



Therapeutic endoscopic ultrasound

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Abstract: Endoscopic ultrasound (EUS) has been continuously evolving for the past three decades and has become widely used for both diagnostic and therapeutic purposes. The efficacy of therapeutic EUS (TEUS) has proven to be superior and better tolerated than conventional percutaneous or surgical techniques. TEUS has allowed the performance of multiple procedures including gallbladder, pancreatic duct and biliary drainage as well as gastrointestinal anastomoses. TEUS procedures generally require the following critical steps: needle access, guidewire placement, fistula creation and stent deployment. The indications and contraindication for TEUS procedures vary with different procedures but common contraindications include hemodynamic instability, severe coagulopathy unable to be reversed, large volume ascites or the inability to obtain access to the target site. Proficiency and high volume in endoscopic retrograde cholangiopancreatography (ERCP) and diagnostic EUS procedures are required for training in TEUS. The complexity of the cases performed can be seen as a pyramid with drainage of pancreatic fluid collections at the base, pancreaticobiliary decompression in the middle, and creation of digestive anastomosis at the top. The mastery of each level is crucial prior to reaching the next level of complexity. TEUS has been incorporated in our arsenal and is impacting on a daily basis the way we offer minimally invasive therapy.

Keywords: Gallbladder drainage; biliary drainage; pancreatic duct drainage; gastroenterostomy (GE); endoscopic ultrasound-directed transgastric endoscopic retrograde cholangiopancreatography procedure (EDGE procedure)

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Introduction

Endoscopic ultrasound (EUS) was developed in 1980 after modifying a side viewing scope by adding an ultrasound probe at the tip of the scope (1). Since then, EUS has been continuously evolving and its use has become widely available. EUS was initially used for better characterization of lesions visible during endoscopy; over time, improvements in the device have allowed not only imaging but sampling, injection, and most recently drainage and anastomosis creation of structures within and adjacent to the gastrointestinal tract (2,3). These advancements

have led to a new era of EUS known as therapeutic EUS (TEUS). TEUS procedures include drainage procedures (pancreatic fluid collections, gallbladder, pancreatic duct and biliary duct) as well as gastrointestinal anastomoses creation [gastroenterostomy (GE) and EUS-directed endoscopic retrograde cholangiopancreatography (ERCP)]. All generally require the following critical steps: access, fistula creation and stent deployment (4). The training for TEUS requires the acquisition of skills beyond those obtained during a traditional GI fellowship. There are no specific guidelines regarding the requirements to credential a trainee in TEUS. However, proficiency and high volume in ERCP and



Figure 1 Distended gallbladder targeted under ultrasonography.



Figure 2 Puncture of the gallbladder under EUS with the cautery enhanced lumen-apposing metal stent. EUS, endoscopic ultrasound.

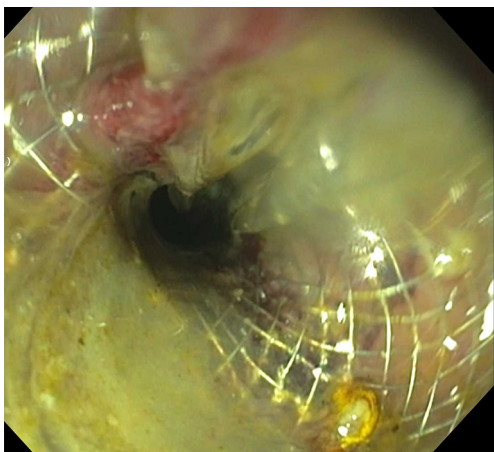


Figure 3 Deployment of the LAMS into the gallbladder. LAMS, lumen-apposing metal stent.

diagnostic EUS procedures seems to be the foundation (4-6).

EUS-guided gallbladder drainage

Acute cholecystitis is a highly prevalent pathology. The

gold standard treatment is surgical cholecystectomy (7). For non-surgical candidates, treatment requires antibiotics and early gallbladder drainage, traditionally percutaneously (PC-GBD) and more recently via transpapillary ERCP (TP-GBD), and now EUS-guided drainage (EUS-GBD) (8). The first use of EUS in the treatment of acute cholecystitis was reported by Baron in 2007 performing a cholecystoduodenostomy with a double pigtail stent (DPS) (9). Since then, different techniques have been used, including placement of a nasocystic drainage catheter or metal biliary stent. With the advent of lumen-apposing metal stents (LAMSs), the technique has been standardized and currently LAMS are widely used in EUS-GBD (10,11). LAMS allow for gallbladder drainage in addition to interventions such as stone removal, lithotripsy, magnifying endoscopy or polyp removal (4,11). Both transgastric and transduodenal approaches have been used for EUS-GBD. Usually during the transgastric approach the gallbladder is accessed at its body from the gastric antrum (*Figures 1-3*). The transduodenal approach is from the duodenal bulb to the neck of the gallbladder. There are advantages and disadvantages with each method. The transduodenal approach is theoretically easier to perform since the duodenum is less mobile than the stomach. It also carries less risk of stent migration or food reflux into the gallbladder. On the other hand, the transgastric approach gives access to the gallbladder body, which constitutes a larger entry site to the gallbladder. Additionally, future cholecystectomies are easier to be performed with the anastomosis in the stomach, since gastric fistula closure is technically less complex than duodenal fistula closure. To date, there is no evidence of one approach being superior to the other. Another unresolved controversy is the placement of DPS through the LAMS. The advantage of placing DPS is to decrease the rate of clogging by food or tissue growth as well as the possibility of keeping the fistula open in case there is LAMS migration, but it's uncertain if this practice improves outcomes (11).

Outcomes

EUS-GBD is an efficacious and safe procedure, with technical and clinical success rate of EUS-GBD ranges from 90–100% and 72–99% respectively, and adverse event (AE) rate ranging from 7–50% based on the largest series of EUS-GBD (*Table 1*). When EUS-GBD was compared to PC-GBD and TP-GBD, EUS-GBD had a technical success slightly lower than PC-GBD (94–95% *vs.* 98–99%) but

Table 1 Selected series of EUS guided gallbladder drainage

Author	Patients	Technical success, %	Clinical success, %	AEs, %
Jang 2012 (12)	30	97	97	7
Choi 2014 (13)	63	98	85	10
Irani 2017 (14)	45	97	95	17
Kahaleh 2016 (15)	35	91	89	25
Walter 2016 (16)	30	90	86	50
Dollhopf 2017 (17)	75	98	95	10
Teoh 2017 (18)	59	96	89	32
Tyberg 2018 (19)	42	95	95	21
Oh 2019 (20)	76	99	99	7
Higa 2019 (21)	40	97	95	17
Tyberg 2020 (22)	48	100	72	19
Teoh 2020 (23)	80	97	92	25

EUS, endoscopic ultrasound; AE, adverse event.

better than TP-GBD (83–88%). The clinical success for EUS-GBD (90–96%) was similar to PC-GBD (89–97%), but better than TP-GBD (80–88%). In terms of AEs, there was no difference between all groups. However, there was a need for repeated procedures after PC-GBD in up to 25% due to tube dislodgement or obstruction (19,24–26).

Although many patients never proceed to cholecystectomy after gallbladder drainage, EUS-GBD can be performed as a bridge to a definitive surgery. A paper by Saumoy *et al.* compared cholecystectomy after EUS-GBD *vs.* PC-GBD and found no differences in terms of AEs or the rate of conversion to an open procedure. Cholecystectomy after EUS-GBD had a shorter operative time compared to the group that had PC-GBD prior to surgery (24).

The learning curve for EUS-GBD is unknown, though one study suggested a learning rate of 19 cases (22).

Conclusions and future directions

EUS-GBD is an alternative to PC-GBD with comparable or, in some series, improved safety and efficacy, with the associated benefit of less pain after the procedure and less morbidity from having an external drain (22,27). The most recent Tokyo consensus has made changes to its recommendations and has included EUS-GBD as one of the options for treatment of cholecystitis in high volume centers (27).

Further randomized controlled trials comparing EUS-GBD and PC-GBD will likely illustrate the dominance of this procedure and ultimately lead to EUS-GBD as the main modality for non-surgical gallbladder drainage.

EUS-guided pancreatic duct drainage

The most common indications for pancreatic duct drainage include: chronic pancreatitis with stricture and/or pancreatolithiasis, post-Whipple procedure with suspected stenosis of the pancreatic anastomosis, prophylactic main pancreatic duct (MPD) stent prior to ampullectomy and disruption of the MPD (28). Endoscopic retrograde pancreatography (ERP) is the standard of care for the management of MPD pathology. Surgery could be used after an unsuccessful ERP or in patients with altered anatomy but it is associated with increased morbidity and mortality (29).

The first EUS pancreatography was described by Harada in 1994 (30). The first use of EUS-guided pancreatic drainage (EUS-PD) was described in 2002 by Francois, developing a pancreaticogastrostomy (31), and by Bataille, performing a pancreaticoduodenostomy with “pancreatic rendezvous” (32). The term “rendez-vous approach” was coined by Ghattas in 1992 and was described in patients with difficult cannulation of the MPD, by accessing the MPD via the minor papillae (33). In 1999 Dumonceau

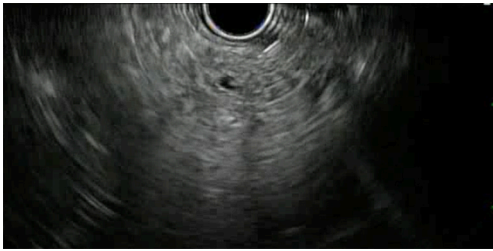


Figure 4 Puncture of the pancreatic duct under ultrasonography.



Figure 5 Contrast injection of the pancreas under EUS and fluoroscopy guidance. EUS, endoscopic ultrasound.

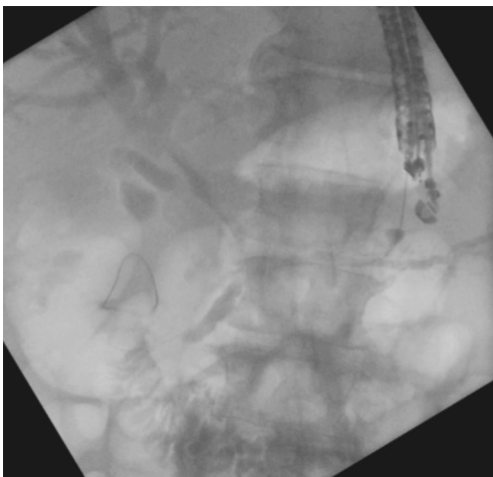


Figure 6 Antegrade advancement of the guidewire into the pancreatic duct and transpapillary.

described the “transduodenal rendezvous” where the MPD was cannulated after duodenal puncture (34). EUS-PD can be performed in different ways, the MPD can be accessed from an area that starts at the gastric cardia and extends to the third portion of the duodenum, and the site is selected based on the shortest space between the MPD and the EUS probe, and the structures in the pathway of the needle. MPD stent placement can be performed via retrograde approach also known as “rendezvous procedure”, crossing the papilla or anastomosis and then inserting a duodenoscope for conventional ERP (*Figures 4-6*), or antegrade from the gastrointestinal lumen into the MPD with or without traversing the site of obstruction. Typically, plastic stents are used, but metal stents can be used as well when the MPD is significantly dilated (28,35).

Outcomes

EUS-PD is a technically challenging procedure with a variable technical success rate ranging from 69% to 100%, clinical success from 69% to 100%, and an AE rate of 6% to 35% in the largest reported series (*Table 2*). The most common AEs include: abdominal pain, pancreatitis, pancreatic fluid collection, abscess, bleeding and perforation (28,35).

Only one study has compared EUS-PD versus enteroscopy-assisted ERP in the setting of prior pancreaticoduodenectomy. In this study, technical success was considerably higher after EUS-PD (92%) than after enteroscopy-assisted ERP (20%). AEs were more common after EUS-PD (35%) than after ERP (2%), but were all mild or moderate. AEs were more common after EUS-PD since the PD was not manipulated in most of the ERP cases (41). Stent migration has been reported to be more common with straight plastic stents compared to DPS (28).

Conclusions and future directions

With the development of EUS-PD, an effective and minimally invasive option has become available for the management of pathology of the pancreatic region. The rendezvous approach should be used as the first modality since AEs are lower with this technique. Pancreaticoduodenostomy is recommended for stenosis

Table 2 Selected series of EUS-PD

Author	Procedure	Patients	Technical success, %	Clinical success, %	AEs, %
Tessier 2007 (36)	EUS-PD A	36	91	69	13
Ergun 2011 (37)	EUS-PD A, R	20	90	72	10
Shah 2012 (38)	EUS-PD A, R	22	54	NR	18
Fujii 2013 (35)	EUS-PD A, R	43	74	NR	6
Will 2015 (39)	EUS-PD A, R	83	56	81*	21
Oh 2016 (40)	EUS-PD A	25	100	100	20
Tyberg 2017 (29)	EUS-PD A, R	80	89	81	20
Chen 2017 (41)	EUS-PD A, R	40	92	87	35
Matsunami 2018 (42)	EUS-PD A	30	100	92	23

*, Reported improvement of symptoms even when stent placement was not possible. EUS-PD, endoscopic ultrasound-guided pancreatic drainage; AE, adverse event; A, antegrade; R, retrograde; NR, not reported.

of the MPD at the level of the head, since the scope is in a more stable position, whereas pancreaticogastrostomy can be used during surgically altered anatomy, although this method is technically more difficult and associated with more complications (43). Although AEs are common with EUS-PD, the safety of the procedure is acceptable and can be implemented in properly selected patients by experienced teams (41,43).

EUS-guided biliary drainage

ERCP is the first-line procedure to provide access to the bile ducts in the vast majority of patients requiring biliary drainage, with a success rate of 93% to 95% (44). However, other options are required in those patients not amenable to conventional drainage or in whom biliary cannulation is unable to be achieved. The most common alternative is percutaneous transhepatic biliary drainage (PTBD). However, PTBD is associated with significant AEs in up to 33% of the patients (44,45). The close proximity of the bile ducts to the stomach and small intestine allows the use of EUS to delineate and access the bile ducts. Wiersema in 1996 described the use of EUS to perform cholangiopancreatography in patients with a failed ERCP, and those patients with abnormalities found during the cholangiopancreatography had an ERCP performed subsequently (3). Later on, in 2001 and 2003, Giovannini reported a palliative choledochoduodenostomy in a patient with pancreatic cancer, and a hepaticogastrostomy to relieve cholangitis in a patient with a hilar obstruction

(46,47).

The concept of insertion of a guidewire in the bile ducts to assist ERCP was initially described in 1985 by Shorvon in patients with a failed initial ERCP, using a combination of percutaneous transhepatic cholangiography with guidewire placement into the duodenum to facilitate conventional ERCP (48). Since the first descriptions of its use (46,47,49), EUS-BD has become more widespread with numerous publications about its efficacy and safety (50). However, a major innovation was the adaptation and further development of the rendezvous approach to TEUS by Kahaleh in 2004 where EUS was used to access the bile ducts for guidewire placement to facilitate conventional ERCP, decreasing the morbidity associated with the percutaneous approach (51). EUS bile drainage (EUS-BD) can be performed via an intrahepatic (*Figures 7-9*) or extrahepatic route, with stent placement transluminally (hepaticogastrostomy or choledochoduodenostomy) or transpapillary (antegrade or using a rendezvous approach assisted by conventional ERCP) (51,52).

Outcomes

The reported technical and clinical success rate of EUS-BD ranges from 90–100% and 62–100% respectively across the largest published series; AE rate ranges from 8–21% (*Table 3*) (64). Hepaticogastrostomy has been compared to choledochoduodenostomy with no difference in technical success, clinical success or AEs (65).

When comparing EUS-BD to PTBD, a meta-analysis



Figure 7 Dilated intrahepatic biliary tree targeted under ultrasonography.



Figure 8 EUS guided puncture of the dilated left hepatic duct. EUS, endoscopic ultrasound.

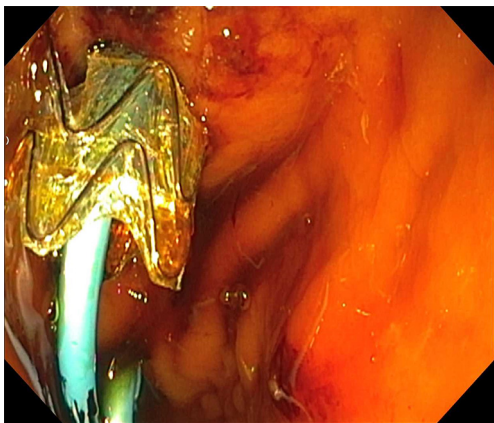


Figure 9 Transgastric deployment of a fully covered metal stent with fins realizing a hepaticogastrostomy, with a double pigtail placed within.

found that EUS-BD has superior clinical success with lower rates of reintervention. Bile leak is the most common AE reported with both techniques and is more common after PTBD (7%) than after EUS-BD (3%). Bleeding and

cholangitis are also more common after PTBD than after EUS-BD (4.3% vs. 2.7%; 5.1% vs. 0.3% respectively). The assessment of cost-effectiveness of the procedures also favors EUS-BD against PTBD (45).

A randomized trial compared EUS-BD to conventional ERCP as primary treatment in patients with biliary obstruction from pancreatic cancer, and there were no differences in terms of outcomes or related AEs between the two groups (63).

Conclusions and future directions

The available evidence favors EUS-BD over PTBD due to higher clinical success with less AEs (45). The type of EUS-BD approach, either intrahepatic or extrahepatic, remains up to the endoscopist discretion unless dictated by patient anatomy. Although currently EUS-BD is considered as an alternative only when ERCP fails, emerging studies suggest that EUS-BD could potentially be considered as the primary option for biliary drainage before conventional ERCP, given its great technical and clinical success and negated risk of pancreatitis. Currently further trials are needed.

EUS-GE

Gastric outlet obstruction (GOO) can be secondary to benign or malignant etiology and is treated with enteral stent (ES) placement or diversion of the gastric content to the jejunum by the creation of a GE, either using surgery or endoscopy. The endoscopic approach by means of ES or EUS-GE has been favored in patients who are poor surgical candidates or have very short life expectancy (66). The development of LAMS allowed lumen to lumen communication with anchorage between non-adherent structures, preventing migration of the stent as well as leakage of content outside of the communication. The covered ends of the stents also decreased tissue trauma caused by the end of regular tubular stents, resulting in the creation of durable anastomoses that previously were only able to be performed by conventional surgery (67). The first use of LAMS to perform a gastrojejunostomy was reported by Binmoeller in 2012 (68), and since then multiple techniques have been described for the performance of EUS-GE for malignant or benign GOO as well as superior mesenteric syndrome (66,69,70). The three main methods for EUS-GE follow the same principle of creating a fistula between the stomach and the small intestine upstream from the obstruction, but the difference lies in the method

Table 3 Selected series of EUS-BD

Author	Procedure	Patients	Technical success, %	Clinical success, %	AEs, %
Park 2011 (53)	EUS-BD IH, EH	57	96	85	19
Poincloux 2015 (54)	EUS-BD IH, EH	96	97	91	12
Sharaiha 2016 (55)	EUS-BD IH, EH	47	93	62	13
Sportes 2017 (56)	EUS-BD IH	31	100	86	16
Khashab 2016 (57)	EUS-BD IH, EH	121	92	83	16
Kunda 2016 (58)	EUS-BD EH	57	98	94	15
Lee 2016 (59)	EUS-BD IH, EH	34	94	87	8
Nakai 2016 (60)	EUS-BD IH	33	100	100	9
Cho 2017 (61)	EUS-BD IH, EH	54	100	94	16
Minaga 2017 (62)	EUS-BD IH	30	96	73	10
Bang 2018 (63)	EUS-BD EH	33	90	87	21

EUS-BD, endoscopic ultrasound guided biliary drainage; AE, adverse event; IH, intrahepatic; EH, extrahepatic.



Figure 10 Distended loop of bowel using saline mixed with methylene blue targeted under ultrasonography.

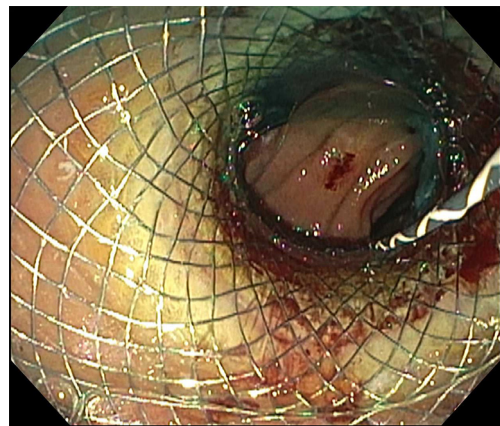


Figure 12 Dilation of the LAMS with small bowel visualization. LAMS, lumen-apposing metal stent.

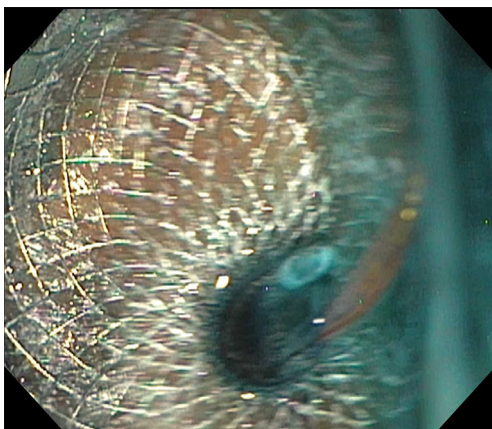


Figure 11 Deployment of the LAMS with methylene blue drainage confirming appropriate position of the gastrojejunostomy. LAMS, lumen-apposing metal stent.

of localizing the small bowel before the site is accessed from the stomach. The direct EUS-GE method offers the advantage to be performed even with complete GOO. Assisted EUS-GE and EUS-guided balloon-occluded gastrojejunostomy bypass (EPASS) require the ability to access the upstream small bowel through the obstruction but offer the advantage of performing the procedure in a distended jejunum. Infusion of methylene blue is also widely used to confirm placement after stent deployment by visualization of methylene-blue tinted fluid (*Figures 10-12*). Usually a liquid diet can be started the next day after the procedure (66,71).

Table 4 Selected series of EUS-GEs

Author	Procedure	Patients	Technical success, %	Clinical success, %	AEs, %
Itoi 2016 (74)	EPASS	20	90	90	10
Tyberg 2016 (75)	EUS-GE A, D	26	92	85	11
Khashab 2017 (76)	EUS-GE A, D, EPASS	30	86	86	16
Perez-Miranda 2017 (77)	EUS-GE A, D	25	92	82	12
Kerdsirichairat 2018 (78)	EUS-GE A, D	37	94	81	2
Chen 2018 (79)	EUS-GE A, D	74	93	91	6
Ge 2019 (73)	EUS-GE A	22	100	90	22
Widmer 2019 (80)	EUS-GE A	10	100	100	0

EUS-GE, endoscopic ultrasound-guided gastroenterostomy; AE, adverse event; EPASS, EUS-guided balloon-occluded gastrojejunostomy bypass; A, assisted technique; D, direct technique.

Outcomes

Only few comparative studies exist comparing EUS-GE against surgical GE or ES. A recent pooled analysis demonstrated that EUS-GE is slightly more difficult to perform with somewhat lower technical success (91%) than ES (97%) or surgical GE (100%). However, the clinical success of EUS-GE (88%) was similar to a surgical GE (87%) and better than the ES (73%) with less AEs (15%) than the surgical GE (30%) and ES (30%) (72). Stent occlusion requiring reintervention is less common after EUS-GE compared with ES (73). *Table 4* includes the largest series of EUS-GE.

Conclusions and future directions

EUS-GE should be considered as an alternative to surgery for patients with GOO in centers with capability of performing this procedure (71,72). Other applications of EUS-GE are also emerging. Enteroentero and enterocolonic anastomosis using EUS and LAMS have also been reported recently for the treatment of strictures or malignancy, as well as to access the small bowel limb hosting the pancreaticobiliary anastomoses in post-surgical patients requiring pancreaticobiliary intervention (81-85). The possibility of bypassing the duodenum with an EUS-GE coupled with an endoscopic gastroplasty and/or pyloric exclusion is being explored in bariatric endoscopy and in duodenal injuries in which diversion of gastric contents is required for healing (86,87).

EUS-directed transgastric ERCP

Due to the obesity epidemic, bariatric procedures have become widespread and Roux-en-Y gastric bypass (RYGB) is one of the most common bariatric procedures. Due to rapid weight loss, these patients are at increased risk of developing cholelithiasis and choledocholithiasis. However, the surgically altered anatomy represents a challenge when attempting to perform ERCP. To access the ampullary region, balloon enteroscopy ERCP (BE-ERCP) or laparoscopy-assisted ERCP (LA-ERCP) was traditionally required (88). A new procedure called EUS-directed transgastric ERCP (EDGE) was described by Kedia *et al.* in which EUS was used to create a gastrogastic fistula between the gastric pouch and the gastric remnant, providing access to the native ampulla through the LAMS (*Figures 13-15*) to facilitate conventional ERCP (89).

Outcomes

The reported technical and clinical success rates and AE rates of EDGE ranges from 92–100% and 0–21% across the largest published series (*Table 5*). The learning curve for the EDGE procedure is unknown, though one study showed a learning rate of nine cases and an estimated requirement of 25–35 procedures to achieve mastery (6). Compared to the conventional LA-ERCP or BE-ERCP, EDGE has a technical success similar to LA-ERCP (95.5% *vs.* 95.3%) and better than BE-ERCP (71.4%). The calculated clinical success for EDGE (95.9%) is better than LA-ERCP



Figure 13 Puncture of the excluded stomach under ultrasonography guidance.



Figure 14 Deployment of the distal flange of the LAMS in the excluded stomach under EUS. LAMS, lumen-apposing metal stent; EUS, endoscopic ultrasound.

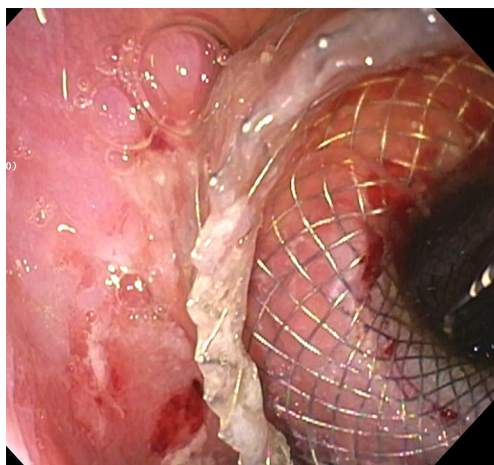


Figure 15 Deployment of the proximal flange of the LAMS in the pouch. LAMS, lumen-apposing metal stent.

Table 5 Selected series of EUS-directed transgastric ERCP

Author	Patients	Technical success, %	Clinical success, %	AEs, %
Bukhari 2018 (90)	30	100	100	6
Chiang 2018 (91)	66	92	NR	19
James 2018 (92)	19	100	100	0
Wang 2019 (93)	10	100	100	20
Tyberg 2020 (6)	19	100	94	21

EUS, endoscopic ultrasound; AE, adverse event; ERCP, endoscopic retrograde cholangiopancreatography; NR, not reported.

(92.9%) and BE-ERCP (58.7%) although the difference between EDGE and LA-ERCP was not significant. Regarding AEs, the rate of perforation is similar between the three groups but bleeding is lower in BE-ERCP when compared to LA-ERCP and EDGE. Some of the AEs are unique to the EDGE procedure including stent migration (13.3%), although the risk can be decreased by allowing maturation of the fistula and performing the ERCP during a second procedure. Another concern is the persistence of the gastrogastic fistula which can lead to weight gain, although most studies report persistent weight loss after EDGE (88). Cost effectiveness has also been evaluated between EDGE, BE-ERCP and LA-ERCP, and after taking into consideration the cost of hospitalization, AEs and subsequent procedures, EDGE represents the most cost-effective strategy in patients with surgically altered anatomy after RYGB (94).

Conclusions and future directions

Although a relatively new procedure, the EDGE procedure has been widely used and adopted at many centers. However, the vast majority of the procedures that have been published have been performed by an experienced endoscopist and the results may not be generalizable (88,94). One of the limitations of the procedure is that it is safest when done in two steps to allow for a mature fistula to decrease stent migration (95). With the availability of LAMS of larger diameter, it could be expected that

dislodgement during the initial procedure will decrease and the procedure can be performed as a single step in all cases (58).

Final conclusion

TEUS has provided groundbreaking procedures permitting safer, faster and more efficient treatment for diseases previously managed via percutaneous and/or surgical techniques. In a healthcare system constantly looking for noninvasive and cost saving interventions, TEUS has become a major player and is reshaping the way patients are being managed.

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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