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Enteroscopy-assisted ERCP in patients with surgically altered anatomy: Multicenter prospective registry (SAMISEN-B) using motorized spiral enteroscopy

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ABSTRACT

Background and study aims This was a prospective study of efficacy and safety of motorized spiral enteroscopy (MSE) to perform biliary endoscopic retrograde cholangiopancreatography (ERCP) in patients with surgically altered anatomy at five European centers.

Patients and methods Consecutive patients with biliary indications for enteroscopy-assisted ERCP were enrolled. Objectives were technical success, adverse event (AE) rate, and patient radiation exposure.

Results Eighty-nine patients were enrolled and one was excluded for a pancreatic indication. All participants had variations of Billroth II reconstruction (29.5%) or Roux-en-Y reconstruction (70.5%), either with naive papilla (39%) or hepaticojejunostomy (61%). Main indications were anastomotic stricture treatment and/or biliary stone removal. Enteroscopy to reach the bile duct was possible in 65 of 88 patients (74%), bile duct cannulation in 54 of 88 (61%), and therapeutic ERCP was technically successful in 48 of 88 (54%). In Billroth II variations, technical success was achieved in 13 of 26 patients (50%) compared with 35 of 62 (57%, $P = 0.5792$ Chi square) in Roux-en-Y reconstructions (including bariatric gastric bypass). ERCP with intact papilla was successful in 17 of 34 patients (50%) compared with 31 of 54 (57%, $P = 0.4968$ Chi square) in hepaticojejunostomy. The study was prematurely terminated July 2023 because MSE was withdrawn by the manufacturer for safety issues. Overall, in 12 of 88 patients (14%), AEs were recorded and six (7%) were considered serious. Only one serious AE was attributable to MSE enteroscopy: perforation of the proximal esophagus during enteroscope insertion.

Conclusions This prospective multicenter study was prematurely discontinued due to withdrawal of the MSE by the manufacturer because of safety issues. Technical success of MSE-assisted biliary ERCP in different types of surgically altered anatomy was 54%, which was lower than anticipated. There was one esophageal perforation attributable to use of MSE. (clinicaltrials.gov: NCT05129449)

Introduction

Surgically altered anatomy of the upper gastrointestinal tract with Billroth II or Roux-en-Y reconstruction type renders biliopancreatic endoscopy more difficult [1]. Device-assisted enteroscopy (DAE) allows for direct endoscopic access to the small bowel and has been shown useful to perform endoscopic retrograde cholangiopancreatography (ERCP) in patients with surgically altered anatomy [2, 3].

The role of different available enteroscopy techniques, including double-balloon enteroscopy (DBE), single-balloon enteroscopy (SBE), and manual spiral enteroscopy (SE), was addressed by recent guidelines [4, 5] and meta-analyses [6, 7]. Motorized spiral enteroscopy (MSE), using the PSF-1 PowerSpiral Enteroscope (PSE, Olympus Medical Systems Corporation, Tokyo, Japan) was introduced into clinical practice in 2016 as "self-propelling enteroscopy", representing a technical refinement of the principle of SE [8]. An integrated electric motor is used to rotate a short single-use spiral overtube at the distal part of the insertion section of the enteroscope. Since then, clinical use of MSE has been shown to be effective and safe for both antegrade and retrograde deep enteroscopy, even allowing complete unidirectional enteroscopy, outclassing other DAE systems in terms of diagnostic success rates, procedure duration, and depth of maximum insertion [9, 10, 11]. Initial single-center and multicenter studies confirmed MSE safety, even in patients with surgically altered anatomy with a mean adverse event (AE) rate of 17.2% and only 0.7% serious AEs (SAEs) ranging from superficial mucosal tears to gastrointestinal perforation [12]. With these promising results in mind, the role of MSE to perform enteroscopy-assisted ERCP in patients with surgically altered anatomy required study. Preliminary reports illustrated its feasibility for this new indication [13, 14, 15, 16]. The current study was designed as an extension of the initial European multicenter SAMISEN registry to prospectively evaluate clinical use of MSE to perform enteroscopy-assisted ERCP in surgically altered anatomy in daily practice [10].

Patients and methods

Study design

This international, multicenter, prospective, observational study (performance and safety of the MSE for ERCP in altered anatomy, SAMISEN-B) was conducted at five European endoscopic tertiary referral centers that also participated in the initial SAMISEN-A study [10]. Data were collected from January 2022 until July 2023. The study protocol was approved by the institutional review board at each center prior to its initiation. The study was registered in the U.S. National Library of Medicine database (clinicaltrials.gov, identifier: NCT05129449, published November 22, 2021).

Study objectives

The aim of the study was to evaluate efficacy and safety of enteroscopy-assisted ERCP using MSE in a large cohort of patients with surgically altered anatomy and indications for biliary interventions in a real-life setting. Peroral enteroscopy performed to perform therapeutic endoscopy of the biliary system in patients with different types of surgical reconstructions was included. Pancreatic indications were excluded. All participating centers had experience with MSE and with ERCP in altered anatomy.

Inclusion and exclusion criteria

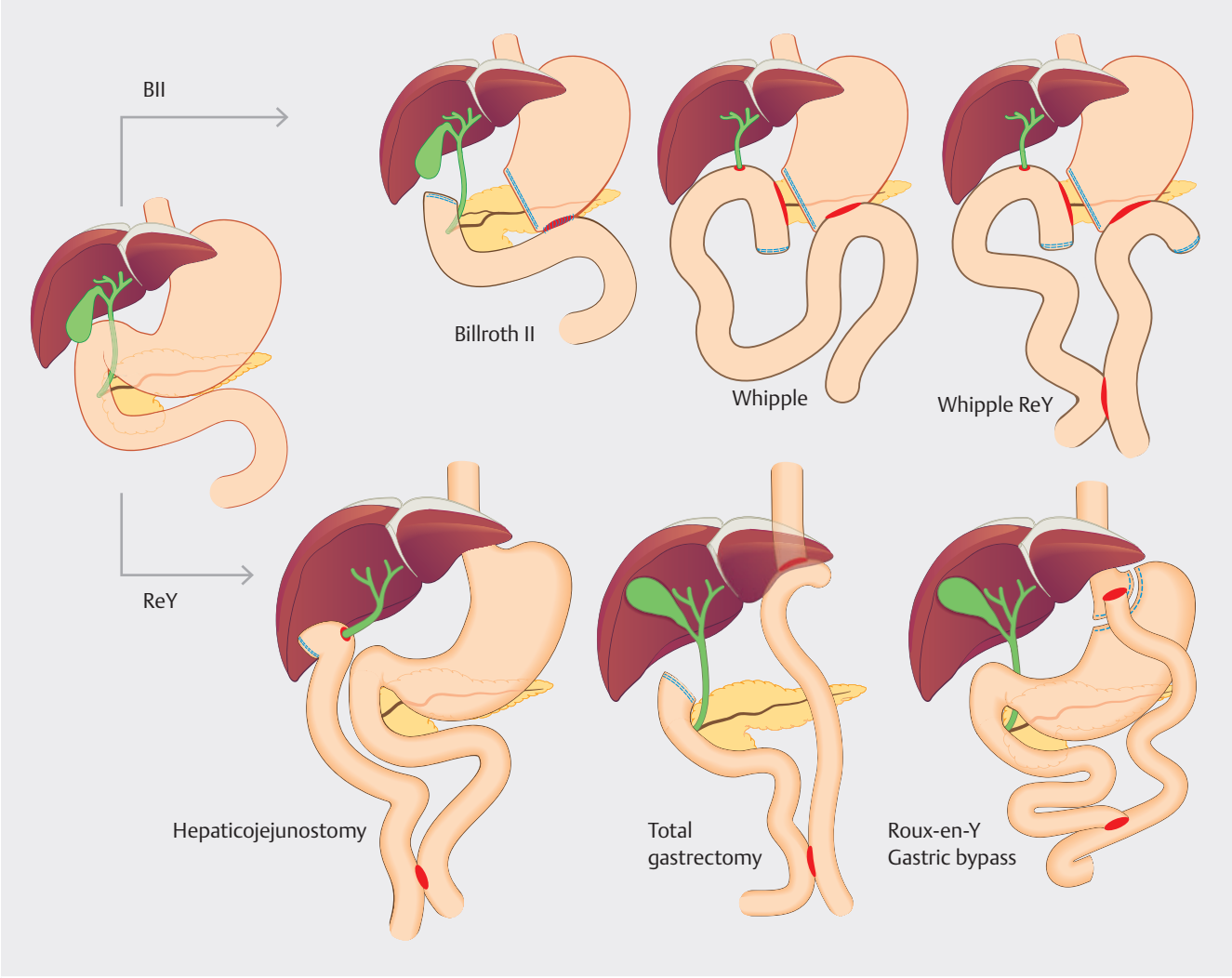
A total of 100 patients with a history of surgically altered anatomy with an indication for biliary endoscopy requiring an enteroscope were planned to be enrolled after obtaining informed consent. Surgical reconstructions needed to be at least 2 weeks old. Surgical types of altered anatomy were divided into Billroth II type (with an afferent and an efferent limb) and Roux-en-Y type (with an alimentary, a biliary and a common limb) as shown in ▶ **Fig. 1**. Billroth II distal gastrectomy and Whipple's duodenopancreatectomy have the surgical configuration of Billroth II type. The Roux-en-Y type was present in Whipple's duodenopancreatectomy with Roux-en-Y, Roux-en-Y hepaticojejunostomy, Roux-en-Y total gastrectomy, and gastric bypass. Indications for biliary ERCP are presented in ▶ **Table 1**.

Data management and Statistical analysis

Consecutive patients at the study centers who fulfilled the inclusion criteria were registered and enrolled after they provided informed consent. An electronic case report form (eCRF) was created using an XClinical platform (Munich, Germany) and data entry was done by the endoscopist at each study center. Statistical analyses were carried out by a professional statistician (SCO:SSiS, Germany) using SAS Version 9.4 (SAS Institute Inc., Cary, North Carolina, United States). Continuous measures were summarized with sample size, mean, standard deviation, minimum, and maximum. Categorical measures were presented with the counts and percentages of subjects in each category. $P<0.05$ was considered statistically significant. All authors had access to the study data and reviewed and approved the final manuscript.

Study device

The motorized spiral enteroscope PSF-1 (Olympus Medical Systems Corporation, Tokyo, Japan) was approved in Europe with CE mark during the entire study period. The MSE system and procedure steps have been described previously [10]. In June



▶ **Fig. 1** Common types of surgically altered anatomy (BII – Billroth II type; ReY – Roux-en-Y type).

2023, the sponsor of the SAMISEN-B study decided to stop the overtube (DPST-1) shipment and in July 2023, the MSE PSF-1 device was withdrawn and recalled from the market by its manufacturing company due to important safety issues (including fatalities, which were unrelated to the current study).

Study investigators and endoscopists requirements

All procedures were performed by accredited endoscopists at each study site. Each study endoscopist had participated in the SAMISEN-A trial [10] and was experienced in deep enteroscopy using MSE and also in enteroscopy-assisted ERCP in altered anatomy using DAE.

Motorized spiral enteroscopy and periprocedural management

Use of a distal transparent attachment on the tip of the enteroscope was allowed and was left to endoscopist discretion [17]. Antegrade MSE was performed to reach the bile duct (intact papilla or hepaticojejunostomy) with subsequent biliary cannulation and intervention. In case of failure to reach the bile duct or to perform the ERCP, it was left to endoscopist discretion to replace the MSE for another endoscope of choice in order to complete the procedure and to treat the patient according to the clinical indication. In these cases, MSE-assisted ERCP was registered as a failure in SAMISEN-B. Redo MSE-assisted ERCP procedures in the same patient were not included in the registry.

Postprocedure measures

In this observational registry, clinical investigations and blood sample analyses were performed according to local policies at each center. The final study visit was completed before hospital discharge of each patient.

Study endpoints, outcome measures and definitions

The main endpoint of the study was overall technical success of MSE-assisted ERCP, which consisted of the enteroscopy phase, cannulation of the bile duct (diagnostic ERCP phase), and biliary intervention (therapeutic ERCP phase) (▶ **Table 2**). The SAE rate (number of patients with at least one SAE) for MSE-assisted ERCP during and after the procedure also was considered a

▶ **Table 1** Patient characteristics, types of surgically altered anatomy, and indications for biliary ERCP.

Patient characteristics	
N overall-N eligible for analysis	89–88
Male/female N (%)	51/37 (58%/42%)
Age mean ± SD [range] (years)	58 ± 16 [24–92]
Body weight mean ± SD [range] (kg)	74 ± 20 [44–178]
ASA classification N (%)	I 7 (8.0%) II 57 (65%) III 24 (27%) IV 0 (0%)
Surgically altered anatomy N (%)	
Billroth II distal gastrectomy	8 (9%)
Whipple's duodenopancreatectomy	17 (19%)
Whipple's duodenopancreatectomy with Roux-en-Y	7 (8%)
Roux-en-Y hepaticojejunostomy	30 (34%)
Roux-en-Y total gastrectomy	4 (4.5%)
Roux-en-Y gastric bypass	21 (24%)
One-anastomosis gastric bypass	1 (1%)
Indications for biliary ERCP N (%)	
Stricture biliary anastomosis	35 (40%)
Biliary stone(s)	25 (28%)
Stricture biliary anastomosis + stones	11 (12.5%)
Cholangiocarcinoma/ampulloma	5 (6%)
Biliary stent replacement/removal	3 (3.5%)
Intrahepatic abscess	3 (3.5%)
Sphincter of Oddi dysfunction	2 (2%)
Postoperative biliary leak/clips	2 (2%)
Unknown (missing data)	2 (2%)

ASA, American Society of Anesthesiologists; ERCP, endoscopic retrograde cholangiopancreatography; N, number of patients; SD, standard deviation.

main endpoint. Further safety endpoints were overall AE rates calculated as per patient. AEs were related to the enteroscopy phase or the ERCP phase of the procedure. All AEs were defined and classified using the most recent version of MedDRA (Medical Dictionary for Regulatory Activities; http://www.meddra.org) and stratified by severity (mild, moderate, severe) and by relation to study treatment and/or study device (unrelated or related according to the categories definite, probable, and possible) (▶ **Table 2**). All SAEs have been reported to an external, independent safety expert to assess the SAE according to professional standards and providing advise to the sponsor. Additional endpoints were technical success related to type of surgically altered anatomy and patient radiation exposure during the procedure. The Kerma area product (KAP), also known as the dose area product (DAP), is the most often used metric for patient radiation exposure [18]. It is expressed as the radiation dose in Gray (Gy) multiplied by the irradiated body surface: $Gy^{*}cm^{2}$ or $\mu Gy^{*}m^{2}$ with 1 $Gy^{*}cm^{2} = 100\ \mu Gy^{*}m^{2}$.

▶ **Table 2** Study endpoint definitions.

Enteroscopy phase: reach the biliary system	% of total patients
Diagnostic ERCP phase: cholangiography	% of total patients
Therapeutic ERCP phase: biliary intervention	% of total patients
Overall technical success: combination of enteroscopy phase and both diagnostic and therapeutic ERCP phases	% of total patients
Patient radiation exposure	Dose area product
Adverse events according to MedDRA	% of total patients
Severity: mild – moderate – severe	
Relation to MSE: not related – possible – probable – definite	

ERCP, endoscopic retrograde cholangiopancreatography; MedDRA, Medical Dictionary for Regulatory Activities.

Definition of analysis populations and subgroup analyses

All patients included were used to study the endpoints regarding efficacy and safety. Radiation exposure was studied in patients in whom MSE-ERCP was successful. Technical success was calculated according to intention to treat (ITT) and per protocol analysis.

Data management and statistical analysis

The primary aim of the study was to evaluate the efficacy and safety of MSE to perform biliary ERCP in patients with surgically altered anatomy. A total of 100 subjects collected in five centers was considered necessary for descriptive statistical analysis.

Results

Patient characteristics and surgically altered anatomy

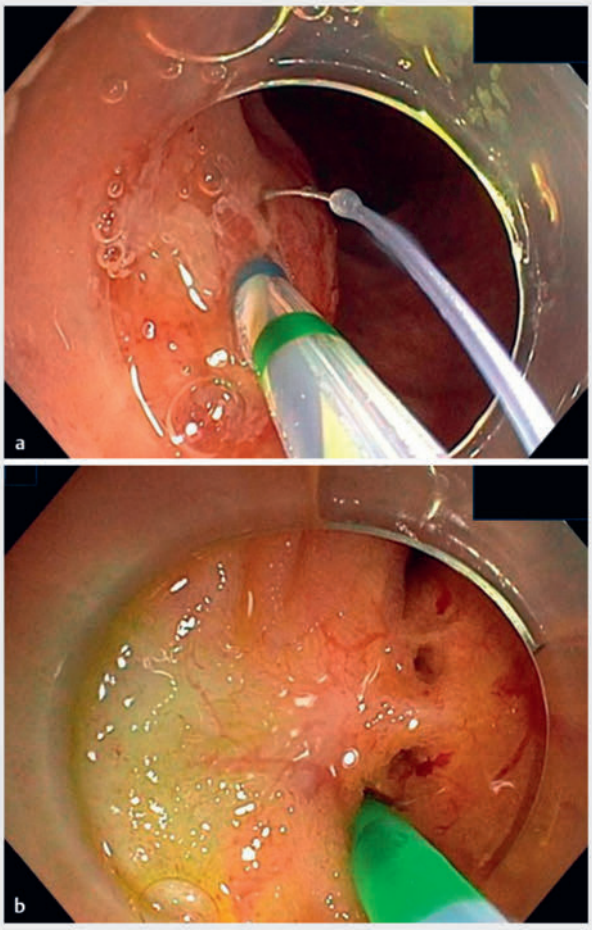
Between January 2022 and July 2023, 89 patients were enrolled in the study. One patient had to be excluded because of a pancreatic indication. A total of 88 patients (51 males, 37 females) were eligible for analysis. Patient characteristics are shown in ▶ **Table 1**.

Surgical types of altered anatomy were divided into variations of Billroth II type (with an afferent and an efferent limb) and Roux-en-Y type (with an alimentary, a biliary and a common limb), as shown in ▶ **Fig. 1** and ▶ **Table 1**. These surgical reconstructions were associated with an intact papilla of Vater in 34 patients (39%) or a biliary anastomosis in 54 patients (61%). Biliary indications for performing ERCP are also shown in ▶ **Table 1**. The majority of indications encompassed endoscopic

▶ **Table 3** Procedure data about overall technical success of MSE-ERCP in surgically altered anatomy.

Enteroscopy phase	65/88 (74%)
Diagnostic ERCP phase	54/88 (61%)
Therapeutic ERCP phase	48/88 (54%)
Dose area product (mean DAP ± SD)	1699 ± 944 µGy*m2
Technical success per type of altered anatomy (%)	
Billroth II distal gastrectomy	Enteroscopy 5/8 (63%)
	Therapeutic ERCP 4/8 (50%)
Whipple's duodenopancreatectomy	Enteroscopy 10/17 (59%)
	Therapeutic ERCP 8/17 (47%)
Whipple's duodenopancreatectomy with Roux-en-Y	Enteroscopy 4/7 (57%)
	Therapeutic ERCP 4/7 (57%)
Roux-en-Y hepaticojejunostomy	Enteroscopy 19/30 (63%)
	Therapeutic ERCP 19/30 (63%)
Roux-en-Y total gastrectomy	Enteroscopy 0/4 (0%)
	Therapeutic ERCP 0/4 (0%)
Roux-en-Y gastric bypass	Enteroscopy 15/21 (71%)
	Therapeutic ERCP 12/21 (57%)
One-anastomosis gastric bypass	Enteroscopy 1/1 (100%)
	Therapeutic ERCP 1/1 (100%)
Adverse events (%)	
Overall AEs	12/88 (14%)
SAE	6/88 (7%)
Mortality	0/88 (0%)

AE, adverse event; DAP, dose area product; ERCP, endoscopic retrograde cholangiopancreatography; SAE, serious adverse event; SD, standard deviation.



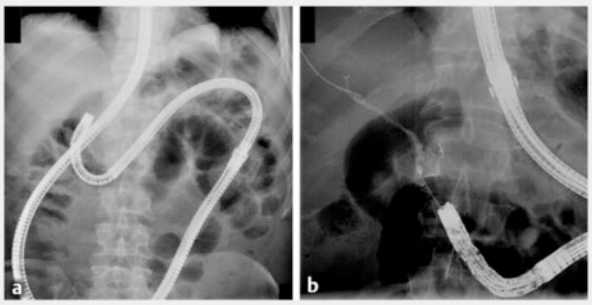
▶ **Fig. 2** Catheterization of **a** an intact Vater's papilla vs **b** quadruple hepaticojejunostomy.

treatment of a strictured biliary anastomosis (40%), bile duct stones (28%), or a combination of both anastomotic stricture and stones (12.5%).

Procedure details and technical success

All MSE-ERCP procedures were performed under sedation on a fluoroscopy table. In 57% of the procedures, general anesthesia with endotracheal intubation was used; the remaining 43% were done under deep sedation without intubation.

Technical success was a primary objective and was defined by the combination of successful enteroscopy followed by diagnostic and therapeutic biliary ERCP. Successful enteroscopy reaching the bile duct was possible in 65 of 88 patients (74%) in a mean time of 29 ± 22 minutes (range 4–104). Retrograde bile duct cannulation with cholangiography was possible in 54 of 88 patients (61%) and overall therapeutic ERCP was technically successful in 48 of 88 patients (54%). Compared with this ITT analysis, technical success per protocol was achieved in 54 of 65 patients (83%) for diagnostic ERCP and 48 of 65 (74%) for therapeutic ERCP. Interventional biliary procedures consisted of sphincterotomy of intact papilla or balloon dilatation of a stricture at the level of the biliary anastomosis, biliary stone extraction, bile duct stent placement and removal, and tissue acquisition from the papilla or bile duct. ▶ **Table 3** shows technical success rates per type of surgically altered anatomy, for both the enteroscopy phase and the therapeutic ERCP phase. It is clear that the majority of failures were related to the unsuccessful enteroscopy phase, with only a minority actual ERCP failures. In reconstructions with Billroth II variants, technical success was achieved in 13 of 26 patients (50%) compared with 35 of 62 patients (57%, $P = 0.5792$ Chi-square) in Roux-en-Y reconstructions. In reconstructions with intact papilla of Vater, technical success was achieved in 17 of 34 patients (50%) compared with 31 of 54 (57%, $P = 0.4968$ Chi-square) in reconstructions with a biliary anastomosis (▶ **Fig. 2**).



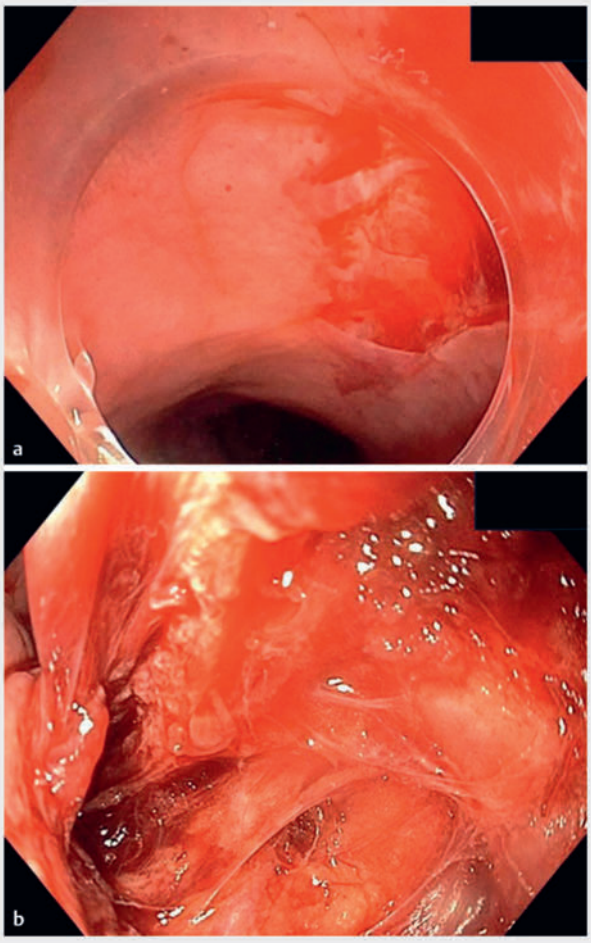
▶ **Fig. 3** Enteroscopy phase **a** in a patient with Roux-en-Y gastric bypass surgery and **b** ERCP phase in the same patient.

In the 48 technically successful MSE-ERCP procedures, patient radiation exposure expressed as mean DAP was 1699 ± 944 μGy*m^2 (range 80–3500), combining the enteroscopy phase and the diagnostic and therapeutic ERCP phases (▶ **Fig. 3**).

Safety analysis

Overall, in 12 of 88 patients (14%), AEs were recorded, of which six (7%) were considered serious (▶ **Table 3**). In July 2023, the study was prematurely terminated because the MSE enteroscope was voluntarily withdrawn from the market by the manufacturer because of safety issues, both related and unrelated to the continuous safety analysis of the SAMISEN-B registry. Therefore, an in-depth analysis of AEs in the SAMISEN-B registry is provided in ▶ **Table 4**. No fatalities occurred in the current study and only one SAE was considered related to use of the MSE. This was a perforation of the upper part of the esophagus that occurred during enteroscope insertion in a 77-year-old female patient who weighed 44 kg and was referred for MSE-ERCP because of common bile duct stones in the setting of a Roux-en-Y total gastrectomy. The patient was in the supine position and airways were protected with an endotracheal tube. Despite procedure precautions to facilitate enteroscope insertion by means of cervical hyperextension and lubrification of both the enteroscope and the overtube, the rotating overtube could not be engaged into the esophagus, activating the security stop function of the rotating motor. It was decided to replace the MSE with a SBE in order to complete the procedure. However, upon retrieval of the MSE from the upper part of the esophagus, a transmural esophageal perforation was seen with exposure of the mediastinal adipose tissue (▶ **Fig. 4**). Immediately, an intraluminal Eso-Sponge (B. Braun, Melsungen, Germany) was placed and connected to a vacuum pump and antibiotics were given intravenously. When the patient awoke, she felt uncomfortable because of the intraluminal position of the Eso-Sponge and inability to swallow saliva. It was decided to surgically repair the esophageal perforation the same day. She recovered without sequalae.

▶ **Table 4** shows another three AEs related to use of the MSE, characterized by mucosal tears and bleeding of the upper part of the esophagus due to the rotating overtube (▶ **Fig. 4**). All other AEs and also SAEs, were considered related to the ERCP procedure itself and not to use of the MSE. However, in two patients, mild self-limiting pancreatitis was diagnosed after the procedure. The first was a 29-year-old female with a Roux-en-Y gastric bypass and intact papilla, referred for suspected sphincter of Oddi dysfunction. She underwent sphincterotomy and the episode of acute pancreatitis was considered post-ERCP pancreatitis. However, in the second case of pancreatitis, a 30-year-old female patient underwent MSE-ERCP because of a biliary stone in the setting of Roux-en-Y hepaticojejunostomy. The enteroscopy was unsuccessful and did not reach the biliary anastomosis and the procedure was aborted. However, the patient subsequently presented with acute mild self-limited pancreatitis, likely related to the MSE enteroscopy attempt. There was one system malfunction at the start of the procedure, with a defective rotational motor, which caused no harm to the patient. The procedure was performed using another DAE instead of the MSE.



▶ **Fig. 4** Mucosal laceration **a** in the upper part of the esophagus and **b** esophageal perforation due to difficult insertion of the motorized spiral enteroscope.

▶ **Table 4** Detailed description of adverse events and treatment.

SAE 1: Sphincterotomy bleeding: biliary SEMS	Not related to MSE
SAE 2: Post-ERCP cholangitis: antibiotics	Not related to MSE
SAE 3: Stapfer I duodenal perforation after MSE was changed for duodenoscope to perform ERCP: surgery	Not related to MSE
SAE 4: Pulmonary embolism by intravascular contrast (and air) injection during ERCP: ICU ventilation	Not related to MSE
SAE 5: Esophageal perforation: Eso-Sponge + surgery	Related to MSE
SAE 6: Post-ERCP cholangitis: antibiotics	Not related to MSE
AE 7–8: Post-ERCP pancreatitis: analgesics	(Not) related to MSE
AE 9–11: Mucosal tears and esophageal bleeding: PPI	Related to MSE
AE 12: System malfunction of rotational motor before start of the MSE-ERCP procedure: no patient harm	Related to MSE

AE, adverse event; ERCP, endoscopic retrograde cholangiopancreatography; ICU, intensive care unit; MSE, motorized spiral enteroscopy; PPI, proton pump inhibitor; SAE, serious adverse event; SEMS, self-expandable metallic sten.;

Discussion

MSE was recently introduced into clinical practice for deep enteroscopy in Europe and parts of Asia. The novel technology using a motorized, self-propelling enteroscope was welcomed with enthusiasm because it showed favorable outcomes for deep and even complete unidirectional enteroscopy, in terms of diagnostic and therapeutic procedures in the small bowel, and also in patients with previous abdominal surgery, as recently reviewed [12, 19, 20]. Although the manufacturer initially recommended that use of the device be restricted to only patients with normal anatomy, its feasibility and safety was soon tested and approved in patients with surgically altered anatomy [10, 21]. The next logical step in the quest to broaden the application of MSE was enteroscopy-assisted ERCP in patients with surgically altered anatomy [22]. The feasibility of MSE to perform enteroscopy-assisted ERCP was shown in a series of selected cases [13, 14, 15, 16]. The current multicenter study aimed to provide unbiased and realistic data on efficacy and safety of MSE-ERCP in five expert centers.

Despite the initial enthusiasm for this new enteroscopy device, which seemed to excel over balloon-assisted enteroscopy, the current study has shown the opposite, both in terms of efficacy and safety. The participating centers were asked to prospectively enroll patients who needed biliary ERCP using an enteroscope in the clinical setting of surgically altered anatomy, in order to avoid selection bias. This resulted in a lower technical success rate of only 54% (combining enteroscopy and diagnostic and therapeutic ERCP), compared with the early MSE case series with technical success rates ranging from 72% to 76% [14, 15]. However, the results of these early case series, which are prone to positive selection bias, also are inferior to the currently available technical success rates for biliary DAE-ERCP using balloon-assisted enteroscopy, which have reached nearly 90% [23, 24]. Despite initial reports about faster and deeper enteroscopy with MSE, the mean time to reach the biliary system in the current study (29 ± 22 minutes) was in line with comparable studies using balloon-assisted enteroscopy [24, 25, 26]. In contrast to the impressive results in terms of deep and complete enteroscopy, the effectiveness of MSE for performing ERCP in surgically altered anatomy turned out to be less convincing. Alternative approaches using balloon-assisted enteroscopy or endoscopic ultrasound-guided biliary drainage seem preferable to MSE [27]. The explanation for this unexpected conclusion should probably be sought in the design of the device, which is a colonoscope with a motor-driven spiral overtube. The MSE enteroscope thus has all the characteristics of a colonoscope: the 1680-mm working length and 11.3-mm diameter and bending capability of a conventional colonoscope seem less efficient than 2000-mm-long SBE and DBE with the bending capability of a slim gastroscope. Moreover, the MSE cannot be advanced or withdrawn independent of the overtube (as compared with balloon-assisted enteroscopy), which makes difficult bile duct cannulation even more challenging. These MSE features may also explain its inability to cross sharply angulated intestinal limbs in patients with surgically altered anatomy, as was previously shown in patients with Roux-en-Y gastric bypass anatomy [28].

The SAMISEN-B study was prematurely terminated before reaching the proposed number of 100 included patients because of manufacturer recall of the MSE device for safety reasons. The safety assessment from the manufacturer included one SAE that occurred during the current study. An esophageal perforation was discovered on withdrawal of the MSE after unsuccessful intubation of the esophagus in a 77-year-old underweight patient with a Roux-en-Y total gastrectomy. The perforation needed surgical repair and the patient recovered without sequalae. Three other patients in the current study also suffered from bleeding mucosal lacerations in the upper part of the esophagus after passage of the rotating overtube, all of which were shown to be mild AE. This problem had been reported previously, and esophageal perforation should be considered an extreme form of these mucosal lacerations [10, 29]. Perforation, especially at the level of the esophagus, is one of the main safety issues that led to recall of the MSE device by the manufacturer in July 2023. According to the manufacturer, one other MSE-related esophageal perforation was reported in a patient not included in this study. The combination of a large, finned spiral overtube (31.1-mm wide) and motorized rotation limiting tactile feedback during both esophageal introduction and withdrawal may explain the sometimes traumatic procedure of both MSE insertion beyond the upper esophageal sphincter into the proximal esophagus and MSE withdrawal from the stomach over the gastroesophageal junction into the esophagus. Redesigning the MSE starting from a slim enteroscope and an overtube with smaller fins may be less traumatic than the current model [30].

In the current study, the overall AE rate was 14% with 7% SAE. However, only three AEs (3.5%) were directly related to use of the MSE: one SAE with esophageal perforation, one device malfunction (defective electrical motor) before starting the procedure which caused no harm to the patient, and one case of enteroscopy-induced pancreatitis. All other (S)AEs were related to the ERCP procedure. Enteroscopy-induced pancreatitis was previously described as an AE related to antegrade DAE induced by compression of the pancreatic head while straightening the enteroscope in the duodenum [31]. This AE can also occur during antegrade MSE, most likely based on the same principle of pancreatic head compression [32,33]. In the current study, one patient with Roux-en-Y hepaticojejunostomy suffered from self-limiting acute pancreatitis after a failed attempt to reach the bile duct.

Finally, patient radiation exposure was studied as a secondary aim, because data in patients with surgically altered anatomy undergoing enteroscopy-assisted ERCP are scarce. In the 48 technically successful MSE-ERCP procedures, patient radiation exposure expressed as mean DAP was 1699 ± 944 µGy*m^2 (range 80–3500) or 17 ± 9 Gy*cm^2. DAP is considered the most important metric for estimating patient radiation exposure during ERCP [18]. The currently observed DAP values are comparable to DAE-ERCP data in the literature, and are even lower than the accepted dose reference levels of 20 to 50 Gy*cm^2 for conventional ERCP by the European Society of Gastrointestinal Endoscopy (ESGE) [18,34]. In enteroscopy-assisted ERCP, fluoroscopy is not only used to perform actual ERCP, but also to guide the enteroscopy part of the procedure. Compared with biliary DAE-ERCP using SBE (2216±173 µGy*m^2), DAP in the current study using MSE was lower (1699 ± 944 µGy*m^2); however, mean time to reach the bile duct was comparable in both studies (28 ± 4 minutes vs. 29 ± 22 minutes) [34]. Despite the combination of enteroscopy and ERCP, both with fluoroscopy, patient radiation exposure does not surpass the currently acceptable dose reference levels for conventional ERCP.

Conclusions

This prospective multicenter study was prematurely discontinued due to voluntary recall of the MSE from the market by the manufacturer because of safety issues. Enteroscopy-assisted biliary ERCP in patients with different types of surgically altered anatomy resulted in an overall technical success rate of only 54%. This result was lower than data in the literature based on balloon-assisted enteroscopy. The SAE rate was 7% with only one SAE attributable to use of MSE (esophageal perforation). Enteroscopy-assisted ERCP using MSE was shown to be feasible in patients with surgically altered anatomy, but other techniques are preferable.

Acknowledgement

All serious adverse events have been reported to an external, independent safety expert, assessing each serious adverse event according to professional standards and providing advice to the sponsor: Prof. dr. Jeanin Van Hooft, Secretary General of the United European Gastroenterology (UEG) and Head of the Department of Gastroenterology and Hepatology at the Leiden University Medical Center, The Netherlands. We would like to thank Prof. Dr. Van Hooft for her active participation in this study.

Conflict of Interest

Tom Moreels, Torsten Beyna, and Marianna Arvanitakis have received consultancy honoraria and lecture fees from Olympus Medical Systems Corporation. All other authors disclose no conflicts of interest.

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Olympus Europa SE & CO. KG.
Project ID 2021-0945

Clinical trial

Trial Registration: ClinicalTrials.gov Registration number (trial ID): NCT05129449 Type of study: prospective multicenter study

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