Endoscopic ultrasound-guided biliary drainage and gastrointestinal anastomoses: the journey from promising innovations to standard of care

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Abstract

Biliary obstruction (BO) and gastric outlet obstruction (GOO) are frequent complications of pancreatobiliary and gastroduodenal neoplasia, which can severely impact oncological outcomes, patient survival and quality of life. Although endoscopic retrograde cholangiopancreatography (ERCP) remains the gold standard for biliary drainage, this may fail or be unfeasible because of duodenal/papillary infiltration or surgically-altered anatomy. Percutaneous transhepatic biliary drainage (PTBD) has been the standard rescue therapy in this setting, but is burdened by high morbidity and reduced quality of life. As for GOO, surgical gastroenterostomy and enteral stenting are limited by invasiveness and suboptimal long-term outcomes, respectively. Endoscopic ultrasound (EUS) has evolved from a diagnostic to a therapeutic modality, providing a safe and effective alternative for draining the pancreatobiliary tract into the stomach or duodenum. EUS-guided biliary drainage (EUS-BD) has already demonstrated similar efficacy, greater safety and fewer reinterventions compared to PTBD, and can be performed in the same session after ERCP failure. Further development of lumen apposing metal stents has paved the way towards the creation of EUS-guided anastomoses. EUS-guided gastroenterostomy (EUS-GE) is nowadays increasingly used to treat GOO, combining the minimal invasiveness of endoscopy with surgical-range efficacy. This review summarizes the technical details, current evidence and society recommendations contributing to EUS-BD and EUS-GE gaining ground in everyday practice or tertiary referral centers and becoming crucial in improving the multidisciplinary management of cancer-related symptoms.

Keywords Endoscopic ultrasound, gastric outlet obstruction, hepaticogastrostomy, choledochoduodenostomy, gastroenterostomy

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Introduction

Biliary obstruction (BO) and gastric outlet obstruction (GOO) are common events in patients affected by pancreatobiliary and gastroduodenal neoplasia, which can occur either simultaneously or sequentially [1,2]. BO leads to jaundice and may be complicated by cholangitis; GOO leads to persistent vomiting with failure to tolerate oral intake, resulting in dehydration and malnutrition. These conditions will lead to clinical deterioration, which severely impairs quality of life, and patients require adequate treatment before commencing oncological therapy.

Although endoscopic retrograde cholangiopancreatography (ERCP) is the standard treatment for BO, retrograde cannulation may fail or be impossible in up to 10% of patients [3,4]. In these cases, percutaneous transhepatic biliary drainage (PTBD) has been regarded as the "go-to" rescue technique, but it is burdened by significant morbidity and hospital stay [5-9]. For GOO, duodenal stenting has been the most widespread alternative to surgical gastroenterostomy (s-GE), owing to its minimally invasive nature, but it has been associated with clinical failure, early stent dysfunction and need for reintervention. These limitations have fueled the development of minimally-invasive alternatives aimed at effectively treating GOO-related symptoms.

During the last 20 years, endoscopic ultrasound (EUS) has evolved from a diagnostic to a therapeutic modality, providing a safe and effective alternative for accessing and draining target structures. After initial innovations in the management of peripancreatic collections, it soon became clear that EUS guidance could be used to drain the pancreatobiliary tract from the stomach or the duodenum. Further development of dedicated lumen apposing metal stents (LAMS) has improved the safety and ease-of-use of these procedures, as well as paving the way towards the development of new procedures, such as gastro-enteric anastomoses. EUS-guided gastroenterostomy (EUS-GE) has recently emerged as a valuable alternative to enteral stenting [10], facilitating the effective reestablishment of the gastrointestinal (GI) transit whilst avoiding recurrences over time [11]. Furthermore, entero-enteral anastomoses have created new possibilities for endoscopic management of other conditions, such as afferent loop syndrome after GI surgery [12,13] or ERCP in post-surgical anatomy [14].

The aim of this review was to discuss how EUS-guided biliary drainage (EUS-BD) and EUS-GE procedures can contribute to the modern management of patients with pancreatobiliary and gastroduodenal neoplasia. These newly developed procedures and indications have been transformed from promising innovations into crucial tools in everyday practice, culminating in a more well-defined place for these techniques in the recent European Society of Gastrointestinal Endoscopy (ESGE) guidelines on therapeutic EUS [15].

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EUS-BD

Surgically altered anatomy, major papilla infiltration and antroduodenal stenosis represent the most common technical reasons for ERCP failure [15-17]. In this context, PTBD has conventionally been used as rescue therapy, but is burdened by a high rate of adverse events (AEs) (e.g., tube dislodgment/occlusion) [6-8] and need for reinterventions [18,19], and a reduced quality of life due to the discomfort of the percutaneous catheter (which can be subsequently removed in a minority of patients) [9].

EUS-BD has found a role as a safe and effective alternative for performing internal drainage during the same session of a failed/impossible ERCP and is now preferred over PTBD as a rescue strategy [15]. EUS-BD encompasses various drainage strategies, differentiated based on the access level and method of stent placement. For instance, the biliary tree can be accessed directly from the stomach or the duodenum under real-time EUS guidance [15]. According to the access level, 2 major approaches can be distinguished. Intrahepatic access is defined as puncture and cannulation of the intrahepatic biliary tree, mostly through the transgastric route. This access can be used either for EUS-guided rendez-vous (EUS-RV), antegrade stenting (EUS-AS) or hepaticogastrostomy (EUS-HGS). Alternatively, extrahepatic access refers to direct access to the common bile duct (CBD), mostly from a transduodenal route, which can be used either for EUS-RV or, more frequently, for choledochoduodenostomy (EUS-CDS). In both approaches, stents can be placed across strictures and/or papilla while respecting the anatomy (EUS-RV, EUS-AS), or alternatively, connect 2 organs and create a new anastomosis (EUS-CDS, EUS-HGS). The favorable results of EUS-BD in case of failed ERCP led to EUS-BD also being investigated as a primary drainage strategy in distal malignant BO.

As for hilar malignant strictures, the approach is more controversial [20]. In the case of unresectable malignancies, since drainage of >50% of liver parenchyma reduces complications and increases survival [21], EUS-BD can help in obtaining a complete internal endoscopic drainage where ERCP has failed, as for example achieving left liver lobe drainage where ERCP achieved retrograde stenting of the right liver lobe [22]. Furthermore, a left EUS-guided access can also be used to bridge a hilar stenosis for drainage of the right liver lobe [23]. However, PTBD still remains fundamental as a primary strategy in case of preoperative drainage, as a complement to endoscopy to optimize the percentage of liver drained [24], or as a rescue strategy to reduce the complications of an attempted-but-failed

EUS-BD [9]. In referral centers involved in the management of pancreaticobiliary malignancies, a multidisciplinary discussion of patients who require complex biliary drainage is desirable to tailor treatment strategy, taking into account the underlying disease and its biology, disease stage (resectable/advanced) and anatomy (site of the obstruction).

Technical aspects

ESGE guidelines suggest that therapeutic EUS should be performed by experienced endoscopists, trained in both EUS and ERCP [14], as many of these procedures require proficiency in EUS as well as guidewire handling and cannulation, cholangiography interpretation and biliary stenting. This allows EUS-BD to be performed as a rescue strategy immediately after failed/impossible ERCP during the same session, potentially preventing therapeutic delay, reducing hospital stay and facilitating early chemotherapy resumption [25]. Moreover, this can assure a prompt management of eventual intraprocedural complications (such as stent misdeployment). As for the learning curve, procedural duration, technical failures and AEs seem to decrease after 30 cases [26,27]. Finally, endoscopists should assure the engagement and awareness of the whole hospital in the performance of these techniques, as on-site radiological or surgical back-up are crucial in the management of AEs [15,28].

Intrahepatic access

EUS-guided intrahepatic access may be considered in cases of biliary obstruction where: 1) the left hepatic ducts are dilated and retrograde drainage has failed; or 2) the extrahepatic biliary tree is not accessible (e.g., surgically altered anatomy or limited bile duct dilation preventing LAMS placement), as an alternative to PTBD [15]. Dilation of the intrahepatic ducts is a prerequisite to performing these procedures, whereas refractory ascites and cancer infiltration of the gastric wall are contraindications for this approach [15].

Under EUS guidance, from the stomach, a dilated intrahepatic left biliary duct (segment II or III) is selected. The target duct should be better dilated ≥5 mm [29] and ideally accessed through a hepatic parenchyma cushion of around 1.5-3 cm to reduce the risk of bile leak during the procedure—of course, without compromising vascular integrity.

Following bile duct puncture with a 19-G needle (Fig. 1), bile aspiration and subsequent contrast injection should be performed to confirm the correct intraductal position. After a cholangiogram has been obtained, a 0.025- or 0.035-inch guidewire is advanced towards the liver hilum and, if possible, transpapillary. In case EUS-RV is desired, creation of a gastro-hepatic fistulous tract is not required, although a cystotome can aid in advancing the guidewire across strictures. Following transpapillary guidewire manipulation, the echoendoscope can be removed, leaving the guidewire in place for traditional ERCP, with retrograde cannulation obtained alongside the antegrade guidewire or by pulling it into the working channel

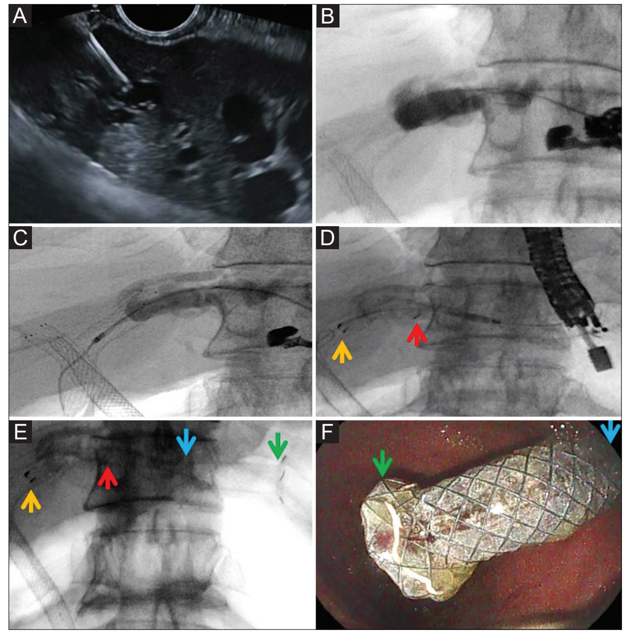

Figure 1 Endoscopic ultrasound-guided hepatico-gastrostomy. (A) Transgastric, transhepatic puncture of a dilated left biliary duct with a 19-G fine-needle aspiration needle under endoscopic ultrasound guidance in a patient with Klatskin tumor and neoplastic ingrowth of previously placed percutaneous metal stents. (B) Contrast injection showing correct biliary access and intrastent neoplastic ingrowth, followed by guidewire cannulation of the biliary duct. (C) Tract creation through a 6-Fr cystotome and guidewire redirected inside the former metal stent. (D) Initial deployment of a partially covered metal stent with the uncovered portion inside the biliary tree and the previous stent, whilst the covered portion is deployed transhepatic and transgastric: yellow arrow, extremity of the stent (uncovered portion); red arrow, transition between uncovered and covered portion of the stent. (E) Final deployment of the stent: yellow arrow, intrabiliary extremity; red arrow, transition between uncovered (endobiliary) and covered (transhepatic) portion; blue arrow, transition between the transhepatic and transgastric portion; green arrow, intragastric extremity with antimigration flange. (F) Endoscopic view of the intragastric end of the hepatico-gastrostomy stent

using a snare or forceps [28,30]. In all other cases, a fistulous tract is usually created using an over-the-wire cystotome or dilation balloon. At this stage, additional cholangiography and guidewire manipulation can be performed. According to the biliary anatomy and indication (e.g., distal vs. proximal stricture; guidewire placed transpapillary or not) the choice between EUS-AS and EUS-HGS can be made. In the former case (EUS-AS), a conventional biliary self-expandable metal stent (SEMS) is advanced over the guidewire and placed across the stricture, with or without preceding balloon dilation of the stricture [15,31,32]. Although some authors have proposed a preventive plastic stent through the fistulous tract [33], in our experience [9] no biliary leak occurs if the biliary tree has been successful drained by the antegrade stent, since the use of a 6-Fr cystotome crates a tract of sufficient size to advance a metal stent, but small enough to allow the tract to collapse, preventing bile leakage. In the latter case (EUS-HGS), dedicated SEMS are available with an uncovered portion, to be placed inside the biliary tree to prevent biliary branch obstruction, and a covered portion, to be placed across the liver parenchyma and gastric wall, with a long intragastric portion to prevent bile leakage and perforation [26,31].

Extrahepatic access

A dilated common bile duct can be easily accessed from the duodenal bulb. This route can be used either for EUS-RV, allowing performance of a standard ERCP, or for direct drainage through EUS-CDS. According to ESGE guidelines, EUS-CDS should be preferred over EUS-HGS in distal malignant biliary obstruction (dMBO), given its lower rate of AEs [15], and is nowadays often considered the primary rescue strategy after ERCP failure in dMBO, especially with regard to ease-of-use. Under EUS control, a dilated CBD is identified through the duodenal bulb and accessed in a single step through an electrocautery-enhanced LAMS (ec-LAMS), avoiding the exchange of multiple devices. Bile leakage and capnoperitoneum are prevented by the compressive properties of the bi-flanged fully-covered LAMS design. The silicone membrane also facilitates stent exchange/removal if the need should arise [34]. A CBD dilation >12 mm (ideally >15 mm) is usually required for a free-hand LAMS deployment [32]. A lower diameter CBD can be drained through over-the-wire LAMS release. In general, only small-caliber ec-LAMS (usually 6x8 or 8x8 mm) should be used in EUS-CDS [16,35,36] (Fig. 2).

Efficacy

The best available literature supporting EUS-BD is synthetized in the ESGE guidelines and technical review [15]. The most recently published meta-analysis on EUS-BD vs. PTBD after ERCP failure in malignant biliary obstruction included 6 randomized controlled trials (RCTs) and four retrospective studies (567 EUS-BD vs. 564 PTBD patients). This study suggested that EUS-BD is associated with similar technical and clinical success compared to PTBD, but with reduced AEs (10% vs. 27.3%, odds ratio [OR] 0.09, 95% confidence interval [CI] 0.02-0.38) and reinterventions (3.7% vs. 13.8%, OR 0.27, 95%CI 0.16-0.45) [36]. The estimated management costs of the 2 approaches were reported to be lower for EUS-BD when all required procedures were considered.

EUS-BD has also been investigated as a primary strategy for biliary drainage in MBO compared to ERCP. A meta-analysis of 3 small RCTs and 2 observational studies suggested that EUS-BD (including both EUS-CDS and EUS-HGS) has comparable technical and clinical success [37], but a lower rate of post-procedural acute pancreatitis, without any difference regarding the rate of reinterventions [38]. Similar results, with no differences in stent patency, reinterventions and procedural time, came from another meta-analysis [16]. These results might even be outperformed by the introduction of ec-LAMS, which have significantly simplified and disseminated the EUS-CDS procedure, and are currently being investigated for primary drainage in dMBO in ongoing RCTs [39].

A RCT of 2018 by Bang J *et al* on EUS-BD vs. ERCP as primary drainage strategy in pancreatic cancer patients, showed no interference in subsequent pancreatic surgery by the EUS-choledochoduodenostomy obtained >3 cm below the liver hilum through a 6 cm fully covered SEMS [40]. Two subsequent retrospective series extended the feasibility of pancreatic surgery after EUS-CDS, also when performed with LAMS [41,42].

As for specific techniques, the level of obstruction and local expertise are the main factors driving the choice between EUS-CDS, usually preferred in patients with distal malignant obstruction, and EUS-HGS, most often used in case of hilar obstruction or as a unique route in patients with post-surgical altered anatomy. The most recent meta-analysis comparing EUS-HGS and EUS-CDS included 13 studies (1 RCT, 3 prospective and 9 retrospective studies) for a total of 759 patients (359 EUS-CDS and 400 EUS-HGS patients) and suggested that the 2 approaches have similar technical/clinical success rates and safety, but with less stent obstruction and need for reintervention in favor of EUS-CDS (OR 0.33, 95%CI 0.15-0.70; I^2=0%). This difference, however, was not confirmed in a sub-analysis that included only fully covered SEMS, while no specific analyses regarding LAMS are available [43].

Recent data by Fugazza *et al* on EUS-CDS performed by LAMS come from a multicentric retrospective series of 256 patients, demonstrating technical and clinical success rates of 93.3% and 96.2%, respectively, with a 10.5% rate of AEs (mostly moderate) and a 9.2% rate of reinterventions [44]. Hathorn *et al* recently published the largest series of 215 patients (61% malignant disease; 43% surgically altered anatomy)

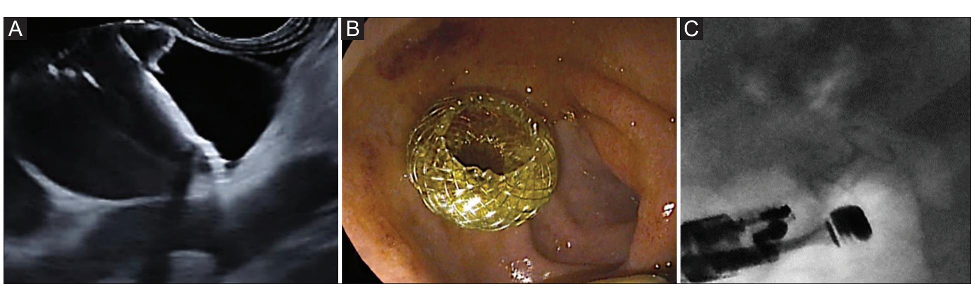

Figure 2 Endoscopic ultrasound (EUS)-guided choledochoduodenostomy. (A) The dilated common bile duct is identified through the duodenal bulb and accessed by an electrocautery-enhanced lumen-apposing metal stent (LAMS), with distal flange released under EUS guidance. (B) The proximal flange is released in the duodenal bulb. (C) Aerobilia on fluoroscopy confirms correct LAMS placement

undergoing transhepatic biliary drainage (87.4% EUS-HGS) by standard fully covered SEMS. Technical success rate was 95.3%, with a lower mean diameter of the intrahepatic duct in technical failures (3.4±1.62 vs. 5.6±1.9 mm). Clinical success among patients with available data was 87.25%. 18.6% of patients experienced AEs (mostly moderate), and amongst cancer patients surviving >6 months, 17.4% required reinterventions [45].

Safety and patency

In a meta-analysis of 756 patients comparing EUS-BD vs. ERCP for the primary management of BO, the pooled rates of AEs for EUS-BD (EUS-CDS and EUS-HGS combined) were 16% [46]. In the previously mentioned meta-analysis comparing EUS-CDS and EUS-HGS [43], the AE rates in the 2 groups were similar, with no difference in bile leakage, bleeding and perforation; however, most EUS-CDS were performed before the introduction of ec-LAMS, with all the limitations of a multistep access/drainage procedure similar to the EUS-HGS. A meta-analysis describing only EUS-CDS reported a pooled AE rate of 14%, reducing to 9.3% when only ec-LAMS were used [47].

Stent misdeployment represents the most undesirable AE during EUS-CDS, as it might lead to GI perforation with bile peritonitis or peritoneal contamination. If misdeployment occurs during EUS-HGS, attempting an over-the-wire stent-in-stent placement or puncturing the dislodged SEMS with a 19-G needle can allow for rescue treatments [28]; if misdeployment occurs during EUS-CDS, EUS-RV with retrograde SEMS placement or EUS-AS are 2 rescue options [28,48]. PTBD represents the salvage therapy when intraprocedural endoscopic rescue fails, as achieving biliary drainage is crucial to reduce the risk of bile leak and favor spontaneous closure of the created tract. Conservative treatment and clinical observation are usually sufficient in case of intraprocedural or late bleeding, especially if metal stents have been placed, securing the created tract, and rarely require interventional radiology management (e.g., arteriobiliary fistula or pseudoaneurysms).

Dissemination of EUS-BD is claiming new strategies for the management of long-term stent obstructions. A multicentric retrospective series of 110 patients, evaluating the long-term outcomes of EUS-HGS with partially covered SEMS, showed a recurrent biliary obstruction in 33% of patients after a median time of 6.3 months [49]. Long-term data on EUS-CDS performed with ec-LAMS are scanty, with a prospective multicenter study in 19 patients showing a 73.7% stent patency after a median follow-up period of 145 (12-819) days [50].

The reported rate of reinterventions following ERCP placement of SEMS, which is around 20-30% in the neoadjuvant setting and potentially higher in the palliative setting, should be taken into account when comparing outcomes [51-53]. An RCT comparing EUS-BD (EUS-CDS and EUS-HGS) with ERCP for primary treatment in MBO revealed that EUS-BD was not only associated with fewer AEs, but also with a higher rate of stent patency during follow up [54]. A recently published meta-analysis on the same topic, including 9 studies and 634 patients (216 EUS-BD and 418 ERCP patients), reported no difference in total AE rate, stent patency and stent dysfunction, but the EUS-BD group was associated with a lower reintervention rate [55]. Whereas through-the-stent balloon swipes might sometimes be sufficient to solve stent occlusions, placement of a stent-in-stent for both EUS-CDS and EUS-HGS represents the most decisive treatment solution for stent occlusion [28].

Very rarely, the EUS-CDS LAMS can spontaneously migrate, especially after the fistula has consolidated. In these cases, a new stent can be placed through the open fistula [34,56]. An interesting recent retrospective series by Ishiwatari *et al*, comparing EUS-HGS with or without additional antegrade stenting in patients with dMBO, suggested that associating antegrade stenting with EUS-HGS might prolong the time to biliary recurrence (P=0.036 on log-rank test) and independently predict a reduced recurrent biliary obstruction (hazard ratio 0.2, 95%CI 0.1-0.9); despite the non-different risk of AEs, fewer cases of peritonitis and cholangitis (but more frequent pancreatitis) were observed in the double procedure than in EUS-HGS alone [57].

EUS-guided gallbladder drainage (EUS-GBD) for biliary drainage

Apart from the promising results in the non-surgical management of acute cholecystitis [50], EUS-GBD (Fig. 3) has also been reported as a rescue strategy for biliary drainage in dMBO when ERCP and EUS-CDS are unfeasible or have failed [58-60]. However, the supporting literature is much

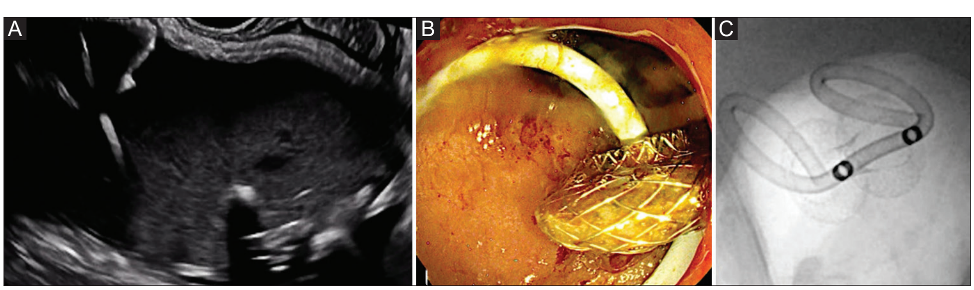

Figure 3 Endoscopic ultrasound-guided gallbladder drainage. (A) Endosonographic appearance of a hydropic gallbladder, with thickened walls and full of sludge, with release of the distal flange of a lumen-apposing metal stent (LAMS). (B) Proximal flange of the LAMS released in the bulb with coaxial double-pigtail stent (DPS). (C) Fluoroscopic view of LAMS and coaxial DPS

scantier than for "standard" EUS-BD procedures. For this technique, the cystic duct must be patent and the level of BO distal to the cystic duct origin [28,61]. The best evidence supporting the role of EUS-GBD in this setting originates from a multicenter retrospective study on 28 patients which reported technical and clinical success rates of 100% and 93%, respectively [60]. Data on this technique are however still limited and future research should provide insight on factors influencing (long-term) clinical success.

EUS-guided anastomoses

Electrocautery-enhanced LAMS have facilitated the juxtaposition of organs/cavities of the GI tract to create a side-to-side fistula, which turns into a stable anastomosis over time. Most data originate from patients with GOO. Pancreatic and gastric cancer represent the most frequent causes of malignant GOO in western and eastern countries, respectively. Subsequent nausea and vomiting may lead to malnutrition and dehydration, impairing quality of life and delaying or impeding oncological therapy. The historical palliative treatment of this condition has been s-GE [62]. Enteral stenting with SEMS used to be the only minimally-invasive alternative to s-GE, characterized by low AE rates, a shorter time to oral intake and a shorter hospital stay, at the expense of a significantly higher rate of symptom recurrence requiring unplanned reinterventions [10,63,64]. EUS-GE is increasingly used in this setting, as it shares the advantages of the 2 alternatives, while reducing their side-effects. By connecting the small bowel with the gastric lumen, it creates a large (usually 20 mm) communication between the stomach and the jejunum, without the invasiveness of a surgical intervention and with a lower risk of stent dysfunction during follow up. Other new possibilities introduced by EUS-guided anastomoses are the management of afferent loop syndrome and biliary drainage in surgically altered anatomy.

Technical aspects

Despite hundreds of published cases, entero-enteral anastomoses are still off-label indications for ec-LAMS, and should ideally be performed in clinical studies. According to ESGE guidelines, these procedures should be performed by experienced endoscopists capable of recognizing and endoscopically solving procedure-related AEs [15]. A recent retrospective analysis showed that about 25 EUS-GE procedures are needed to achieve proficiency and 40 to achieve mastery [65]. Preliminary revision of radiological imaging is fundamental to evaluate clinical and anatomical variables (e.g., cancer resectability) and to exclude eventual contraindications to the procedure (e.g., significant ascites, diffuse malignant infiltration of the gastric wall or extensive peritoneal carcinomatosis) [15]. Whereas mild ascites should not be regarded as a strict contraindication for EUS-GE, it might raise the suspicion of an undetected peritoneal disease potentially causing an undetected obstruction downstream from the EUS-GE, and a longer course of prophylactic broad-spectrum antibiotics may be required [66]. Furthermore, ascites and extensive peritoneal carcinomatosis might be undesirable in cases where surgical backup is required in case of stent misdeployment. All these aspects suggest that multidisciplinary discussion should be considered before proceeding with EUS-GE.

Patients scheduled for EUS-GE should follow a clear-liquid diet for few days before and total fasting in the 24 h before the procedure, or placement of a nasogastric tube to minimize the gastric residue and risk of aspiration pneumonia. All patients should receive large-spectrum prophylactic antibiotic therapy and adequate anesthesiology should be considered. Fluoroscopy, carbon dioxide insufflation, and adequate preprocedural measures to prevent aspiration (clearing gastric contents by means of nasogastric tube and/or tracheal intubation) are required to perform the procedure safely [28].

EUS-GE

EUS-GE consists of a minimally-invasive endoscopic creation of a surgical-like anastomosis. The design of LAMS has made this procedure possible through the following characteristics: 1) electrocautery-enhanced penetration of the 2 walls allows single-step access and stabilization of the fistula, without accessory exchange; 2) the dumb-bell shape of the LAMS reduces the risk of migration; 3) the high radial force and progressive dilation of the stent facilitates compression of the 2 walls, gradually fusing them into a stable anastomosis; and 4) the silicon covering of the stent avoids leakage [67].

Optimizing the trajectory towards the target jejunal loop represent the most challenging part of the procedure, with 3 main techniques reported: the direct, the wireless endoscopic simplified (WEST) and the assisted technique [28]. According to the direct technique, the target jejunal loop is identified under EUS guidance, and a transgastric puncture is performed by a 19-G FNA needle. The targeted jejunal loop is therefore filled with saline and the ec-LAMS is advanced into the jejunal loop, with or without the use of a guidewire. Finally, the distal flange of the stent is deployed under EUS guidance and the proximal one under EUS/endoscopic view, as usually performed in procedures involving LAMS [16].

The wireless EUS-GE simplified technique (WEST, Fig. 4) involves placement of an orojejunal catheter across the luminal stenosis under fluoroscopy guidance, to facilitate a controlled and continuous distention of the jejunum using saline instillation, with or without dye (e.g., indigo carmine). Identification of the distended jejunal loop is therefore simplified by the endosonographic recognition of both the catheter and the fluid flow. Thereby, the ec-LAMS is advanced into the targeted jejunal loop using a "freehand technique" under EUS control. Following ec-LAMS release, correct positioning can be confirmed by direct visualization of the enteral mucosa, by contrast injection and/or aspiration of blue dye [11,68].

In the device-assisted technique, a double balloon device or dilation balloon is advanced into the jejunum over a guidewire

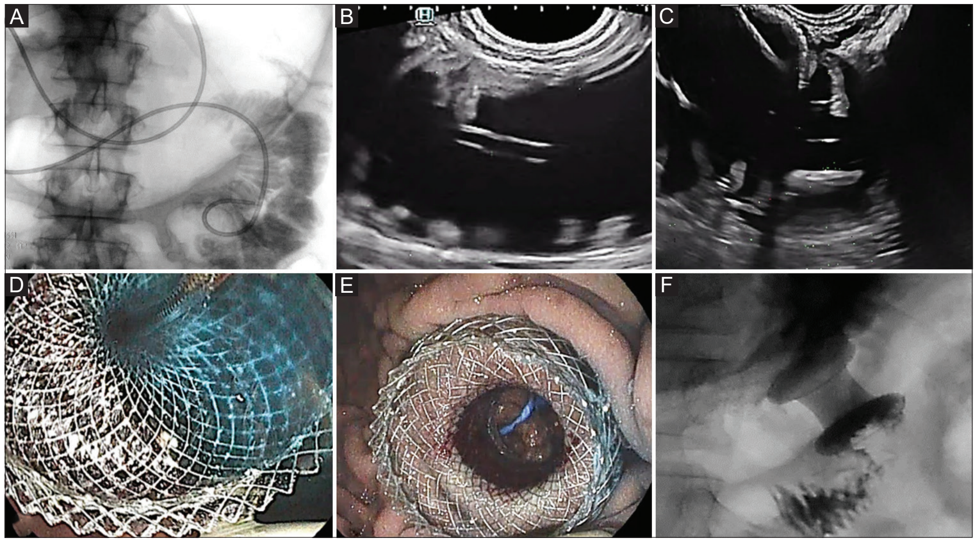

Figure 4 Endoscopic ultrasound (EUS)-guided gastroenterostomy with the wireless endoscopic simplified technique (WEST). (A) Endoscopic placement of an orojejunal tube bypassing the stenosis for controlled injection of saline, with or without contrast dye (e.g., indigo carmine). (B) EUS-guided identification of a dilated jejunal loop containing the orojejunal tube. (C) Freehand release of the distal flange of an electrocautery-enhanced lumen-apposing metal stent (LAMS) inside the jejunum. (D) Release of the proximal flange of the LAMS with blue-dyed liquid aspirated into the stomach through the LAMS. (E) LAMS after pneumatic dilation, with jejunal mucosa and the orojejunal tube visible through the stent. (F) contrast injection through the orojejunal tube can be aspirated into the stomach through the LAMS without leakage

previously inserted across the stenosis. The fluid filled balloon or the occluded jejunal loop is therefore punctured with a 19-G needle and the procedure carried out as in the direct technique [69]. Although there is a lack of high quality prospective comparative data, technical success seems to be similar between the different techniques [70,71].

EUS-directed transenteric/transgastric ERCP (EDEE/EDGE)

Roux-en-Y gastric bypass (RYGB) nowadays represents the most frequently performed bariatric surgery [72]. A significantly proportion (about one third) of post-bariatric patients develop gallstones due to the increased lithogenicity following weight loss [73]. While food follows a route passing by the gastric pouch and the gastrojejunal anastomosis, the papillary region remains only accessible through the excluded stomach, thus making performance of standard ERCP impossible when needed. Different surgical or endoscopic techniques have been developed to overcome this situation, such as laparoscopy-assisted ERCP (LA-ERCP) and enteroscopy-assisted ERCP (EA-ERCP), but these suffer from high invasiveness or a low rate of technical success, respectively [74]. However, intraoperative exploration of the bile duct (or eventually LA-ERCP) might represent the most reasonable option in patients with a gallbladder in place, as those patients already have an indication for cholecystectomy. More recently, EDGE has been developed, connecting the gastric pouch and the excluded stomach to restore the access to the papilla by a standard duodenoscope [75], potentially overcoming the invasiveness of LA-ERCP and the technical limitations of EA-ERCP [15,74]. From the gastric pouch, the excluded stomach is identified under EUS guidance using the "sand dollar" sign [76], punctured using a 19-G needle and then filled with saline. An ec-LAMS is then released between the excluded stomach and the gastric pouch, creating a gastro-gastrostomy [77]. Depending on the clinical context, it is better to postpone through-the-LAMS ERCP until at least 7 days after LAMS placement whenever possible [16], to allow for fistula maturation. Both postponing ERCP and using 20-mm LAMS have been associated with better safety related to the prevention of LAMS migration. When reinterventions are no longer deemed necessary, the ec-LAMS should be removed and closure of the fistula can be considered. Regarding fistula closure, various techniques have been described, such as a watch-and-wait-approach and immediate closure with argon plasma coagulation and/or over-the-scope clip placement [78]. No significant weight gain has usually been reported following EDGE.

In patients with surgically altered anatomy other than RYGB, requiring pancreatobiliary interventions, EUS-HGS might represent a solution, especially in case of malignancy. Non-dilated intrahepatic bile ducts, total gastrectomy, liver resection and/or transplantation, represent some technical limitations for EUS-HGS [79]. EDEE represents another alternative. This technique consists of the creation of a gastro-enteric or an entero-enteric anastomosis between the proximal GI tract and the "biliary" loop in which the papilla or the biliodigestive anastomosis is located. Similar to EDGE, ERCP can be performed thereafter through the LAMS, usually using a forward-viewing endoscope. However, randomized controlled studies comparing EDEE to LA-ERCP and EA-ERCP are needed to define the best strategy for biliary interventions in surgically altered anatomy, as nowadays most choices are driven by local expertise and preference.

Efficacy

Open or laparoscopic s-GE has been the historical treatment for GOO and still has a role, as it grants long-term resolution of symptoms at the cost of high invasiveness [80]. Since their introduction, enteral SEMS, compared to s-GE, showed faster oral intake resumption, shorter hospital stay, and fewer AEs. For this reason, international consensus indicates enteral SEMS placement in patients with short life expectancy [81,82]. On the other hand, these procedures have been associated with a higher symptom recurrence and reintervention rate [83].

In the last decade, EUS-GE has emerged as a valuable alternative, combining the advantages of the previous techniques, since it creates a wide surgical-like gastro-enteral anastomosis in a minimally-invasive procedure, at a distance from the tumor, reducing the risk of recurrence [84].

Available evidence is mostly based on retrospective series that have been included in different meta-analyses, reporting technical and clinical success ranging from 91-94% and 88-90%, respectively [70,71,85,86].

One of the latest meta-analyses, by Boghossian *et al*, included 7 studies for a total of 513 patients, and provided comparative data of EUS-GE vs. enteral SEMS and s-GE (88 EUS-GE, 182 enteral SEMS and 142 s-GE patients). EUS-GE, compared to enteral SEMS, was associated with higher clinical success and fewer severe AEs, less stent obstruction and a lower reintervention rate. Compared to s-GE, EUS-GE was associated with less technical success, but a significantly shorter hospital stay, and no differences in all other outcomes [87].

The main limitation of these comparative data is that they came from retrospective case-control studies with poor control of baseline confounders. In an attempt to reduce this selection bias, our group recently published 2 multicentric, propensity score-matched comparisons, controlling for baseline demographic and oncological characteristics. When EUS-GE was compared to s-GE, the former showed similar technical and clinical success, but a shorter time to oral intake, a shorter hospital stay, and a lower rate of AEs (overall and severe) compared to laparoscopic GE [11,13]. When EUS-GE was compared to enteral SEMS placement, it showed better primary clinical success, less stent dysfunction and need for reintervention during follow up, with similar safety [88].

There is lack of evidence on the role of EUS-GE in the bridge-to-surgery scenario. We recently published a case of a double EUS-guided bypass (EUS-GE + EUS-CDS) undergoing 8 months of symptom-free neoadjuvant chemotherapy, and subsequently undergoing uncomplicated pancreaticoduodenectomy [84].

EUS-GE has also been investigated for refractory benign GOO treatment in patients unfit for surgery [89,90]. The most representative series reported a technical success of 95.4% and an overall surgical sparing in 83% of cases, whereas surgery (when necessary) was performed after a mean of 270 days, allowing for re-establishment of nutritional status [89].

EUS-GE has also been evaluated in the setting of afferent loop syndrome, defined by "biliary" limb obstruction in patients following major GI surgery (e.g., pancreaticoduodenectomy, Roux-en-Y hepaticojejunostomy or Billroth II gastrectomy). Clinical symptoms include jaundice, abdominal pain, cholangitis and/or even pancreatitis. The possibility of draining the excluded limb into the stomach (or jejunum) using EUS-GE represents an effective minimally invasive approach to this post-surgical entity, leading to swift symptom resolution in the majority of cases. A retrospective multicenter series of 18 cases showed technical and clinical success rates of 100% and 89%, respectively [13]. Interestingly, EUS-HGS has also been described as an effective rescue procedure in this setting [12]. A description of evidence from EUS-directed ERCP data can be found in the recently published ESGE guidelines, but is outside the scope of this paper [15].

Safety

EUS-GE remains a technically demanding procedure. Available evidence shows procedure-related AEs in 11-12% of patients. Most of these are mild-to-moderate, with a low rate of severe/fatal complications (<5%) [70,71,85,86]. Stent misdeployment represents the most undesirable intraprocedural event, as it might lead to perforation or peritoneal contamination; other AEs might be bleeding (intraluminal, intramural or intraperitoneal) and anesthesia-related (e.g., aspiration pneumonia). A large multicentric retrospective series of 467 procedures has provided a classification of EUS-GE-related misdeployment according to the position of the 2 flanges [91], reporting an overall misdeployment rate of 9.4%, with type I (distal flange in the peritoneum and proximal flange in the stomach without jejunotomy) as the most common type of misdeployment. In most cases, however, misdeployment can be successfully treated with LAMS extraction, immediate repeat EUS-GE and, if required, clip closure [91].

There is a lack of evidence regarding long-term follow up after EUS-GE. Eventual LAMS obstruction by food, migration or tissue ingrowth or overgrowth can be endoscopically managed by debris removal, stent replacement or stent-in-stent placement [28].

Concluding remarks

In the last 2 decades, the role of EUS in the management of GI and pancreaticobiliary neoplasia has evolved from a purely diagnostic modality into a valuable therapeutic tool. In the era of precision medicine, this is particularly relevant, because new oncological multimodal therapies have improved the survival of patients with GI neoplasia, yet depend on effective treatment of cancer-related symptoms. In this light, BO and GOO deserve a multidisciplinary management, offering state-of-the-art solutions with reduced invasiveness, whilst maximizing long-term effectiveness. Therapeutic EUS has offered new possibilities, with growing evidence embedding these procedures in clinical management algorithms. What is clear is that volume and expertise, as demonstrated for surgery, have a relevant role in providing better outcomes for patients, and multidisciplinary discussion in referral centers can improve clinical management [92]. While dedicated training programs and guidelines are standardizing these procedures, networking and referral pathways should be settled to provide the best clinical solution, as well as to allow these patients to enter large prospective high-quality trials, providing much-needed confirmation of these promising results.

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