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A prospective comparison of performance during back-to-back, anterograde manual spiral enteroscopy and double-balloon enteroscopy

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ABSTRACT

Background: Spiral enteroscopy is a recently introduced technology alternative to balloon-assisted enteroscopy for examination of the small bowel.
Aim: To compare small bowel insertion depths and procedure duration by spiral enteroscopy and double-balloon enteroscopy performed in the same cohort of patients, in immediate succession, using the same method of insertion depth estimation.
Methods: A prospective, back-to-back comparative study was performed in 15 patients. Spiral enteroscopy procedures were performed first and a tattoo was placed to mark the most distal point.
Results: Double-balloon enteroscopy passed the tattoo placed at spiral enteroscopy in 14/15 cases (93%). Median insertion depths for double-balloon enteroscopy and spiral enteroscopy were 265 cm and 175 cm, respectively ($P = 0.004$). Median time to achieve maximal depth of insertion was significantly shorter for spiral enteroscopy compared with double-balloon enteroscopy (24 min vs. 45 min, respectively; $P = 0.0005$). However, in 14 patients no differences were found in median time to reach the same insertion depth ($P = 0.28$).
Conclusion: Double-balloon enteroscopy achieved significantly greater small bowel insertion depth than spiral enteroscopy. Although overall double-balloon enteroscopy procedure duration was longer, the time taken to reach the same small bowel insertion depth by both spiral enteroscopy and double-balloon enteroscopy was similar.

1. Introduction

Since the introduction of double-balloon enteroscopy (DBE) in 2001 [1], two other significant device-assisted enteroscopy methods have become available: single-balloon enteroscopy (SBE) [2,3] and spiral enteroscopy (SE) [4]. For DBE and SBE an inflatable balloon is incorporated onto an overtube, while the SE overtube has a raised soft-plastic spiral (helix) at its tip [1–4]. Although DBE is a safe and useful technique that can achieve complete enteroscopy, procedures frequently last over 60 min [5]; similar times have been reported for SBE [6–8].

The more recently developed SE, introduced in 2008 [4], requires manual rotation of the SE overtube to progress through the small bowel as an alternative to balloon-assisted traction and may enable faster enteroscopy than DBE [4,9–13]. However, there is debate as to whether SE in its current form achieves equivalent small bowel (SB) insertion depth. It is recognised that accurate measurement of insertion depth during deep enteroscopy is difficult due to small bowel mobility, elasticity and length. An estimate therefore has to be made which introduces an element of subjectivity. Nevertheless, accepting this intrinsic limitation, we consider the estimation of insertion depth method described by May et al. [14] to be the most practically applicable, since it is based on step-wise advancement of a measured length of enteroscope during insertion through the SB. In contrast, insertion depth estimation as recommended for

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SE, is performed during withdrawal and according to number of SB folds visualised [4], which we consider more difficult to interpret. In previous prospective studies [5,15–17] that have compared SE to DBE, different methods were used to estimate SB insertion depth, although Messer et al. [16] circumvented this limitation by directly comparing pan-enteroscopy rates achieved by bi-directional SE or DBE. According to our centre's deep enteroscopy experience [11] and following a literature review, we performed a prospective, back-to-back study comparing insertion depth and other performance measures achieved at SE and DBE. For this study, both types of enteroscopy procedures were carried out (in tandem) in the same patients, during the same session, using the same method for SB insertion depth estimation [14].

2. Methods

2.1. Patients

The study was conducted between August 2010 and September 2011. All patients ≥18 years of age referred to our institution for oral deep enteroscopy under general anaesthesia (GA) were considered for recruitment. Exclusion criteria were: unwillingness of patients to undergo deep enteroscopy or take part in the study, contraindications to deep enteroscopy (bleeding tendency, pregnancy) or latex allergy. All patients who participated in the study provided written informed consent.

The research protocol and conduct of the study was approved by the regional research ethics committee and by the institution's research and development review board (North London REC 3 Ref. 10/H0709/48; RD 10/32). The study was carried out in accordance with the World Medical Association Declaration of Helsinki, 1964 (incorporating all later amendments) [18] at the Wolfson Unit for Endoscopy, St Mark's Hospital and Academic Institute, London, UK.

2.2. Procedures and equipment

Deep enteroscopy procedures were carried out by two experienced enteroscopists (CF, EJD) who had both received dedicated training in DBE and SE [11]. All procedures were performed via the oral route with patients in the left-lateral position under GA after a 6–8 h fast. Carbon dioxide (CO_2), (CO_2 Efficient™ systems, E-Z-EM Inc., NY, USA) was used for SB insufflation.

The Endo-Ease Discovery® SB overtube (Spirus Medical, LLC, MA, USA) over the EN-450T5 (9.5 mm diameter, 200 cm working length and 2.8 mm instrument channel diameter) enteroscope (Fujifilm Inc., Saitama, Japan) was used for SE. The overtube is 118 cm long with an outer diameter of 16 mm. The oral-end incorporates a 21 cm long, soft-plastic (compressible) spiral, 5.5 mm in profile in order to 'engage' the SB and provide gentle-traction. Insertion and withdrawal are achieved by respective clockwise and counter-clockwise manual rotation of the overtube handle [4].

The EN-450P5 (8.5 mm diameter, 200 cm working length and a 2.2 mm instrument channel diameter) enteroscope, also manufactured by Fujifilm Inc., was used for DBE. During DBE, the two balloons which are attached to the tip of the overtube and enteroscope respectively, are inflated or deflated sequentially using a dedicated pressure-controlled pump system and DBE insertion is achieved using the push-and-pull technique as described by Yamamoto et al. [1].

Each patient first underwent a SE procedure immediately followed by a DBE. Our rationale for this rather randomised order of procedure, was to enable the use of a single method for insertion depth estimation as described by May et al. [5,14] to provide a more robust comparison of insertion depth for both procedures [19]. Maximal SB insertion depth at SE was considered achieved when further SB intubation was no longer possible despite continued rotation of the overtube or use of ancillary techniques such as the 'Cantero manoeuvre' [4,9,10], the 'over-the-scope manoeuvre' [4,9,10] and the use of external abdominal counter-pressure [11]. The deepest point of SB insertion reached at SE was marked by a submucosal tattoo of sterile India ink (Spot®, GI Supply, PA, USA) prior to withdrawal. For DBE, the maximal SB insertion depth was considered reached when enteroscope insertion was no longer possible despite manoeuvres for managing deep looping [20]. In keeping with the routine clinical practice of the authors, fluoroscopic guidance was not used. Estimated SB insertion depth by DBE was calculated using the method described by May et al. [5,14]. Procedure duration and other performance related measures were recorded by an endoscopy research fellow in real time using a specific proforma. Start and end of procedures were defined by entry or exit of the enteroscope into/from the patient's mouth respectively with exclusion of time spent applying endotherapy, which was applied only during DBE.

2.3. Collected data

Data collected included demographics (age and gender), indications for deep enteroscopy, history of abdominal or pelvic surgery, estimated insertion depth, time to reach maximal insertion depth, time to reach the tattoo placed during the preceding procedure, total procedure duration, limitations encountered and estimation of procedure difficulty using a 10 cm VAS (where 0 = very easy and 10 = very difficult). Enteroscopy findings, including evidence of procedure-related mucosal trauma, which was graded according to the 6 point trauma score described by Buscaglia et al. [10] and adverse events were also recorded.

2.4. Endpoints

The primary aim of the present study was to compare SB insertion depth by SE and DBE procedures performed in immediate succession, in the same cohort of patients, using the same method of SB insertion depth estimation [14]. Secondary end-points included comparisons of procedure duration and procedure difficulty, based on the visual analogue scale (VAS) score recorded by the endoscopist performing the enteroscopy.

2.5. Statistical analysis

The study was powered to detect a difference in insertion depth between the two procedures. Based on our experience, the within-subject standard deviations were considered to be 75 cm and a difference of 50 cm in insertion depth between methods was arbitrarily considered to be of clinical importance. Although it was initially calculated that 24 patients were required to achieve a 5% significance level and 90% power, interim analysis of the results from the first 15 patients (30 procedures) at 13 months, demonstrated statistically significant differences between SE and DBE procedures; it was therefore considered ethically prudent to conclude the study at this point.

Data were collated into a computer database (Microsoft Office® 2010, Microsoft Corporation, WA, USA) and analysed using GraphPad® InStat, version 3.0 (GraphPad software Inc., CA, USA) software. Descriptive statistics were used to examine patient demographics. Two-sided non-parametric testing (Mann–Whitney *U* test) was used to examine for differences in SB insertion depths and procedure duration. VAS scores for procedure difficulty were examined using a two-sided *t* test. Results are presented as means ± standard deviation (SD) and medians (with 95%