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Advances in Biliary Access

Abdul H. El Chafic[1] **· Janak N. Shah**[1]

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Abstract

Purpose of Review Bile duct cannulation using conventional techniques fails in up to 16% of endoscopic retrograde cholangiopancreatography (ERCP) procedures. Advanced techniques to gain biliary access include ERCP-based maneuvers, and newer endoscopic ultrasound (EUS)–guided interventions. In this article, we review the evidence supporting the use of various ERCP and EUS techniques for biliary access, as well as studies comparing these different techniques.

Recent Findings In comparative studies, biliary access after failed conventional cannulation was more successful with EUS-rendezvous compared to precut papillotomy. EUS-guided drainage compares favorably with percutaneous drainage with respect to clinical success, safety profile, and cost-efficiency. Recent randomized trials comparing EUS to ERCP drainage in malignant obstruction have found similar success rates between these techniques.

Summary EUS-guided techniques compare favorably to ERCP-based methods for biliary access and drainage. The advent of newer technologies to facilitate interventional EUS may further change current treatment approaches.

Keywords Endoscopic retrograde cholangiopancreatography (ERCP) · Endoscopic ultrasound (EUS) · Biliary access · Bile duct cannulation · Biliary drainage

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the procedure of choice for minimally invasive treatment of bile duct disorders. Deep biliary access is the first and key component of successful ERCP. Standard techniques for bile duct access usually include attempts using a cannula or papillotome, with or without a wire. Unfortunately, bile duct cannulation using these conventional techniques fails in up to 16%, even in expert hands. [1–3] Difficult cannulation can be defined as the inability to achieve selective biliary cannulation by these standard ERCP techniques within 10 min or up to 5 cannulation attempts. [4] In such cases, endoscopists should consider the use of advanced techniques to facilitate successful endobiliary therapy. These advanced techniques include ERCP-based maneuvers, and newer EUS-guided interventions.

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✉ Janak N. Shah
Janak.shah@ochsner.org

[1] Department of Gastroenterology, Ochsner Health – New Orleans, 1514 Jefferson Hwy, New Orleans, LA 70121, USA

Advanced ERCP Biliary Access Techniques

Commonly used, ERCP-based, advanced access techniques include the use of pancreatic guidewire-assisted cannulation and precut techniques. The specific choice of the next-line modality for biliary access when standard cannulation fails is highly dependent on the endoscopist's preference, level of training, and personal expertise. However, with the popularity of wire-based standard cannulation techniques, the pancreatic duct is often inadvertently accessed during cannulation attempts. In such cases, the pancreatic guidewire-assisted technique is likely the most commonly used advanced technique given its simplicity and the ability to immediately place a pancreatic duct stent to reduce the risk of post-ERCP pancreatitis. The technique involves maintaining a guidewire in the pancreatic duct while attempting biliary cannulation with another instrument (cannulation instrument or a 2nd guidewire) alongside the pancreatic duct wire. In theory, this technique stabilizes endoscope positioning with respect to the papilla and facilitates insertion of the 2nd cannulation tool directly into the bile duct. The pancreatic guidewire-assisted technique is associated with high success rate in achieving biliary access (74–91%). [5–7] However, this technique is also associated with increased risk of post-ERCP pancreatitis when compared to precut modalities, and thus, placement of prophylactic pancreatic duct stents should be strongly considered. [7–9]

Precut biliary access techniques include needle-knife papillotomy, needle-knife fistulotomy, and transpancreatic septotomy. They all have in common the concept of making electrosurgical incisions to expose the intraduodenal segment of the bile duct to facilitate deep biliary access. If the pancreatic duct is inadvertently accessed and the pancreatic guidewire-assisted technique fails or is not attempted, a transpancreatic septotomy using a traction papillotome or a precut papillotomy or fistulotomy using a needle-knife catheter can be attempted. We recommend placing pancreatic duct stents prior to needle-knife precut techniques and after transpancreatic septotomy to reduce the risk of post-procedure pancreatitis. [10] The pancreatic duct stent also serves to guide the direction of precut towards the biliary orifice when using needle-knife catheters.

If the pancreatic duct is not accessed, neither the pancreatic guidewire-assisted technique nor transpancreatic septotomy is possible and freehand needle-knife precut can be attempted. In this setting, needle-knife fistulotomy (incision above the biliary orifice) is preferred to needle-knife papillotomy (incision at the orifice) due to a reduced risk of post-procedure pancreatitis. [11] If the pancreatic duct can be accessed after freehand needle-knife precut, a pancreatic duct stent should be placed to reduce the risk of post-procedure pancreatitis. [12]

Transpancreatic septotomy and both types of needle-knife precut techniques result in an overall biliary cannulation rate of around 90% with a low post-ERCP pancreatitis rate (10%). [12–14] In a recent meta-analysis, no major differences were noted between these techniques with respect to cannulation success and adverse events when including data from only randomized trials. [15]

EUS-Guided Biliary Access

EUS-guided interventions to facilitate endobiliary access and therapy are relatively newer compared to advanced ERCP techniques, and have substantially evolved over the last decade (Table 1). These techniques include EUS-guided techniques to facilitate retrograde biliary access (e.g., EUS-guided rendezvous), as well as direct EUS-based interventions to perform endobiliary therapy.

Table 1 Advanced biliary access techniques

ERCP-based	EUS-based
Pancreatic guidewire-assisted	EUS-rendezvous
Transpancreatic septotomy	EUS-guided choledochoduodenostomy
Needle-knife fistulotomy	EUS-guided hepaticogastrostomy
Needle-knife papillotomy	EUS-guided anterograde stent/intervention

EUS-Guided Rendezvous

EUS-guided rendezvous (EUS-RV) can only be performed if the papilla is endoscopically accessible. The technique involves puncture into the bile duct using an EUS-fine needle aspiration (FNA) needle. After intraductal puncture, contrast is injected to obtain a cholangiogram, and a guidewire is then advanced through the needle into the bile duct and negotiated across the papilla. The guidewire should be advanced deeply and/or allowed to loop a few times in the small bowel to ensure stability when exchanging the echoendoscope for the duodenoscope. “Rendezvous” access to the biliary system is then performed by cannulating alongside the EUS-placed transpapillary guidewire or by grasping and retracting the distal portion of guidewire through the duodenoscope working channel for over-the-wire cannulation.

In recent and larger studies that have compared outcomes of EUS-RV to other types of access techniques, success with EUS-RV has been > 94%. [16, 17] Adverse events occur in up to 15%, and include pancreatitis, bile leak, bleeding/hematoma, and bacteremia/infection. [16, 18–20] Interestingly, the most common adverse event is pancreatitis. Given that all studies on EUS-RV have reported outcomes of patients with same session, failed ERCP, it is not known whether the pancreatitis is due to the initial failed cannulation attempt or related to EUS-RV maneuver (we suspect the former).

Many variables may influence the specific procedural technique in a particular patient, and these include the location of ductal puncture (intrahepatic vs. extrahepatic), the trajectory of the puncture with respect to the direction towards the papilla, and FNA needle gauge and wire size. There is no consensus on needle size or specific guidewire for EUS-RV. When technically feasible, we prefer using 0.025 in. or smaller guidewire through a larger gauge needle (e.g., 19-gauge) in order to minimize the risk of wire shearing, improve fluoroscopic visualization, and have available a wider array of guidewire designs.

The main reason for EUS-RV failure after successful intraductal puncture is the inability to negotiate the guidewire across the stricture or papilla. We believe a stable endoscope position and appropriate selection of the biliary duct puncture point is essential. We recommend using fluoroscopy prior to intraductal puncture to guide a favorable trajectory that facilitates wire advancement towards the papilla. There are two main biliary segment targets for EUS puncture (intrahepatic and extrahepatic), and two echoendoscope locations from where to perform the puncture (transgastric and transduodenal). Specifically, for the intention of performing EUS-RV, we have found that a transgastric-intrahepatic puncture usually works best but does require intrahepatic duct dilation. The disadvantage for this puncture route is a relatively longer length to the papilla, but the direction of guidewire advancement can be more easily aligned towards the papilla.

The extrahepatic bile duct is usually a larger and easier puncture target. This is most commonly targeted transduodenally, but can be targeted transgastrically with a puncture route that traverses through the head of the pancreas. Dhir and colleagues compared intra- to extrahepatic approaches and found no difference in the technical success (94.1 vs. 100%). [21] That said, in our experience, the most stable position for extrahepatic puncture is usually with the echoendoscope in a “long” position with the tip in the duodenal bulb. From that angle, the trajectory of puncture and guidewire advancement is often suboptimal with respect to the direction towards the papilla. Angled guidewires may help overcome difficult trajectory, but wire manipulation does require inherent skills.

EUS-Guided Biliary Interventions/Drainage

EUS-RV is essentially a technique to assist ERCP by facilitating retrograde access to the papilla. In certain clinical settings in which the papilla cannot be reached (e.g., duodenal stenosis or altered anatomy) or when retrograde endotherapy is not imperative and the option for an EUS-based intervention exists, EUS can be used as the platform to actually perform the intended endobiliary therapy. The two categories of EUS-based biliary interventions include EUS-guided anterograde treatments and EUS-guided transluminal drainage.

EUS-Guided Anterograde Therapy

EUS-guided anterograde therapy entails performing the intended ERCP intervention through the EUS puncture tract. This is most commonly performed through an intrahepatic bile duct puncture, and for the purpose of placing a transpapillary stent. The technique specifically involves the following: (1) EUS-guided puncture into the bile duct, (2) guidewire advancement across the stricture and/or papilla, (3) over-the-wire dilation of the fistulous tract (if needed), followed by (4) over-the-wire intervention (e.g., stricture sampling, dilation, stent placement). The entire procedure is performed mainly under sonographic and fluoroscopic guidance through the echoendoscope without need to exchange to a duodenoscope.

The most common procedure performed is the anterograde placement of a stent across the papilla or bilioenteric anastomosis. The main limiting step in EUS-guided anterograde treatment is negotiating and transmitting the pushing force of the guidewire and over-the-wire instruments over a relatively long distance across the puncture site, into the left intrahepatic duct, down the extrahepatic duct, and then across the papilla and into the small bowel. This could potentially explain the relatively lower success rate of this approach (77%) compared to other types of EUS-guided biliary interventions found in a review of published data in 2014. [22] However, careful selection of the intrahepatic puncture site likely improves success rate. Iwashita et al. conducted a prospective pilot study on EUS-guided anterograde stenting for malignant biliary obstruction in altered anatomy and found that technical and clinical success can be achieved in 95% of cases when the EUS puncture site is carefully selected in segment II of the liver in order to facilitate a straight course of the guidewire. [23]

Other types of EUS-guided anterograde interventions can also be performed. Weilert et al. described a small case series in which common bile duct stones in patients with prior Roux-en-Y gastric bypass were managed using EUS-guided anterograde interventions. After puncture and wire access across the papilla, anterograde papillary dilation and stone clearance across the papilla was successfully achieved in 4 of 6 attempts (67%). [24]

EUS-Guided Transluminal Biliary Drainage

Transluminal biliary drainage involves placement of a stent across the puncture route to create a new drainage tract between the gastrointestinal tract and the biliary system, essentially resulting in an EUS-guided hepaticogastrostomy or EUS-guided choledochoduodenostomy. Technical steps for these procedures include (1) EUS-guided puncture into the bile duct, (2) guidewire advancement across the puncture tract, (3) over-the-wire balloon, catheter, or cautery-assisted dilation of the puncture tract, and (4) placement of a plastic or metal stent across the puncture tract to create a new route for biliary drainage.

The procedure is usually reserved for treating malignant biliary obstruction. Although initial reports of EUS-guided biliary drainage involved use of plastic stents, over the last decade there has been a shift to using covered metal stents. Several studies from expert centers have shown high success with these techniques, for both EUS-hepaticogastrostomy and EUS-choledochoduodenostomy (89–95%). [25–27] Since this technique involves tract dilation and creation of a fistulous tract between two lumens, major adverse events such as bleeding and perforation can occur and are reported in up to 7% and 3%, respectively. [25–27] Given the technical steps of the procedure, some extent of bile leakage is expected but is likely of minimal consequence when successful biliary drainage is achieved. If stent placement fails after bile duct puncture and tract dilation, a more substantial bile leak that requires prompt management may occur. Thus, these types of EUS-drainage procedures should be performed at centers where interventional radiology and surgery services are readily available.

Studies Comparing EUS-Biliary Access and Drainage to Other Techniques

EUS-RV vs. ERCP Precut

Few studies have directly compared EUS-RV to precut papillotomy. Dhir et al. compared a cohort that underwent EUS-RV to a historical cohort who underwent precut papillotomy after failed selective biliary cannulation. Biliary access was more successful among the EUS-RV group (57/58 patients) compared to the precut papillotomy group (130/144 patients) (98.3% vs. 90.3%; $P = 0.03$). Adverse events rate was similar in both cohorts. [16]

A more recent study by Lee et al. compared two large (> 1000) ERCP cohorts. In one cohort, both precut papillotomy and EUS-guided access was available to assist failed cannulation. In the other cohort, only precut papillotomy was utilized for failed access. In addition to finding higher overall ERCP success in the cohort with both EUS and precut available, they found significantly higher success with EUS-guided biliary access attempts (95.1%) compared to precut (75.3%; $P < 0.001$). [17]

Although these data support that EUS-RV may be more effective than precut in expert hands, it is a more time-consuming ordeal, requiring switching from a duodenoscope to an echoendoscope, and then back to a duodenoscope. Thus, we suspect that in practice precut papillotomy will be tried first, prior to attempting EUS-RV.

EUS-Guided vs. Percutaneous Biliary Drainage

Traditionally, when standard and advanced biliary cannulation techniques fail, patients undergo percutaneous transhepatic biliary drainage. At most institutions, percutaneous drainage necessitates a separate procedure after the failed ERCP. The advent of EUS-guided biliary drainage offers the advantages of (a) achieving biliary drainage internally during the same session as the failed ERCP, and (b) avoiding percutaneous drainage related complications that may occur in up to 40%, including catheter dislodgement and occlusion, cholangitis, and skin infection. [28]

Artifon et al. first compared the two modalities in a small randomized trial, and found similar success, complication rates, costs, and quality of life measures. [29] Two meta-analyses have since been published comparing the two modalities. In one, Baniya et al. found that technical and clinical success rates were similar but EUS-biliary drainage was safer than percutaneous drainage. [30] In a 2nd meta-analysis, Sharaiha et al. found similar technical success and hospital length of stay, but improved clinical success, safety profile, and cost-efficiency with EUS-drainage. [31••] These results suggest that EUS-guided biliary drainage may be the first-line drainage method after failed ERCP at institutions where interventional endosonography skills are available.

EUS-Guided Transluminal vs. ERCP Biliary Drainage

The high success of EUS-biliary drainage along with expanding endoscopists' experience and improved accessories to perform these procedures has steered some to investigate whether EUS-biliary drainage could substitute ERCP as the first-line method for malignant biliary decompression. Three recent randomized controlled trials, 2 from Korea and 1 from the USA, compared EUS-guided vs. ERCP-guided biliary drainage for malignant biliary obstruction as a first-line technique. [32••, 33, 34] Bang et al. performed EUS-choledochoduodenostomy using a fully covered self-expanding metal stent (SEMS) with anti-migration fins (Viabil; Conmed, Utica, NY). [32••] Park et al. performed EUS-choledochoduodenostomy using SEMS with an uncovered sleeve part and a fully covered body part with anti-migration features (Hanarostent, MI Tech, Seoul, South Korea). [34] Paik et al. performed EUS-choledochoduodenostomy and EUS-hepaticogastrostomy for transmural biliary drainage using a dedicated stent introducer/dilator system with an SEMS consisting of an uncovered proximal portion, covered mid-portion, and distal funnel-shaped uncovered portion to prevent stent migration (DEUS; Standard Sci Tech Inc., Seoul, South Korea). [33] All three randomized trials compared these EUS-biliary drainage techniques to ERCP drainage with transpapillary SEMS, and found similar technical and clinical success rates between EUS and ERCP techniques. Paik et al. also showed that EUS-drainage was superior to ERCP drainage in terms of longer duration of stent patency, lower rates of adverse events and reinterventions, and improved quality of life. [33] Bang et al. additionally found that EUS-choledochoduodenostomy did not impede subsequent pyloric-sparing pancreaticoduodenectomy. [32••] The aforementioned randomized trials were included in 3 recently published meta-analyses reaching the same conclusion of similar efficacy and safety between the two techniques. [35–38] These data support that EUS-guided transmural biliary drainage may be a comparable substitute to ERCP drainage in expert hands.

New Technologies for EUS-Biliary Access and Drainage

A limited number of tools have emerged recently to facilitate EUS access and EUS-guided biliary drainage. In 2015, an electrocautery enhanced lumen apposing metal stent (ECE-LAMS; Hot AXIOS™, Boston Scientific, Marlborough, MA) became available in the USA. It was developed to facilitate one-step drainage of pancreatic fluid collections. This device offers the ability to pass the delivery system of a bi-flanged, lumen apposing metal stent across the GI wall using the electrocautery enhanced

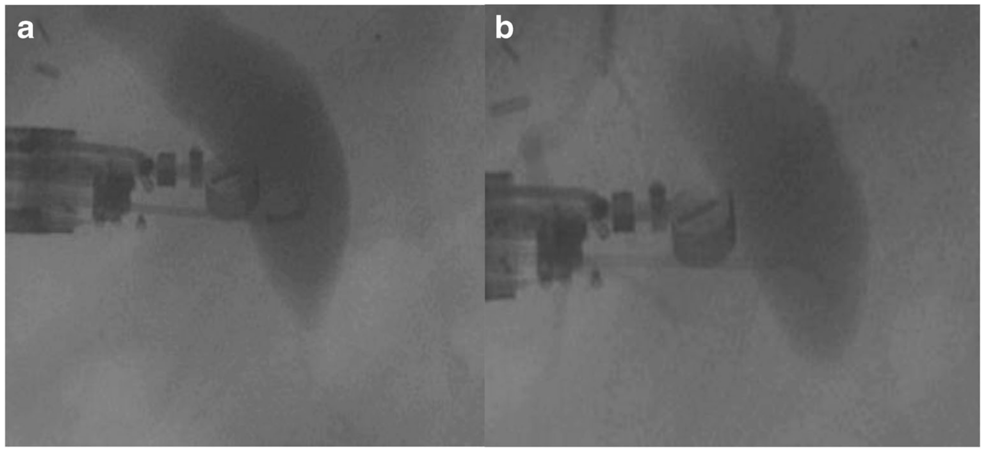

Fig. 1 Steerable access needle with upward curve towards proximal bile duct (**a**) and downward curve towards papillary orifice (**b**)

cutting tip, obviating the need for tract dilation. Such a device may be particularly useful for EUS-choledochoduodenostomy given the perceived ease to place the tip of the stent delivery system into the bile duct, followed by deployment of a bi-flanged LAMS that should theoretically reduce risk of stent migration. An Italian group reported the use of ECE-LAMS in EUS-choledochoduodenostomy with a technical success in 43/46 (94%) and a clinical success of 98%. Adverse events occurred in 5 (11.6%) patients including one fatal bleeding. Smaller-diameter ECE-LAMS of 6 mm and 8 mm were thought to be more ideal for this procedure, and were the most commonly used in this study. [35] Although these smaller-sized ECE-LAMS are not yet available in the USA, several tertiary centers here have been performing EUS-choledochoduodenostomy with the 10-mm diameter model over the last few years. We spearheaded a multicenter, retrospective US study to investigate the outcomes of using the 10 × 10 mm ECE-LAMS and found similar results to the European study. Technical success was achieved in 64/67 (96%), and clinical success in 100% of those who were followed for > 4 weeks. Adverse events occurred in 4 (6.3%) patients without any procedure-related mortality. [39•]

Another recent novelty is a steerable access needle (Beacon EUS Access System; Medtronic, Inc., Sunnyvale, Calif, USA) that may reliably direct the angle of guidewire advancement during EUS-guided biliary interventions (Fig. 1). Upon ductal access, removal of the sharp stylet changes the blunt-ended needle tip into a curved shape that can be rotated as desired by the operator. Ryou et al. reported the first experience with this system. They found that needle puncture and selective wire advancement in the intended direction were successful in 100% of cases (22/22) followed by technical success with the EUS intervention in 95%, which included 13 successful EUS-RV and 7 successful EUS-drainage procedures. [40]

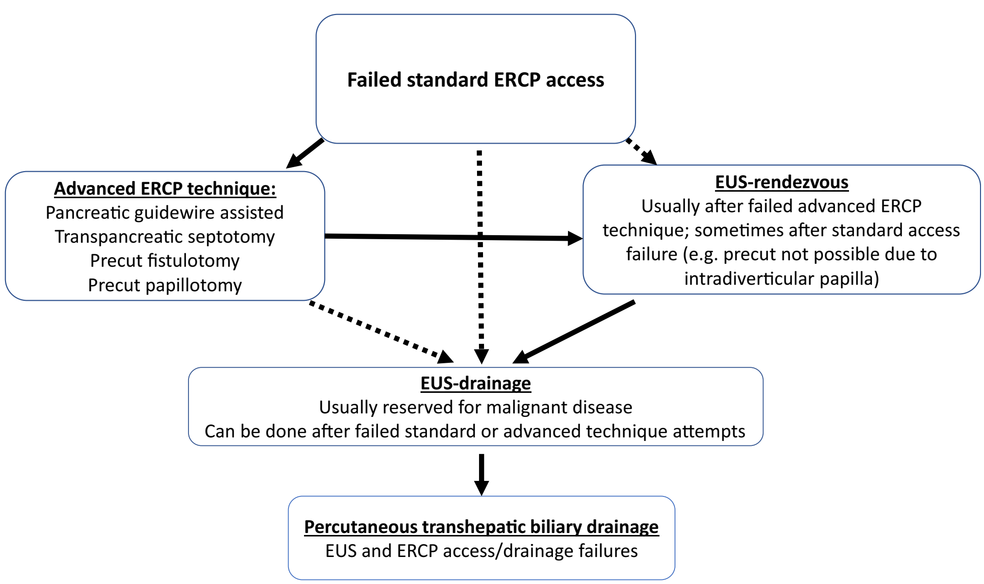

Fig. 2 Algorithm used for biliary access after failed cannulation in patient with unaltered upper GI tract anatomy. Solid line arrows depict usual pathways. Dotted line arrows suggest alternate pathways that may supersede usual pathway, often depending on specific situations leading to biliary access failure and the underlying indications for biliary obstruction

Biliary Access in Gastric Bypass

Roux-en-Y gastric bypass (RYGB) constitutes 47% of all bariatric surgeries worldwide. [41] Endobiliary interventions in patients with prior RYGB are a particular challenge. Up until recently, the two main options included deep enteroscopy-assisted and laparoscopic-assisted ERCP. In 2014, Kedia et al. reported the first EUS-directed transgastric ERCP (EDGE). [42] EDGE utilizes EUS to create a fistulous tract between the gastric pouch and gastric remnant using a LAMS, following which a duodenoscope is advanced across the fistulous tract to perform standard ERCP. A recent meta-analysis compared EDGE (4 studies) to deep enteroscopy-assisted (5 studies) and laparoscopic-assisted ERCP (18 studies). Technical and clinical success with EDGE were similar to laparoscopic-assisted ERCP (95.5% and 95.9% vs. 95.3% and 92.9%) and better than deep enteroscopy-assisted ERCP (95.5% and 95.9% vs. 71.4% and 58.7%). EDGE also has a similar safety profile (21.9%) compared to LA-ERCP (17.4%) but a higher adverse event rate compared to deep enteroscopy-assisted ERCP (8.4%). [43] The most common adverse event with EDGE was migration of the luminal conduit stent (13.3%). Sequalae from this can be minimized by either (1) performing EDGE as a 2-stage procedure where the ERCP is performed 1–2 weeks after LAMS placement to allow the fistula to mature, or (2) endoscopically suturing the LAMS flange to the gastric pouch before performing ERCP. The fistulous tract is usually endoscopically closed (clipping or suturing) after ERCP treatment is achieved to minimize risk of oral intake flowing into the remnant stomach and potential weight gain. Fortunately, the majority of published studies have not shown any significant weight gain up to an average 28 weeks following EDGE. [43, 44•, 45] Other advantages of EDGE over laparoscopic-assisted ERCP include shorter hospital stay and reduced cost. [44•, 46] These results support considering EDGE as first-line treatment for biliary access and intervention in suitable RYGB patients.

Conclusion and Future Directions

Achieving biliary access remains the first, most important, and, often, the most challenging aspect of even routine ERCP. There is no other endoscopic procedure for which the acceptable failure threshold is up to 10%. [47] ERCP-based access techniques, such as pancreatic guidewire-assisted cannulation and precut, are long established and do improve biliary access when standard cannulation fails. However, the newest advances in endobiliary access involve EUS. These include EUS-RV- and EUS-guided drainage. On the whole, these techniques appear to be at least on par to, if not better than, than ERCP-based methods for biliary access and drainage, and can be useful to facilitate endobiliary therapy. We generally recommend the algorithm shown in Fig. 2 after failed standard ERCP access. We anticipate that new technologies designed specifically for interventional EUS, dissemination of techniques, and additional outcomes data as well changes in training paradigms in which more advanced endoscopy trainees emerge with skills in both ERCP and EUS will all lead to major growth in interventional EUS.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- • Of importance
- •• Of major importance

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