Surgical Endoscopy (2019) 33:2024–2033
https://doi.org/10.1007/s00464-019-06715-z

DYNAMIC MANUSCRIPT

Gastric access temporary for endoscopy (GATE): a proposed algorithm for EUS-directed transgastric ERCP in gastric bypass patients

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Received: 5 September 2018 / Accepted: 19 February 2019 / Published online: 25 February 2019

Abstract

Background Performing endoscopic retrograde cholangiopancreatography (ERCP) in patients with Roux-en-Y gastric bypass (RYGB) anatomy is technically challenging. Device-assisted enteroscopy and laparoscopic-assisted methods suffer from high failure rates and/or post-procedural complications. A novel endoscopic technique termed EUS-Directed Transgastric ERCP (EDGE) or Gastric Access Temporary for Endoscopy (GATE) has recently emerged, demonstrating excellent technical and therapeutic success. The technique involves endoscopic ultrasound-guided deployment of a lumen-apposing metal stent (LAMS) to gain access into the remnant stomach to facilitate standard ERCP. In this case series, we describe our center's experience and unique approach with the GATE procedure and discuss several key strategies and differences.

Methods Patients underwent the GATE procedure via a novel algorithmic approach. Key information on procedural details, technical and clinical success, follow-up, and adverse events was prospectively collected and retrospectively reviewed.

Results 10 patients underwent the GATE procedure from May 2017 to March 2018. Technical and clinical success were both 100%. Gastric and jejunal access points for LAMS deployment were 30% and 70%, respectively. Total procedure time per patient, including LAMS deployment, ERCP, and all follow-up procedures, averaged 2.37 ± 0.63 h. 2 out of 10 patients (20%) had adverse events that were resolved either intra-procedurally or after repeat endoscopy with no long-term complications and none requiring surgery. For patients with complete follow-up ($n = 7$), access tract closure rate was 100% with the aid of a temporary plastic double pigtail stent to facilitate closure.

Conclusions GATE appears to be a safe and effective procedure and may be considered the preferred approach to ERCP in patients with RYGB anatomy at centers with LAMS experience. The procedure offers more definitive and higher range of ERCP interventions compared to traditional methods and is associated with fewer adverse events. Improvements in strategies and methods with the GATE technique may reduce risks and improve outcomes.

Keywords Roux-en-Y gastric bypass · Lumen-apposing metal stent · Endoscopic ultrasound-directed transgastric ERCP · Gastric access temporary for endoscopy · Plastic double pigtail stent

The prevalence of obesity in the United States continues to rise and has reached 40% in 2015 [1]. At the same time, bariatric surgeries are becoming more prevalent. Over the past decade, the American Society for Metabolic and Bariatric Surgery estimates that 40,000–65,000 Roux-en-Y gastric bypass (RYGB) procedures have been performed every year in the United States [2]. As a result, gastroenterologists and surgeons are increasingly seeing more patients with RYGB anatomy presenting with pancreaticobiliary disease.

Endoscopic retrograde cholangiopancreatography (ERCP) can be technically difficult in patients with RYGB anatomy [3]. Device-assisted ERCPs in these patients, such as those performed with a single or double balloon enteroscopy or with a spiral overtube, are associated with an average success rate of 70% (range 38–100%) in one systematic review [4]. Laparoscopic-assisted ERCPs, in contrast, have

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00464-019-06715-z) contains supplementary material, which is available to authorized users.

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much higher rates of therapeutic success of nearly 100%, but require coordinating schedules among endoscopists and surgeons, which can be challenging at times, and are associated with higher costs, longer post-procedural hospitalization stay, and increased adverse event rate due to the added laparoscopy [5, 6].

Recently, a novel endoscopic technique with similar success rate to laparoscopic-assisted ERCPs has been reported in multiple case series across the U.S. The procedure has been referred to in the literature as either endoscopic ultrasound-directed transgastric ERCP (EDGE), endoscopic ultrasound-guided transgastric fistula (EUS-TG), or EUS-guided gastrogastrostomy-assisted ERCP (EUS-GG-ERCP), and involves a fully covered, lumen-apposing metal stent (LAMS; AXIOS Electrocautery Enhanced System, Boston Scientific, Marlborough, MA) [7–9]. The LAMS facilitates the endoscopic creation of a temporary transgastric access tract to facilitate advanced therapeutic endoscopy of the foregut, including traditional ERCP using a standard duodenoscope.

Technical details surrounding the EDGE technique have been previously discussed in a published case series [10]. A recent multicenter review of the EDGE procedure has shown similar rates of therapeutic success and adverse events when compared to laparoscopic-assisted ERCPs, but with shorter procedural times and post-procedural hospitalization stay [11]. Another report describing three tertiary centers' experience with EUS-TG was even more favorable, with 100% technical and clinical success with no major post-procedural complications [8].

Due to the importance and novelty of the creation of an internal gastric access, and to avoid confusion with surgically assisted transgastric ERCPs, our center has performed the procedure under an alternative name, Gastric Access Temporary for Endoscopy (GATE), to facilitate easier understanding with patients and other medical providers when explaining the procedure. From our understanding and review of the literature, the terms Internal EDGE, EUS-TG, and GATE describe the same procedure and can be used interchangeably. In this paper, we describe our experience in performing the GATE procedure, and through the detailed clinical case series highlight several key additions and differences from our center's technique that may reduce the incidence of technical complications and improve clinical outcomes.

Materials and methods

Our center first started to perform the GATE procedure in May 2017. All patients who had since undergone the GATE procedure were included as part of a registry. Within this registry, we retrospectively reviewed prospectively collected data on patient demographics, medical history, and all procedural and hospitalization details. This study was approved by our hospital's human research committee institutional review board.

Procedural technique

GATE and all additional follow-up procedures were performed in the endoscopy suite by two experienced advanced endoscopists, each having performed more than 2000 endoscopic ultrasound (EUS) procedures and more than 2000 ERCP procedures.

EUS access assessment

To start the GATE procedure, a linear echoarray or forward-viewing echoendoscope (Curved Linear Array, model #GF-UCT180, Olympus America, Center Valley, PA) was advanced into the gastric pouch. EUS was then attempted to visualize the remnant stomach either at the gastric pouch or from the surrounding jejunal structures (i.e., blind limb, saddle, or Roux limb). (Note: the saddle is defined as the jejunal segment immediately distal to the gastrojejunostomy, bridging the blind and Roux limbs.) An access point for LAMS deployment was considered optimal if the area was 1 cm or less in distance from the remnant stomach as determined by EUS. Attention was made to avoid the staple line in the gastric pouch as an entry point due to concerns of ischemia in the region post stent deployment. Color Doppler imaging was utilized prior to needle puncture to confirm a lack of significant vascular structures within the needle path prior to needle insertion.

LAMS deployment and dilatation

A 19-gauge FNA needle (either EchoTip Ultra, Cook Medical, Bloomington, IN, or BNX fine needle aspiration system, Covidien, Mansfield, MA) was then used to create either a gastric–gastric (G–G) or jejunal-gastric (J-G) access. Contrast (50–50 dilution, > 200 cc, Omnipaque (iohexol), GE healthcare, Marlborough, MA) was instilled into the cavity under fluoroscopic guidance to confirm filling of the remnant stomach and to optimize target size. A 0.035 inch × 450 cm guidewire (Dreamwire, Boston Scientific, Marlborough, MA) was then coiled within the remnant stomach, and the needle was exchanged for the LAMS deployment catheter. Under fluoroscopic, endosonographic, and endoscopic guidance, one 15 mm × 10 mm lumen-apposing metal stent (AXIOS, Boston Scientific, Marlborough, MA) was deployed with cautery enhancement across the tract. The stent's position was then re-confirmed endoscopically, and a 12 × 13.5 × 15-mm balloon dilatation catheter (CRE

Pro Wire-guided, Boston Scientific, Marlborough, MA) was then used to dilate the LAMS lumen up to 15–18 mm in diameter. Example sites of deployment are illustrated in Fig. 1. Summary of key steps are outlined in Table 1.

Gastro-gastric tract considerations

For G-G tracts (i.e., access point between the gastric pouch and remnant stomach), ERCP would be completed during the same procedure as it was felt that LAMS flanges anchoring against the gastric wall would be robust enough to prevent migration. Afterwards, the LAMS would be immediately exchanged for a plastic 10Fr × 3 cm double pigtail stent (Solus Stent, Cook Medical, Bloomington, IN) to maintain bi-directional drainage at the access site lumen while encouraging access closure. Stent exchange was facilitated by a 6.0-mm diameter channel gastroscope (GIF-XTQ160, Olympus America, Center Valley, PA).

Jejuno-gastric tract considerations

For J-G tracts, the timing of the ERCP and LAMS exchange would depend on the urgency of the case. For urgent cases, ERCP would occur at the same time as LAMS deployment; otherwise, the LAMS would be left to mature for 2–3 weeks prior to ERCP given relative concerns of slippage of the LAMS flange when anchoring against a thinner, more pliable jejunal wall. Moreover, LAMS exchange for a plastic double pigtail stent would occur only after 2–3 weeks had passed to allow for tract maturation, regardless of clinical urgency.

After stent exchange

For all cases after stent exchange, the plastic stent would be removed at a future date, and surveillance esophagogastroduodenoscopy (EGD) or imaging (upper GI series) would be conducted post stent removal to monitor for complete access tract closure.

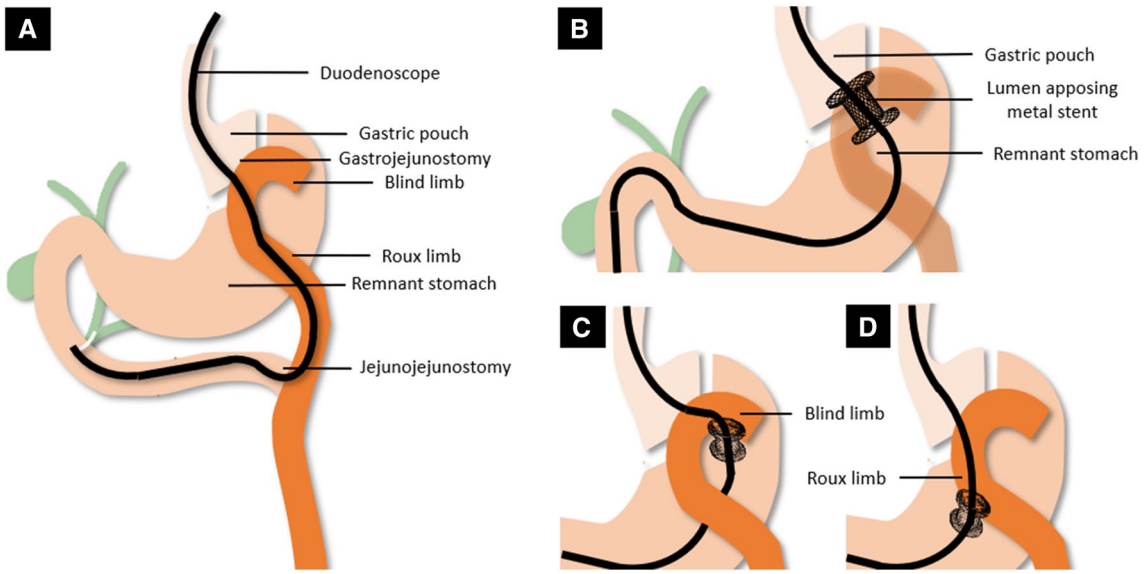

Fig. 1 Visualization of possible access sites for GATE in RYGB anatomy. **A** Endoscopic route of duodenoscope without LAMS access to engage the ampulla under RYGB anatomy. Images **B**–**D** illustrate the path of the duodenoscope when a LAMS is placed under EUS guidance, providing access to the remnant stomach from either the gastric pouch (**B**), blind limb (**C**), or Roux limb (**D**)

Table 1 Summary of key equipment and steps for GATE procedure

Step	Description
1	Identify optimal (minimal distance, blood vessel free) location for access site
3	Establish initial access with a 19-gauge needle
4	Confirm filling of remnant stomach and optimize target size with instillation of contrast
5	Loop a 0.035″ guidewire into the remnant stomach via the access site
6	Exchange the needle for the LAMS deployment catheter to create the access tract
7	Dilate the AXIOS stent lumen up to 15–18 mm

Summary

A summary of this algorithmic approach is illustrated in Fig. 2. Figures 3 and 4 provide a visualization of parts of the GATE procedure through ultrasound and endoscopy, and **Video 1** summarizes the methodology of the GATE procedure via a virtual tour of a live case.

Results

Data collected for each individual case are summarized in Table 2. Table 3 lists average procedural time separately, broken down by procedural type.

Demographics and indications

A total of 10 patients underwent GATE between May 2017 and March 2018 at our single center study. 9 out of 10 patients are female, with average age at 60 (range 53–71). The most common primary indication for GATE in our case series was choledocholithiasis (5/10) followed by biliary obstruction (3/10) from strictures or obstructing mass lesions.

Technical and clinical success

The LAMS was successfully deployed in all cases (100%). Creation of a gastro-gastric (G-G) access tract (i.e., access from the gastric pouch to the remnant stomach) occurred in 3 out of 10 cases. The remaining were jejunal-gastric (J-G) access tracts, with 4 taking place at

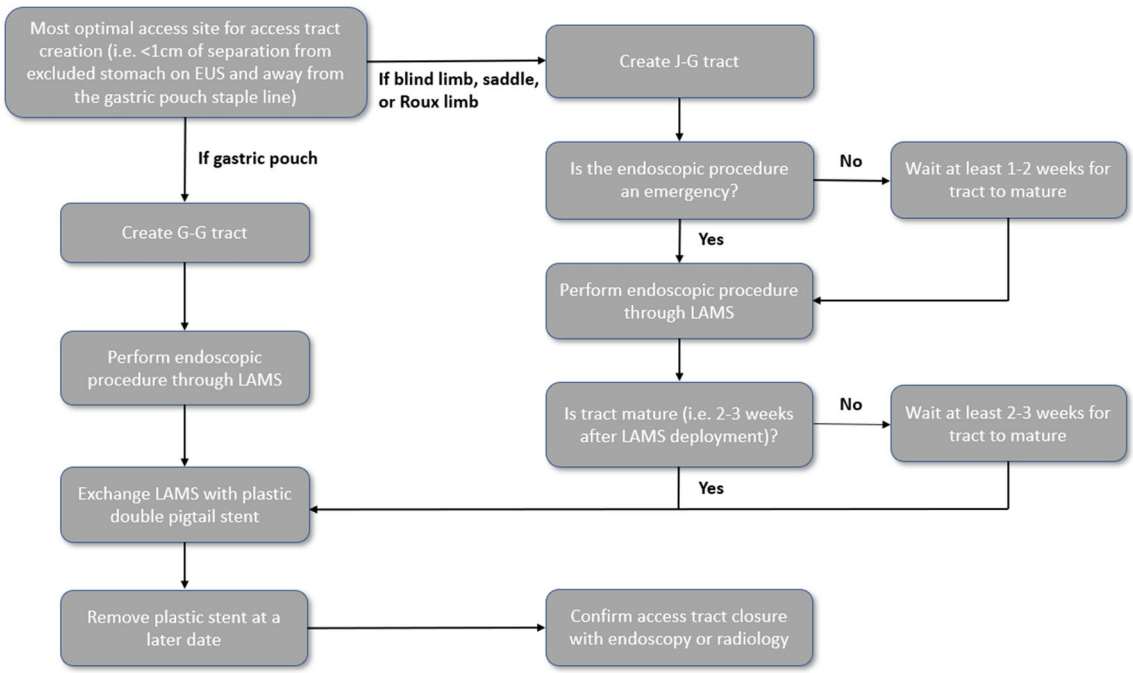

Fig. 2 Algorithmic approach in access site selection, ERCP timeline, LAMS exchange, and access tract closure for patients undergoing GATE

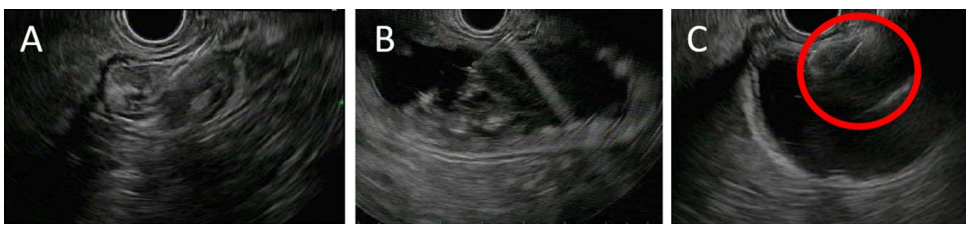

Fig. 3 Endoscopic ultrasound images of GATE procedure. **A** needle puncturing from gastric pouch into the remnant stomach, **B** contrast injected to confirm target and to increase target size, followed by guidewire, **C** the deployed AXIOS stent flange visualized under EUS

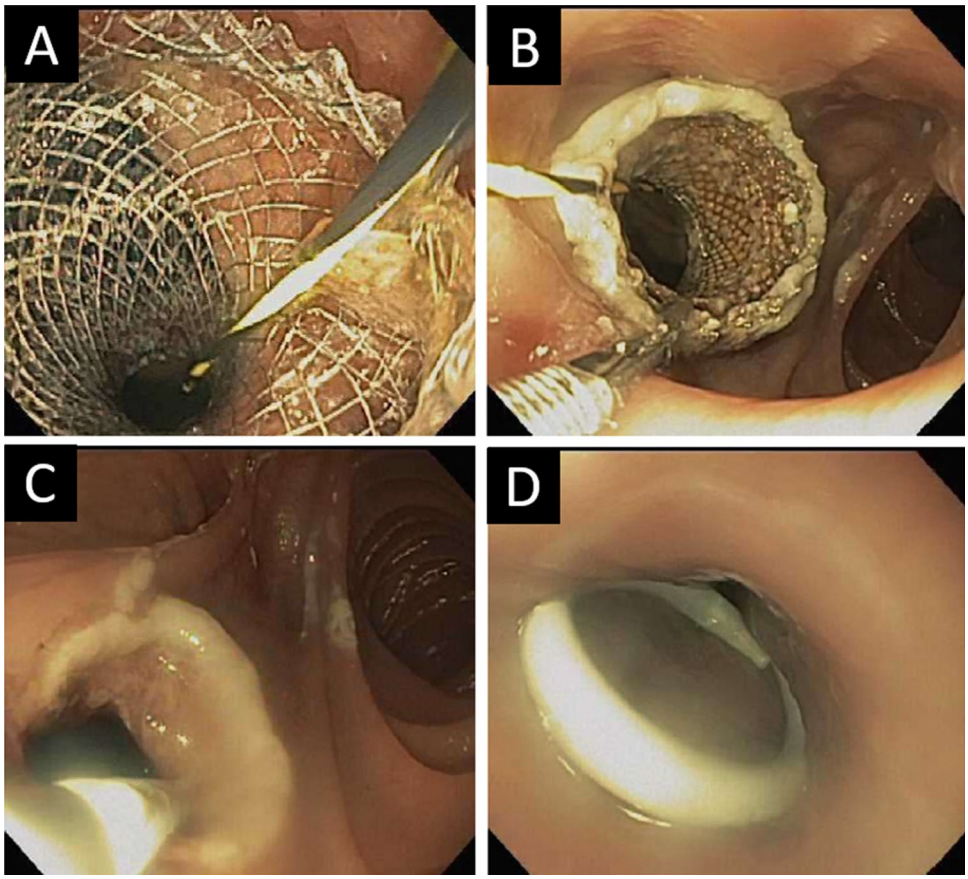

Fig. 4 Endoscopic images of LAMS deployment, removal, and exchange. **A** placement of the LAMS with the guidewire still in place, **B** subsequent removal of the stent with forceps, **C** exchange for the plastic double pigtail stent, and **D** plastic stent in place prior to conclusion of procedure

the blind limb, 1 at the saddle (i.e., immediately distal to the gastrojejunostomy), and 2 at the proximal Roux limb.

Nine of the 10 GATE cases were performed for eventual ERCPs. The remaining GATE case #8 was for an endoscopic ultrasound followed by an endoscopic submucosal dissection (ESD) of a duodenal mass lesion. In 7 of the 9 ERCP cases, ERCP was performed at the same time as the index GATE procedure. For the other two cases, both access sites were from the blind jejunal limb, and there was concern of insufficient tract maturation to safely accommodate the duodenoscope. Additionally, neither case featured an emergent indication for ERCP; therefore, the tracts were allowed to mature 2–3 weeks prior to ERCP. All ERCPs and the one upper endoscopy/ESD were performed successfully (100% clinical success). ERCPs included a wide range of diagnostic and therapeutic maneuvers, many of which could not be performed through an enteroscope (e.g., large sphincterotomy, aggressive stone extractions, and placement of fully covered biliary self-expanding metal stents (SEMS), in addition to endoscopic ultrasound and endoscopic submucosal dissection as noted above).

Stent exchange

Of the 7 ERCPs performed in the initial visit, 3 patients had their LAMS immediately exchanged with a plastic double pigtail stent. Of the 4 cases in which an immediate exchange did not occur, one had a suspected pancreatic malignancy and therefore the LAMS was purposely left in place due to anticipation of additional ERCPs and increased caloric requirements. For the remaining 3 cases, all had J-G access sites, with attendant concern of an immature J-G tract. Therefore, follow-up EGDs were scheduled for these patients for LAMS exchange at a subsequent date.

Closure of temporary access tract

Of the 10 GATE cases, one patient was lost to follow-up and two pursued hospice care and declined further procedures or examination to confirm access tract closure. Therefore, of the seven remaining GATE patients in which access tract closure was verifiable, all 7 (100%) had documented confirmation of access tract closure.

Table 2 Detailed summary of clinical case series

Case #	Initial procedure					Follow-up procedures			Evidence of access tract closure
	Indication	Access site	ERCP	Interventions performed	Immediate LAMS exchange	#	# Days after initial	Interventions performed	
1	Metastatic cholangiocarcinoma, biliary obstruction	Blind limb	Yes	Placement of metal biliary stent	No	1 2	49 217	Evaluation of AXIOS stent, no issues Stent exchange	N/A
2	Biliary obstruction, possible ampullary lesion	Blind limb	No	N/A	No	1 2	21 43	ERCP with sphincterotomy and balloon sweep, stent exchange Plastic stent migrated, tract closed	EGD
3	Choledocholithiasis, gallstone pancreatitis	Gastric pouch	Yes	Stone removal, biliary sphincterotomy	Yes, for plastic stent	1	22	Plastic stent removal, access tract clipped to ensure closure	UGIS
4	Choledocholithiasis, elevated LFTs	Roux limb	Yes	Stone removal, biliary sphincterotomy	No	1 2	14 28	Stent exchange Plastic stent removed, tract closed	UGIS, EGD
5	CBD stricture, elevated LFTs	Gastric pouch	Yes	Brushing of biliary stricture for cytology, sphincterotomy	Yes, for plastic stent	1	20	Plastic stent migrated, tract closed	CT, EGD
6	Choledocholithiasis, elevated LFTs	Gastrojejunostomy	Yes	Brushing for cytology, balloon sweeps, sphincterotomy	Yes, for plastic stent	1 2 3	3 7 69	New AXIOS and 2 plastic stents placed to evaluate new hematemesis Diagnostic, stents in position Removal of AXIOS + plastic stents	N/A
7	Ascending cholangitis, known pancreatic head mass	Gastric pouch	Yes	Stone removal, placement of metal stent, sphincterotomy	No			Declined follow-up procedures	N/A
8	Suspected duodenal mass on MRCP	Roux limb	No	Upper endoscopy only - biopsy of duodenal polypoid mass	No	1 2	14 28	ESD of polypoid mass, suturing, exchange of AXIOS stent Plastic stent migrated, tract closed	EGD
9	Choledocholithiasis	Blind limb	No	N/A	No	1 2	14 35	ERCP with sphincterotomy and balloon sweep, stent exchange Plastic stent migrated, tract closed	EGD
10	Choledocholithiasis	Blind limb	Yes	Stone removal, sphincterotomy	No	1	21	Stent exchange	UGIS

Table 3 Summary of procedure time by type

Procedure type	N	Average time ± STD
Initial GATE-ERCP	9[a]	2 h 12 min ± 37 min
ERCP same procedure	7	2 h 1 min ± 25 min
ERCP separate procedure (time with both procedures combined)	2	2 h 51 min ± 55 min
Closure of GATE	6[b]	14 ± 7 min
Total time per patient	9	2 h 22 min ± 38 min

[a]GATE-ESD case was excluded from the analysis given complexity and difference from the rest of the GATE-ERCP cases

[b]Only cases that had complete follow-up for fistula closure were included. All follow-up AXIOS stent exchange for plastic double pigtail stent, plastic stent removal, and endoscopic assessment for fistula closure was included in this category

All 7 cases had plastic pigtail stents exchanged for the LAMS prior to access tract closure. In 5 of the 7 cases, the access tract was confirmed to have closed completely on its own on follow-up EGD, with the plastic stent spontaneously expelled. The 2 remaining cases required manual stent removal. Modalities to confirm closure included EGD (5), upper GI series (UGIS) 6–8 weeks after LAMS exchange (3), and CT with oral contrast (1). Sample images of access tract closure are included in Fig. 5.

Adverse events

Two patients experienced adverse events. One patient (case #6) had bleeding at the J-G access site 72 h following LAMS exchange for a double pigtail stent. The bleeding was endoscopically treated with epinephrine and replacement with another LAMS to tamponade the bleeding site. In that same procedure, attempts to endoscopically traverse the stent to inspect the remnant stomach resulted in slippage of the LAMS' proximal flange, which was immediately recognized and definitively endoscopically corrected. This patient was observed without need for surgery. In another patient with J-G access (case #2), attempt at an immediate ERCP resulted in similar dislodgement of the LAMS during duodenoscope advancement. This was also immediately recognized and endoscopically corrected. The patient was discharged home post procedure.

Discussion

Gastric Access Temporary for Endoscopy (GATE) appears to be a safe and effective approach to ERCP in patients with Roux-en-Y gastric bypass anatomy. Moreover, GATE allows for other endoscopic procedures of the foregut (e.g., endoscopic ultrasound, endoscopic submucosal dissection) with standard endoscopes and equipment in this patient population historically constrained by their surgically altered anatomy. In our case series, all GATE and subsequent endoscopic interventions had 100% technical success and 100% clinical success. Here, we would like to discuss a few observations based on our center's experience with GATE and differences in approach compared to other centers.

Risk of non-closure of the access site

A significant concern with the GATE procedure is the risk of non-closure of the access tract and subsequent reversal of the metabolic effects of bariatric surgery. This may not be an issue in specific clinical scenarios (e.g., end-stage cancer), but in most cases, confirmation of access site closure should be a top priority.

One factor that may heighten the risk of non-closure is creation of an access tract close to the gastric pouch staple line, the usual location for gastro-gastric fistula formation. Thus, the staple line should be avoided when possible, and a jejunal access site can be considered if the gastric pouch is otherwise not optimal.

Additionally, discussion with our surgical colleagues has suggested, that from their perspective, the blind jejunal limb

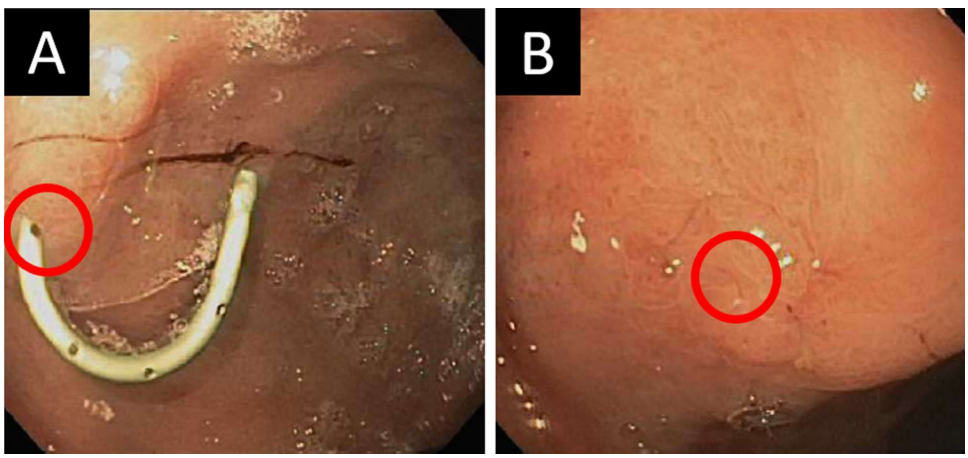

Fig. 5 Images of Access Tract Post Stent Exchange and On Follow-up EGD. **A** Plastic double pigtail stent in position at an access tract present in the gastric pouch (circled in red), and **B** showing the same location of the prior access tract having completely closed after stent removal

is the most preferable access site due to the relative ease of surgical resectability of the blind limb should a persistent fistula occur. Ultimately, more long-term data should help elucidate the fistula rates of various access sites and whether a particular access site should be prioritized if anatomically feasible.

Avoiding LAMS dislodgement

Another concern with the GATE procedure is the risk of dislodgement of the lumen-apposing metal stent during duodenoscope advancement. In our case series, we had two LAMS dislodgements. In both instances, LAMS dislodgement was immediately recognized and corrected. LAMS dislodgement is not uncommon and has occurred at rates of 18.8% (3/16) and 15.4% (2/13) in two previously published multicenter studies [8, 10]. Our rate of stent dislodgement is comparable at 20.0% (2/10). Of note, both cases occurred at a J-G access site. From our experience, J-G tracts require heightened caution during duodenoscope advancement since the proximal flange can more easily dislodge against the thinner jejunal wall, in contrast to gastric walls which are on average 3 times thicker [12].

Several strategies may be helpful to reduce risk of LAMS dislodgement. First, a thinner diagnostic duodenoscope may be used instead of a therapeutic duodenoscope. Second, a G-G access site may be more robust for immediate duodenoscope advancement. Third, if a J-G access site is used, deferment of ERCP for 2–3 weeks while the tract matures may be recommended if the clinical indication for ERCP is non-urgent. Fourth, the newer 20 mm diameter AXIOS stent with 27 mm anchoring flanges (only 15 mm AXIOS stents were used in this study) may theoretically allow more consistent safe passage of the duodenoscope immediately following LAMS placement.

Role of the plastic double pigtail stent

A unique strategy to facilitate the closure of the access tract is exchange of the LAMS with a plastic double pigtail stent once future ERCPs are no longer anticipated. There is already ample historical precedent for a "placeholder" plastic stent to aid access tract closure in the management of post-operative anastomotic leaks and direct endoscopic necrosectomy of walled-off pancreatic necrosis [13–16]. The plastic stent likely aids tract closure by rubbing against the access tract, causing irritation and granulation tissue to form around the stent while providing bi-directional drainage between the remnant stomach and gastric pouch.

At our center, we had 7 confirmed closures and 3 unconfirmed (1 lost to follow-up, and 2 declined further procedures while in hospice care). All 7 of the confirmed cases had the AXIOS stent exchanged with a plastic double pigtail stent, and interestingly for 5 of the 7 patients, a follow-up EGD or upper GI series showed the plastic stent spontaneously expelled, along with the access tract already completely closed on its own without further endoscopic interventions. Thus, for most of our patients, the plastic stent provides the further advantage of avoiding the need of suturing or over-the-scope clip for final access tract closure. These are small but encouraging numbers suggesting reliable closure using the pigtail stent exchange technique; however, larger comparison studies would be required to confirm this observation.

The plastic double pigtail stent has several advantages as a closure strategy. First, it is a relatively inexpensive endoscopic prosthesis. Second, unlike the over-the-scope clip, it is not a permanent prosthesis. Third, it is straightforward to deploy compared to the technical requirements of endoscopic suturing. Fourth, it does not require stringent surveillance for endoscopic removal, as in many instances the double pigtail stent is spontaneously expelled when tract closure is complete and safely passed through the bowels. In fact, based on our observations, it may be reasonable to obtain an upper GI series 2–4 weeks following double pigtail stent placement to assess for both stent and tract closure; if stent expulsion and tract closure are confirmed, a final endoscopy may be obviated. This modified algorithmic approach is described in Fig. 6.

Limitations

Our study has several limitations. Although all procedural data were prospectively collected, data on clinical outcomes (e.g., adverse events, confirmation of fistula closure) were retrospectively reviewed and would be dependent on the accuracy and availability of data in the electronic medical record. In addition, although there were a respectable number of GATE cases over 9 months, our cohort was objectively small in size [9, 10]. Furthermore, all procedures were performed at a single institution by two specialists at interventional endoscopy; thus, the results and outcomes from our study may not be as generalizable to other institutions as larger, multicenter studies. Lastly, we were not able to assess the procedural costs of GATE and compare them to other treatment modalities, although this is the subject of a future study.

Nomenclature

Finally, a word regarding nomenclature can be confusing. As mentioned in the introduction, this relatively new procedure has been referred to in the literature with multiple names, including EDGE, EUS-TG, and EUS-GG-ERCP. We would like to propose a new name, Gastric Access Temporary for Endoscopy or GATE, for two simple reasons.

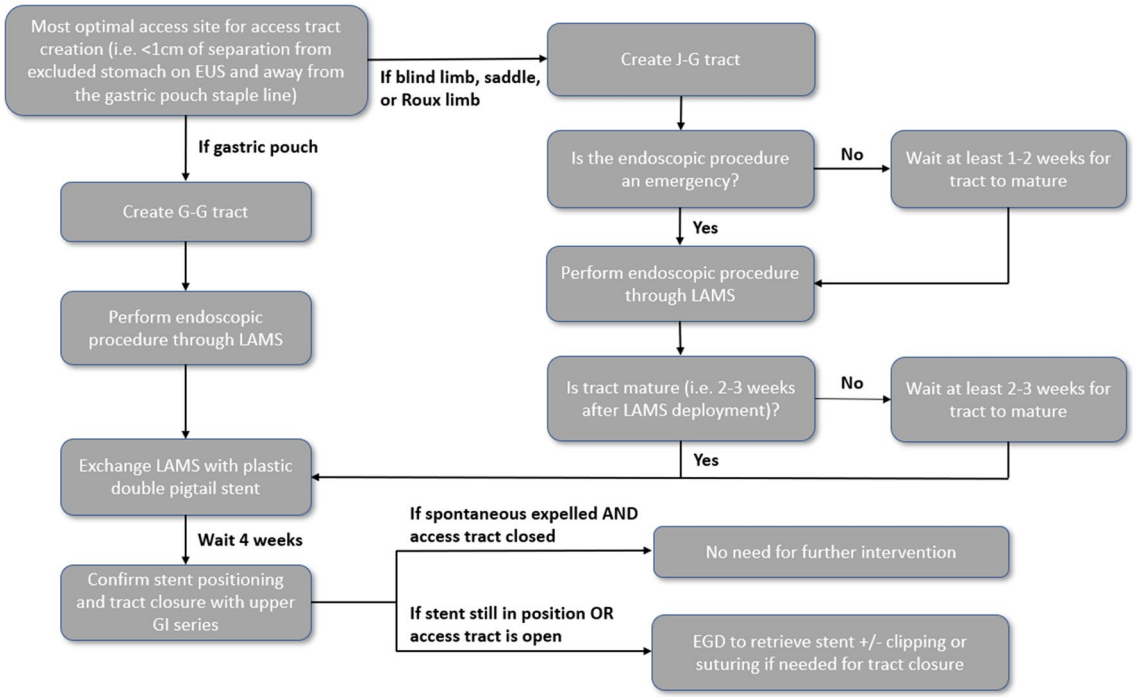

Fig. 6 Modified algorithmic approach in access site selection, ERCP timeline, LAMS exchange, and assessment of access tract closure for patients undergoing GATE

First, the technique allows more than just ERCP, including endoscopic ultrasound, endoscopic mucosal resection, and endoscopic submucosal dissection of the foregut. Second, we have anecdotally discovered it is much easier for patients to understand the procedure when it is explained that the "GATE is being opened" and the "GATE is being shut" to allow for foregut endoscopic procedures.

Conclusions

In conclusion, the GATE procedure offers an effective and safe approach to perform ERCP in patients with RYGB anatomy. Additionally, GATE allows for the use of a variety of standard scopes indicated for examination and treatment of diseases of the foregut and pancreaticobiliary tree, and a diverse range of interventions that would often be impractical or far more difficult with enteroscopic and surgical approaches, e.g., EUS biopsy of pancreatic head mass due to limited maneuverability of instruments in those settings. Moreover, the purely endoscopic approach offered by GATE obviates the often laborious task of coordinating with surgery, interventional radiology, and/or endoscopy for repeat ERCPs in cases of device-assisted enteroscopy failure. GATE-ERCP should be trialed at centers with expertise with LAMS and with close monitoring of access tract closure. Early outcomes of GATE appear promising but further studies focusing on improving the efficacy and safety profile of GATE, as well as comparative studies with other established approaches, are required.

Acknowledgements We would like to thank Dr. Matthew James Skinner for his time in editing and providing voice narration for the video that accompanied this manuscript.

Compliance with ethical standards

Disclosures Dr. Christopher C. Thompson is a consultant for Boston Scientific and Olympus America Inc. Dr. Marvin Ryou is a consultant for Medtronic, Inc. Dr. Thomas Wang has no conflict of interest or financial ties to disclose.

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