SINGLE-01: a randomized, controlled trial comparing the efficacy and depth of insertion of single- and double-balloon enteroscopy by using a novel method to determine insertion depth

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Background: Single-balloon enteroscopy (SBE) was introduced as an alternative to double-balloon enteroscopy (DBE) for the investigation and management of small-bowel conditions. To date, there is only 1 randomized, controlled trial comparing SBE and DBE in a Western population.

Objective: To compare the 2 instruments in a Western population to assess for differences in clinical outcomes and insertion depth (ID). A novel method to determine ID by counting folds on withdrawal was used.

Design: Multicenter, randomized, controlled trial.

Setting: University hospitals in Melbourne and Sydney, Australia.

Patients: Patients with suspected or proven small-bowel disease.

Interventions: SBE and DBE.

Main Outcome Measurement: The primary endpoint was diagnostic yield (DY). Secondary endpoints were therapeutic yield (TY), procedure times, and ID. An intention-to-treat analysis was performed.

Results: A total of 116 patients were screened, and 107 patients were enrolled between July 2008 and June 2010, in whom 119 procedures were undertaken (53 SBEs and 66 DBEs). DY was 57% for SBE and 53% for DBE (P = .697). TY was 32% for SBE and 26% for DBE (P = .490). The median enteroscopy times were identical for SBE and DBE at 60 minutes. The mean ID by the fold-counting method for antegrade procedures was 201.1 folds for SBE and 258.6 folds for DBE (P = .046). After multiple comparisons adjustment, this difference did not reach statistical significance. Mean IDs by using the visual estimation method for SBE and DBE were, respectively, 72.1 cm and 75.2 cm (P = .835) for retrograde procedures and 203.8 cm and 234.1 cm (P = .176) for antegrade procedures.

Limitations: Unable to reach target sample size, mostly single-center recruitment, novel method to determine ID, which requires further validation.

Conclusions: SBE has DY, TY, and procedure times similar to those of DBE. There were no statistically significant differences in ID between SBE and DBE. By using the fold-counting method for antegrade procedures, the estimated IDs for SBE and DBE were 201.1 folds versus 258.6 folds (P = .046; P = not significant after adjustment for multiple comparisons). (Clinical trial registration number: ACTRN12609000917235.) (Gastrointest Endosc 2012;76:972-80.)

Despite increasing experience and the availability of different systems, deep small-bowel endoscopy remains challenging. Push enteroscopy provides therapeutic access to the small bowel; however, its insertion depth (ID) is limited to approximately 100 cm.[1] Capsule endoscopy provides views of the whole small bowel, but without the capacity for biopsy or therapy. Double-balloon enteroscopy (DBE) was described by Yamamoto et al[2] in 2001

Abbreviations: DBE, double-balloon enteroscopy; DY, diagnostic yield; ID, insertion depth; SBE, single-balloon enteroscopy; TY, therapeutic yield.

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and provides access much deeper into the small bowel via the oral or anal route.[3-5] Single-balloon enteroscopy (SBE) was introduced by Olympus (Tokyo, Japan). Preliminary studies suggest that SBE is safe and effective,[6-9] and the lack of an enteroscope tip balloon may simplify the enteroscopy technique.

Three studies have compared SBE and DBE to date. The first, by May et al,[10] demonstrated much higher total enteroscopy rate in a Western cohort by using standard DBE compared with using the Fujinon enteroscope (Tokyo, Japan) without a tip balloon. Whether these results are representative of the performance of the Olympus SBE system is unclear. Domagk et al[11] undertook the first randomized trial comparing the Fujinon DBE and Olympus SBE in a Western cohort. They demonstrated similar IDs and diagnostic yield (DY) for SBE and DBE. Takano et al[12] compared SBE and DBE for total enteroscopy (in a Japanese cohort) and found SBE to be inferior. Thus, this study is the second randomized, controlled trial comparing SBE and DBE in a Western cohort for procedural and clinical outcomes.

Total enteroscopy is uncommon in Western patients undergoing DBE.[3,4,13] Therefore, ID is an important endpoint to measure when comparing DBE and SBE. Accurate and reliable assessment of ID is difficult to achieve. We describe a new method to assess ID based on counting folds on withdrawal of the endoscope, which is likely to provide a more reliable determination of ID and therefore allow a true comparison of IDs achieved with DBE compared with SBE.

The primary aim of the study was to assess and compare the DY of SBE and DBE. Secondary aims were to assess and compare therapeutic yield (TY), procedure times, and ID.

Take-home Message

- In a Western cohort of patients with suspected or proven small-bowel pathology, single- and double-balloon enteroscopy have similar diagnostic yield, therapeutic yield, and insertion depth (ID).
- Fold counts on withdrawal of the enteroscope have a good correlation with measured ID and provide a simple alternative to existing methods of estimating ID.

METHODS

Participants

The St. Vincent's Hospital Human Research Ethics Committee approved the study. After this, the trial was registered with the Australian New Zealand Clinical Trials Registry (trial number: ACTRN12609000917235).

Consecutive patients 18 years of age and older, referred to St. Vincent's Hospital (Melbourne), The Alfred Hospital (Melbourne), and Royal Prince Alfred Hospital (Sydney) for balloon enteroscopy for the investigation or management of proven or suspected small-bowel disorders, were invited to participate.

Written information regarding the study was provided to patients in advance of the procedure. On the day of the procedure, the investigators met with patients, screened patients suitable for inclusion, and obtained informed consent. Patients were excluded if any of the following was present: (1) inability to provide informed consent, (2) pregnancy or lactation, (3) high-risk esophageal or gastric varices (antegrade procedures only), (4) suspected perforation of the GI tract, and (5) inability to tolerate sedation or general anesthesia because of comorbidities.

Interventions

Eligible patients were randomized to SBE using the Olympus SIF-180 enteroscope/overtube or DBE using the Fujinon ET-45 enteroscope/overtube. All procedures were performed by gastroenterologists with expertise in enteroscopy (A.T., G.B., A.K.) or by fellows under direct supervision (M.E., R.L.). All senior endoscopists had performed at least 200 DBEs and at least 20 SBEs. Both fellows had performed approximately 20 DBEs before study commencement.

Bowel preparation for retrograde procedures involved a fluid-only diet on the day before the procedure, 3 L of polyethylene glycol lavage solution, 1 sachet of PicoPrep (sodium picosulfate 10 mg, heavy magnesium oxide 3.5 g, anhydrous citric acid 12 g), and an overnight fast. For antegrade procedures, an overnight fast was required. For patients with pathology identified by imaging modalities including capsule endoscopy, the estimated location of the pathology was used to determine the route of enteroscopy. For the remaining patients, the route of enteroscopy was determined by the endoscopist based on the clinical presentation.

Enteroscopies were performed as outpatient procedures. Procedures at St. Vincent's Hospital and the Alfred Hospital were performed with the patients under general anesthesia with endotracheal intubation, whereas deep sedation with propofol was used at Royal Prince Alfred Hospital. All enteroscopies began with the patient in the left lateral decubitus position. Air was used for insufflation. Changes in patient position were permitted at the discretion of the endoscopist. The use of fluoroscopy to assist insertion was permitted but not mandatory.

Participants were contacted by telephone within 6 months of their enteroscopy, and a postprocedure questionnaire was administered to assess for postprocedure complications.

Outcomes

The primary endpoint of the study was the DY for clinically significant findings on enteroscopy. Secondary endpoints included TY, procedure duration, and ID.