

Safe and Rapid Intubation of the Distal Small Bowel Using the Discovery SB[®] Overtube Device during Small Bowel Enteroscopy: Results of the Spiral Enteroscopy Training Initiative

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Abstract

Introduction: Indications for small bowel (SB) enteroscopy are increasing, but advancing the endoscope to the distal small intestine remains challenging. The Endo-Ease Discovery[®] SB device (Spirus Medical, Stoughton, MA), a novel spiral-shaped overtube FDA-approved for small bowel enteroscopy, may allow for simple and quick intubation of the ileum comparable to current methods.

Aims & Methods: To evaluate ease-of-use, safety, and efficacy of the Discovery SB during small bowel enteroscopy. 33 endoscopists without prior Discovery SB experience from 19 academic centers along with 2 Spirus instructors performed SB enteroscopy in human patients as clinically indicated during 1 of 4, 2-day training modules. All procedures performed without endo-tracheal intubation. Data was collected prospectively. Patient demographics, indication, depth and time to maximal insertion, total procedure time, and findings were recorded. Any trauma was documented during scope withdrawal and scored 0-5 (0=no trauma, 1 = edema/ erythema, 2=superficial hematoma/erosion, 3=superficial laceration, 4=deep laceration, 5=perforation). Overall means were calculated; Day 1 and Day 2 results were compared. Data was analyzed using 2-tailed t-test or rank-sum test for non-normally distributed data.

Results: 90 procedures were successfully performed in 95 patients (72.6% women; mean age = 48.8 ± 14.2 years). The most common indication was chronic abdominal pain. Mean BMI was 28.4 ± 17.2 with median Mallampati (M)--airway assessment--score=2 (range=1-4). Endoscopists performed a mean of 5 cases. Mean time required for device to engage SB was 10 ± 5.5 minutes, with mean time to maximal scope insertion of 20.9 ± 6.4min. Mean depth achieved was 262 ± 57.4cm beyond the ligament of Treitz. Total procedure time was 33.6 ± 8.0min. In 83.9%, 89.3% and 78.5% of patients, trauma score less than or equal to 2 was recorded in esophagus, stomach, and intestine respectively. There were no perforations. Trauma score greater than 2 was documented in 3 out of 5 of patients with a M- score of 4, versus 4 out of the 28 patients with a M-score of 1 (p=0.075). There were no statistically significant associations between trauma score and the following: age, BMI, time to SB engagement, depth of insertion, time to maximal insertion, total procedure time, or Day 1 vs. Day 2 procedures. Depth of insertion was significantly greater among endoscopists on Day 2 vs. Day 1 (276.9 ± 53.7 vs. 252 ± 58cm, respectively; p=0.043). In 88.9% of cases, endoscopists rated the quality of withdrawal, position, and control in the intestine greater than or equal to 4 (scale of 1-5; 5=excellent, 1=poorest).

Conclusion: The Discovery SB allows for safe and easy advancement of the endoscope into the distal small bowel. Maximum depth of insertion utilizing spiral enteroscopy is comparable to balloon enteroscopy while taking less time. The device is easy to use and provides deep penetration of the small intestine in as few as 5 training cases.