Digestive Endoscopy

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REVIEW

Accessing the Pancreatobiliary System via Lumen-Apposing Metal Stents: A State-of-the-Art Review of Endoscopic Ultrasound-Directed Interventions

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ABSTRACT

The growing number of bariatric and oncologic gastrointestinal and hepatopancreatobiliary surgeries has fueled the increased need for biliary interventions in patients with surgically altered anatomy (SAA), where standard endoscopic retrograde cholangiopancreatography (ERCP) is often unfeasible. Traditional alternative methods, such as enteroscopy- or laparoscopy-assisted ERCP, are associated with technical and logistical limitations. Endoscopic ultrasound (EUS)-directed ERCP uses lumen-apposing metal stents (LAMS) to create temporary anastomoses between adjacent lumens, thus restoring access for standard ERCP. These procedures include EUS-directed transgastric (EDGE), transenteric (EDEE), transduodenal (EDDE), and transcholedochal/transcystic (EDCE) ERCP. This review provides an evidence-based analysis of the available techniques and comparative outcomes, with a particular focus on technical and strategic aspects including: (1) how to create an EUS-guided anastomosis across different surgical scenarios; (2) how to perform a through-the-LAMS ERCP, including endoscope and accessory selection, ERCP timing and LAMS fixation; and (3) how to manage the fistula after completion of therapy, including timing of LAMS removal and fistula closure. An algorithm is proposed to guide the endoscopist through the complex decision-making inherent to pancreatobiliary interventions in SAA.

1 | Introduction

Pancreatobiliary endoscopy in surgically altered anatomy (SAA) is an increasingly common challenge, driven by the broader use of bariatric procedures and surgery for biliopancreatic and gastrointestinal malignancies [1–4]. In such patients, biliary obstruction may develop as a direct consequence of anatomical modifications (e.g., the increased risk for gallstones associated with total gastrectomy, vagotomy, and rapid weight loss following bariatric surgery [5, 6]), recurrent oncological diseases, or post-surgical complications (such as benign anastomotic strictures) [7]. However, SAA creates anatomic barriers that make

TABLE 1 | Overview of surgically altered anatomies with a didactic classification relevant to ERCP feasibility.

Type	Description	Examples	ERCP feasibility/technical notes
Type 1—Anatomies with Gastroduodenal continuity	Anatomies in which the native gastroduodenal route is preserved.	• Sleeve gastrectomy • Billroth I gastroduodenostomy	Access to the ampulla of Vater is usually straightforward with standard side-viewing duodenoscopes.
Type 2—Anatomies with disconnected duodenum or excluded stomach	Duodenum not reachable via natural Gastroduodenal route due to gastric exclusion or resection.		Feasibility depends on distance and angulation between access point and biliary tract.
Type 2a—Reconstructions with short or intermediate biliary limb length	Distance from access to biliary district may allow ERCP with conventional duodenoscopes or forward-viewing endoscopes. Cannulation success depends on endoscopist experience and patient anatomy.	• Billroth II gastrojejunostomy	ERCP feasible, with specific technical considerations (see Section 4.2).
		• Pancreatoduodenectomy—HJ usually within ~60 cm (often shorter) of gastro/duodeno-jejunostomy.	Moderate distance allows forward-viewing scope access; lack of elevator may hinder cannulation. Water immersion intubation, pediatric colonoscopes, and cap-assisted techniques can improve success.
Type 2b—Reconstructions with long biliary limb length	Long jejunal limb between access route and papilla/HJ.	• Roux-en-Y Gastric Bypass (RYGB)—native ampulla of Vater • Roux-en-Y Gastrectomy—native ampulla of Vater • Roux-en-Y Hepaticojejunostomy (RY-HJ) • Other variations	Standard ERCP generally not feasible. PTBD has been standard, but with notable morbidity and discomfort. Alternative options include LA-ERCP, EA-ERCP, EUS-BD (including antegrade interventions) or EUS-directed ERCP.

Note: Elton et al. [4], Spadaccini et al. [8], Fugazza et al. [9], Mauro et al. [10]. Color shading are used to represent the degree of endoscopic reach complexity, with green indicating low complexity, yellow moderate complexity, and red high complexity.
Abbreviations: EA-ERCP, Enteroscopy-Assisted ERCP; EUS-BD, EUS-guided Biliary Drainage; HJ, hepaticoJejunostomy; LA-ERCP, laparoscopy-assisted ERCP.

conventional endoscopic retrograde cholangiopancreatography (ERCP) difficult or impossible. Understanding anatomical changes is essential to select the most appropriate drainage strategy. Table 1 and Figure 1 provide a didactic classification relevant to ERCP feasibility.

2 | Limitations of Standard Endoscopic Alternatives in SAA

Traditional endoscopic alternatives include enteroscopy-assisted ERCP (EA-ERCP) or laparoscopy-assisted ERCP (LA-ERCP).

Enteroscopes enable access to the pancreatobiliary tract via the gastrointestinal route thanks to their extended length and adjunctive tools such as overtubes or anchoring balloons. However, the estimated overall technical and clinical success rate of 77% (69%–83%) and 64% (56%–71%), respectively [11], is affected by several factors. The length of the intestinal loops impacts procedural outcomes (e.g., the limbs in Roux-en-Y Gastric Bypass [RY-GB] are generally longer than in RY-Hepaticojejunostomy [RY-HJ] or pancreatoduodenectomy). Moreover, the forward-viewing configuration and absence of an elevator restrict precision in cannulation and device control, especially in native papillae compared to biliary-enteric anastomoses. As a result, EA-ERCP is more effective in pancreatoduodenectomy with HJ, and less so in RYGB with native papillae [12–15].

Related to enteroscopes' design, their smaller working channels (typically 2.8, compared to 4.2 mm of duodenoscopes) restrict the use of standard ERCP accessories (Table 2) and some therapeutic options such as self-expanding metal stent (SEMS) placement or lithotripsy. Additionally, the extended scope length also reduces accessory compatibility and impairs torque, stability, and device pushability. Newer shorter enteroscopes (e.g., the EI-580BT [Fujifilm, Tokyo, Japan]) offer improved performance with a 3.2 mm working channel, accommodating up to 8.5Fr devices or 7Fr when two

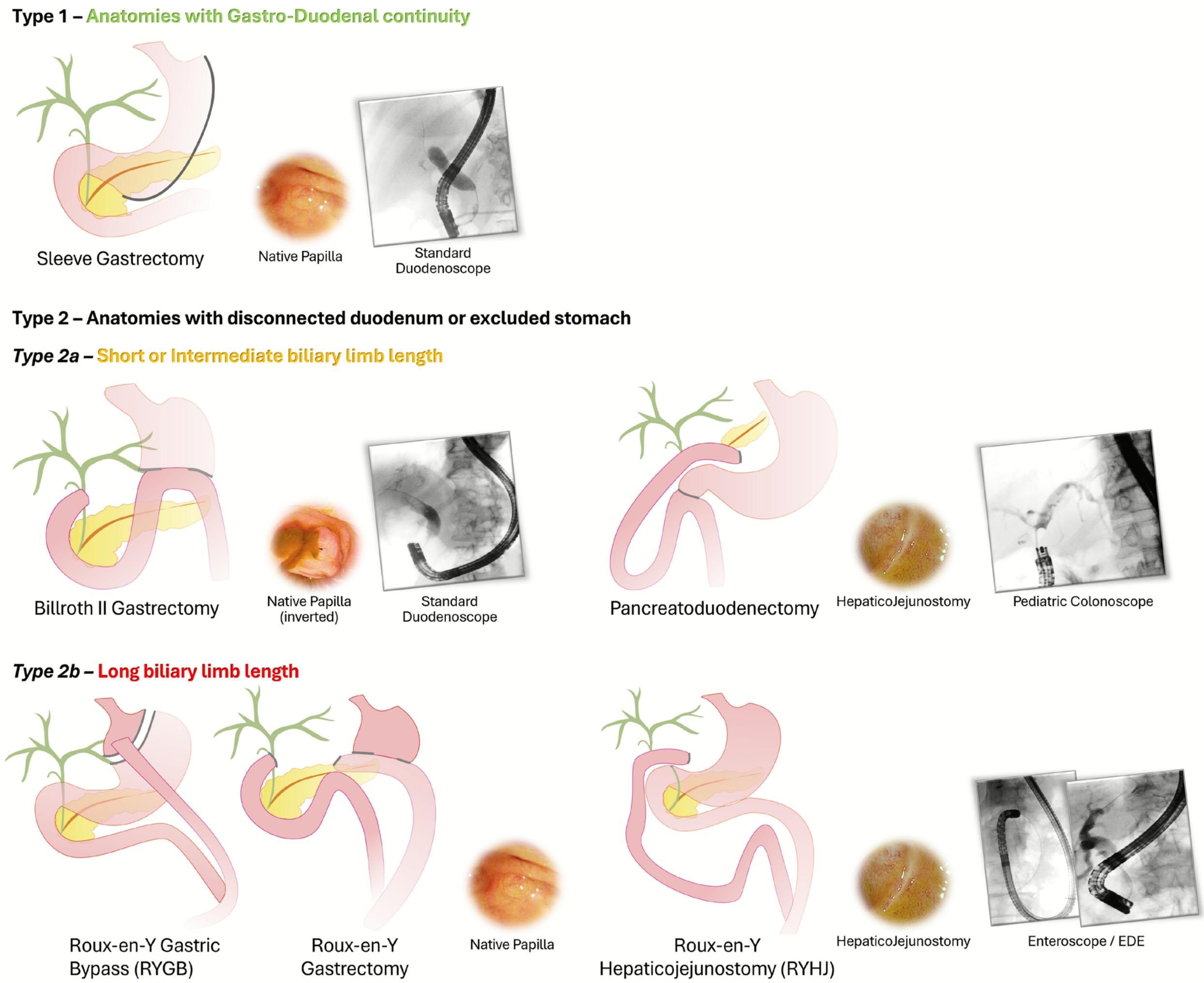

FIGURE 1 | Post-surgical anatomies. Overview of Surgically Altered Anatomies with a didactic classification relevant to ERCP feasibility. Type 1: Anatomies with Gastroduodenal continuity, in which the native gastroduodenal route is preserved (e.g., Sleeve gastrectomy). ERCP is usually straightforward with standard duodenoscopes. Type 2: Anatomies with disconnected duodenum or excluded stomach, can be divided into: (2a) Reconstructions with short or intermediate biliary limb length. On the left, Billroth II Gastrectomy: Distance from access to native ampulla usually allows conventional ERCP; on the right, Pancreatoduodenectomy: The Hepaticojejunostomy (HJ) is usually within 60 cm from the stomach: Moderate distance allows forward-viewing scope access, such as pediatric colonoscopes, with some technical specifications. (2b) Reconstructions with long biliary limb length, such as Roux-en-Y Gastric Bypass (RYGB), Roux-en-Y Gastrectomy, or Roux-en-Y Hepaticojejunostomy, where standard ERCP is generally not feasible, and endoscopic alternatives usually include enteroscopy-assisted or EUS-directed ERCP.

0.25″ guidewires are placed [16]. It should be noted that these limitations reflect the current landscape of device availability, which may differ across regions and institutions and is also continuously evolving, with new technologies, such as smaller-caliber cholangiopancreatoscopes and slimmer stent delivery systems, increasingly becoming available.

Although perforations have been described, especially in patients with adhesions or angulated limbs, EA-ERCP is overall safe [15, 17]. However, the procedure might be time-consuming. Moreover, the path taken to reach the treatment site cannot be maintained or reused; thus, any need for endoscopic reintervention requires repeating the entire procedure.

Conversely, Laparoscopy-assisted ERCP (LA-ERCP) allows use of standard duodenoscopes and accessories by surgical creation of a temporary entry point (gastrostomy or enterostomy). However, the final position of the duodenoscope is more unstable; furthermore, this approach is resource-intensive, requiring coordination between surgical and endoscopic teams, with potential increases in costs, procedural time, and perioperative risk [18–20].

3 | EUS-Directed Interventions: Evidence and Techniques

The above-mentioned limitations have paved the way for Endoscopic Ultrasound-guided Biliary Drainage (EUS-BD) [10, 21–23].

EUS-BD includes:

TABLE 2 | Overview of ERCP accessories and related minimum endoscope operative channel size required for their use.

Accessory	Function	Minimum Operative Channel Size (mm)
Single-Lumen Cannula	Cannulation	2.8
Needle Knife	Pre-cut Access	2.8 – 3.2
Plastic Biliary Stent (7 Fr)	Drainage, Stricture Management	2.8 – 3.2
Cytology Brush	Sampling for Biliary Strictures	2.8 – 4.2
Double-lumen Sphincterotome	Cannulation, Sphincterotomy	2.8 – 3.2
Extraction Balloon	Stone Extraction	2.8 – 3.2
Dormia Basket	Stone Extraction	3.2
Plastic Biliary Stent (8.5 Fr)	Drainage, Stricture Management	3.2
Dilating Balloon (6–12 mm)	Stricture Dilatation, Sphincteroplasty	3.2
Large Dilating Balloon (>12 mm)	Stricture Dilatation, Sphincteroplasty	3.7
Plastic Biliary Stent (10 Fr)	Drainage, Stricture Management	3.7 – 4.2
SEMS (Self-Expandable Metal Stent)	Malignant Strictures, Long-term Patency	3.2 - 3.7
* SEMS with a 6Fr delivery system		2.8
Lumen Apposing Metal Stents	Drainage, Stricture Management	3.7
Standard Cholangioscopes	Direct Visualization, Biopsy and Lithotripsy	4.2
* Smaller cholangioscopes (≈ 9 Fr)		3.2
Stone Extraction Lithotripter	Fragmentation of Large Stones	4.2

Note: The requirement for the minimum endoscope operative channel size was graded in a semiquantitative manner, with colors from green (devices requiring smaller channels) to red (devices that can only be advanced through a duodenoscope or echoendoscope). A black line indicates the threshold beyond which devices can be used with short large-channel enteroscopes. The models and specifications listed represent the most commonly available and widely used devices at the time of writing. They do not encompass all commercially available variants, as specific models may differ across regions and institutions. The endoscopic device market is rapidly evolving, and new technologies (*), such as smaller-caliber cholangioscopes and slimmer stent delivery systems, are increasingly becoming available.

1. Direct transmural drainage, such as EUS-guided Choledochoduodenostomy or Hepaticogastrostomy (HGS), mostly reserved for malignant biliary obstruction [24, 25].
2. Antegrade transhepatic interventions [26–28]: in this scenario, an EUS-HGS created with removable SEMS or plastic stents is used for antegrade interventions such as stone clearance or cholangioscopy-guided therapy. Despite the absence of comparative evidence, these approaches may overcome some of the discomfort and morbidity issues associated with percutaneous transhepatic biliary drainage (PTBD); yet, they do not overcome its therapeutic limitations, since stent exchange and stone extraction remain technically more challenging in the antegrade direction compared to ERCP.
3. The possibility to create EUS-guided anastomoses [29, 30] with Lumen-Apposing Metal Stents (LAMS), to shorten the path to the pancreatobiliary district, known as EUS-directed ERCP (EDE; Figure 2, Table 3), which is the focus of this review. These shortcuts allow advancement of standard scopes for ERCP through the LAMS, with the advantage of maintaining the same access for repeated procedures. LAMS > 15 mm (typically 20 mm) are deployed through a therapeutic linear echoendoscope; eventual subsequent exchange can be performed through a therapeutic gastroscope (working channel ≥ 3.7 mm).

3.1 | EDGE: EUS-Directed Transgastric ERCP (For RYGB Anatomy)

RYGB (Figure 1) is the second most common bariatric surgery procedure: [31] the stomach is divided to create a small gastric pouch connected directly to the jejunum, bypassing and excluding the larger gastric remnant, duodenum, and proximal small bowel; the EDGE procedure (Figure 2) reverses this surgical bypass by creating a temporary fistula between the gastric pouch and the excluded stomach, allowing for conventional ERCP. Pancreatobiliary interventions in this scenario are mostly related to choledocholithiasis in patients with a native ampulla of Vater (Table 3). However, the same route can be used for any diagnostic and therapeutic maneuver on the gastric remnant or duodenum (e.g., EUS with/without FNA, EUS-guided gallbladder drainage, and resection of gastric or duodenal adenoma).

3.1.1 | Techniques

The echoendoscope is placed into the gastric pouch or, if needed, in the post-anastomotic jejunum to identify the excluded stomach: the “sand-dollar sign” [32] refers to a characteristic endosonographic appearance in which the rugal folds radiate outward from a central point (Figure 3a). The distance between the gastric pouch and the excluded stomach should ideally be < 10 mm. The remnant is then punctured using a

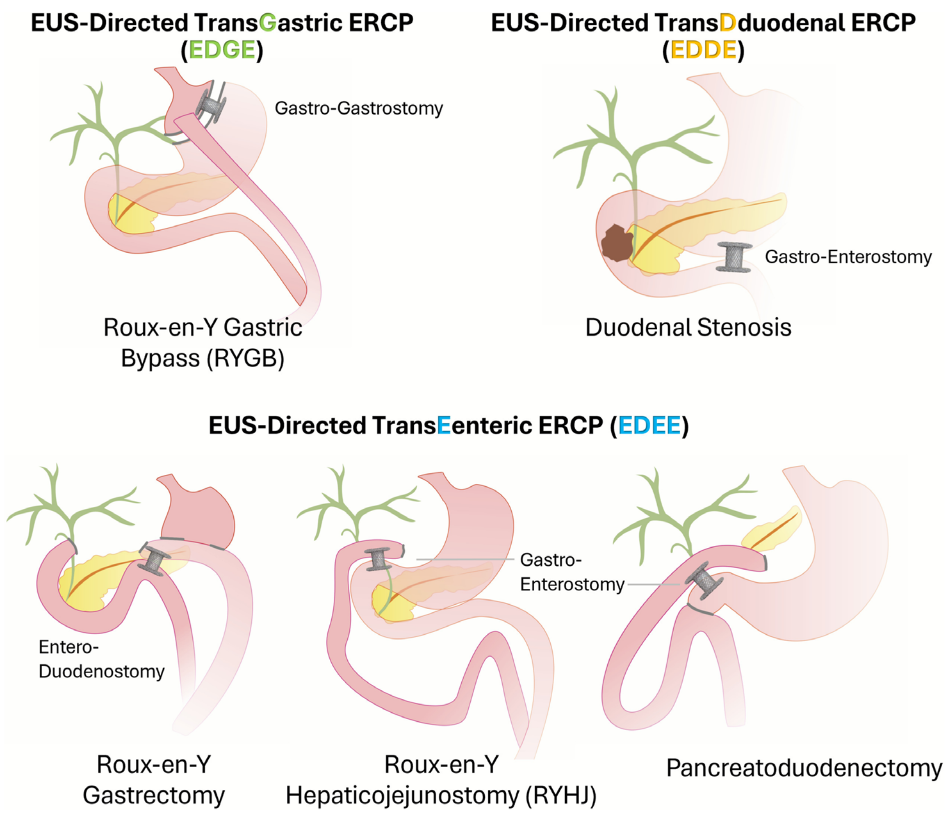

FIGURE 2 | Overview of EUS-directed ERCP (EDE) procedures. EUS-directed TransGastric ERCP (EDGE) reverses a Roux-en-Y Gastric Bypass by creating a temporary fistula between the gastric pouch (or the post-anastomotic jejunum) and the excluded stomach, allowing for a standard duodenoscope to reach the duodenum and perform conventional ERCP. EUS-directed TransDuodenal ERCP (EDDE) takes advantage of an EUS-guided Gastroenterostomy (placed for a duodenal stenosis) to retrogradely access the ampullary region with a duodenoscope or a therapeutic gastroscope, provided that the alimentary stenosis is proximal to the papilla and that EUS-GE is relatively close to the Treitz angle. EUS-directed transEnteric ERCP (EDEE) reconnects the upper GI tract and the pancreatobiliary limb through a LAMS. In case of a Roux-en-Y Gastrectomy, the LAMS is usually entero-duodenal (from the post-anastomotic jejunum to the duodenal stump), while in Roux-en-Y Hepaticojejunostomy, it is more frequently gastro-enteric. A gastroenterostomy or an entero-enterostomy can also be created in post-pancreatoduodenectomy anatomy, when retrograde access (e.g., pediatric colonoscope) fails.

TABLE 3 | Overview of EUS-directed ERCP procedures according to the type of surgically altered anatomy, with the most prevalent indications for pancreatobiliary endoscopy (the most common in bold) and the most common endoscopes used after LAMS placement.

Full name (acronym)	Type of altered anatomy	Most common indications	Type of access created	Types of scopes commonly used
EUS-directed transgastric ERCP (EDGE)	Roux-en-Y Gastric Bypass	*Choledocholithiasis* Pancreatobiliary interventions (biliary strictures, etc.) Need for diagnostic EUS ± FNA/B Luminal interventions in the gastric remnant or duodenum	Gastro-Gastrostomy (or Jejuno-Gastrostomy)	Standard duodenoscope
EUS-directed transenteric ERCP (EDEE)	Roux-en-Y Hepaticojejunostomy Roux-en-Y Gastrectomy Pancreatoduodenectomy	*Hepaticojejunostomy strictures* Choledocholithiasis Recurrent neoplastic stenosis.	Gastroenterostomy Entero-Duodenostomy (in cases with duodenal stump) Entero-Enterostomy	Therapeutic gastroscope (more common in case of HJ) Standard duodenoscope (more common in case of native Papilla) Pediatric colonoscope
EUS-directed transduodenal ERCP (EDDE)	Duodenal stenosis (proximal to the papilla)	*Stent exchange/revision* Biliary drainage in double obstruction.	Gastroenterostomy (usually previously placed for GOO)	Standard duodenoscope Therapeutic gastroscope

Abbreviations: EUS, Endoscopic Ultrasound; FNA/B, Fine-Needle Aspiration or Biopsy; GOO, Gastric Outlet Obstruction; HJ, HepaticoJejunostomy.

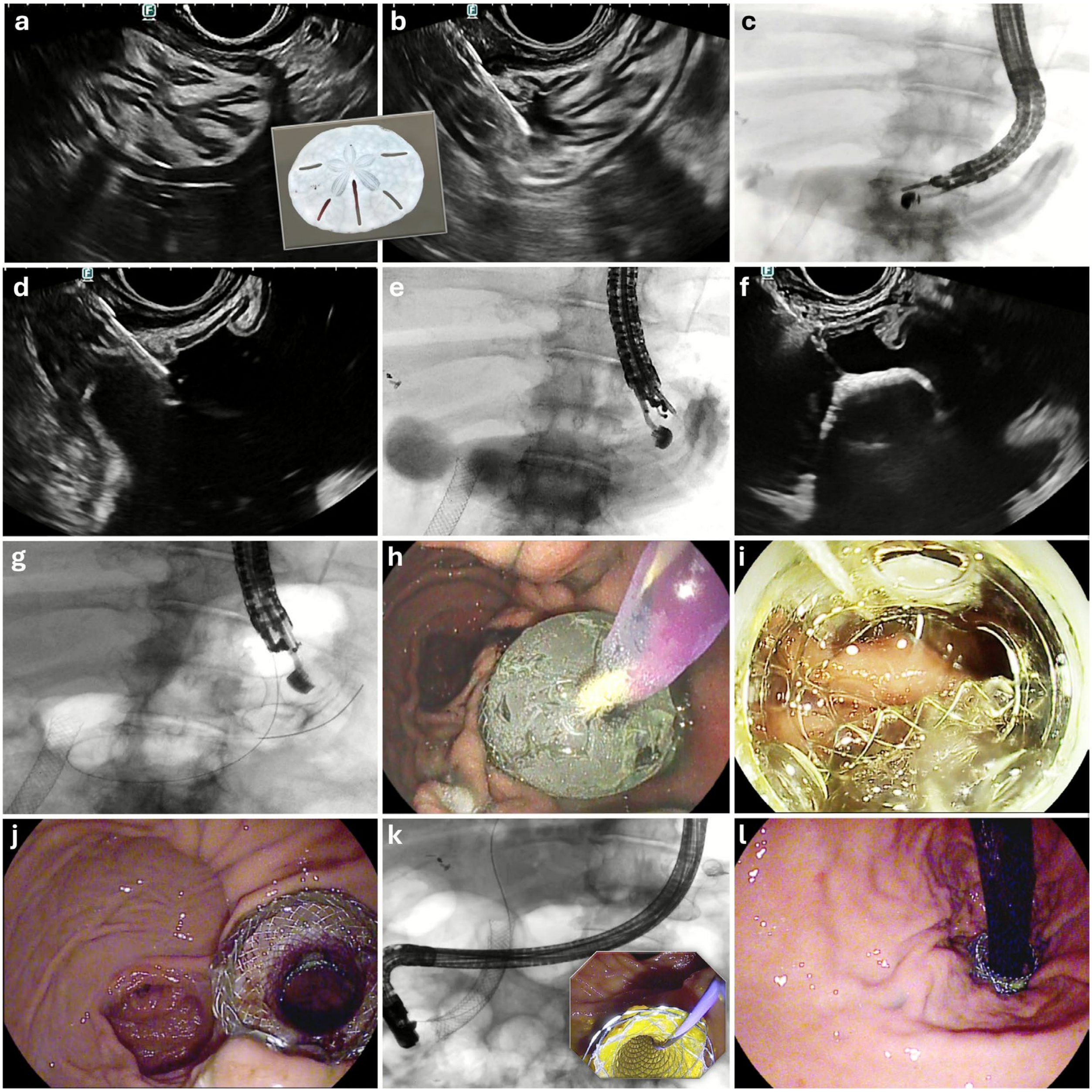

FIGURE 3 | EUS-directed TransGastric ERCP (EDGE). (a) The "sand-dollar sign" refers to the appearance of the rugal folds of the remnant stomach radiating outward from a central point, resembling a sand dollar (inset image; courtesy of Lucia Guillabert, MD). (b) The remnant is punctured using a 19-Gauge EUS-FNA needle; a small pulse of saline distends the lumen between the folds. (c) After access is confirmed, saline mixed with contrast is injected to distend the remnant stomach. (d,e) After initial distention, an alternative window for stent placement is found in the body of the stomach and injected again using the FNA needle; (f) a 20 mm Lumen-Apposing Metal Stent (LAMS) is advanced into the remnant stomach; (g) the LAMS is released between the gastric pouch and the gastric remnant; (h) the LAMS is dilated up to 18 mm; (i, j) the LAMS is anchored through an Over-the-Scope fixation Clip; (k) a duodenoscope is advanced for same-session ERCP with insertion of a metal stent; (l) duodenoscope through the LAMS upon scope removal. See Supporting Information for enlarged figures.

19-gauge fine-needle aspiration (FNA) needle (Figure 3b), and a small pulse of saline should be seen creating bubbles inside the lumen rather than a submucosal wheal. Alternatively, a small injection of contrast under fluoroscopic guidance should result in contrast flow within the gastric lumen rather than a contrast bleb. After access is confirmed, a larger quantity (~250–500 cc) of saline (with/without dye and/or contrast) is injected to distend the remnant stomach. Antiperistaltic drugs can help in retaining the fluid. After retraction of the needle, the appropriate window for LAMS advancement is selected, with careful attention to changes in the stomach morphology created after FNA injection (Figure 3c–e). One retrospective study suggested that a jejuno-gastric (versus gastro-gastric) fistula and access to the distal/proximal stomach (rather than central gastric body) is associated with more difficult subsequent ERCP [33]. An electrocautery-enhanced LAMS is then deployed freehand. The preferred stent size is 20 mm to reduce the risk of LAMS dislodgement [34]. Proper placement is confirmed by the backflow of contrast/dye through the LAMS. Additional LAMS dilation and/or anchoring depend on the need to perform same-session versus separate-session ERCP (see Section 5). After LAMS expansion, the duodenoscope is carefully advanced through the LAMS and standard ERCP is performed.

A variation of RYGB anatomy occurs when a patient with previous gastroplasty or sleeve gastrectomy undergoes conversion to RYGB. This "double-modified" anatomy presents unique anatomical challenges, including reduced gastric remnant volume, suboptimal gastric saline instillation, and increased adhesions [35, 36]. Sometimes, the smaller excluded stomach lies in a more distal or more lateral location (e.g., toward the liver). EDGE is still feasible in these scenarios [37, 38], but the increased complexity suggests referral to high-volume centers.

3.1.2 | Evidence

The American (ASGE [39]) and European (ESGE [24]) Society for Gastrointestinal Endoscopy guidelines support EDGE as a first-line therapy for pancreatobiliary disorders in RYGB patients in centers with expertise, emphasizing superior technical and clinical success rates (> 95%) compared to EA-ERCP (≈75%) [11, 19, 39–42]. LA-ERCP offers similar efficacy and safety, being considered in patients who require concomitant cholecystectomy [19, 39–41]. Nevertheless, EDGE over LA-ERCP demonstrates shorter procedure durations, easy re-access, reduced hospital stays, and more favorable cost-effectiveness [18, 20, 43].

Overall potential EDGE Adverse Events (AEs, 14%–18%) [44–46] encompass intraprocedural events, such as marginal ulcers, weight regain, bleeding (3%–5%) or perforation (2%–4%), but also AEs related to subsequent use of the LAMS (such as dislodgement [4%–7%]) and fistula persistence (up to 9%) upon LAMS removal. For the latter events, established risk factors and protective measures will be discussed later. A recent prospective study has demonstrated satisfactory efficacy and safety standards for EDGE, with no persistent fistula during follow-up [47].

In terms of comparative evidence, AEs have not been proven to be significantly different between EDGE, LA-ERCP, and EA-ERCP, although no randomized studies are available [11].

3.2 | EDEE (EUS-Directed Transenteric ERCP)

Reconstructions with disconnected/resected duodenum (Table 1, Figure 1) are often employed in oncological surgery. Indications for pancreatobiliary interventions in this scenario are more frequently related to benign HJ strictures or neoplastic recurrences. Whenever transmural EUS-BD is not desirable, EUS-directed transenteric ERCP (EDEE, Figure 2) further extends the EDGE concept toward these anatomies by connecting the upper GI tract and the pancreatobiliary limb. After LAMS is placed, either a standard duodenoscope (favored in the presence of a native ampulla) or a therapeutic gastroscope (favored in the case of an anastomosis) can be advanced through the LAMS (Table 3). Despite the absence of published cases, the PancreaticoJejunostomy can theoretically also be reached using this modality when transmural EUS-guided pancreatic duct drainage is not desirable.

3.2.1 | Technique

The objective of EDEE is not merely to deploy a LAMS in the pancreatobiliary limb, but to ensure an optimal route and axis for the subsequent ERCP.

Surgical anatomy can vary widely, even in patients with seemingly similar reconstructions, and should be carefully reviewed through surgical reports and dedicated high-quality cross-sectional imaging prior to any procedure.

Compared to EDGE, EUS-guided identification and distention of the collapsed jejunal limb can be the most challenging and time-consuming step of EDEE [48]. Several possibilities have been described [48]:

1. *Direct EUS screening and puncture* (Figure 4a–d): depending on the surgical reconstruction and therapeutic target, two options are feasible: (1) following the biliary tree from the liver to the duodenum (Ampulla) or jejunum (HJ) or (2) following the pancreatic duct from the pancreas to the duodenum (Ampulla) or jejunum (Pancreaticojejunostomy), acknowledging whether the pancreatic and bile duct end in the same loop (as in most pancreatoduodenectomies). Visualization of surgical clips at the blind end of the loop can also help. The loop is punctured with a 19G EUS-FNA needle for distention [49] (as for EDGE, see Section 3.1.1).
2. *Jejunal Catheter-assisted anastomosis* can be performed (Figure 4e–h), as in standard EUS-guided Gastroenterostomy (EUS-GE) [50]. A jejunal catheter (7-10Fr) can be retrogradely placed through a forward-viewing scope (e.g., pediatric colonoscope) that has been advanced in the pancreatobiliary limb. Although this maneuver may be time-consuming and require dexterity in identification of the correct loop (especially when multiple anastomoses are present), it does allow for complete control of jejunal distention, which may improve safety during anastomosis. Indeed, for EUS-GE, the "assisted" techniques have superseded the "direct" technique [50, 51].
3. in patients with a prior PTBD, a *Percutaneous-assisted anastomosis* is preferred (Figure 4i–l) [52]. This involves antegrade saline and/or contrast instillation through the percutaneous catheter into the pancreatobiliary limb. Some authors prefer to exchange the standard PTBD catheter for one without intrahepatic holes to avoid overinjection of the biliary tree.
4. *EUS-guided puncture of the left intrahepatic bile ducts* (Figure 4m–p) enables opacification of the pancreatobiliary limb and antegrade placement of a transhepatic catheter for loop distention, but carries additional morbidity.

In general, selecting a site near the blind end of the limb or the HJ results in better stability of the loop. A transgastric access is preferred, but not always feasible. In case of transduodenal approach, a distance of 4–5 cm from the HJ can increase stability of subsequent ERCP.

If adequate loop dilation is achieved, a large-caliber LAMS can be placed freehand. As for any LAMS placement in narrow

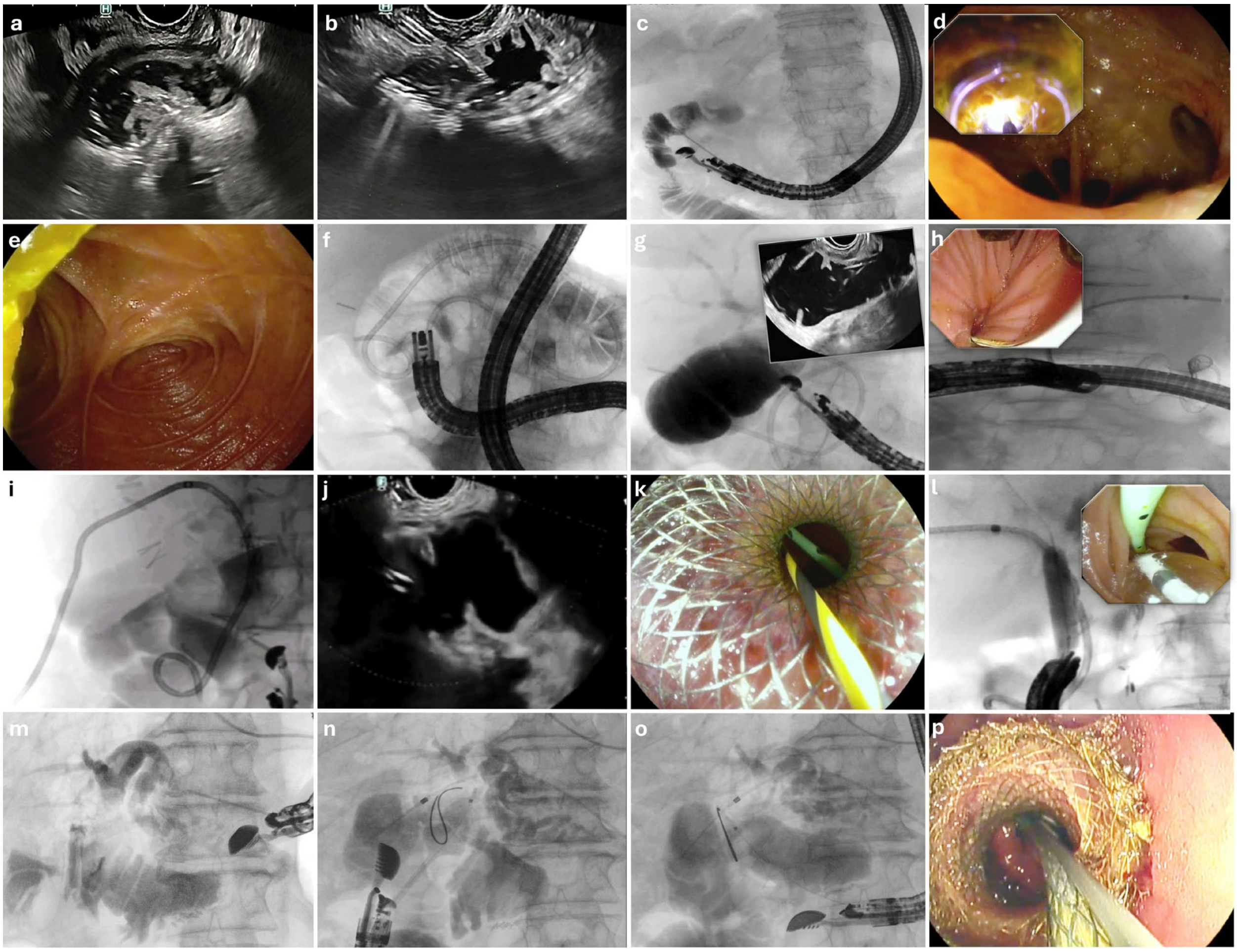

FIGURE 4 | Different modalities for loop distention during EUS-directed TransEnteric ERCP (EDEE). (a–d) Direct EUS screening and puncture. (a) The biliary tree is followed from the liver to hepatico-jejunostomy; (b) the loop close to the anastomosis is punctured with a 19G EUS-FNA needle; (c) injection of saline mixed with contrast depicts the biliary loop and creates a room for Lumen-Apposing Metal Stent (LAMS) placement; (d) the hepaticojejunostomy is reached to treat a large intrahepatic stone through lithotripsy. (e–h) Jejunal catheter-assisted anastomosis. (e) a pediatric colonoscope is advanced through the small bowel in the correct biliary loop (right in the figure); (f) an 8.5Fr orojejunal tube is placed with the pigtail at the blind end of the biliary limb; (g) saline mixed with contrast is injected for jejunal distention, creating adequate space for LAMS placement (see inset image for EUS appearance of the dilated loop containing the catheter); (h) same-session through-the-LAMS ERCP is performed with cannulation of the hepaticojejunostomy and stone extraction. (i–l) Percutaneous-assisted anastomosis. (i) A previously placed percutaneous catheter is used for antegrade saline plus contrast instillation; (j) EUS identification of the distended jejunal loop containing the percutaneous catheter; (k) after LAMS release, the percutaneous catheter can be seen through the LAMS; (l) a therapeutic gastroscope is advanced through the LAMS, and the hepaticojejunostomy is cannulated; removal of the percutaneous catheter and placement of two plastic stents will follow. (m–p) EUS-guided intrahepatic injection. (m) The left intrahepatic biliary tree is identified under EUS guidance and punctured through a 19G needle; guidewire insertion across the hepaticojejunostomy will follow; (n–o) a transhepatic catheter is left in place for jejunal distention; the loop is then identified under EUS guidance and a LAMS is placed over-the-wire, through which (p) ERCP with metal stenting is performed, without even crossing the LAMS with the therapeutic gastroscope. See Supporting Information for enlarged figures.

spaces, it is essential to allow time for the distal flange to fully deploy. Alternatively, an over-the-wire advancement or the "push" technique [50] can be used.

3.2.2 | Evidence

Comparative evidence between EDEE and standard alternatives is not yet available.

In the most recent series (94 consecutive procedures) [53], most indications were benign (87.3%), encompassing HJ strictures (RY-HJ or pancreatoduodenectomy) or choledocholithiasis (RY-Gastrectomy). Direct EUS identification was the most frequent modality for loop distention. Creation of the anastomosis was successful in 100%, while ERCP succeeded in 87.3%. The series registered 20% of AEs, mostly related to the subsequent ERCP. Among the LAMS-related AEs (9.1%), the more frequent were LAMS migration or misdeployment [53].

In the largest series (80 consecutive patients) focused on HJ stricture, anastomosis creation and ERCP success rates were 98.7% and 100%, respectively. AEs occurred in 32%, of which 7.2% were procedure-related, mainly attributable to LAMS placement rather than the subsequent ERCP. The use of state-of-the-art therapeutics (such as large-bore fully covered SEMS)

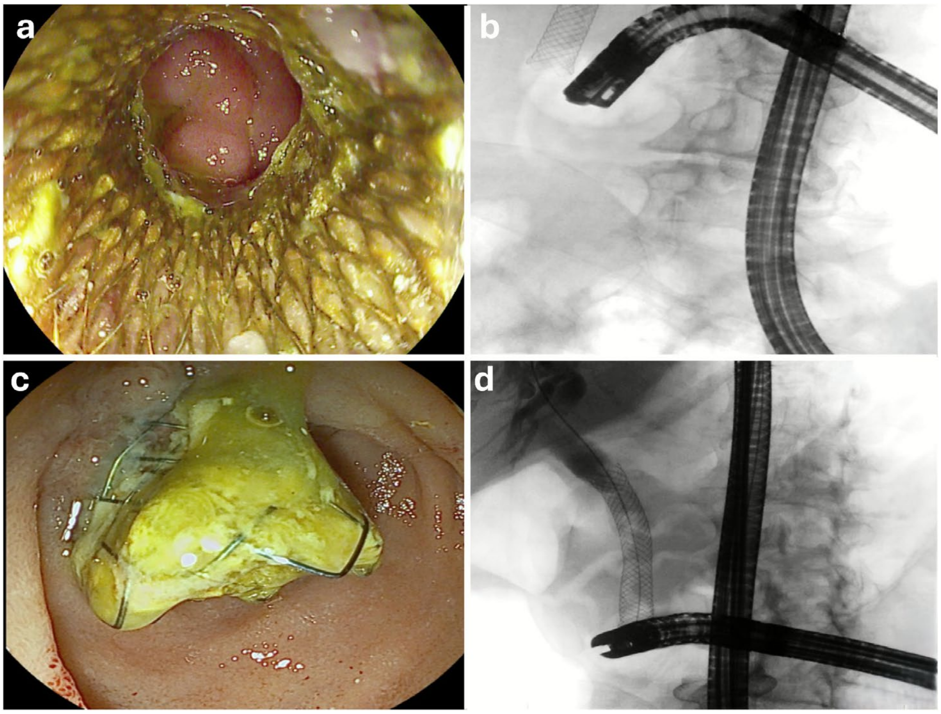

FIGURE 5 | EUS-directed TransDuodenal ERCP (EDDE). (a) A gastro-jejunostomy Lumen-Apposing Metal Stent (LAMS) was previously placed for gastric outlet obstruction; (b) after LAMS dilation, a duodenoscope is advanced through the LAMS toward the duodenum; (c,d) a previously placed self-expandable metal stent is identified and cleaned from biliary debris using a Fogarty balloon. See Supporting Information for enlarged figures.

resulted in high long-term clinical success, with a 3.8% rate of biliary recurrence during a median 4-year follow-up [54]. A smaller series reported similar outcomes [55].

As an indirect comparison, PTBD in this scenario demonstrated an estimated AE rate of 18%–29% and suboptimal long-term efficacy, with 71%–78% clinical success rates and 22%–29% recurrence [56–60]. Multiple interventions and prolonged catheterization are often required, with an obvious impact on quality of life [56–60]. When PTBD involves placement of percutaneous stents, they are usually longer than endoscopic ones and may induce hyperplastic reactions on the biliary side and decubitus, perforation, and migration on the jejunal side. In addition, removal at the end of the therapeutic cycle is highly complex [60, 61]. EDEE carries significant advantages over PTBD in patients with more than one biliary anastomosis, when reinterventions are anticipated or when single-operator cholangioscopy is required.

3.3 | EDDE (EUS-Directed Transduodenal ERCP)

Initial evidence supports the use of a previously created EUS-GE as access to perform ERCP [62, 63]. When biliary and gastric outlet obstruction (GOO) present simultaneously, single-session double EUS-guided bypass demonstrated excellent performances [64–66]. However, in some instances, jaundice can develop later than GOO, or there might be the need to revise a formerly placed transpapillary SEMS. In those cases, the EUS-GE LAMS can be used to retrogradely access the ampullary region with a duodenoscope or a therapeutic gastroscope (Figure 2, Table 3), provided that the alimentary stenosis is proximal to the papilla and that EUS-GE was placed close to the Treitz angle (Figure 5). The EUS-GE LAMS will lead to two intestinal lumens: fluoroscopy can help in selecting the correct (afferent) duodenal loop instead of the alimentary jejunal (efferent) loop. ERCP in this scenario resembles the ones performed in Billroth II anatomies, with an inverted papillary orientation (see Section 4.2). Since the EUS-GE tract is typically mature at the time of ERCP, EUS-GE LAMS dislodgement rarely results in clinically significant consequences, with most AEs being related to the ERCP.

3.4 | EDCE (EUS-Directed Transcholedocal or Transcystic ERCP)

Although beyond the scope of this Review, ERCP may be performed through a previously placed EUS-guided choledochoduodenostomy or gallbladder drainage, with the LAMS serving as an access route for therapeutic interventions, including stone extraction, anterograde or retrograde stent placement, and rendezvous procedures [67–69].

4 | Once Anastomosis Is Created: ERCP in SAA

4.1 | Hepaticojejunostomy Stricture Management

HJ strictures represent the most common complication of RY-HJ, reaching 36% of living donor liver transplantations [70]. The preferred therapeutic approach in normal anatomy involves

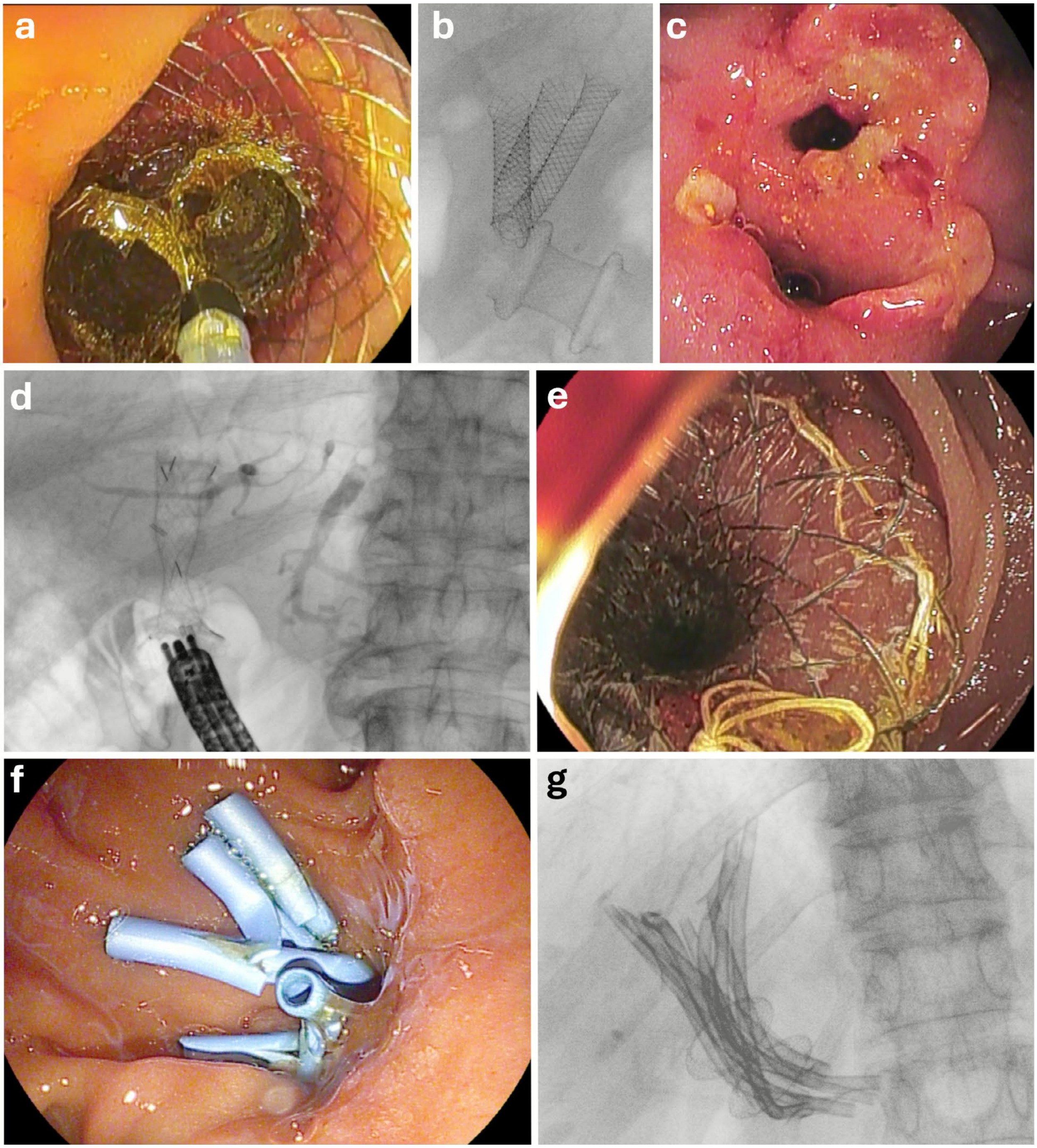

FIGURE 6 | Hepaticojejunostomy stricture management. (a–c) After a Lumen-Apposing Metal Stent (LAMS) has been placed close to the hepaticojejunostomy, multiple self-expandable metal stents (SEMS) of different sizes have been placed in the left and right hepatic ducts to model a hepaticojejunostomy stricture; (d,e) use of a larger diameter biflanged metal stent (NAGI, Taewoong Medical Co. Ltd., South Korea) to treat a choledochojejunostomy stricture; (f, g) plastic multistenting of a hepaticojejunostomy stricture. See Supporting Information for enlarged figures.

FC-SEMS [71, 72] as the radial force overcomes the resistance of the anastomotic stricture (Figure 6a–c).

Importantly, HJ strictures are frequently accompanied by strictures of the perianastomotic jejunal wall, as a result of fibro-ischemic phenomena [54, 70]. For this reason, balloon dilation alone might be less effective than in pure biliary anastomotic strictures [60, 73], and strong radial force is essential. Apart from standard FC-SEMS, large-diameter (12–16 mm) biflanged metal stents (such as the NAGI, Taewoong Medical Co. Ltd., South Korea) can be used to match the upstream bile duct caliber (Figure 6d,e). Stent length is equally critical: the intra-biliary and extra-biliary segments should be nearly equal to reduce the risk of migration; this often requires ultra-short stents (<4 cm), and the option of manual re-sizing has been described [54]. All these techniques demand the availability of large operative and excellent positional stability to facilitate cannulation with one or more guidewires and placement of multiple stents (Figure 6f,g). In parallel, a short distance (a few

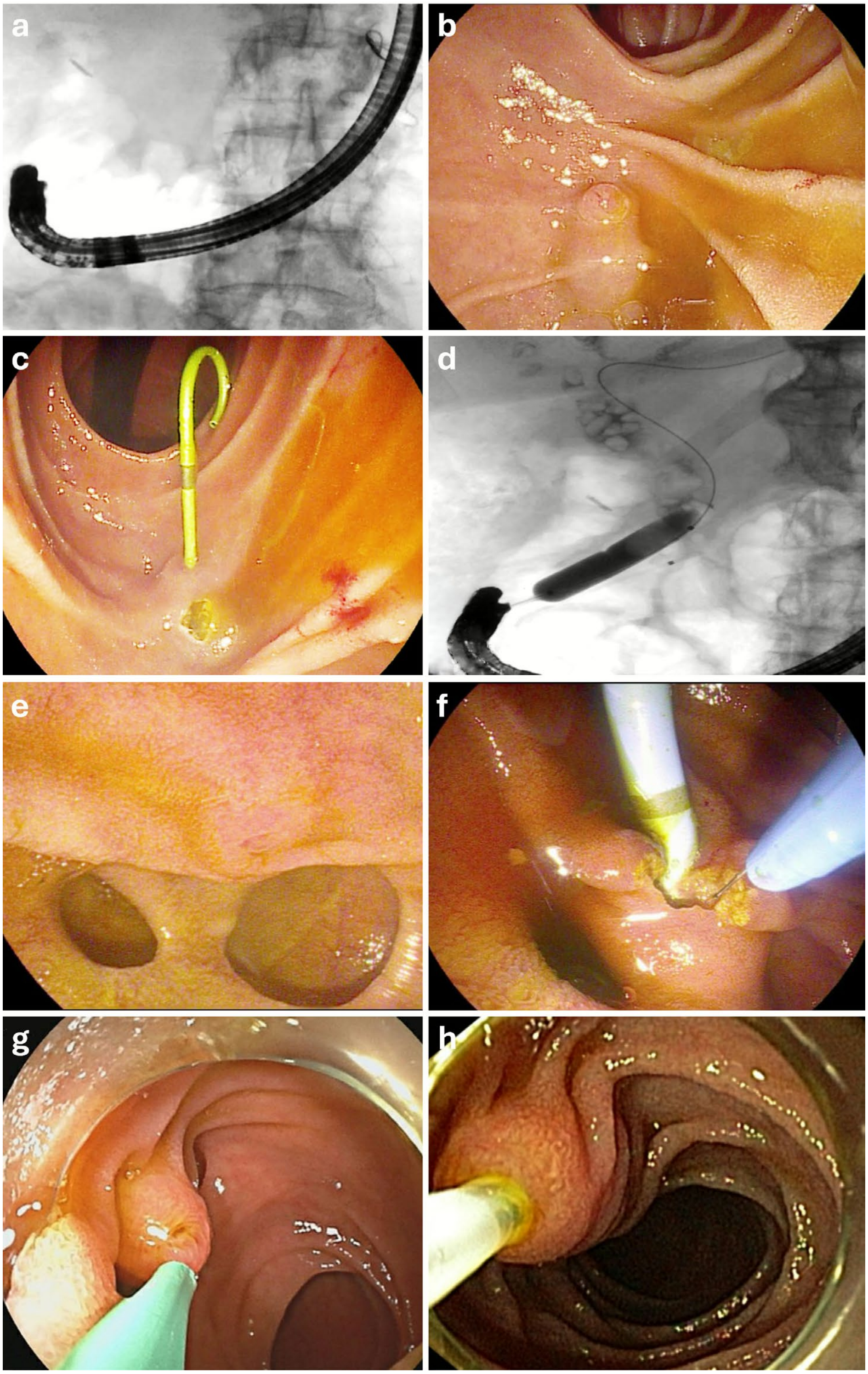

FIGURE 7 | Approaching a native papilla during EUS-directed ERCP. (a) A jejuno-jejunal 20 mm Lumen-Apposing Metal Stent (LAMS) has been placed to reconnect a biliary limb after a Roux-en-Y gastrectomy; after LAMS anchoring, a same-session EUS-directed TransEnteric ERCP is performed; a duodenoscope is advanced through the LAMS; (b) the native Ampulla of Vater is found with a reversed orientation, with the biliary infundibulum directed at 6 o'clock; (c) since catheter-assisted cannulation resulted in cannulation of the pancreatic duct, a pancreatic prophylactic stent was placed and a needle-knife pre-cut was performed, with the incision directed toward the actual bile duct axis; (d) biliary cannulation was achieved through the pre-cut and the biliary access was perfectioned through balloon dilation; (e,f) after biliary cannulation, sphincterotomy was replaced by needle-knife pre-cutting over a plastic biliary stent; (g,h) a transparent cap attached to the tip of a forward-viewing endoscope (cap-assisted ERCP) is used to improve visualization and stability at the papilla during cannulation with a sphincterotome (g) or cannula (h). See Supporting Information for enlarged figures.

centimeters) between the LAMS and the HJ might be preferred, avoiding long jejunal loops that reduce device pushability and increase the risk of stent dislodgement.

Once biliary (and possibly enteral) stenting succeeds, postprocedural management does not differ from normal anatomy [10, 54, 74]: the first cholangiographic control is usually planned within 6 months; in case of clinical success, the LAMS is left in place for an additional 6 months and then removed in case of asymptomatic course and normal liver tests. An average of two to three endoscopic revisions is needed until clinical success is achieved or failure is identified.

4.2 | Approaching a Native Papilla in SAA

In the majority of EDEE and EDDE cases, a native Ampulla of Vater will present with a reversed 6 o'clock biliary orientation, resembling Billroth II anatomy. ERCP in this scenario has been demonstrated to have an 81%–87% technical success with a 7%–10% rate of AEs [75].

The endoscopist should be able to discriminate between standard and reversed orientation based on the appearance of the infundibulum and the position in the lumen (Figure 7b).

A straight cannulation catheter or a sphincterotome (preferably rotatable) can be used for cannulation. In cases of difficult cannulation, a needle-knife pre-cut can be performed, with the incision directed toward the actual bile duct axis (Figure 7c). After achieving biliary cannulation, a rotatable or a specific Billroth II sphincterotome (with a reverse cutting wire direction) can help in completing the sphincterotomy to the appropriate direction; alternatively, papillary balloon dilation (Figure 7d) or pre-cutting over a plastic biliary stent (Figure 7e,f) can be used [75–77].

Whenever a forward-viewing gastroscope is used, a transparent cap attached to the tip (Figure 7g,h) may improve visualization and stability at the papilla [78, 79].

5 | Same-Session Versus Staged ERCP, Risk of LAMS Dislodgement and Related LAMS Fixation

The timing of ERCP has been a key topic of discussion since the introduction of EDE. Performing ERCP during the index procedure, when the fistula is immature, can have disastrous consequences in case of LAMS dislodgement due to anastomotic dehiscence and peritoneal leak of gastrointestinal contents [80]. Delaying interventions, ideally for 1–2 weeks (but shorter [2–4 days] intervals have been described [80]), facilitates fistula tract maturation and reduces the risk of LAMS dislodgement. On the other hand, disadvantages include the increased procedural burden for the patient and department, as well as delaying pancreatobiliary treatment, especially in cholangitis or ongoing bile leaks.

However, timing is not the sole determinant of procedural safety [24, 34, 81–83].

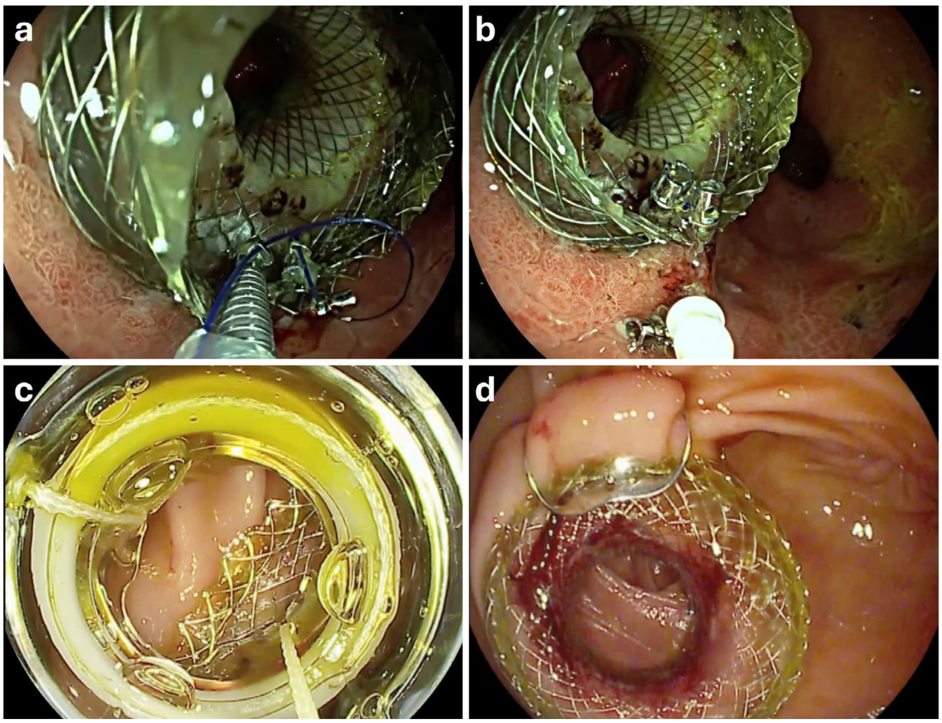

FIGURE 8 | LAMS fixation. (a,b) A through-the-scope endoscopic suturing device (X-Tack Endoscopic HeliX Tacking System, Boston Scientific, Marlborough, USA) is used for Lumen-Apposing Metal Stent (LAMS) anchoring; (c,d) an over-the-scope clip (Stentfix, Ovesco Ag Tübingen, Germany) is used for LAMS fixation after former LAMS dilation. See Supporting Information for enlarged figures.

Large-caliber LAMS (20 mm versus 15 mm) substantially reduce the risk of dislodgement [34, 84]. Moreover, forward-viewing scopes (with their smaller diameter) exert reduced friction on the LAMS compared to larger scopes, such as linear echoendoscopes. Finally, an unfavorable LAMS location (see Section 3.1.1) [33] resulting in excessive force, angulation, or torquing during subsequent scope advancement, advises a staged ERCP if clinically permissible.

Careful endoscopic and fluoroscopic assessment of LAMS position during scope maneuvers is essential, especially during same-session ERCP. LAMS dislodgement can occur during insertion or withdrawal (which can be decreased by releasing scope brakes); upon ERCP completion, it is recommended to stabilize one or more stiff guidewires in the duodenum during scope removal to facilitate rescue maneuvers in case of LAMS dislodgement, such as bridging the tract with a new LAMS or a fully covered SEMS, or aiding subsequent identification of the gastrostomy site upon scope exchange, though supporting data is limited [83].

Beyond LAMS size and position, anchoring the LAMS can prevent dislodgement. Retrospective series have reported success using suturing devices such as X-Tack and Overstitch (Boston Scientific, Marlborough, USA) with a notably negligible dislodgement rate (Figure 8a,b) [34, 46, 85]. Nevertheless, drawbacks include increased procedure complexity and longer duration associated with endoscopic suturing; the increased costs are negligible in light of potential complications requiring surgery.

The use of over-the-scope clips (OTSC, Stentfix, Ovesco Ag Tübingen, Germany, Figure 8c,d) has recently been described to effectively prevent LAMS dislodgement in a proof-of-concept study, at significantly reduced costs and application times of a few minutes [81]. Contrary to common beliefs, OTSC removal is usually straightforward and can be performed simultaneously with the LAMS using standard forceps, eliminating the need for specialized removal devices [86]. Direct comparisons between OTSC and suturing devices exist only in the context of FC-SEMS placements within the upper GI tract, showing comparable outcomes [87, 88]. Consequently, the choice should be guided by local expertise and availability. It is important to note that these techniques secure only the proximal LAMS flange; thus, dislodgement at the distal flange, although rare, remains a theoretical potential risk.

The combination of effective LAMS fixation, use of larger (20 mm) caliber LAMS, and improved awareness of the risk factors described above has significantly enhanced the safety profile of single-session EDE, offering the potential to reduce the total number of procedures and overall hospitalization for the patient, and endoscopy suite workload and overall healthcare costs for the institution [89].

6 | The Post-EDE Dilemma: Approaches to Fistula Management

Fistula management following EDE procedures remains a subject of ongoing debate. Especially after EDGE, which commonly follows bariatric surgery, the focus is to reverse the created connection as soon as a successful biliopancreatic treatment has been obtained. Naturally, the LAMS cannot be removed at the index procedure, as the immature fistula would become an overt perforation. However, once tract maturation has occurred, the LAMS can be removed. This can be done as early as 1–2 weeks (especially in the absence of ascites), but more commonly, an interval of 3–4 weeks is used.

This also reflects a key variable influencing fistula persistence: several studies have shown that prolonged LAMS indwelling time (beyond 6 weeks, with a risk that increases with time) is associated with a significantly higher risk of persistent fistula (independently of active closure). Although the association of this event with increased weight regain is debated [45, 90–92], minimizing LAMS indwelling time is the most evidence-based strategy to reduce this risk [90, 91, 93].

Beyond timing, there is open debate as to whether the mature fistula should be actively closed. Retrospective and prospective studies have suggested that primary closure (Figure 9) with endoscopic suturing or OTSC, particularly when used in combination with Argon Plasma Coagulation [93], might result in significantly lower rates of persistent fistula compared to passive strategies [45, 94]. However, risk differences seem to become diluted when adjusting for LAMS indwelling time [93], questioning the need to upscale the overall costs, duration, and complexity of the treatment. Other factors, such as diabetes mellitus, might have a role [45]. Further high-quality prospective and comparative data are needed.

Conversely, in other scenarios such as EDEE, where weight regain is not an issue, LAMS indwell might be longer (e.g., up to 12 months when treating an HJ stricture, see Section 4.1), and eventual fistula persistence can be even an advantage in case of symptoms recurrence.

7 | Conclusions

Managing biliary drainage in SAA remains a complex challenge, but recent innovations have adequately addressed shortcomings of existing techniques, significantly expanding the endoscopic armamentarium. In addition to "modified" ERCP techniques, EA-ERCP, EUS-guided transmural drainage, and antegrade interventions, the advent of EUS-guided anastomoses has enabled the (re)connection of distant gastrointestinal loops to allow a more "standard" ERCP approach, namely EUS-directed ERCP. However, EDE is a technically demanding procedure, involving specific technical specifications for anastomosis creation and subsequent through-the-LAMS procedures.

The key to success is a multidisciplinary approach. An algorithm tailored to the underlying anatomy and specific indication is proposed in Figure 10. For instance, PTBD may be a more straightforward option in temporary indications (such as a post-surgical bile leak) compared to more challenging scenarios like HJ strictures, where EDE may offer long-term advantages. Comparative data are still needed to define its role relative to EA-ERCP and PTBD.

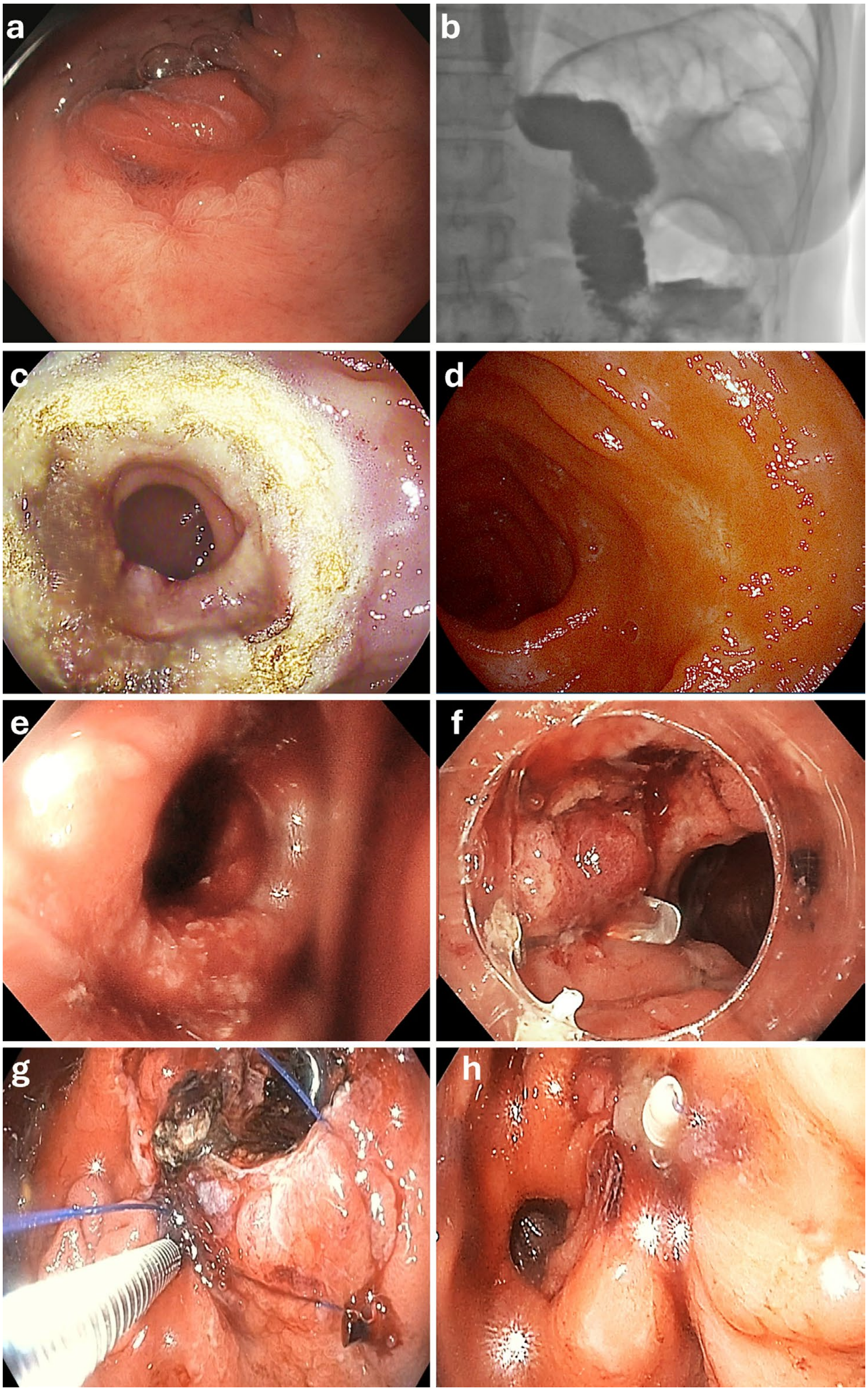

FIGURE 9 | Fistula closure. (a,b) No active closure is one option after Lumen-Apposing Metal Stent (LAMS) removal. Endoscopic (a) and radiologic (b) follow-up showing spontaneous healing of the fistula after LAMS removal; (c,d) Argon Plasma Coagulation (APC) of the fistula edges can be performed to induce controlled ablation of the epithelial lining and promoting granulation tissue formation thereby enhancing secondary intention healing; APC can be used in combination with additional endoscopic closure techniques; (d) 3-months endoscopic follow-up; (e,f) EDGE fistula closed with OTSC (Ovesco Ag Tübingen, Germany); (g,h) EDGE fistula closed with the X-Tack (Boston Scientific, Marlborough, USA) using a figure-of-eight suture pattern (g) and cinch (h) to apply tension on the suture and anchor the tacks together. See Supporting Information for enlarged figures.

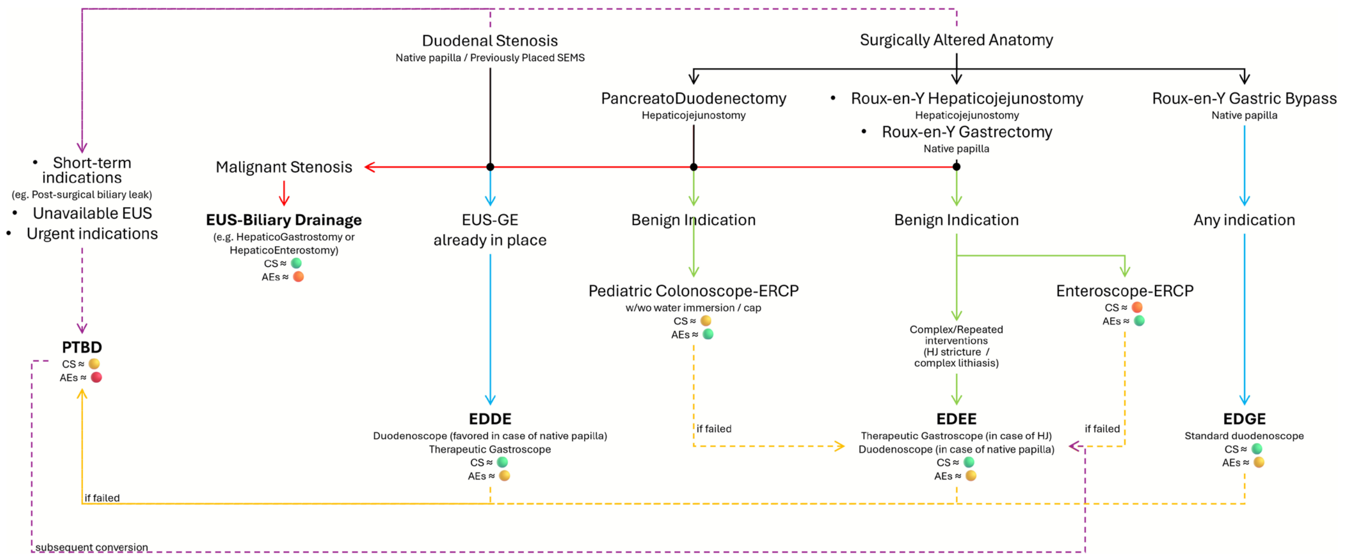

FIGURE 10 | Tailored algorithm for management of biliary drainage according to the specific anatomy and clinical indication. The flowchart starts from the type of specific anatomy and progresses through decision knots based on the underlying indication (e.g., malignant versus benign). Each available minimally invasive endoscopic or percutaneous approach is positioned according to feasibility and the preferred sequence of use. Each technique is associated with color-coded symbols reflecting the median procedural performance and safety profile. ● = very high clinical/technical success or very low adverse events; ● = good success or low event rate; ● = moderate success or moderate event rate; ● = low success or high event rate. EDDE, EUS-directed TransDuodenal ERCP; EDEE, EUS-directed TransEnteric ERCP; EDGE, EUS-directed TransGastric ERCP; EUS-GE, EUS-guided Gastroenterostomy; PTBD, percutaneous transhepatic biliary drainage.

Importantly, EDE remains in its early developmental phase, and its applicability may be limited by local expertise and available resources. Operators with extensive experience in both interventional EUS and ERCP, should undergo stepwise structured proctorships dedicated to these specific techniques. Implementation of EDE requires multidisciplinary management and shared protocols for AEs, with around-the-clock surgical and radiological backup. Finally, the duration and technical principles of these procedures usually recommend an anesthesiologic support.

In summary, while EDE represents a promising and conceptually elegant technique to "re-map" the gastrointestinal tract and reach the pancreatobiliary district in nearly any situation, its implementation requires individualized patient selection, institutional readiness, training programs, and further clinical evidence to define best practices and clinical algorithms.

Author Contributions

G.V., M.B., E.P.-C.-R., R.L.J.W., S.V.M., and P.G.A. conceptualized the paper. G.V., M.B., E.P.-C.-R., R.L.J.W., P.C., E.F., C.G., M.S., A.F., M.K., A.S., A.T., M.P.-M., M.M., R.K., M.K., S.V.M., and P.G.A. drafted the paper and revised it for important intellectual content. All authors approved the final version of the Manuscript and agree to be accountable for all aspects of the work.

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Conflicts of Interest

G.V. is an editorial board member of Digestive Endoscopy and reports lecture fees and consultancy agreements with Boston Scientific and travel grants from Euromedical; M.B. received grant support from Boston Scientific. R.L.J.W. holds a consultancy agreement with Boston Scientific and Cook Medical, and received a speaker's fee from Olympus. E.P.-C.-R. is a former editorial board member of Digestive Endoscopy and reports a consultancy agreement with Boston Scientific. A.S. consults for Boston Scientific, Cook Medical, Olympus, Medtronic; advisory board for Endosound. M.P.-M. reports lecture fees and consultancy agreement with Boston Scientific, Olympus, Medtronic, Lumendi & M.I. Tech; R.K. is a consultant and speaker for Boston Scientific, Merit Medical, Olympus, Omega Medical Imaging, Ambu and Pentax. M.K. is a consultant for Boston Scientific and Olympus and receives royalties from Elsevier and UpTodate. S.V.M. holds the Cook chair in Interventional endoscopy, has consultancy agreements with Cook, Pentax, and Olympus and co-chairs the Boston Scientific Chair in Therapeutic Biliopancreatic Endoscopy. All other Authors report no conflicts of interest relevant to this article.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Data S1:** den70098-sup-0001-Supinfo.docx.