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Maximizing success in single-session EUS-directed transgastric ERCP: a retrospective cohort study to identify predictive factors of stent migration

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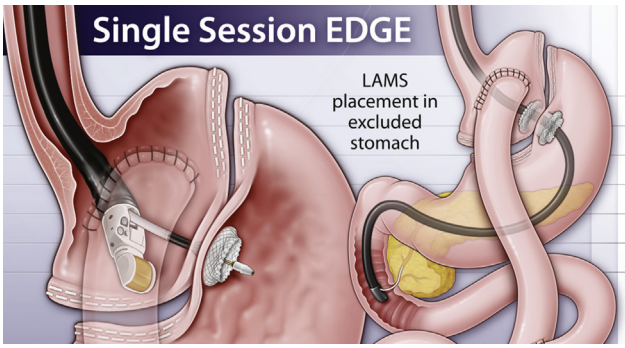
GRAPHICAL ABSTRACT



Univariate analysis of factors associated with 11 total migrations

	RR	95%CI	*P* value
Stent size 15mm vs 20mm	5.271	1.473-18.868	0.007
Sutures vs no sutures	0		0.033
Dilation vs no dilation	0.221	0.061-0.808	0.084
Gastric route vs jejunal	1.972	0.447-8.708	0.502
Electrocautery vs no electrocautery	0.300	0.077-1.163	0.141
Double pigtail vs no double pigtail	3.989	1.233-12.905	0.007
Stent size 15mm vs 20mm	5.271	1.473-18.868	0.504

Background and Aims: EUS-directed transgastric ERCP (the EDGE procedure) is a simplified method of performing ERCP in Roux-en-Y gastric bypass patients. The EDGE procedure involves placement of a lumen-apposing metal stent (LAMS) into the excluded stomach to serve as a conduit for passage of the duodenoscope for pancreatobiliary intervention. Originally a multistep process, urgent indications for ERCP have led to the development of single-session EDGE (SS-EDGE) with LAMS placement and ERCP performed in the same session. The goal of this study was to identify predictive factors of intraprocedural LAMS migration in SS-EDGE.

Methods: We conducted a multicenter retrospective review that included 9 tertiary medical centers across the United States. Data were collected and analyzed from 128 SS-EDGE procedures. The primary outcome was intraprocedural LAMS migration. Secondary outcomes were other procedural adverse events such as bleeding and perforation.

Results: Eleven LAMS migrations were observed in 128 procedures (8.6%). Univariate analysis of clinically relevant variables was performed, as was a binary logistic regression analysis of stent diameter and stent dilation. This revealed that use of a smaller (15 mm) diameter LAMS was an independent predictor of intraprocedural stent migration (odds ratio, 5.36; 95% confidence interval, 1.29-22.24; $P = .021$). Adverse events included 3 patients who required surgery and 2 who experienced intraprocedural bleeding.

Conclusions: Use of a larger-diameter LAMS is a predictive factor for a nonmigrated stent and improved procedural success in SS-EDGE. Although larger patient cohorts are needed to adequately assess these findings, performance of LAMS dilation and fixation may also decrease risk of intraprocedural LAMS migration and improve procedural success. (Gastrointest Endosc 2021;94:727-32.)

(footnotes appear on last page of article)

Roux-en-Y gastric bypass anatomy poses a unique challenge when performing ERCP because of the difficulty in reaching the duodenum through the altered anatomic route and with accessing the ampulla.[1-4] In this patient population, the biliary tree has historically been accessed through laparoscopic assistance with gastrotomy to the excluded stomach (laparoscopy-assisted ERCP) or balloon-assisted enteroscopy ERCP (BAE-ERCP). BAE-ERCP uses an overtube and a balloon-assisted forward-viewing endoscope to reach the duodenum. This procedure consists of navigation down the "roux limb," crossing an often acutely angulated jejunojejunostomy, advancement through the biliopancreatic limb, and then identification of the ampulla without the use of a side-viewing endoscope.[5] Access to the intact papilla is a significant obstacle using this technique because the absence of an elevator on the balloon-assisted endoscopes increases the difficulty in selective cannulation. BAE-ERCP can be a lengthy and technically challenging procedure with a success rate as low as 63%.[6-8] BAE-ERCP also has high rates of adverse events, specifically perforation, which has been reported to be as high as 10%.[9]

To overcome the challenges and difficulties of laparoscopy-assisted ERCP and BAE-ERCP, EUS-directed transgastric ERCP (EDGE) was first described by Kedia et al.[10] The EDGE procedure uses a lumen-apposing metal stent (LAMS) to access the excluded stomach from the gastric pouch or jejunal limb under EUS guidance. The LAMS functions as a conduit to allow passage of a standard duodenoscope and echoendoscope into the excluded stomach and duodenum for pancreatobiliary interventions. EDGE allows for more efficient and successful biliary tree access in patients with Roux-en-Y gastric bypass anatomy when compared with alternative methods.[1,7,10-13]

EDGE has traditionally been performed in a multistep process with initial placement of the LAMS followed by ERCP weeks later to allow the fistula to mature. However, endoscopists encounter situations that warrant urgent ERCP such as ascending cholangitis and bile leaks, and these have led to the advent of single-session EDGE (SS-EDGE).[2,3,14,15] This procedure consists of placement of a LAMS followed immediately by ERCP in the same endoscopic session. The most serious and common adverse event of SS-EDGE is intraprocedural migration of the LAMS resulting in a perforated viscus, particularly at the site of the excluded stomach where endoscopic closure may not be possible. This adverse event is mitigated in the multistep EGDE procedure because the time interval between procedures allows for epithelialization of the fistula and stabilization of the LAMS.[10]

Variations of technique are favored by different physicians that may affect outcomes for SS-EDGE. Among these differences are LAMS diameter, postplacement LAMS dilation, securing of the LAMS with endoscopic suturing, and route of LAMS placement (transgastric vs transjejunal). Limited data compare these factors with regard to outcomes and adverse events. The purpose of this study was to identify factors predictive of SS-EDGE adverse events, specifically intraprocedural stent migration. The primary results of this study were presented at Digestive Disease Week 2020.

METHODS

This was a retrospective study approved by the Thomas Jefferson Institutional Review Board for Human Research on January 9, 2020 (control no. 20E.04) and complied with Health Insurance Portability and Accountability Act regulations. All patients older than 18 years of age who underwent SS-EDGE at 9 different medical centers between March 2016 and October 2019 were included in the study. SS-EDGE was defined as a procedure involving EUS-assisted placement of a LAMS to access the excluded stomach followed by ERCP during the same endoscopic session. The electronic medical record was queried to obtain pertinent clinical information such as patient demographics, indications for the procedure, and periprocedural data. Procedural data collected included endoscope manufacturers and model, LAMS diameter (15 mm vs 20 mm), intraprocedural stent dilation, use of stent fixation, type of fixation (clip, double-pigtail plastic stent, or endoscopic suturing), route of LAMS placement (transgastric vs transjejunal), and procedural adverse events, specifically intraprocedural stent migration, bleeding, and perforation requiring surgery. Intraprocedural stent migration was defined as migration of the LAMS inserted for access to the excluded stomach. All included procedures were completed in the same endoscopic session. Patients with incomplete data were excluded from the study. No data from patients included in this study have been published previously.

Baseline demographic and clinical characteristics at the time of the procedure were reported using descriptive statistics, including the Fisher exact test and risk ratios. The associations between LAMS diameter (15 mm vs 20 mm) and stent migration were modeled separately, and the odds ratios were adjusted for LAMS dilation. The results of the logistic regression were expressed as odds ratio with 95% confidence intervals and P values. Two-tailed $P < .05$ was considered statistically significant. Statistical analysis was performed using SPSS (IBM, version 26; Chicago, Ill, USA).

The primary outcome was intraprocedural LAMS migration during SS-EDGE. Secondary outcomes were additional intraprocedural adverse events and interventions required for management of adverse events (eg, endoscopic therapy for bleeding, salvage stent placement, endoscopic closure of perforations, and need for surgery).

Procedural techniques

LAMS placement. The EDGE procedure is performed in a series of sequential steps (Fig. 1). Initially, the

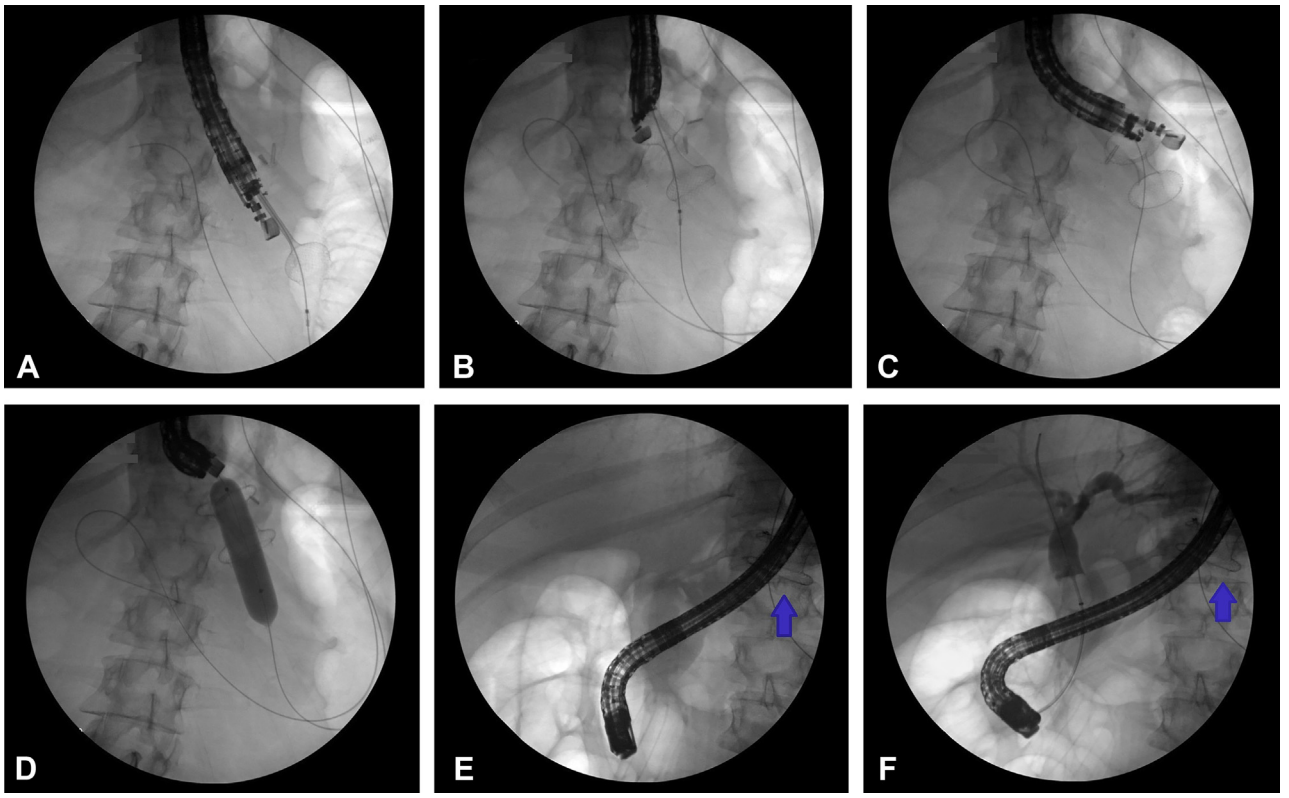


Figure 1. Fluoroscopic images detailing steps of single-session EUS-directed transgastric ERCP. **A,** Lumen-apposing metal stent (LAMS) deployment: distal flange. **B,** LAMS deployment: proximal flange. **C,** Guidewire access maintained through LAMS. **D,** Balloon dilation of LAMS. **E,** Duodenoscope passed through LAMS (*arrow*). **F,** ERCP is performed.

excluded stomach is identified endosonographically from the remnant gastric pouch and/or the jejunum to determine the most ideal location for access using an echoendoscope (GF-UCT series [Olympus, Central Valley, Pa, USA] and EG-3870UTK [Pentax, Montvale, NJ, USA]). Considerations include proximity to the excluded stomach, presence of intervening blood vessels, stability of the echoendoscope, and anticipated location of gastric puncture (body of the stomach or antrum). The excluded stomach is then accessed using an EUS needle, followed by injection of contrast for confirmation of the intraluminal location. The stomach is distended with fluid and a wire then passed through the needle into the excluded stomach over which the LAMS (Axios; Boston Scientific, Marlborough, Mass, USA) is advanced and deployed, thereby forming a fistula from the gastric pouch or jejunum to the excluded stomach. After LAMS placement, the echoendoscope is removed. Dilation of the LAMS and fixation are performed according to the preference of the endoscopist.

ERCP. The duodenoscope (TJF-Q180V [Olympus] and ED34-i10T2 [Pentax]) is advanced under endoscopic and/or fluoroscopic guidance through the LAMS into the excluded stomach and then navigated into the duodenum. Care is taken to preclude dislodgement of the duodenoscope. ERCP is then performed with standard technique, and on completion the duodenoscope is withdrawn. The LAMS is not removed in this session to allow for a fistula to mature and prevent a free perforation of the excluded stomach, which cannot readily be closed endoscopically.

RESULTS

One hundred twenty-nine patients met inclusion criteria for this study. Two patients underwent a second SS-EDGE procedure at a later date, yielding a total of 131 SS-EDGE procedures. Three SS-EDGE procedures were excluded from the study because of incomplete data availability. Thus, 128 procedures were included in the final analysis. The median patient age was 58 years. Demographics and descriptive statistics of the 128 procedures are illustrated in Table 1. Indications for ERCP were biliary obstruction (91 patients), bile leak (15 patients), cholangitis (13 patients), and pancreatic intervention (9 patients).

Of the 129 procedures reviewed, 11 intraprocedural LAMS migrations were observed, yielding a migration rate of 8.6%. The associated risk ratios of factors associated with migration are summarized in Table 2. On univariate analysis, use of a smaller (15 mm diameter) LAMS was predictive of intraprocedural stent migration. Statistically fewer intraprocedural stent migrations occurred in patients with the 20-mm-diameter LAMS (3/85, 3.5%) compared with the 15-mm-diameter LAMS (8/43, 18.6%) (risk ratio, 5.271; 95% confidence interval, 1.47-18.87; $P = .007$). Factors not found to significantly influence

TABLE 1. Descriptive statistics on the patient population and procedures (128 procedures)

	Migration (n = 11)	No migration (n = 117)	*P* value
Gender			
Women	9	88	1.000
Men	2	29	
Age			
<50 y	6	24	.089
50-59 y	2	35	
60-69 y	2	36	
≥70 y	1	22	
Stent size			
15 mm	8	35	.007
20 mm	3	82	
Sutures			
Yes	0	38	.033
No	11	79	
Dilation			
Yes	9	113	.084
No	2	4	
Location			
Gastric	9	80	.502
Jejunal	2	37	
Electrocautery*			
Yes	9	111	.141
No	2	6	

*Lumen-apposing metal stents (LAMSs) without electrocautery were used before the advent of the clinical availability of electrocautery-enhanced LAMSs.

the rate of intraprocedural stent migration were LAMS dilation (9/122 migrations in dilated LAMS vs 2/6 migrations in nondilated LAMS, $P = .084$), route of LAMS placement (9/89 migrations in transgastric access vs 2/39 migrations in transjejunal access, $P = .502$), and the use of electrocautery-enhanced stents (9/120 migrations in electrocautery stents vs 2/8 migrations in nonelectrocautery stents, $P = .141$).

Thirty-eight LAMSs were secured with endoscopic suturing. Of the sutured LAMSs, none experienced intraprocedural migration compared with 3 of 11 nonsutured LAMSs. On univariate analysis, absence of stent fixation with endoscopic suturing was found to be a statistically significant predictive factor of intraprocedural stent migration ($P = .033$). Double-pigtail stents were used to anchor the LAMS in 11 procedures. Of the LAMSs anchored with double-pigtails stents, 3 of 11 experienced intraprocedural migration. On univariate analysis, anchoring with a double-pigtail stent was not found to be a statistically significant predictive factor of stent migration ($P = .504$). The mean duration to LAMS removal was 45 days after initial placement.

A binary logistic regression analysis of stent diameter and dilation was performed. Stent diameter was included as a factor given that it achieved statistical significance on univariate analysis. Stent dilation was also included as a factor given its clinical importance and trend toward significance on univariate analysis (Table 3). This analysis demonstrated that a smaller stent diameter was an independent predictor of LAMS migration, although dilation of the LAMS was not. The 15-mm LAMSs were more likely to migrate than the 20-mm LAMSs (odds ratio, 5.36; 95% confidence interval, 1.29-22.24; $P = .021$). Although the effect of suture fixation on logistic regression was of interest clinically, the lack of any migrated sutured stents and the small sample size of the study did not allow for its incorporation into the model.

Of the 11 patients who experienced LAMS migration, 3 required surgery, 3 were rescued with esophageal stent bridging, and 2 had placement of a second LAMS. In 1 patient, the defect was closed with an over-the-scope clip, and in 2 other procedures the stents that had migrated were able to be replaced during the same procedure. Bleeding occurred in 2 patients and was managed endoscopically at the time of the procedure without recurrence. No deaths occurred in the cohort.

DISCUSSION

The EDGE procedure is a novel endoscopic procedure that allows ERCP access to the duodenum in patients with Roux-en-Y gastric bypass anatomy. EDGE improves success and shortens procedure duration. SS-EDGE has been described in the literature in case reports and a single small case series of 5 patients. This is the first multicenter collaborative study of SS-EDGE demonstrating that the procedure can be performed safely when there is a need for urgent pancreaticobiliary intervention.[2,3,14,15] Intraprocedural stent migration, which can occur in both multistep and SS-EDGE procedures, is the most concerning adverse event in SS-EDGE, and factors that affect this outcome are of great interest. This is the first multicenter study to investigate factors that may impact LAMS migrations in SS-EDGE.

We found that the use of the 15-mm diameter LAMSs is the strongest predictor of intraprocedural stent migration. Suture fixation of the LAMS was clinically significant and improved procedural success because none of the sutured LAMSs experienced migration; however, this factor was not incorporated into the multivariate analysis because of the lack of observed adverse events in this small-sized cohort, resulting in statistical limitation. The fact that there were no migrations suggests that this may be a powerful method of avoiding this adverse event, and suture fixation of the LAMS has been routinely incorporated into practice for SS-EDGE by some practitioners. Although the performance

TABLE 2. Univariate analysis of factors associated with 11 total migrations

	Risk ratio	95% Confidence interval	*P* value
Stent size 15 mm vs 20 mm	5.271	1.473-18.868	.007
Sutures vs no sutures	0		.033
Dilation vs no dilation	.221	.061-.808	.084
Gastric route vs jejunal	1.972	.447-8.708	.502
Electrocautery vs no electrocautery	.300	.077-1.163	.141
Double pigtail vs no double pigtail	3.989	1.233-12.905	.504

TABLE 3. Logistic regression (reference: no dilation and 20-mm LAMS)

Variable	*P* value	Odds ratio	95% Confidence interval
LAMS dilation	.235	.313	.046-2.125
LAMS diameter 15 mm	.021	5.355	1.289-22.241

LAMS, Lumen-apposing metal stent.

of stent dilation after deployment was not significant on binary logistic regression, a trend toward significance was noted, and further investigation with a larger cohort may provide the power to further evaluate the impact of this variable.

There were limitations to this study. The first limitation was the small size of our cohort in measuring some of our outcomes. The small number of observed adverse events of the primary outcome was another limitation. These factors limited our ability to show statistical significance of several variables that may impact intraprocedural LAMS migration. The decision to perform SS-EDGE was determined by the care teams in the course of clinical care. The degree of urgency was not uniform across sites because of institutional protocol and the unique nature of each case. The retrospective nature of each case precludes determination of a standardized set of indications. Until more data are available, we recommend that SS-EDGE be considered in cases with time-sensitive indications such as cholangitis or bile leak as an exception rather than as routine. Future prospective multicentered designs with larger patient cohorts might be needed to validate the predictive factors of intraprocedural LAMS migration.

In conclusion, we have demonstrated that SS-EDGE is a technique that can be performed safely and should be considered for situations when procedural delay may adversely affect patient outcomes. In this study we identified several factors that impact intraprocedural stent migration, the most concerning adverse event in SS-EDGE procedures. Of all factors investigated, stent fixation with sutures and use of a 20-mm-diameter LAMS were found to be predictors of a nonmigrated LAMS, therefore avoiding adverse events. Although stent dilation after deployment may improve procedural success based on clinical experience, this factor did not reach statistical significance in this study. Based on these results, we suggest use of larger-diameter 20-mm LAMSs for the EDGE procedure. Endoscopic suturing for stent fixation may also serve to decrease LAMS migration during SS-EDGE procedures.

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Abbreviations: BAE-ERCP, balloon-assisted ERCP; EDGE, EUS-directed transgastric ERCP; LAMS, lumen-apposing metal stent; SS-EDGE, single-session EUS-directed transgastric ERCP.

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