advancement but rather bowing of the overtube.

The enrolled patient population had a significant percentage of comorbidities, which reflects the obscure GI bleeding population in the United States (Table 1). This included coronary artery disease (36%), congestive heart failure (11%), chronic obstructive pulmonary disease (14%), diabetes (32%), and hypertension (52%). Prior abdominal or pelvic surgery was common, noted in 52% of participants. A documented history of intra-abdominal adhesions was reported in 8.5% (n = 12) of patients. Although the condition was not exclusionary, no patients with prior Nissen fundoplication were enrolled. The use of chronic anticoagulant medication before the procedure was common, including aspirin (27%), clopidogrel (12%), warfarin (6.4%), and nonsteroidal anti-inflammatory drugs (5.6%). The mean (± standard deviation [SD]) patient body mass index was 28.8 ± 9.0 kg/m^2, with a range of 15.6 to 69.4 kg/m^2.

Procedure indications

Obscure GI bleeding was the indication for deep enteroscopy in nearly three-fourths of patients (n = 101, 72%). Of those cases with obscure GI bleeding, 32% were overt and 68% occult (stool occult blood test positive or iron deficiency anemia). Two-thirds of this obscure GI bleeding cohort (n = 67) had received transfusions within 6 months of the procedure.

Prior diagnostic evaluations included EGD (83%), colonoscopy (89%), push enteroscopy (26%), and balloon enteroscopy (8.5%) (Table 2). The majority of participants (n = 113) had undergone capsule endoscopy before enrollment, and 79% had abnormal results. Abnormal imaging results also were a common indication for spiral enteroscopy, including abdominal CT (n = 22), small-bowel follow-through (n = 5), and other imaging (n = 8). There were no documented prior diagnostic or therapeutic angiography evaluations.

Procedure efficacy

Spiral enteroscopy was successful in 93% (132 of 142) of cases, with advancement beyond the proximal jejunum and the presumptive extent of push enteroscopy. In 6 cases, only the proximal jejunum was accessed, and in 4 cases, the angle of Treitz could not be reached, including the patient with the cervical web. The use of fluoroscopy was limited to 16 cases (11%). The standard profile DSB overtube was used in nearly all cases (93%). The Olympus and Fujinon enteroscopes were used in 68% and 32% of cases, respectively, according to site availability and preference. Most procedures were performed with patients under

moderate conscious sedation with a combination of midazolam, fentanyl, or meperidine and propofol administered either by an anesthesiologist or qualified endoscopy nursing staff.

The median depth of insertion beyond the angle of Treitz, estimated as described in Materials and Methods, was 250 cm (mean ± SD = 250.3 ± 94.6 cm; range 10–600 cm). The frequency plot of depth estimations demonstrates a gaussian distribution, an expected result given variable patient anatomy and also arguing against significant bias in the depth estimations (Fig. 1). The terminal ileum was reached in one case, in a patient with a Roux-en-Y anastomosis with an estimated 100 cm of small bowel excluded.

The median total procedure time was 43.0 minutes (range 21–104 minutes). The mean therapeutic intervention time was 11.4 minutes (range 0–73 minutes). The mean (± SD) adjusted diagnostic procedure time for all procedures was 34.4 ± 10.1 minutes, calculated for each patient. Importantly, this estimation was in agreement with the total procedure time in nontherapeutic cases (35.4 minutes, n = 12). The mean (± SD) times to helix engagement beyond the pylorus, maximum DSB overtube insertion time, and maximum enteroscope insertion time were 8.4 ± 5.9 minutes, 22.1 ± 11.5 minutes, and 25.7 ± 12.1 minutes, respectively.

Diagnostic and therapeutic yields

Abnormalities were detected at spiral enteroscopy in 65.2% (n = 92) of the evaluations, of which 44% were felt to be definite findings and 21% probable findings (Table 3). The most common diagnostic findings in those with positive study results included vascular ectasias (56.2%), inflammation (15%), and neoplasia (7.9%). For study purposes, inflammation included erosions, ulcerations, and/or mucosal changes suggestive of Crohn's disease, such as thickened or denuded villi, mucosal erythema and edema, or fold thickening with or without associated strictures. The majority of these diagnostic findings were found in the mid-jejunum (48 of 82). The correlation with capsule endoscopy findings, according to protocol grading, was 40% definite, 32% probable or possible, and 28% negative. Ablation with argon plasma coagulation of vascular ectasias accounted for the majority (64%) of therapeutic interventions. Resection of polyps and mucosal biopsy were performed in 16% of patients.

Procedure-related mucosal changes

Systematic assessment of mucosal changes related to the enteroscope and DSB overtube in each segment of the small bowel and intestines was performed upon withdrawal. Mucosal changes were limited in the majority of procedures (Table 4). Mucosal disruption was noted in 8 cases, including small intestine (2), duodenum (1), pylorus (3), and proximal esophagus (2). There were no perforations. The areas in which the mucosal changes occurred were consistent among centers and operators, as assessed by significant erythema and mucosal disruption (angle of Treitz, pylorus, esophagus).

Adverse events and side effects

Physicians judged the overall procedure as well-tolerated (77%), fairly well-tolerated (14.5%), or average (5%). A small number (3.5%) of cases were poorly tolerated. Significant symptoms during the procedure were limited but included agitation (1.4%), significant cough (1.4%), and transient stridor (2%). One transient intussusception of the pleated bowel was observed, with rapid resolution by gentle manipulation of the bowel by using the enteroscope.

The most common procedure side effects at 24 hours included sore throat (28.3%) and/or swallowing discomfort (24%) and abdominal bloating or discomfort (19%). Residual side

effects at 7 days included sore throat (0.7%), swallowing discomfort (2.2%), and abdominal bloating or discomfort (6.7%). There were no serious adverse events recorded such as perforation, pancreatitis, ileus, or death. Ten office visits were recorded during the week after the spiral enteroscopy.

DISCUSSION

Our study shows that spiral enteroscopy is a safe and effective deep enteroscopy technique. The mean procedure time (mean endoscope insertion to removal time) of 45 minutes compares favorably with the other deep enteroscopy approaches.[8–13] In the U.S. multicenter, double-balloon enteroscopy study, the mean procedure duration was 92.1 ± 37 minutes (n = 114).[9] In particular, the time to maximal advancement of the enteroscope (mean 25.7 ± 12 minutes) is efficient, suggesting that the continuous pleating of the small bowel by using a clockwise rotation of the helix overtube may be a more efficient advancement method than the push-pull technique used with balloon-assisted enteroscopy. As noted, the terminal ileum was reached in one patient with a gastric bypass, suggesting efficient pleating of the small bowel. We acknowledge that our depth of insertion estimation method has not been adequately validated, and therefore a comparison with historic cohorts may not represent an adequate control group.

The diagnostic and therapeutic yields of the procedures in this study compare favorably with data previously published regarding balloon-assisted enteroscopy. As anticipated in these patient populations, the most common indication for spiral enteroscopy was obscure GI bleeding, and the most common finding was vascular malformations. It is worth mentioning that all endoscopists participating in this study had previously performed balloon-assisted enteroscopies, yet the overall impression was that spiral enteroscopy was a very stable platform for interventions such as cautery, biopsy, polypectomy, or solution injection. One potential technical limitation with the single-balloon enteroscopy device is that air can escape from the bowel distal to the enteroscope through the space between the endoscope shaft and the overtube. This was not thought to be the case with spiral enteroscopy because of the locking device in the overtube handle. Clearly, more comparative studies are required to further elucidate the performance aspect of this procedure. The aims of the present study were to determine the performance and yield of spiral enteroscopy in the small bowel. Therefore, the prevalence of significant findings within the reach of standard endoscopy (such as stomach, duodenum, or colon) was not consistently reported.

Despite the high prevalence of serious comorbid conditions including chronic obstructive pulmonary disease, coronary artery disease, congestive heart failure, and diabetes, the procedure was well-tolerated by the majority of patients, with a relatively limited incidence of side effects such as sore throat, dysphagia, or odynophagia. There were no serious complications such as pancreatitis, perforation, bleeding, or infection. The incidence of significant mucosal trauma was measureable (8 mucosal disruptions were noted), in contrast to the experience in the U.S. double-balloon enteroscopy study of similar design, which included one mucosal tear.[9] It was observed that the mucosal changes in the esophagus were often related to the depth of sedation at procedure initiation. Only one patient could not be intubated with the overtube, this because of an unrecognized cervical web. This compares favorably with data published with alternative deep enteroscopy techniques.[9,12,14–17]

It is noteworthy that most procedures in the study were performed under deep sedation with intravenous propofol. A small proportion of procedures were performed with the patient under moderate sedation or general anesthesia. In the latter case, we noted that allowing the endotracheal tube to deflate at the beginning of the procedure facilitates intubation of the esophagus, with minimal resistance and minimal or no mucosal trauma.

The prospective study design, with the use of a centralized database, strengthened the validity of our study data. The patient population is representative of individuals with obscure GI bleeding and, in general, patients in the United States requiring deep enteroscopy. In addition, the evaluation of mucosal changes upon enteroscope withdrawal was systematically performed to capture the spectrum of iatrogenic mucosal changes.

We acknowledge that this study was not a randomized trial with a comparative arm with capsule endoscopy, push enteroscopy, or other deep-enteroscopy modalities. Assessment of the learning curve was not included because all gastroenterologists had prior experience with balloon enteroscopy and spiral enteroscopy. Although the study population was representative of the U.S. obscure GI bleeding population, patients with upper GI strictures and severe liver disease were excluded. We also were not able to evaluate long-term clinical outcomes such as improvement or cessation of bleeding and survival. The study may have had limited power to detect infrequent serious complications (eg, pancreatitis, perforation). Last, this study did not evaluate retrograde spiral enteroscopy or spiral enteroscopy–assisted ERCP.

What are the potential limitations of spiral enteroscopy (Table 5)? The procedure efficiency is balanced by the overtube diameter (16 mm) in this “first generation” version of the technology. This may increase the number of procedure-related mucosal changes and the anesthesia requirements. We observed one patient who could not be intubated with the spiral overtube because of a cervical web. The areas of procedural mucosal changes and mucosal disruption were similar among centers, which suggests that these are expected “pressure points” in spiral enteroscopy and that technique or overtube modifications and physician experience may serve for prevention. In addition, the current spiral overtube technique requires two operators—two gastroenterologists or a gastroenterologist and an assistant. Importantly, latex allergy is not an issue with the spiral overtube.

In this initial study of spiral enteroscopy by endoscopists experienced in deep enteroscopy at tertiary-care U.S. centers, spiral enteroscopy by the oral approach appears safe in selected patients and can be used for diagnostic and therapeutic maneuvers in the mid-bowel and possibly the proximal ileum. The performance and procedure duration appear comparable with those of alternative deep-enteroscopy techniques. Further comparative prospective studies are warranted to analyze outcomes such as procedure yields, transfusion burden, and survival.

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Abbreviation

DSB Discovery small-bowel overtube

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Take-home Message

- Spiral enteroscopy appears to be safe and effective for evaluation of the small bowel. The procedure duration, depth of insertion, and diagnostic and therapeutic yields compare favorably with other deep enteroscopy techniques such as single-balloon and double-balloon enteroscopy. Comparative studies are warranted.

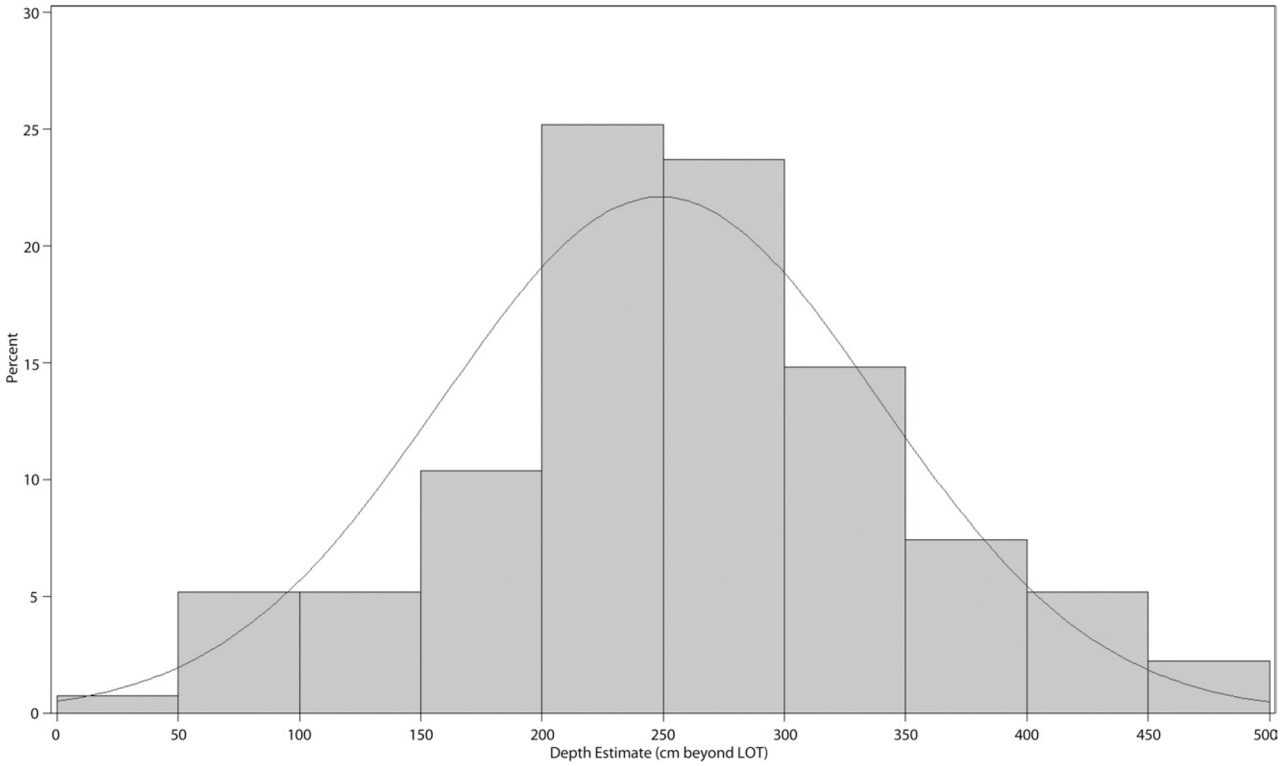

Figure 1.

Spiral enteroscopy: small-bowel maximum depth of insertion beyond the ligament of Treitz (LOT). Spiral enteroscopy was successful in 93% of cases, with advancement beyond the proximal jejunum and the presumptive extent of push enteroscopy. In 4 patients, the angle of Treitz could not be reached, including a patient with a cervical web. In 6 patients, the examination was limited to the proximal jejunum. The maximum depth of insertion estimates, expressed in centimeters, demonstrate a gaussian distribution, fulfilling criteria for normality.

TABLE 1

Spiral enteroscopy: patient medical and surgical history

Chronic medical condition	No. of patients (%)
Coronary artery disease	51 (36.2)
Congestive heart failure	16 (11.4)
Chronic obstructive pulmonary disease	20 (14.2)
Hypertension	73 (51.2)
Diabetes	45 (31.2)
Crohn's disease	6 (4.3)
Surgical history	
Cholecystectomy	25 (17.7)
Appendectomy	24 (17.0)
Hysterectomy	25 (17.7)
Altered gastric anatomy	3 (2.1)
Intestinal resection, colon or small bowel	9 (6.4)

TABLE 2

Spiral enteroscopy: antecedent diagnostic evaluations

Diagnostic evaluation	No. (%)
Endoscopy	
Capsule endoscopy	113 (79%)*
Upper endoscopy	117 (83.0)
Colonoscopy	124 (88.0)
Push enteroscopy	37 (26.2)
Balloon enteroscopy	12 (8.5)
Radiology	
Abdominal CT, abnormal result	22 (15.6)
Small-bowel follow-through	17 (12.1)
Enterography (CT, MR)	8 (5.7)

*Eighty-nine of the 113 antecedent capsule endoscopy results were characterized as abnormal.

TABLE 3

Spiral enteroscopy: summary of small-bowel findings

	Angiectasia	Neoplasia	Inflammation
Upper GI tract	21	3	6
Duodenum, distal	9	2	0
Jejunum			
Proximal	24	1	4
Middle	33	0	6
Distal	18	4	2
Ileum	4	2	2
Total	109	10	20

Upper GI tract includes findings in esophagus, stomach, and/or proximal duodenum. Inflammation refers to mucosal erythema, congestion, thickened folds, thick or denuded villi, ulceration, erosions, and/or erythema. The characterizations of small- bowel segments are gross estimations for lesion localization.

TABLE 4

Spiral enteroscopy: mucosal changes

	Erythema, none or minimal (%)	Erythema, moderate (%)	Mucosal disruption (no.)
Esophagus, proximal	85	15	2
Esophagus, distal	66	34	0
Gastric, lesser curve	93	6.7	1
Gastric, pylorus	75	25	3
Duodenum	80	20	0
Angle of Treitz	84	16	2
Small bowel	79	21	0

TABLE 5

Comparison of deep enteroscopy techniques, U.S. experience

	Double balloon[9*,12,15]	Single balloon[16,17]	Spiral enteroscopy
Overtube material	Latex	Silicone	PVC
OD/ID, mm	13.2/10.8	13.2/11	16/9.8
Length, cm	135	132	118
Sedation routine	Deep, propofol	Moderate, conscious	Deep, propofol
Insertion depth, cm	218–370	132	250
Duration, minutes	68–101	38–49	45

PVC, Polyvinyl chloride; *OD*, outer diameter; *ID*, inner diameter.

* The U.S. multicenter double-balloon enteroscopy study reported for antegrade double-balloon enteroscopy procedures a mean (± SD) insertion depth of 370 ± 167 cm, with a mean (± SD) procedure duration of 90.3 ± 37 minutes.[9]