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Endoscopic Ultrasound-Directed Transgastric ERCP in Patients With Roux-En-Y Gastric Bypass: A Multicenter Prospective Cohort Study (EDGE-Pilot)

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ABSTRACT

Objectives: Endoscopic retrograde cholangiopancreatography (ERCP) is frequently indicated in patients who underwent Roux-en-Y gastric bypass (RYGB) surgery. Endoscopic ultrasound-directed ERCP (EDGE) is a technique that is used to create a gastro-gastrostomy by placing a lumen-apposing metal stent (LAMS) between the gastric pouch and the excluded stomach, facilitating subsequent ERCP. However, prospective studies on EDGE are lacking. The aim of this study is to provide prospective evidence for the efficacy and safety of EDGE, including fistula closure.

Methods: This multicenter prospective cohort study included patients scheduled for elective ERCP after RYGB surgery. EDGE was performed as a two-step procedure. The primary endpoint was overall technical success. Secondary endpoints were the technical success of LAMS placement and ERCP individually, persistent fistula, and adverse events (AEs).

Results: Between January 2021 and August 2024, 26 patients were included in four Dutch hospitals. Overall technical success was achieved in 25/26 patients (96.2%). Median LAMS indwelling time was 14 days [IQR 11–28 days]. Two EDGE-related AEs occurred (7.7%): one perforation of the duodenal wall following scope insertion and one bleeding after LAMS placement. Two ERCP-related AEs occurred (7.7%): one CBD perforation and one post-ERCP pancreatitis. Two patients were lost to follow-up. None of the remaining patients had a persistent fistula (0/24). No mortality occurred.

Conclusions: This prospective study shows that two-step EDGE is relatively safe and associated with high technical success, without any cases of a persistent fistula. However, AEs occurred in 4 patients (15.4%), of which two were EDGE-related (7.7%).

1 | Introduction

Roux-en-Y gastric bypass (RYGB) is the most commonly performed bariatric surgery in the Netherlands and constitutes almost 30% of all bariatric procedures worldwide [1]. As a result of rapid weight loss, patients who underwent RYGB are more likely to develop symptomatic cholelithiasis [2, 3]. A proportion of these patients present with choledocholithiasis and require an endoscopic retrograde cholangiography (ERCP). Furthermore, indications for endoscopic diagnostics and treatment regarding

hepato-pancreato-biliary (HPB) malignancy become more frequent, as the incidence of pancreatic ductal adenocarcinoma rises by 0.5%–1.0% annually [4].

The anatomical alterations following RYGB surgery can be challenging for endoscopists. Current options for obtaining access to the pancreaticobiliary tract in these patients include enteroscopy-assisted ERCP or laparoscopy-assisted ERCP (LA-ERCP). Enteroscopy-assisted ERCPs have variable technical success rates of 60%–84%, mainly because of failure to reach the papilla or cannulating the naive papilla using a forward-viewing endoscope [5–9]. Laparoscopy-assisted ERCP facilitates placement of a duodenoscope through a transabdominal trocar directly into the remnant (i.e., excluded) stomach. This is a sensible approach for patients who require a cholecystectomy that can be performed simultaneously. The success rate of LA-ERCP is higher compared to enteroscopy-assisted ERCP, though disadvantages include surgically related complications, logistical challenges, and increased costs [6, 8, 10–14].

Recent advances in therapeutic endoscopic ultrasound (EUS) have given endoscopists new possibilities for creating gastrointestinal anastomoses [15]. In 2014, the first case of EUS-directed transgastric ERCP (EDGE) was described [16]. This relatively new technique uses EUS to gain pancreaticobiliary access by placing a lumen-apposing metal stent (LAMS) between the gastric pouch (or the proximal jejunum) and the excluded stomach [15, 17–19]. In 2022, the European Society of Gastrointestinal Endoscopy (ESGE) recommended performing EDGE as a two-step procedure to prevent intraprocedural stent dislodgment. After successful placement of the LAMS, the endoscopist can proceed with a conventional ERCP in a separate session, followed by immediate LAMS removal. Another option would be to leave the LAMS in situ in anticipation of repeat ERCPs in the near future. Recent retrospective studies on EUS-directed transgastric ERCP have shown encouraging results with high technical and clinical success rates [12, 19–23]. A few of the main concerns regarding EDGE are stent dislodgment, persistent fistula formation following LAMS removal, and subsequent weight regain [12, 22, 23]. Currently, the available evidence mostly consists of retrospective studies, which may have resulted in underestimation of failures and (long-term) complications [20, 24–27].

Therefore, the aim of this study is to provide prospective data on the efficacy and safety of EDGE, including closure of the fistula.

2 | Patients and Methods

2.1 | Study Design and Patient Eligibility

This multicenter prospective cohort study was carried out in four Dutch hospitals: two academic and two nonacademic hospitals. The Medical Ethics Review Committee confirmed that the Dutch Medical Research Act does not apply to this study, as all study procedures are according to current standard care.

All consecutive patients scheduled to undergo a (semi-)elective ERCP after previous RYGB surgery were eligible to participate in this study. Patients were excluded if they were younger than 18 years of age, had an indication for subsequent laparoscopic cholecystectomy, or were scheduled to undergo an urgent ERCP. Lastly, patients were excluded if the LAMS was intentionally left in place for an extended period of time (> 6 months), in anticipation of repeat ERCP procedures. All patients provided written informed consent before inclusion.

2.2 | Study Procedures

All procedures were performed under deep sedation with propofol, with the patient in a left lateral or prone position. All patients received peri-procedural antibiotics during step 1 (i.e., LAMS placement). Anticoagulants were stopped if applicable, with an INR of 1.5 or lower. In the first procedure (step 1), a therapeutic linear echoendoscope was used to identify the remnant stomach from the gastric pouch or proximal jejunum and accessed with a 19-gauge fine-needle aspiration needle. The excluded stomach was distended by injecting saline mixed with contrast. Consequently, the needle was removed, and the most appropriate site was determined, preferably proximal in the excluded stomach. A 20 × 10 mm LAMS was deployed using a free-hand technique (Hot Axios, Boston Scientific).

The second step of the EDGE procedure was performed after at least 7 days. This allowed the newly formed fistula tract to properly mature. A duodenoscope was then advanced through the LAMS into the duodenum, followed by a conventional ERCP.

Removal of the LAMS was the third and final step. If pancreaticobiliary access was no longer needed, grasping forceps were utilized to remove the stent without any additional intervention, allowing for spontaneous fistula closure. Step 3 was either performed immediately after step 2 in the same session or at a later time if a potential repeat ERCP was anticipated. The standardized EDGE study procedures are summarized in a flowchart (see Figure 1), and fluoroscopic and endosonographic images demonstrate the key procedural steps (see Figure 2). All procedures were performed or closely supervised by endoscopists with at least 5 years of experience in interventional EUS and ERCP.

2.3 | Follow-Up After the EDGE Procedure

An outpatient visit took place between 2 and 4 weeks after steps 2–3. A video fluoroscopic swallowing exam (VFSE) and/or upper endoscopy was then carried out at least 6 weeks after LAMS removal to confirm fistula closure. In case of a persistent fistula, either argon plasma coagulation (APC) or over-the-scope clips was considered a valid option for achieving fistula closure. A final (telephone) consultation took place around 12 weeks after stages 2–3. All patients were followed until fistula closure was confirmed.

2.4 | Outcome Parameters

The primary endpoint was the overall technical success of EDGE, defined as the technical success of the gastro-gastrostomy as well as the ERCP. Secondary endpoints included technical success of LAMS placement and subsequent ERCP individually, overall clinical success (defined as relief of presenting symptoms), adverse events (AEs) requiring re-intervention, LAMS indwelling

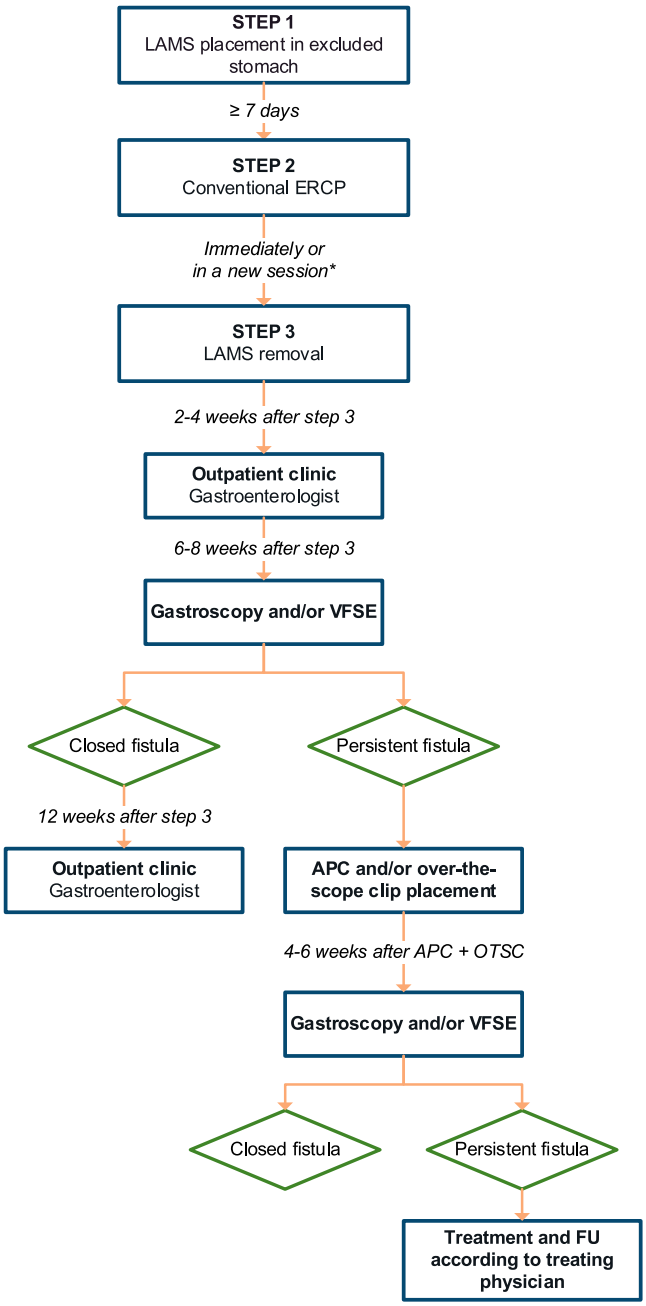

FIGURE 1 | Flowchart for standardized EDGE study procedures and follow-up. APC, argon plasma coagulation; ERCP, endoscopic retrograde cholangiopancreatography; FU, follow-up; LAMS, lumen-apposing metal stent; OTSC, over-the-scope clip; VFSE, video fluoroscopic swallowing exam.

time, total procedure time, mortality, persistent fistula, and hospital stay. Total procedure time is defined as the duration of all procedure steps combined. EUS procedure time was defined as the duration of step 1 (LAMS placement), and ERCP procedure time as the duration of steps 2 and 3 (ERCP and LAMS removal), in minutes. AEs were rated according to the AGREE classification. EDGE-related AEs were defined as complications that occur during LAMS placement itself or complications during ERCP unlikely to occur in the setting of a conventional ERCP (e.g., stent dislodgement, stent dysfunction, bleeding after LAMS placement, and perforation potentially due to improper LAMS placement). ERCP-related AEs were defined as known complications directly related to a conventional ERCP (e.g., post-ERCP pancreatitis, bleeding after sphincterotomy, perforation of the CBD) [28]. Hospital stay was defined as the total number of days that the patient was admitted to the hospital, including admissions due to the EDGE procedure itself and/or procedure-related complications. Persistent fistula was defined as either oral contrast visible in the excluded stomach by VFSE, or a visible persistent fistula during gastroscopy.

2.5 | Statistical Analysis

Descriptive statistics were analyzed using SPSS version 28 (IBM, New York, US). Numerical data were expressed as the median with interquartile ranges (IQR), and categorical data were expressed as absolute and relative frequencies.

3 | Results

3.1 | Patient Characteristics

Between January 2021 and August 2024, 37 consecutive patients with an indication for EDGE after RYGB surgery were identified. Eleven patients were excluded for various reasons: ERCP was no longer indicated after LAMS placement ($n = 3$), an emergency Whipple procedure was required ($n = 1$), a planned LAMS indwelling time of longer than 6 months in anticipation of repeat ERCPs ($n = 5$), and single-session EDGE procedures ($n = 2$). Two patients were lost to follow-up after enrollment (see Figure 3); one patient did not show up for the upper GI series during follow-up, and the other patient was in a palliative setting due to metastatic disease. Table 1 provides the patient characteristics of all included patients ($n = 26$) at baseline.

3.2 | Primary and Secondary Outcomes

Overall technical and clinical success of EDGE was achieved in 25/26 patients (96.2%). Step 1 (LAMS placement for gastrogastrostomy) was successful in all cases (see Table 2). ERCP through the LAMS (step 2) failed in one patient due to the inability to obtain an adequate position in front of the papilla for cannulation. Eventually, adequate biliary drainage was obtained via a percutaneous transhepatic cholangiography drain (PTC-drain). Other procedure-related outcomes are reported in Table 3. The median LAMS indwelling time was 14 days [IQR: 11–28], and the median total procedure time was 89 min [IQR: 73–120].

3.3 | Adverse Events

Overall AEs were reported in four patients (4/26, 15.4%), with two events directly related to the EDGE procedure (2/26, 7.7%). In one case, it was not possible to obtain an adequate position in front of the papilla, and the attempt resulted in an iatrogenic perforation of the contralateral duodenal wall. Figure 4 provides an illustrative explanation of different positions of LAMS placement and their potential impact on the pressure of the bending shaft of the scope on the wall of the stomach or

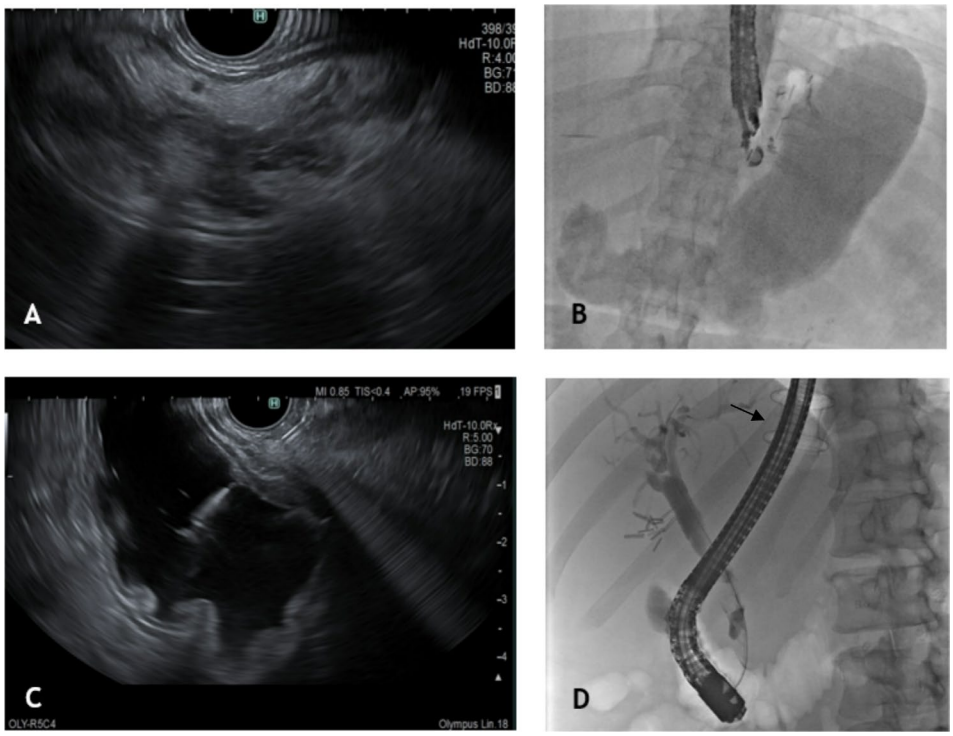

FIGURE 2 | Endosonographic and fluoroscopic images of the procedural steps. (A) Endosonographic image of the collapsed excluded stomach prior to needle insertion. (B) Fluoroscopic image of the excluded stomach filled with contrast. (C) Endosonographic image showing the LAMS with its distal flange being deployed in the lumen of the excluded stomach. (D) Fluoroscopic image showing the duodenoscope successfully advanced through the LAMS (arrow) with access to the common bile duct. LAMS, lumen-apposing metal stent.

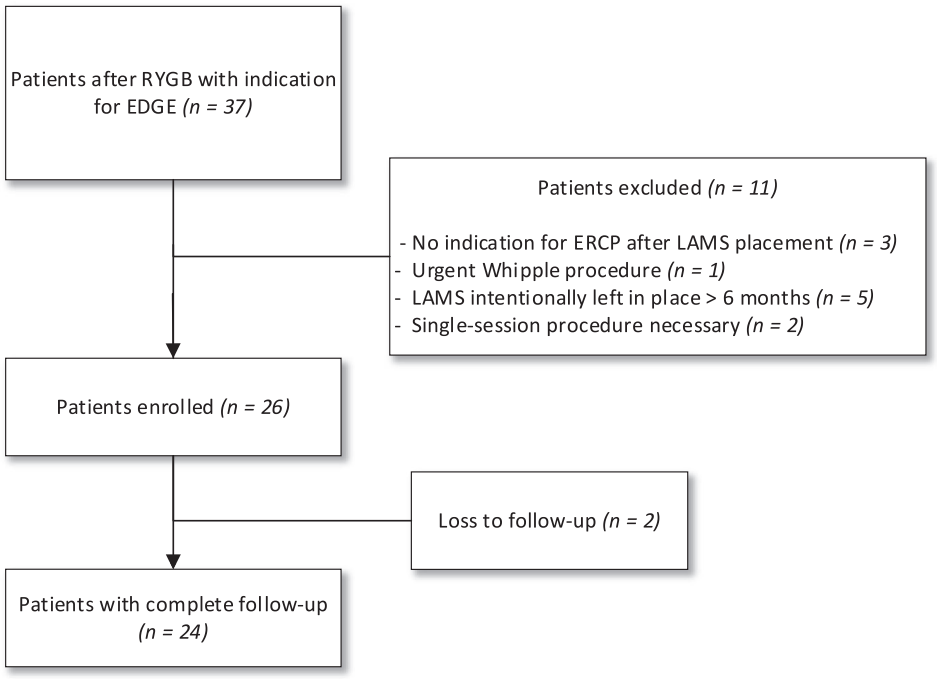

FIGURE 3 | Flowchart for screening and enrollment.

duodenum. In this specific case, the LAMS was placed near the proximal portion of the antrum. Although the duodenum could be reached, the maximum pressure caused by the bending section of the endoscope—which normally lies along the greater curvature of the stomach—was instead applied to the contralateral wall of the duodenum, resulting in a longitudinal duodenal perforation. A laparotomy was performed to close the iatrogenic longitudinal tear. Ultimately, the patient was discharged for rehabilitation and the LAMS was removed several months later. The other patient suffered from bleeding following LAMS placement and required a blood transfusion during readmission.

TABLE 1 | Patient characteristics.

Variable	Total ($n = 26$)
Female sex, *n* (%)	22 (84.6)
Age during procedure, median (IQR)	58.0 (44.5–64.3)
BMI, mean (SD)	28.8 (4.9)
ASA score, *n* (%)	
I	3 (11.5)
II	13 (50.0)
III	8 (30.8)
IV	2 (7.7)
V	0 (0.0)
Cholecystectomy prior to procedure, *n* (%)	23 (88.5)
Type of bariatric surgery, *n* (%)	
Roux-en-Y gastric bypass	26 (100.0)
Other	0 (0.0)
Indication for EDGE, *n* (%)	
Choledocholithiasis	23 (88.5)
(Presumed) benign obstruction	0 (0.0)
(Presumed) malignant obstruction	2 (7.7)
Iatrogenic bile duct injury	1 (3.8)

Abbreviations: ASA, American Society of Anesthesiologists physical status; BMI, body mass index; EDGE, endoscopic ultrasound-directed ERCP; IQR, interquartile range; SD, standard deviation.

TABLE 2 | Primary and secondary outcomes.

Variable	Total ($n = 26$)
Overall technical success, *n* (%)	25 (96.2)
Overall clinical success, *n* (%)	25 (96.2)
Persistent fistula, *n* (%)	0/24 (0.0)
Lost to follow up: 2	
Median total procedure time[a], min (IQR)	89 (73–120)
EUS procedure time	30 (30–34)
ERCP procedure time	45 (45–64)
EDGE-related adverse events, *n* (%)	
Stent dislodgment	0 (0.0)
Stent dysfunction	0 (0.0)
Bleeding	1 (3.8)
Perforation duodenal wall	1 (3.8)
ERCP-related adverse events, *n* (%)	
Perforation common bile duct	1 (3.8)
Post-ERCP pancreatitis	1 (3.8)
Bleeding	0 (0.0)
Severity of adverse events[b]	
Grade I	0 (0.0)
Grade II	2 (7.7)
Grade IIIa	1 (3.8)
Grade IVb	1 (3.8)
Mortality	0 (0.0)
Hospital stay, days (IQR)[c]	1 (0–2)

Abbreviations: EDGE, endoscopic ultrasound-directed ERCP; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; IQR, interquartile range.
[a]Total procedure time of all sessions combined.
[b]According to the AGREE classification.
[c]Total hospital stay of all sessions combined.

In two other patients (2/26, 7.7%), ERCP-related AEs occurred. One patient experienced a CBD perforation, resulting in bile leakage. This was adequately managed with the placement of a fully covered self-expanding metal stent (fcSEMS) in a separate session. Another patient developed mild post-ERCP pancreatitis.

3.4 | Fistula Closure After LAMS Removal

Persistent fistula occurred in none of the patients with complete follow-up (0/24, 0.0%). The remaining two patients were lost to follow-up, without any evidence of fistula closure. In 16/24 patients (66.7%), there was radiological evidence of fistula closure during follow-up; 15/24 patients (62.5%) underwent a gastroscopy to provide evidence of fistula closure, and in 7/26 patients (26.9%), both modalities were reported. Median follow-up time was 141 days [IQR 66–252]. Median hospital stay was 1 day [IQR 0–2].

4 | Discussion

This multicenter study reports the prospective outcomes on the efficacy and safety of the EDGE procedure according to a predefined follow-up protocol. The results show a high technical and clinical success rate without any occurrence of persistent fistula during follow-up. However, AEs occurred in about 15% of cases (4/26), of which two AEs were EDGE-related.

The high technical success rate found in this present study is consistent with current literature [17]. Two systematic reviews of mostly retrospective series reported a similar high technical success rate for the creation of the gastro-gastrostomy/jejunogastrostomy and subsequent ERCP [22, 29].

Despite these high success rates, the EDGE procedure is also accompanied by technical challenges, and enteroscopy-assisted ERCP remains a valid alternative approach. One of the most commonly reported adverse events of EDGE is intraprocedural LAMS migration, which may require emergency surgery [17]. To mitigate this risk, the ESGE recommended a two-step EDGE procedure, with a delay of at least 7 days before performing subsequent ERCP after LAMS placement [15]. This allows the gastro-gastrostomy fistula tract to mature, preventing the spill of gastrointestinal content in case of LAMS dislodgement during step 2. In the present study, we adopted this recommendation into our protocol and carried out a two-step EDGE procedure.

TABLE 3 | Other procedure-related outcomes.

	Total ($n = 26$)
Step 1 (LAMS placement)	
Type of anastomosis, *n* (%)	
Gastro-gastrostomy	22 (84.6)
Gastro-jejunostomy	4 (15.4)
Antibiotic prophylaxis	21 (80.2)
Technical success	26 (100.0)
Step 2 (ERCP through LAMS)	
Median time from LAMS placement until ERCP, days (IQR)	10 (7–14)
Multiple ERCPs performed after LAMS placement	3 (11.5)
Technical success	25 (96.2)
Step 3 (LAMS removal)	
Median LAMS indwelling time, days (IQR)	14 (11–28)
Timing of LAMS removal, *n* (%)	
Single-session	13 (50.0)
Separate session	12 (46.2)
Left in situ: 1	
Follow-up (missing: 2)	
Median follow-up time, days (IQR)	141 (66–252)
Evidence of fistula closure	
Both	7 (29.2)
Radiologic (VFSE)	16 (66.7)
Endoscopic (gastroscopy)	15 (62.5)

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; IQR, interquartile range; LAMS, lumen apposing metal stent; VFSE, video fluoroscopic swallowing exam.

However, the field of therapeutic EUS is quickly evolving, and several solutions have been reported in the meantime to mitigate the issue of LAMS migration [30]. Last year, Khan et al. performed a pilot study in which six patients with an RYGB underwent a single-session EDGE procedure with stent fixation using a through-the-scope suturing system [31]. Clinical and technical success were achieved in all six patients without any occurrence of stent migration. Van Bronswijk et al. (2024) assessed the feasibility of a dedicated over-the-scope-clip (OTSC) fixation device for single-session EDGE procedures and reported no stent migration in 20 patients. Prospective studies are needed to confirm these promising results.

Another essential step to reduce the risk of stent migration is optimal LAMS positioning in the excluded stomach. Placing the LAMS in the proximal part of the excluded stomach is essential to mimic the normal "ERCP route" as much as possible. This approach may help to minimize intraprocedural traction on the LAMS while performing the subsequent ERCP, thereby reducing the risk of LAMS dislodgement. It also ensures that when the scope is advanced, it follows the greater curvature of the stomach. In this present study, one serious adverse event was likely related to the suboptimal LAMS position in the excluded stomach. Due to an unfavorable angle, the duodenoscope could not be adequately introduced in front of the papilla, and the pushing of the endoscope probably caused looping in the duodenum instead of the greater curvature. This eventually led to a perforation of the contralateral duodenal wall. This specific case underlines the importance of proper LAMS placement. ERCP-related complications occurred in two patients. In one of these cases, a (precut-)sphincterotomy resulted in a CBD perforation. Although this complication is commonly observed in ERCP procedures without EDGE, it cannot be ruled out that this was a consequence of limited endoscope maneuverability resulting from the EDGE technique.

Another possible complication associated with EDGE procedures is the occurrence of a persistent fistula following LAMS removal. In this present study, none of the patients had a persistent fistula after LAMS removal (0/24 patients,

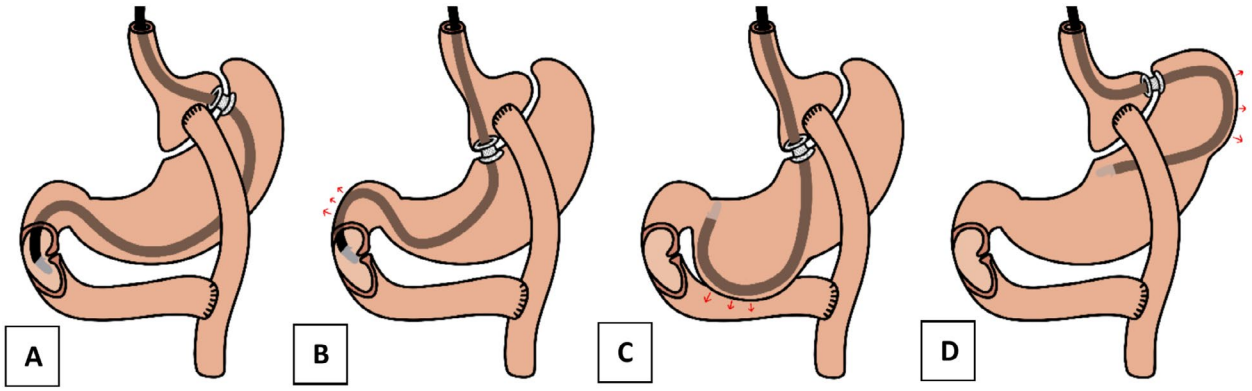

FIGURE 4 | Illustrative examples of how different LAMS placements affect scope insertion. (A) Ideal placement of the LAMS in the proximal part of the excluded stomach; the endoscope can follow the normal 'ERCP route' along the greater curvature of the stomach. (B) The LAMS is placed too distal: This prevents the endoscope from following the greater curvature of the stomach, leading to pressure on the duodenal wall. (C) The LAMS is placed too distal: The endoscope is over-angulated in the antrum of the stomach, leading to pushing away the gastric wall, hampering passage toward the duodenum. (D) The LAMS is placed too proximal: The endoscope is over-angulated in the fundus of the stomach, leading to pushing away the gastric wall, hampering passage toward the pylorus.

0%). Retrospective data have shown conflicting results, with reported persistent fistula rates of up to 31% [32]. Ghandour et al. (2023) carried out a case–control study to determine risk factors associated with the development of persistent fistulas after LAMS removal [33]. The researchers found that the LAMS indwelling time was significantly longer in the cases group ($n = 25$) compared to the controls group ($n = 50$): 127 days versus 48 days, respectively (p-value = 0.02). They also reported that a LAMS indwelling time of more than 40 days was associated with an odds ratio of 4.5 for the development of a persistent fistula [33]. This association between prolonged LAMS indwelling time and the occurrence of persistent fistulas after LAMS removal is supported by other retrospective studies [32, 34]. Notably, the median LAMS indwelling time in our study was only 14 days, with a maximum of 28 days, which may explain the absence of persistent fistulas observed. This implies that once the LAMS is removed as soon as possible, there seems to be a negligible risk for a persistent fistula.

This study has several limitations. Due to the pilot study design, the overall sample size was relatively small, and the outcomes were not compared to a control group. Furthermore, we only included patients undergoing the two-step EDGE procedure. Novel stent fixation strategies enhance the feasibility of single-session EDGE procedures, expanding their application to more urgent indications, such as acute cholangitis. The strength of this study is its prospective design, which evaluates the outcomes of EDGE according to a predefined protocol. Moreover, this multicenter study included both academic and nonacademic hospitals. Since the participating endoscopists were not exclusively from high-volume expert centers, the outcomes could be more generalizable to daily clinical practice.

Lastly, this study included a few patients with malignant disease. Given that these patients often require multiple endoscopic interventions, EDGE could offer the advantage of facilitating repeated access by leaving the LAMS in situ. One could argue that LAMS placement could be more technically challenging due to tumor infiltration, previous surgeries, or radiotherapy. However, since the indication for ERCP usually concerns HPB malignancies, these potential difficulties are not expected at the site of LAMS placement.

Future research should aim to provide prospective evidence regarding the safety and feasibility of single-session EDGE procedures, as well as a randomized controlled trial on EDGE versus laparoscopic-assisted ERCP.

In conclusion, this prospective cohort study showed that EDGE is a feasible procedure with a high technical success, without any cases of persistent fistula after protocolized LAMS removal and follow-up. However, EDGE-related AEs occurred in 7.7% of patients.

Author Contributions

This study was primarily designed by S.H. and R.P.V. The study was conducted by S.H., A.G.O., and R.P.V. The data were collected and analyzed by A.G.O., who also drafted the manuscript under the supervision of R.P.V. All authors contributed to the interpretation of the data and to the draft of the manuscript. All authors have approved the final manuscript. The guarantor of the article is R.P.V.

Ethics Statement

The research protocol was approved by the Medical Ethics Review Committee Amsterdam UMC on 24-02-2020. This Committee confirmed that the Dutch Medical Research Act does not apply to this study. All patients provided written informed consent prior to participation. Registry: None. Animal studies: None.

Conflicts of Interest

R. P. Voermans reports research grants from Boston Scientific and Prion Medical, performed as a consultant for Cook Medical and Boston Scientific, and received a speaker's fee from Mylan and Zambon. R. L. J. van Wanrooij performed as a consultant for Boston Scientific. J. E. van Hooft reports lecture fees for Cook Medical, Boston Scientific, Fuji Film, and Falk, and received a consultancy fee for Olympus, all outside the submitted work. All other authors declare no conflicts of interest.

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