The performance and safety of motorized spiral enteroscopy, including in patients with surgically altered gastrointestinal anatomy

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The performance and safety of motorized spiral enteroscopy, including in patients with surgically altered gastrointestinal anatomy: a multicenter prospective study

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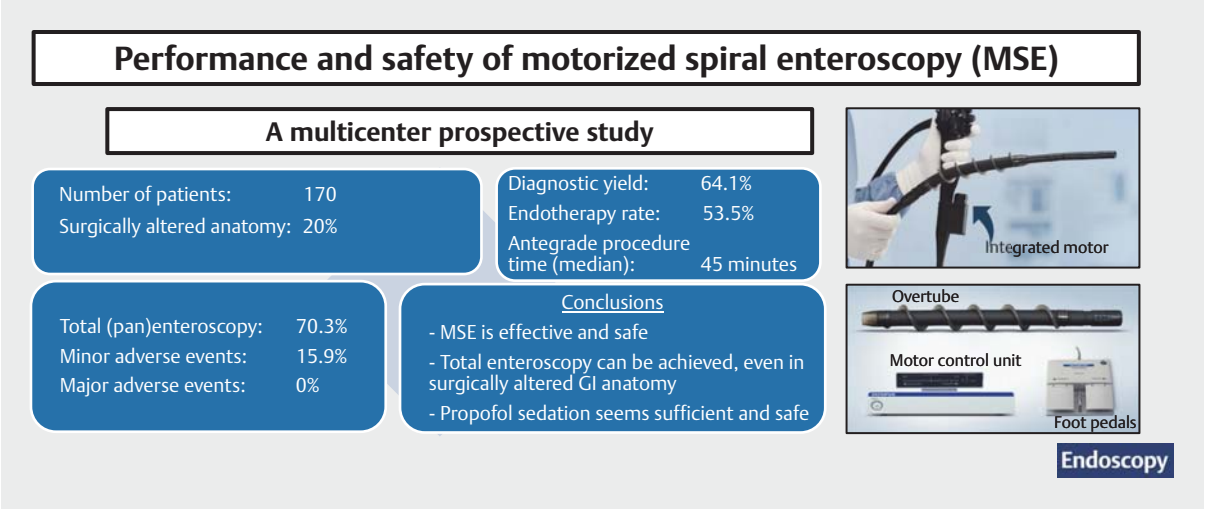

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ABSTRACT

Background Data are scarce on the efficacy and safety of motorized spiral enteroscopy (MSE). No data are available on the utility of this technique in patients with surgically altered gastrointestinal (GI) anatomy. We aimed to evaluate the safety and efficacy of MSE in patients with suspected small-bowel disease, including those with surgically altered GI anatomy.

Methods A multicenter prospective observational, uncontrolled study evaluated MSE in consecutive patients with suspected small-bowel pathology and an indication for diagnostic and/or therapeutic intervention.

Results A total of 170 patients (102 men; median age 64 years, range 18–89) were included. The overall diagnostic yield was 64.1 %. Endotherapy was performed in 53.5 % of procedures. The median total procedure times for the antegrade and retrograde approaches were 45 minutes (interquartile range [IQR] 30–80) and 40 minutes (IQR 30–70), respectively. When total (pan)enteroscopy was intended, this was achieved at rate of 70.3 % (28.1 % by antegrade approach and 42.2 % by a bidirectional approach). Surgically altered GI anatomy was present in 34/170 of all procedures (20.0 %) and in 11/45 of the successful total enteroscopy procedures (24.4 %). Propofol sedation or general anesthesia were used in 92.9 % and 7.1 % of the procedures, respectively. Minor adverse events were observed in 15.9 % of patients, but there were no major adverse events.

Conclusion MSE seems to be an effective and safe endoscopic procedure. Total (pan)enteroscopy can be achieved, in one or two sessions, even in the presence of surgically altered GI anatomy. The total procedure time is relatively short. For both antegrade and retrograde MSE procedures, propofol sedation seems sufficient and safe.

Introduction

The turn of the millennium has marked a great shift in diagnostic and therapeutic endoscopic techniques for the small bowel. First, video capsule endoscopy (VCE) became available for clinical use, followed almost immediately by the introduction of device-assisted enteroscopy (DAE), with double-balloon enteroscopy (DBE; Fujifilm, Tokyo, Japan), single-balloon enteroscopy (SBE; Olympus, Tokyo, Japan), and manual spiral enteroscopy (Spiral Medical, USA) being introduced [1–3].

Deep enteroscopy has made it possible to perform diagnostic and therapeutic interventions in regions that are exceptionally long distances into the small bowel [1, 4]. Despite these impressive improvements in enteroscopy, the small-bowel anatomy remains challenging and it is almost impossible to perform total enteroscopy of the entire small bowel. Although DAE has proven useful, being time-consuming to perform is a major limiting factor for both DBE and SBE, while manual spiral enteroscopy is a two-operator technique [5].

Motorized spiral enteroscopy (MSE; Olympus) is the latest advancement in the field of enteroscopy [6]. This system uses the same basic principle as that of manual spiral enteroscopy but has an integrated user-controlled motor. The electric motor is operated by a footswitch that rotates a short spiral segment/overtube to pleat and unpleat the small bowel [6]. This increases the speed of the procedure, facilitates insertion, and simplifies the technique with a single operator required, thereby overcoming the shortcomings of DAE [7].

Data are scarce on the utility, safety, and efficacy of MSE [6–10]. Except for one case [11], all reported procedures thus far were performed with the patients under general anesthesia, with endotracheal intubation particularly for antegrade procedures. No data are available on the utility of this technique in patients with surgically altered gastrointestinal (GI) anatomy.

In this study we present the results of the performance of MSE in patients with suspected small-bowel diseases, using both antegrade and/or retrograde approaches, and also in patients with surgically altered GI anatomy.

Methods

Study design

This prospective, investigator-initiated, observational, uncontrolled study was conducted at five referral enteroscopy centers in the Netherlands. MSE procedures were performed by endoscopists (1–2 per center) who had good experience in DAE. During the preparation phase, all participant endoscopists received training on the use of MSE. Training included lectures on theoretical and practical issues concerning MSE, hands-on-training using an endoscopy training bowel model, and participation in the performance of at least one live enteroscopy procedure.

Inclusion and exclusion criteria

The inclusion criteria were: age 18 years or older; an indication for diagnostic and/or therapeutic enteroscopy based on clinical presentation, small-bowel imaging, or VCE; and written informed consent. Exclusion criteria were: known severe GI tract inflammation, intestinal obstruction, gastroesophageal varices, or eosinophilic esophagitis that precluded a safe enteroscopy procedure; coagulopathy or thrombocytopenia that could not be corrected; pregnancy; American Society of Anesthesiologists (ASA) class > 3; and inability to tolerate propofol sedation or general anesthesia for any reason.

Definitions

Procedure time was recorded in minutes from the moment of introduction to the moment of total withdrawal of the endoscope.

The technical success rate was defined as the rate of cases with successful introduction of the enteroscope beyond the ligament of Treitz for antegrade procedures or proximal to the ileocecal valve for retrograde procedures. Procedural success

rate was the percentage of procedures when the anatomical region of interest could be reached. The total enteroscopy rate (TER) was the proportion of patients with inspection of the entire small bowel. Premature discontinuation of enteroscopy was any situation where enteroscopy was stopped because of further non-advancement or when the patient's condition necessitated withdrawal of the enteroscope before achieving the intended goals.

The depth of maximal insertion (DMI) was the point where no further advancement was possible, the target lesion was reached, or cecal intubation was achieved via the oral route [12]. The distance was then estimated in cm beyond the ligament of Treitz (antegrade route) or ileocecal valve (retrograde route) on withdrawal of the enteroscope, according to the current European Society of Gastrointestinal Endoscopy (ESGE) technical guideline for DAE [12].

Diagnostic yield was the percentage of procedures that either confirmed a finding from previous studies or established a new diagnosis or findings that could explain the clinical symptoms. Therapeutic yield was the percentage of procedures with successful interventions, excluding biopsies and injections used for marking.

Adverse events (AEs) were recorded during and after the procedure within a 30-day follow-up period. AEs were classified as minor or serious AEs (SAEs). Minor events included: mucosal abrasions or superficial lacerations in the small bowel, stomach, esophagus, or colon; sore throat of less than 72-hours duration, abdominal discomfort lasting less than 48 hours, and mild nausea or vomiting not requiring hospital admission. SAEs included: perforation, significant bleeding requiring blood products, pancreatitis, or unplanned hospital admission related to the procedure.

The MSE system

The MSE system and procedure have been described in detail by others [6, 8]. In summary, MSE is composed of three subsystems. The first is a reusable endoscope with a working channel length of 168 cm, a large-caliber 3.2-mm working channel, and an integrated motor permitting the rotation of a spiral overtube segment (second subsystem). Its additional features are high definition imaging, narrow-band imaging, and a separate dedicated waterjet irrigation channel. This irrigation aims to provide clear vision and to facilitate advancement of the endoscope beyond sharp angles.

The third subsystem is a control unit with a foot pedal and visual force gauge, which allows monitoring of the direction of and resistance encountered by the spiral overtube.

The enteroscopy procedure

The primary route for enteroscopy (ante-, retrograde, or a combination of both) was chosen depending on the information gained by antecedent VCE and/or radiological examination.

If the enteroscope could not be advanced beyond the upper esophageal sphincter (UES), a wire-guided esophageal bougienage dilation up to 18–20 mm could be performed. Balloon dilation of anastomoses was also permissible.

If the objective of the procedure was not achieved using the antegrade approach, if indicated, India ink tattooing or hemoclipping was done at the point of maximal insertion. This was followed by retrograde enteroscopy in the same or subsequent session.

When indicated, fluoroscopy was used to monitor and guide the movement of the motorized spiral enteroscope.

Sedation and hemodynamic monitoring

Procedures were performed with the patient under propofol sedation or general anesthesia, depending on local availability and the experience of the anesthesia team. During propofol sedation, oxygen therapy using nasal cannula, which delivers high flow heated and humidified oxygen and air via nasal prongs at a prescribed fractional inspired oxygen (Optiflow), was usually used [13, 14]. This technique enabled the maintainence of blood oxygenation for a significant period of time, even under breathless conditions.

Continuous hemodynamic monitoring was mandatory during the whole procedure and immediately thereafter. When general anesthesia was used, endotracheal intubation was necessary.

End points

The primary end points were: (i) the diagnostic and therapeutic yield of MSE in patients with positive findings on prior small-bowel imaging or other clinical indication for deep enteroscopy; and (ii) the safety of MSE as measured by AEs during and after the procedure within a follow-up interval of 30 days.

The secondary end points were: the technical success rate; DMI; procedure time; TER; and an estimation of the learning curve. Analysis of the learning curve was based on the following variables: technical success rate, diagnostic and therapeutic yield, TER, and AEs for every quartile of consecutively enrolled patients (patient numbers 1–45, 46–90, 91–135, and 136+).

Ethics

All patients provided written consent. The study was approved by the institutional review boards of all participating centers.

Statistical analysis

Statistical analyses were carried out using SPSS version 25 (IBM Corp., Armonk, New York, USA). Continuous measures were expressed with sample size, mean and SD, and median and range or interquartile range (IQR) when required. Categorical measures were presented as number of patients and percentage. Fisher's exact test was used to compare qualitative data. *P* values less than 0.05 were considered statistically significant. The study is considered exploratory; therefore, no correction was done for multiple testing.

Results

Patient characteristics

Between March 2020 and September 2021, a total of 178 consecutive patients were screened for eligibility of inclusion; eight patients were excluded because of advanced co-morbidity

▶ **Table 1** Characteristics of the 170 patients included in the study and their indications for enteroscopy.

Sex, male/female, n	102/68
Age, median (range), years,	64 (18–89)
American Society of Anesthesiologists score, n (%)	
▪ 1	19 (11.1 %)
▪ 2	120 (70.6 %)
▪ 3	31 (18.2 %)
Body mass index, median (range), kg/m^2	23.4 (14.9–40)
Type of sedation, n (%)	
▪ Propofol sedation	158 (92.9 %)
▪ General anesthesia	12 (7.1 %)
▪ Conscious sedation	0 (0 %)
Clinical indications, n (%)	
▪ Suspected mid-GI bleeding or iron deficiency with positive findings at VCE or radiology	115 (67.6 %)
▪ Overt GI bleeding	14 (8.2 %)
▪ Suspected inflammation	3 (1.8 %)
▪ Dilation of stenosis	7 (4.1 %)
▪ Other abnormalities at VCE or radiology	16 (9.4 %)
▪ Other indications	15 (8.8 %)
– Familial adenomatous polyposis	4
– Lynch syndrome	2
– Peutz–Jeghers syndrome	6
– Polyp	2
– Abdominal pain after Roux-en-Y gastric bypass	1
Antecedent VCE, n (%)	145 (85.3 %)
▪ Arteriovenous malformations	93
▪ Inflammatory changes	3
▪ Blood	10
▪ Polyp	6
▪ Suspected tumor	5
▪ Celiac disease	1
▪ Suspected Meckel's diverticulum	1
▪ No abnormality	26
Presence of surgically altered GI anatomy, n (%)	34 (20.0 %)
▪ Partial small-bowel resection/stricturoplasty	12
▪ Bariatric Roux-en-Y gastric bypass	7
▪ Ileocecal resection	4
▪ Whipple operation with gastro-jejunostomy	5
▪ Subtotal colectomy/ ileorectal anastomosis	2
▪ Sigmoid resection	2
▪ Billroth-II gastrectomy	1
▪ Right hemicolectomy	1

GI, gastrointestinal; VCE, video capsule endoscopy.

(ASA class > 3; n = 7) or the presence of large esophageal varices (n = 1). The remaining 170 patients (102 men, median age 64 years, range 18–89) met the inclusion criteria and were enrolled. **Fig. 1 s** (see online-only Supplementary material) shows a flowchart that summarizes study inclusion and exclusion.

The characteristics of the patients and their indications for enteroscopy are listed in ▶ **Table 1**.

Diagnostic and therapeutic yield

▶ **Table 2** summarizes the diagnostic and therapeutic results. The overall diagnostic yield was 64.1 % (95 %CI 58.6 %–71.4 %).

The findings were classified into the following categories: vascular, 61 (35.9 %); inflammatory, 24 (14.1 %); mass lesions, 19 (11.1 %); and anatomic abnormalities, 5 (2.9 %).

The findings from prior small-bowel imaging (VCE or radiology) were confirmed in 73.1 % (68/93) and 76.0 % (19/25) of patients with suspicion of vascular lesions or polyps/neoplasia, respectively. Some example endoscopic findings, along with endoscopic dilation, are shown in ▶ **Fig. 1**.

Therapeutic interventions were performed in 93 procedures (53.5 %, 95 %CI 46.5 %–60.2 %) and included argon plasma coagulation, endoscopic hemoclipping, stricture dilation, and endoscopic mucosal resection. Endoscopic stricture dilation was performed in eight sessions, which were for patients with Crohn's disease who had postoperative strictures.

Technical success

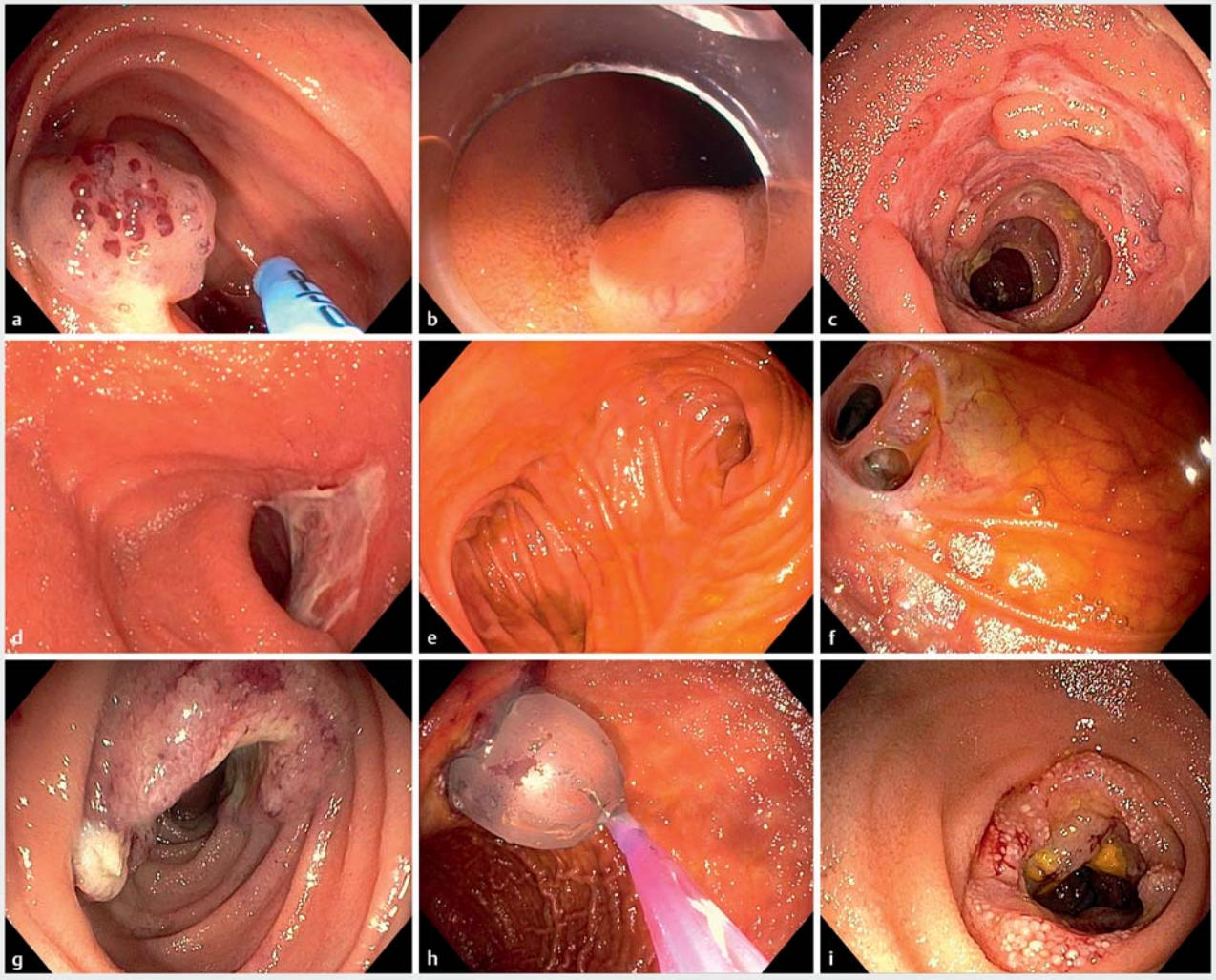
Except for three procedures, all of the intended antegrade MSE procedures were successful. Two patients had too much resistance at the UES, and one had status asthmaticus just before introducing the MSE. Therefore, these procedures were prematurely discontinued. No predilation of the UES was performed.

The technical success rate was 96.5 % by the antegrade approach and 100 % by the retrograde approach. Three scheduled bidirectional enteroscopy procedures were deemed unsuccessful. Two patients had too much resistance at the UES, and the third unexpectedly had signs of portal hypertension.

In 146 of 170 procedures (85.9 %) the anatomical region of interest could be reached (procedural success rate). The DMI was reached within a median 25 minutes (IQR 15–50) from an antegrade approach and 30 minutes (IQR 18–60) from a retrograde approach. The technical results are summarized in ▶ **Table 3**.

Total enteroscopy

Total enteroscopy was indicated in 64 patients. It was achieved in 45 patients (70.3 %, 95 %CI 57.5 %–81.0 %); 18 (28.1 %) using the antegrade approach only and 27 (42.2 %) using a bidirectional approach, with 26/27 of the latter (96.3 %) being completed in a single endoscopy session.



▶ **Fig. 1** Example images of findings and interventions during motorized spiral enteroscopy (MSE) showing: **a** a cavernous hemangioma in a female patient with overt gastrointestinal bleeding, the lesion being found during an antegrade procedure approximately 200 cm beyond the ligament of Treitz; **b** a neuroendocrine tumor seen in the ileum approximately 500 cm beyond the ligament of Treitz during a retrograde procedure; **c** severe inflammation, seen during an antegrade MSE, consistent with Crohn's disease at approximately 450 cm from the ligament of Treitz; **d** ulcerative and stenotic nonsteroidal anti-inflammatory enteropathy seen approximately 300 cm from the ligament of Treitz during antegrade MSE; **e** a Meckel's diverticulum seen during antegrade MSE; **f** hepaticojejunostomy seen during antegrade MSE in a patient with familial polyposis syndrome; **g** metastasis from lung carcinoma seen during antegrade MSE at a distance of 500 cm from the ligament of Treitz; **h** endoscopic dilation of a postoperative stricture approximately 200 cm from the ligament of Treitz in a patient with Crohn's disease; **i** B-cell non-Hodgkin lymphoma seen during antegrade MSE at a distance of 350 cm from the ligament of Treitz.

Surgically altered GI anatomy was present in 11/45 of successful total enteroscopy procedures (24.4 %). ▶ **Table 4** shows data on total enteroscopy procedures.

Adverse events

▶ **Table 5** summarizes the AEs. Procedure-related AEs were observed in 27 patients (15.9 %). In four patients deep mucosal tears were observed (1 in ileum and 3 at UES, all during antegrade MSE) and two patients had submucosal hematomas, all of which were clinically asymptomatic.

Mild rectal bleeding was observed in one patient, known to have Peutz–Jeghers syndrome and an enteroenteral anastomosis. The patient recovered completely without any need for further intensive observation, second-look endoscopy, transfusion, or treatment.

No SAEs related to MSE were observed either in patients with a normal GI anatomy or in those with surgically altered GI anatomy.

Sedation

Propofol sedation was used in 158/170 of the procedures (93 %), while general anesthesia was used in 12/170 (7 %). No important hemodynamic changes were observed during procedures or immediately thereafter.

▶ **Table 2** Diagnostic yield with diagnoses obtained and therapeutic yield with endotherapy performed.

Overall diagnostic yield, n/N (%) [95 %CI]	**109/170 (64.1 %) [58.6 %–71.4 %]**
Diagnoses obtained, n (%)	
Vascular lesions	61 (35.9 %)
▪ Arteriovenous malformation	54 (31.8 %)
▪ Other vascular lesions	7 (4.1 %)
– Dieulafoy lesion	3
– Portal hypertensive enteropathy	2
– Cavernous hemangioma	1
– Ischemia	1
Inflammatory lesions	24 (14.1 %)
▪ Ulcers, erosions	13 (7.6 %)
▪ Stenotic lesions (Crohn's or postoperative)	10 (5.9 %)
▪ Ulcerative jejunitis in celiac disease	1 (0.6)
Mass lesions	19 (11.1 %)
▪ Polyps	8 (14 polyps)
▪ Neuroendocrine tumor	5
▪ Gastrointestinal stromal tumor	3
▪ Other tumors	3
– Neurofibromatosis	1
– Metastasis	1
– Lymphoma	1
Diverticulum	5 (2.9 %)
▪ Meckel's	2
▪ Duodenal and jejunal	3
Therapeutic interventions performed, n (%) [95 %CI]*	93 (53.5 %) [46.5 %–60.2 %]
Endotherapy performed, n (%)	
▪ Argon plasma coagulation	63 (67.7 %)
▪ Endoscopic hemoclipping	10 (10.7 %)
▪ Stricture dilation	8 (8.7 %)
▪ Balloon dilation to facilitate introduction beyond anastomoses	4 (4.3 %)
▪ Endoscopic mucosal resection	8 (8.7 %)

* Excluding injections performed for marking of tumor location.

Learning curve

For this purpose, we divided our consecutively enrolled patients into four quartiles. The data are shown in **Table 1 s**. No significant difference was noticed between the four groups in terms of technical success, diagnostic and therapeutic yield, TER, or the occurrence of AEs.

▶ **Table 3** Technical data for the enteroscopy procedures according to intended route.

	Ante-grade only	**Retro-grade only**	**Bidirec-tional**
Number of procedures	85	39	46
Technical success rate, n/N (%)	82/85 (96.5 %)	39/39 (100 %)	43/46 (93.5 %)
Total procedure time, median (IQR), minutes	45 (30–80)	40 (30–70)	70 (50–95)
Estimated distance from ligament of Treitz to DMI, median (IQR), cm	350 (100–500)	–	400 (100–540)
Estimated distance from ileocecal valve to DMI, median (IQR), cm	–	150 (50–270)	100 (60–300)
Insertion time to point of maximal insertion, median (IQR), minutes	25 (15–50) from the UES	30 (18–60) from the ICV	–
Withdrawal time, median (IQR), minutes	15 (10–30)	10 (5–20)	–
Time needed for cecal intubation, median (IQR), minutes	–	7 (3–14)	–
Premature procedure discontinuation, n	5	0	0

IQR, interquartile range; DMI, distance of maximum insertion; UES, upper esophageal sphincter; ICV, ileocecal valve.

Discussion

The results of this multicenter prospective observational study suggest that MSE can achieve high diagnostic and therapeutic yield, and, when indicated, total (pan)enteroscopy.

MSE represents a landmark addition to the arsenal of enteroscopy [1]. Technically, it offers multiple favorable characteristics, including self-propulsion, shorter working length, large working channel of 3.2 mm, and a separate waterjet channel, which keeps the view clear and facilitates introduction beyond sharp angulations. The PowerSpiral control unit allows gradual and controlled withdrawal of the enteroscope, thereby providing a stable position, which improves the chances of lesion detection and facilitates therapeutic procedures.

In comparison with DAE, MSE works on a different principle. The motorized spiral enteroscope is a self-propulsive motorized enteroscope that pulls the bowel toward it by rotation of the spiral overtube [10]. This rotation creates linear energy that pleats the small bowel onto the shaft of the enteroscope, whereas balloon-assisted enteroscopy is a push-and-pull technique.

There has still been no head-to head comparison between these two technologies, therefore only indirect comparisons of our study results with the available historical data on DAE are

▶ **Table 4** Details of the total (pan)enteroscopy procedures.

Number of intended total enteroscopy procedures	64
Successful total enteroscopy procedures, n (%) [95 %CI]	45 (70.3 %) [57.5 %–81.0 %]
▪ Antegrade route only, n (%)	18 (28.1 %)
▪ Bidirectional route, n (%)	27 (42.2 %)
– One session	26
– Two different sessions	1
Procedure duration, median (IQR), minutes	70 (50–80)
▪ Antegrade route only	50 (45–75)
▪ Bidirectional	70 (60–75)
Intended but deemed unnecessary, n (%)*	15 (23.4 %)
Intended but was not possible, n (%)	4 (6.3 %)
Presence of surgically altered gastrointestinal anatomy among the successful procedures, n (%)	11 (24.4 %)
▪ Bariatric Roux-en-Y gastric bypass	3
▪ Partial small-bowel resection	3
▪ Gastrojejunostomy and subtotal colectomy	2
▪ Whipple resection	2
▪ Right hemicolectomy	1

* Procedures were considered unnecessary because a diagnosis had been made without needing to achieve total enteroscopy.

▶ **Table 5** Adverse events occurring during the procedure or in the following 30 days.

Overall adverse events, n (%)	27 (15.9 %)
Serious adverse events, n	0
Adverse events during procedure, n (%)	13 (7.6 %)
▪ Superficial mucosal abrasions	6
▪ Deep mucosal tears	4
– Upper esophageal sphincter	3
– Small bowel	1
▪ Submucosal hematoma	2
– Proximal esophagus	1
– Duodenum	1
▪ Cardiopulmonary events	1[1]
▪ Significant hemodynamic changes	0
Adverse events after procedure, n (%)	14 (8.2 %)
▪ Sore throat	8
▪ Abdominal pain	4
▪ Gastrointestinal bleeding	1[2]
▪ Other	1[3]

[1] Hypoxia in patient with chronic obstructive airways disease.
[2] After introduction beyond sharp entero-enteral anastomosis via anal route.
[3] Hypothermia.

possible. **Table 2 s** summarizes the important data for comparison between these techniques.

In this study, the median time to complete the MSE procedure was shorter than has been previously reported for DAE, particularly for balloon-assisted enteroscopy. The antegrade and retrograde MSE procedures were completed in a median time of 45 minutes (IQR 30–80) and 40 minutes (IQR 30–70), respectively, compared with a previously reported median (SD) times of 65.0 (12.8) minutes for antegrade DBE and 43.3 (9.3) minutes for manual spiral enteroscopy [15]. A prospective crossover study comparing manual spiral enteroscopy with DBE concluded that the spiral enteroscopy technique reduced the examination time, but that the insertion depth with DBE was superior [16].

Our data show that MSE has overall diagnostic and therapeutic yields of 64.1 % and 53.5 %, respectively. One systematic review on DBE procedures reported an overall diagnostic yield of 68.1 % [17]. The diagnostic yield of SBE ranges from 47 % to 60 %, with a similar therapeutic yield to that achieved with DBE [18]. The diagnostic yield of manual spiral enteroscopy varied between 43 % and 65 % in larger trials [15, 19, 20]. A systematic review and meta-analysis comparing the efficacy and safety of balloon-assisted enteroscopy and manual spiral enteroscopy showed that both procedures achieved similar outcomes; however, spiral enteroscopy had the benefit of a shorter procedural time [15].

With regard to the DMI, our estimated median DMIs from the ligament of Treitz and the ileocecal valve to the points of maximal insertion were 350 cm (IQR 100–500) and 150 cm (IQR 50–270), respectively. A prospective randomized controlled trial comparing SBE and manual spiral enteroscopy found no significant difference in mean DMI beyond the pylorus, with 330 cm for spiral enteroscopy and 285 cm for SBE [21]. We have to stress that DMI is always an estimation, therefore an accurate comparison between different techniques in different studies is difficult.

The TER in the current study was 70.3 % of the intended procedures: 28.1 % by antegrade approach and 42.1 % by bidirectional approach. The data on TER using DAE vary widely. A meta-analysis of 23 studies using DBE reported a TER < 1 % via the antegrade approach [17]. On the other hand, a TER of up to 66 % using DBE vs. 22 % for SBE has been reported from expert centers, these being achieved either by antegrade alone or bidirectional approach [22]. Another large meta-analysis by Lenz et al. found a pooled complete enteroscopy rate for DBE of 33.9 %, for SBE of 12.4 %, and for manual spiral enteroscopy of 2.9 % [23]. Therefore, total enteroscopy using DAE is usually achieved with a bidirectional approach, and is highest for DBE with 40 %–70 %, compared with 15 %–25 % for SBE and 2.9 % for spiral enteroscopy [24–26]. Furthermore, although the diag-

nostic and therapeutic impact of these techniques seems to be comparable, the TER achieved with MSE is clearly higher. Our data also showed that retrograde MSE significantly shortens the time needed to achieve cecal intubation (median 7 minutes [IQR 3–14]) and intubation of the ileocecal valve is much easier than with DAE. Taken together, the procedure time seems to be shorter than for other enteroscopy modalities.

Limited data are available on the efficacy of MSE. A retrospective study reported a technical success of 93.4% [7]. The overall diagnostic yield was 65.5%; TER was 60.6% (31.1% by antegrade approach and 29.5% by bidirectional approach).

A prospective study conducted by two leading European centers, using MSE for antegrade enteroscopy only, showed a TER of 10.6% and a technical success of 97% [8]. The diagnostic yield was 74.2%, and endotherapy was performed in 68.2% of patients. The same group reported on the achievement of total enteroscopy using MSE, with overall a TER of 70% (16.6% via antegrade alone and 53.4% via bidirectional approach) [10]. The median total procedure time was 51 minutes (range 32–133).

In all these three studies, patients with surgically altered GI anatomy were excluded, all antegrade procedures were performed with the patient under general anesthesia, and routinely Savary bougie dilation of the UES was performed before antegrade MSE. In our study, there was a comparable technical success rate using both antegrade (96.5%) and retrograde routes (100%). In addition, the TER was almost the same. Furthermore, performing a total enteroscopy in one session was possible within a relatively short time (median procedure time 70 minutes [IQR 50–80]).

As mentioned, 34 of our patients (20%) had some form of surgically altered GI anatomy. In 11 of them (24.4%), total enteroscopy was achieved. Furthermore, we did not routinely perform Savary bougie dilation of the UES before antegrade MSE. To facilitate introduction of the motorized spiral enteroscope, dilation was performed in two patients with a gastrojejunostomy and in one patient with subtotal colectomy and an ileorectal anastomosis.

Regarding the estimated learning curve, we did not find a significant difference between the early and late procedures in terms of the following parameters: technical success, diagnostic and therapeutic yield, TER, or the occurrence of AEs. This is in line with the estimation reported by Beyna et al. [8]. Therefore, it seems that an enteroscopist needs few procedures to gain command of the MSE technique.

Procedure-related AEs were observed in 27 patients (15.9%). SAEs related to MSE were not observed. In particular, post-enteroscopy pancreatitis, as seen with DAE, was not reported [17].

It is worth mentioning that, if resistance beyond the preset safety "limit function" is felt, the forward movement of the enteroscope stops, preventing any major injury to the bowel. Except for one patient who had clinically nonsignificant bleeding after introduction beyond a sharp enteroenteral anastomosis via the anal route, there were no differences in the AEs between those patients who had normal anatomy and those with surgically altered GI anatomy.

Deep sedation is required, especially during introduction of the enteroscope into the esophagus and stomach. Thus far, except for one case [11], all previously reported procedures were performed with the patients under general anesthesia with endotracheal intubation, particularly antegrade procedures. In our study, propofol sedation was used in 92.9% of the procedures. The decision as to which method to use depended on local availability and the experience of the anesthesia team. One participating center has a preference for general anesthesia in case an immediate withdrawal of the MSE is deemed necessary. In theory, an unanticipated SAE may require immediate withdrawal of the enteroscope, which for the motorized spiral enteroscope takes a few more minutes. However, our data showed that it is possible to achieve complete enteroscope withdrawal via the antegrade route within a relatively short time (median 15 minutes [IQR 10–30]). This depended on the depth of insertion and the need to perform an intervention. There were no important hemodynamic changes observed during any of our procedures or immediately thereafter. Furthermore, we did not encounter unfavorable hemodynamic changes or respiratory compromise necessitating immediate withdrawal of the motorized spiral enteroscope. Therefore, for both antegrade and retrograde MSE procedures, propofol sedation (without the need for endotracheal intubation) seems to be sufficient and safe.

The requirement for deep sedation with propofol or general anesthesia, especially for antegrade procedures, might be regarded as a possible drawback of MSE procedures. Moreover, it is contraindicated in patients with large esophageal varices or untreated eosinophilic esophagitis, and no data are available on its use in pediatric patients, especially infants and toddlers. Furthermore, it might be difficult to introduce the enteroscope in the presence of a severely stenotic sigmoid colon. Sharp angulation may pose some difficulty to advancement of the spiral segment, especially after Whipple pancreaticoduodenectomy. Because of the integrated safety feature, the "limit function" that stops the forward movement when high resistance is measured, it might be difficult to perform this procedure smoothly in the presence of postoperative adhesions and sharp bends.

Sometimes, mucosal erosions seen during the withdrawal phase of the procedure may make it difficult to recognize vascular malformations. Therefore, it may be advisable to perform endotherapy for these lesions during the introduction phase of the procedure.

The current study has its limitations. It is an observational trial and no head-to-head comparison with other DAE systems was possible. Furthermore, the study was conducted at centers with different levels of expertise with deep enteroscopy, which might create a degree of heterogeneity in the results, in particular the analysis of the learning curve per center or per individual endoscopist.

In conclusion, our study suggests that MSE has brought small-bowel enteroscopy to a higher level. Both antegrade and retrograde approaches take less time to perform compared with DAE. Total (pan)enteroscopy can often be achieved if indicated. It is not necessary to routinely perform Savary bougie dilation of the UES before antegrade MSE. For both antegrade and

retrograde MSE procedures, propofol sedation seems to be sufficient and safe. Provided that certain safety measures are followed, MSE is easy to perform, with a high diagnostic and therapeutic yield, and few AEs. It represents a promising alternative to the present DAE techniques, even in patients with surgically altered GI anatomy.

Clinical trial

Trial Registration: ClinicalTrials.gov | Registration number (trial ID): NCT04884113 | Type of study: Prospective Multicenter Study

Competing interests

The authors declare that they have no conflict of interest.

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