

# Is Spiral Enteroscopy Superior to Double-Balloon Enteroscopy in Diagnosing The Small Intestine? First Results of a Large Prospective Randomized Comparative Study

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## ABSTRACT

**Introduction:** The indications for enteroscopy of the small intestine are rising. Reaching the deep ileum remains a challenge. The Endo-Ease Discovery SB system is an overtube with an outer spiral, which was cleared for enteroscopy by the FDA in 2008. This overtube provides a quicker and simpler intubation of the ileum in comparison to double-balloon enteroscopy (DBE).

**Aims and Methods:** From August 2008 to September 2009, patients were prospectively randomized and the following features were evaluated: Simplicity, security and efficiency of spiral enteroscopy (SE) in comparison to DBE. The following data was collected and evaluated: Patient demographics, indication(s) for the procedure, depth and time for maximum insertion, total time of examination, results and type/quality of the therapy, trauma based on a scale of 0 to 5 where 0 equals no trauma and 5 equals a perforation.

**Results:** 20 patients were examined with SE (15 per-oral, 5 per-anal) and 22 patients with DBE (16 per-oral, 6 per-anal). Indications: Locate a bleeding source in the ileum, search for a tumor (confirmation of a capsule endoscopy finding and for histology), chronic stomach ache and Crohn's Disease. Results: 19 angiodysplasias, 12 tumors (GIST and others), 6 segmental inflammations (Crohn's and others), 3 mucosal ischemia's, 2 Meckel's diverticulae. 19 patients underwent APC therapy successfully and in 18 the diagnosis was confirmed by histology. SE: Average time for the engagement of the rotation mechanism: 8 +/-5 min and for maximum insertion depth: 18 +/- 8 min. DBE: 64 +/- 16 min ( $p < 0.05$ ). Average insertion depth with SE was 284 +/- 88 cm between the Ligament of Treitz and the ileocecal valve, and with DBE 272 +/- 82 cm (not significant). Total length of examination: 27 +/- 11 min with SE and 86 +/- 18 min with DBE ( $p < 0.05$ ). In over 90% the trauma score was  $\leq 2$  with SE and DBE (not significant). Safety on positioning during retrieval: All of the examinations with SE were excellent (maximum in a five point evaluation scale), with DBE 3 ( $p < 0.05$ )

**Conclusion:** SE allows similar insertion depths to be reached as with DBE but in a significantly quicker time. The positioning with SE for collecting samples and for therapy is more stable than with DBE. The procedure can be performed similarly atraumatically as with DBE. Familiarization with the rotation mechanism of SE in an initial training phase is absolutely necessary.

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