Review Article

EUS-guided drainage: Summary of Therapeutic EUS consortium meeting

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ABSTRACT

EUS-guided drainage is a safe and efficacious endoscopic technique for biliary, pancreatic, and gallbladder decompression. Recent literature has described many successful procedural techniques and devices to achieve EUS-guided drainage. This consortium gathering advanced endoscopists with expertise in both ultrasonography and therapeutic endoscopy, discuss the introduction to learning several EUS-guided drainage approaches, devices, and technology involved, possible obstacles to certain procedural and all potential complications.

Key words: Consortium, drainage, EUS

LEARNING EUS-GUIDED BILIOPANCREATIC DRAINAGE

Proficiency in both EUS-FNA and therapeutic ERCP is required for endoscopists willing to perform EUS-guided biliopancreatic ductal access. Threshold numbers of supervised procedures have been set to define competence at around 100 for EUS-FNA and 200 for ERCP. However, those numbers are no guarantee of competence and the real numbers for true competence are probably higher in practice.[1]

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A working knowledge of linear EUS anatomy and familiarity with the nuances of large caliber (19G) needle advancement into small targets at different scope positions are necessary to successfully puncture the bile or pancreatic ducts (PDs). EUS-guided ductal puncture is comparable to cannulation. Even if cannulation is a critical step of therapeutic ERCP, it is less challenging than the therapeutic steps that follow it, such as large stone removal or hilar stenting. Similarly, ductal puncture is only the beginning and probably the easiest step of EUS guided biliary drainage (EUS-BD). Following needle

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access contrast is injected for ductography, a guidewire advanced into the duct under fluoroscopy, and the needle exchanged for flexible devices. Fluoroscopy-guided manipulation of over the wire flexible devices (dilators and stents) belongs in the realm of ERCP.

EUS-GUIDED DRAINAGE

Pseudocysts are the paradigm targets for EUS-guided access and drainage. In addition to EUS-FNA and therapeutic ERCP skills, experience in pseudocyst drainage is highly recommended before EUSBD. Pseudocysts are larger in size and adherent to the GI lumen. Both features render them much easier targets for drainage than bile duct or PDs. For operators, already proficient in EUS-FNA, the median procedure duration of EUS-guided pseudocyst drainage significantly decreased from 70 to 25 min after the initial 25 cases.[2] Procedural duration is a surrogate marker of technical difficulty.

BILIOPANCREATIC EUS-GUIDED ACCESS

There is scant information on the learning curve of EUSBD. Novel operators have much lower success rates than experienced operators. A multicenter study including biliary and pancreatic EUS-guided access and drainage procedures during the early cases of 23 different endoscopists revealed an overall success rate of only 67% (84 out of 125). When the procedures were broken down by different approaches, hepaticogastrostomy had the lowest success rate (64%) and the highest complication rate (29%), whereas choledochoduodenostomy exhibited the highest success rate (86%) and lowest complication rate (15%) in that study.[3] Rendezvous (RDV) was in a reasonable middle point, with low success and complication rates [Table 1].

TRAINING MODELS

EUS biliopancreatic access is not only a challenging but also risky procedures requiring trainees with high baseline expertise. Learning is also hampered by the fact that these procedures are relatively uncommon, even in busy units. Porcine models of bile duct obstruction have traditionally been created by laparoscopic ligation of the common bile duct (CBD). More convenient porcine models to obtain bile duct dilatation by means of endoscopy have been recently reported. Hemoclips, endoloops, or a combination of both, as well as Ovesco clips, result in significant dilation of the porcine bile duct. These animals have been used to test new devices for EUSBD and to train novel operators in EUSBD with background expertise in EUS-FNA and ERCP.[4-6] Cost and ethical considerations limit the availability of live porcine models. *Ex vivo* duct models with plastic three-dimensional printing based on human magnetic resonance imaging imprints have also been tested at training courses with promising results. If these preliminary experiences can be replicated, a useful and affordable model may become available.[7]

LEARNING IN PRACTICE

The difference in success and complication rates during early experience[3] provides support to the concept of gradual learning based on a complexity scale during actual clinical cases.[1] Given the limitations discussed above for hands-on learning, a viable strategy to get started after having performed at least 10 EUS-guided pseudocyst drainage procedures, would be to select the extrahepatic (EH) bile duct for access. A hugely dilated CBD imaged from the duodenal bulb is closer to a pseudocyst based on size, proximity, and relative lack of mobility. RDV is also easier from EH than intrahepatic (IH) approach.[7] If RDV fails, salvage choledochoduodenostomy can be performed with relative safety, especially if needle knives are avoided and graded dilation or coaxial cautery are used instead.[6]

After a minimum of 20 well-selected patients with malignant distal biliary obstruction not amenable to ERCP (either concurrent malignant duodenal obstruction or failed precut) have been undertaken through RDV

Table 1. Outcomes of the different EUS-guided biliary techniques

Technique	*n*	Benign/malignant	Technical success (%)	Complications (%)
EUS-HGS	34	0/34	64.7	11 (29)
		3 biloma, 3 bleeding, 2 perforations, 2 liver hematoma, 1 abcess		
EUS-CDS	26	22/4	86.3	4 (15.3)
		1 biloma, 1 bleeding, 1 acute pancreatitis, 1 cholangitis		
Rendezvouz	60	29/31	68.3	13 (21.6)
		3 biloma, 2 bleeding, 2 perforations, 4 acute pancreatitis, 2 cholangitis		

HGS: Hepaticogastrostomy, CDS: Choledochoduodenostomy

or choledochoduodenostomy with at least a 70% success rate and no more than 30% complication rate, it may be legitimate to consider IH access for EUSBD (RDV, antegrade, and/or hepaticogastrostomy) in patients with malignant obstruction exhibiting dilated IH ducts >5 mm within a range of 2 cm. The last step of these suggested protocols of gradual learning through a complexity scale would be PD access and drainage procedures, with a similar pattern of attempting RDV as a preferred approach.

DIFFICULT CANNULATION: WHAT SHOULD I DO BEFORE EUS GUIDED ACCESS?

ERCP is a technically-demanding procedure and an important tool in diagnosis and therapy of benign and malignant disorders of the biliary tree.[8]

The ability to selectively cannulate the bile duct quickly and atraumatically is the key to successful therapeutic ERCP, and to minimizing post-ERCP complications, especially pancreatitis (PEP).[9]

The selective cannulation of the CBD is a difficult procedure, the success of which mainly depends not only on the skills of the examiner but also the anatomical variants and the underlying illnesses.[8]

The access can usually be overcome using basic anatomic principles to optimize endoscope position and cannula axis, and by selecting accessories based on identified challenges.[10]

The clinical success of a procedure is determined by the balance between clinical efficacy, technical success, and adverse events.[11]

Skilled biliary specialists achieve successful cannulation 95%–99% of the time while experienced community endoscopists should reach cannulation rates above 90%.[10] However, selective bile duct cannulation can fail in up to 10% of patients, with an increased risk of post-ERCP PEP.

CRITICAL ANALYSIS OF THE ACCESSORIES FOR CONVENTIONAL CANNULATION

A variety of instruments and techniques exist to achieve selective CBD cannulation, including the use of a standard or tapered catheter, sphincterotomes, performance of precut papillotomy, and the use of guidewires.[12]

Most catheters used for ERCP are 5F to 7F in diameter and can accept guidewires up to 0.035 in diameter. Regular cannulas with or without guidewires can be difficult to use because the angle of approach cannot be varied. Standard papillotomes are widely used for cannulation.[11]

A randomized trial comparing the success of biliary access using a sphincterotome with that of a regular cannula found, in 100 patients, that a sphincterotome without a guidewire was successful in 84% using a sphincterotome compared with 62% using a standard cannula ($P < 0.05$).[13]

These findings were confirmed in another randomized trial.[12]

Rotatable papillotomes are widely used now, which allow the endoscopist to match of the angle of approach of the papillotome to the specific course of the bile duct within the papilla. These devices may improve cannulation in surgically altered anatomy, distorted and peridiverticular papillas, or unusual angulation of the bile duct.[11]

A randomized trial of conventional cannulation technique using sphincterotome and contrast injection *versus* guidewire cannulation technique has been conducted by Artifon *et al.*, and demonstrated that guidewire cannulation was associated with significantly lower likelihood of post-ERCP PEP ($P < 0.05$) by facilitating cannulation and reducing the need for precut sphincterotomy.[14]

A comprehensive list of devices for biliary cannulation and sphincterotomy was published in Gastrointestinal Endoscopy in 2010.[15]

LIMITING FACTORS

There are a lot of possible causes of difficult cannulation [Table 2].

The presence of periampullary duodenal diverticula used to be considered a risk factor for failed biliary cannulation. However, most of the time, the papilla remains accessible, often on a side wall of the

Table 2. Causes of difficult cannulation

Ampullary diverticulum
Periampullary tumor
Opie syndrome
Biliopancreatic junction
Surgically altered anatomy (bariatric surgery, Billroth II)
Papillitis
Sphincter of Oddi dysfunction
Small or tortuous papilla
Difficult approach to papilla
Patient with CBD stones and coagulopathy
Patient with cardiac pacemaker
Obstructive papillary tumor
Difficult access of papillary orifice
Recanalization of CBD due to ligation during cholecystectomy or postliver TX biliary anastomosis stricture

CBD: Common bile duct, TX: transplant

diverticulum. The difficulty arises when the papilla lies deep within a diverticulum and/or its orientation is unfavorable.[9]

The papilla can be difficult to locate in the setting of tumor infiltration of the papilla or the duodenum, or PEP that causes duodenal edema and distortion.[11]

Another anatomical rearrangement that presents technical challenges for ERCP is the Roux-en-Y biliary diversion performed in the latest iteration of bariatric (weight loss) surgery. Typically, the papilla cannot be reached with a standard duodenoscope, due to the considerable length of the Roux diversion.

In 2013, Choi *et al.* compared indications and outcomes between ERCP through gastrostomy (GERCP) *versus* double-balloon enteroscopy (DB-ERCP) to access the pancreatobiliary tree in patients with prior bariatric Roux-en-Y gastric bypass surgery (RYGB). They concluded that GERCP is more effective than DB-ERCP in gaining access to the pancreatobiliary tree in patients with RYGB, but it is hindered by the gastrostomy maturation delay and a higher morbidity.[16] Nevertheless, technical improvements in each method are needed.

"TRICKS" FOR CANNULATION

Using PD techniques to facilitate biliary cannulation is becoming increasingly popular. An advantage of this approach is that a PD stent can be placed to reduce the likelihood of PEP in the setting of difficult biliary cannulation.[11]

Over the last decade, the placement of small caliber stents in the PD has been recognized as the most effective technique identified to date to prevent the development of post-ERCP PEP.[9]

The efficacy and safety of biliary cannulation after PD wire placement was assessed in a randomized trial of 53 patients in whom biliary cannulation failed after 10 min. The patients were then randomized to further attempts using biliary techniques *versus* PD wire placement followed by repeat attempts at biliary cannulation. Successful cannulation was achieved in 93% when using the pancreatic wire, compared with 58% in the standard biliary techniques group ($P < 0.05$). No differences in PEP were observed, although the amylase tended to be higher when using PD access technique.[17]

Another group using pancreatic wire-assisted biliary cannulation in 32% of all ERCPs requiring biliary access reported no difference in complications when compared with easy conventional cannulation (mild PEP in 7.8% and 8.3%, respectively).[18]

These findings were confirmed by Chan *et al.*, suggesting that leaving a PD stent in place following needle-knife sphincterotomy reduced the PEP rate from 21.3% to 2.2%.[19]

A variety of "tricks" may have to be tried to obtain a view of the papilla from which it can be cannulated. The tip of the duodenoscope may have to be negotiated inside the diverticulum, which risks injury and possible perforation. Blind probing of the diverticulum with guide wires and catheters is even more dangerous and should be avoided. Advancing the duodenoscope into the "long position" is one way to alter its orientation to the diverticulum and the papilla within.[9]

Papilla-related factors for the successful selective cannulation of the CBD were assessed in 50 patients with a papilla with no prior sphincterotomy needing an ERC and suggest that the typical position of the duodenoscope is the single most important factor determining success. The combination of two variables – typical position of duodenoscope and visible orifice – has a positive predictive value of 96%. These variables can be evaluated easily at the beginning of the procedure and can be used by the examiner to quickly predict success.[8]

DIFFICULT CANNULATION

We can define difficult cannulation depending on the time taken to achieve deep cannulation of the bile duct (more than 5 min) or the number of cannulation of the PD while accessing the biliary tree (more than 10 attempts).

Quick, atraumatic access is the ideal, but this is not always possible, even for experts. Repeat cannulation of the PD when the bile duct is the intended target invites PEP; there is a direct (linear) relationship between the number of PD instrumentations and the likelihood of this complication, especially if contrast medium is repeatedly injected.[8]

OPTIONS FOR BILIARY ACCESS

Precut

Precut papillotomy can be accomplished by a variety of techniques, the success, and complications of which heavily depend on technique-related factors and the risk profile and anatomic variations of the patient. In particular, the skill of the endoscopist, the indication for the procedure, and the use of pancreatic stents all influence the outcome of this procedure.[11]

Precut papillotomy, when performed as a rescue measure, is widely considered as the procedure of choice and improves the success rate of ERCP to 95%–98% at expert centers.[20]

The decision to use a precut technique relies on a variety of factors. For example, one group reported that this technique was more necessary in unusual or distorted anatomy of the papilla, such as in the case of duodenal stenosis or malignancy.[11]

In a randomized study of 103 patients with choledocholithiasis, needle-knife fistulotomy was compared with needle-knife precut papillotomy.[21] Precutting was successful in 90.54% of patients in the needle-knife fistulotomy group, and 88.6% of patients in the needle-knife precut papillotomy group. Both methods were effective in the management of choledocholithiasis. When needle-knife fistulotomy is performed, however, lithotripsy is needed more often. Needle-knife fistulotomy was safer than needle-knife precut papillotomy with respect to pancreatic complications.[21]

TRANSPANCREATIC SPHINCTER PRECUT

A more common technique, known as "transpancreatic precut sphincterotomy," involves intentional seating of a standard papillotome into the PD and making a transseptal incision to access the bile duct.

The trans PD precut to gain access to the bile duct for diagnostic and therapeutic maneuvers has been described as useful. To further evaluate this technique, Goff performed a review on 200 consecutive endoscopic sphincterotomies. Precutting was successful in 96% of patients.[22] The overall complication rate for the standard sphincterotomy was 2.1%; that for the transpancreatic approach was 1.96%. There were no cases of post-ERCP PEP after trans PD precut sphincterotomy.[22]

PAPILLARY NEEDLE PUNCTURE

The suprapapillary needle-puncture is a technique allowing selective cannulation of the bile duct using suprapapillary needle puncture of the bile duct followed by balloon dilation of the tract. It avoids potential mechanisms that precipitates PEP associated with conventional transpapillary biliary cannulation and endoscopic sphincterotomy.[23]

Available techniques for biliary cannulation are shown in Table 3.

CURRENT ALTERNATIVES FOR BILIARY CANNULATION

Failed biliary cannulation has been traditionally managed with percutaneous transhepatic biliary drainage (PTBD) or surgery. The potential complications associated with these procedures, along with the patient dissatisfaction associated with external drainage make these options less desirable. EUS-guided cholangiopancreatography followed by biliary drainage (BD) has been described in many case reports and series confirming both the success and safety of this technique.

EUS-guided RDV drainage of the bile duct can be performed in the endoscopy room in the same session and involves gaining access to the biliary tree through the duodenum or stomach using a 19-gauge needle.[20]

The efficacy and safety profile of the EUS-guided RDV technique with the use of the short wire system and

Table 3. Current alternatives for biliary cannulation

Author	Technique	Success	Complications (%)	
			Hemorrhage	Pancreatitis
Seifert, 1999	Micropapillotome (1 mm)	98% (53/54)	-	-
Farrel, 1996	Ampullectomy	100% (10/10)	10	-
Heiss, 2002	Endoscopic scissors	75% (8/12)	0	0
Hashiba, 2004	Suprapapillary dissection	100% (48/48)	0	8
Artifon, 2005	Suprapapillary puncture	90% (28/30)	0	0

a comparison of the clinical outcomes with patients who underwent precut papillotomy for biliary access were evaluated in a retrospective study. Treatment success was significantly higher for the EUS-guided RDV than for those undergoing precut papillotomy techniques (98.3% *vs.* 90.3%; $P < 0.03$). There was no significant difference in the rate of procedural complications between the EUS and precut papillotomy techniques (3.4% *vs.* 6.9%, $P < 0.27$).[20]

Selective cannulation of the CBD can be difficult, so multiple strategies have been developed to overcome the situation: different papillotome instead of the standard catheter, precut papillotomy using precut needle knives or precut papillotome, transpancreatic papillary septotomy, and stenting of the PD. However, these methods carry a high complication rate.

Bile duct cannulation remains an important benchmark of successful ERCP. Alternative biliary access techniques are crucial if biliary cannulation remains unsuccessful.

EUS-GUIDED BILIOPANCREATIC DRAINAGE COMPLICATIONS AND ACCEPTANCE

EUS-guided bile duct drainage (EUS-BD) is an available option for biliary decompression as an alternative to the percutaneous or surgical intervention when ERCP fails.[24,25] However, over the past 18 years, the technique of EUS-guided biliary, and pancreatic access has not gained widespread acceptability. Although multiple case series have been published over the past few years, the technique has not become as popular as expected. Even at the larger tertiary centers, the use of EUS-guided cholangiopancreaticography (ESCP) varies considerably. For example, in a reported series from Shah *et al.*, rate of ESCP was about 4% (95 ESCP cases in a total of 2566 ERCP over a period of 4 years).[26]

For any new technique to gain widespread acceptance, it should meet the basic criteria of safety, easy availability, and superiority to other available options. Some of the reasons contributing to the lack of widespread acceptance of ESCP include:

- Concern for safety
- Lack of documented superiority to the current available options
- Lack of dedicated devices
- Lack of widespread expertise
- Lack of randomized control trial comparing ESCP to other minimally invasive options.

SAFETY AND EFFICACY OF EUS-GUIDED CHOLANGIO-PANCREATICOGRAPHY

ESCP can be subcategorized to EUS-guided biliary access (EUS-BD) and EUS-guided pancreatic access (EUS PD).

EUS-BD has been described using extrahepatic and IH approach. A review of 20 published case series of EUS-BD using extrahepatic approach involving five or more patients shows the rate of technical success to range from 70% to 100% with a total success rate of 90% (325/360).[27] The rate of adverse events in these series ranged from 0% to 47% with a total rate of adverse events of 14% (51/360).[27] The average rate of technical success and adverse events was similar in the IH approach EUS BD (technical success: 109/123: 88% and adverse events 19/123: 15%).[27] The adverse events associated with EUS-BD by any approach included: pneumoperitoneum, cholangitis, bile leak, peritonitis (including a death from peritonitis), hemobilia, stent dysfunction, aspiration pneumonia, and cardiopulmonary failure due to fluid overload.

In the largest series published to date, 240 patients who underwent EUS-guided bile duct access and drainage (EUS-BD) were retrospectively analyzed.[28] Success was achieved in 87% of cases, with a similar success rate in EH and IH approaches. In a recently published meta-analysis,[29] EUS-BD had a cumulative success rate of 90% and cumulative adverse events rate of 17%.[29]

COMPARISON WITH PERCUTANEOUS DRAINAGE

Percutaneous transhepatic biliary drainage allows for duct decompression when ERCP fails. Success and complications of PTBD in dilated biliary ducts seem related to the level of obstruction. In a series of 75 patients with distal biliary obstruction treated with PTBD, technical success was achieved in 100% of patients. Early complications occurred in 21%, with 1% procedure-related mortality. Stent occlusion occurred in 5% of patients after a median of 152 days. The results are similar to other published series.[3,30-32]

In patients with proximal (hilar or proximal) PTBD can be more challenging. There is a higher risk of cholangitis by injecting contrast medium into the undrained ducts. In one series of 45 patients with hilar tumors, the technical success was achieved in all patients; complications were seen in 16% of patients with 4% procedure-related mortality.[33] Cholangitis was the most common complication. Comparable results are found in other published series with a technical success rate >90%, clinical success rate of 77%–98% and complication rates of 7%–30%.[34-36] Procedure-related complications of PTBD include cholangitis, septicemia, bile leakage into the abdominal cavity, empyema of the pleural space, hemorrhage, pain during or after the procedure, and catheter dislocation.

A small trial compared ESCP to PTBD, where 25 patients with failed ERCP were randomized to ESCP *vs.* PTBD. There were no differences between the two groups in terms of technical success, clinical success, complications, and cost of treatment.[37] In a recent randomized control trial both techniques had similar levels of efficacy; however, EUS-BD produced fewer procedure-related adverse events and unscheduled re-interventions.[38]

In expert hands, rates of technical success and adverse events appear similar in the two techniques. However, ESCP needs advanced training and has a significant learning curve.

EUS-guided gallbladder drainage

Percutaneous transhepatic gallbladder drainage (PTGBD) is considered a safe alternative to early cholecystectomy, especially in surgically high-risk patients with acute cholecystitis.[39] Endoscopic gallbladder drainage including nasogallbladder drainage and gallbladder stenting through a transpapillary techniques are alternative methods, but both of them have lower success rates than that of PTGBD.[39] Recently, EUS-guided transmural gallbladder drainage (GLB) has been reported as a novel technique for gallbladder drainage.[40]

Several investigators have reported that procedure-related complications occurred in approximately 11%.[39,40] Complications include pneumoperitoneum and bile leak with or without bile peritonitis. Initially, double-pigtail plastic stents or naso-gallbladder catheter had been used for this procedure. More recently, EUS-GLB appears to be safer by using fully covered metal stent with fins or the dedicated bi-flanged, fully covered metal stent.[41] Interestingly, a recent meta-analysis was published demonstrating the efficacy and safety EUS-GLB when compared to PTGBD.[42]

EUS-guided pancreatic duct drainage

Only seven published series of EUS PD with five or more patients were available for review. The total number of patients in these series was 115, with the largest series of 37 patients.[27] The overall technical and clinical success rates were 90/115 (78%, range 48%–91.7%) and 51/68 (75%, range 50%–100%), respectively.[27] The overall complication rates were 19/115 (16.5%, range 10%–42.9%) and included mild and severe PEP, abdominal pain, bleeding, perforation, fever, and peripancreatic abscess. The rate of adverse events in pancreatic access may be higher due to risks of PEP and lack of an easy "fall back option" after the PD has been punctured and track dilated but drainage could not be achieved.

LACK OF DEFINED CONSENSUS

A wide range of techniques is currently being used in ESCP with a lack of clear consensus. Multiple techniques are being used to access and drain the obstructed ducts. A recent paper proposed an interesting algorithm in which patients with a dilated IH biliary tree (IHBT) on cross-sectional imaging received an IH approach with anterograde biliary stent placement or hepaticogastrostomy stent placement. Patients with a nondilated IHBT on cross-sectional imaging underwent an EH approach with an RDV technique or a transenteric stent placement if the RDV technique was not feasible. If IH drainage was attempted but unsuccessful, conversion to an EH approach was performed. The technical success was achieved in 50 (96%) patients.[43]

LACK OF EASILY AVAILABLE EXPERTISE

ESCP requires a high level of proficiency in both EUS and ERCP procedures. As of today, the technique is predominantly limited to large, tertiary care centers. There is a shortage of endoscopists trained in EUS and ERCP. Even at many tertiary centers with physicians trained in EUS and ERCP, the use of ESCP is low as many of them are uncomfortable with the technique. There is a significant learning curve, as shown in the Spanish national survey study.[3] ESCP demands a much higher technical proficiency than the other endoscopic techniques including pseudocyst drainage.

Trained interventional radiologists, on the other hand, have a wider presence including the smaller community hospitals.

In centers lacking ESCP expertise, an endoscopist may find it easier to send a patient failed ERCP for in-hospital IR drainage rather than transfer to a referral center due to various logistic and financial reasons.

ROLE OF EUS-GUIDED CHOLANGIO-PANCREATICOGRAPHY AS OF TODAY

As a technique, ESCP is still in the process of evolution and refinement. In our view, ESCP may be considered, in appropriate patients, only by an experienced endoscopist. The careful selection of access techniques and availability of proper devices is crucial. It is important to have surgical and/or interventional radiology backup in case of failure or an adverse event.

EUS-GUIDED DRAINAGE: NEW DEVICES

At present, dedicated endoscopic devices for transluminal stenting are limited. The aim of this section is to evaluate the new stent dedicated for EUS-guided drainage.

Lumen apposing metal stents

Four types of lumen apposing metal stents have invaded the market and include AXIOX and HOT-AXIOS (Boston Scientific, Natick, MA), NAGI (Taewoong Medical Co, Ltd., South Korea), and SPAXUS (Taewoong Medical Co, Ltd., South Korea).

The "HOT-AXIOS" is the only cautery enhanced LAMS which permit to reduce dramatically the time of the procedure since the delivery system is equipped at its top of a metal part which allows cautery and created a communication between the target and the enteral wall. The main indication of this new device is choledocoduodenostomy and cholecysto-duodeno or gastrostomy. Itoi *et al.* reported the results of a multicenter study on these indications.[44] EUS-guided cholecystogastrostomy for decompression of the bile duct is suitable in the following situations: (i) distal biliary obstruction; (ii) the cystic duct is not obstructed and takes off above the stricture; (iii) duodenal obstruction that requires a duodenal stent; and (iv) inappropriate EUS-guided hepaticogastrostomy as a result of a nondilated IH bile duct.

Hybrid stent

This hybrid stent (GIOBOR, Taewoong Medical Co, Ltd., South Korea) has been manufactured for EUS-BD to prevent bile leakage and migration. The originality of this stent is to be half covered with a large flange. The uncovered part of the stent should be inserted in the biliary tree while the covered part with the large flange is placed in a transluminal fashion. Song *et al.*[45] have reported their experience in 27 consecutive patients. EUS-guided hepaticogastrostomy was performed in 10 patients, and EUS-guided choledochoduodenostomy was performed in 17 patients. The technical success rate of EUS-BD with the hybrid metal stent was 100% (27/27), and clinical success was achieved in 96.3% (26/27) of the cases. Adverse events developed in five patients (5/27, 18.5%), including a self-limited pneumoperitoneum in three patients, minor bleeding in one patient, and abdominal pain in one patient. During the follow-up (median 134 days), proximal or distal stent migration was not observed.

One step delivery system

A novel dedicated device for one-step EUS-guided biliary drainage system (DEUS) introducer has size 3F tapered catheter with size 4F metal tip for simple puncture of the intestinal wall and liver parenchyma without graded dilation.[5] A self-expandable metal stent, consisting of both uncovered and nitinol-covered portions, was preloaded into DEUS introducer. After the establishment of a biliary dilatation model using endoscopic hemoclips or band ligation with argon plasma coagulation in 9 mini-pigs, EUS-BD using a DEUS was performed following 19-G needle puncture without the use of fistula dilation devices. One-step EUS-BD was technically successful in seven pigs (7/9 [77.8%] as intention to treat) without fistula dilation from the

body of the stomach or far distal esophagus to the IH (n = 2) or common hepatic (n = 5) duct. The primary technical failure occurred in two cases that did not show adequate biliary dilatation. In seven pigs with a successful bile duct dilatation, the technical success rate was 100% (7/7 as per protocol). The median procedure time from confirmation of the dilated bile duct to successful placement of a metallic stent was 10 min (interquartile range; 8.9–18.1). There were no immediate procedure-related complications. A modified tapered metal tip and low profile introducer may be technically feasible for one-step EUS-BD in the experimental porcine model.

CONCLUSIONS

Dedicated accessories are necessary to increase efficacy and reduce the complication rate of EUS-guided procedure.

Take home message

1. Conventional Techniques should be attempted whenever possible for biliary or pancreatic access
2. EUS-guided biliary and gallbladder drainage in expert hands are safe and efficacious and can be used as an alternative to percutaneous drainage to improve quality of life
3. EUS-guided pancreatic drainage is the most difficult EUS-guided procedure
4. Training in EUS-guided pancreaticobiliary procedures require training in ERCP, EUS, and therapeutic EUS, using *ex vivo* models, *in vivo* models and proctoring of initial cases
5. Complication of EUS-guided drainages can be limited by appropriate selection of tools, techniques, and prompt recognition
6. Acceptance and wide distribution of EUS-guided pancreaticobiliary procedures require appropriate training of the next generation of therapeutic endoscopists
7. The arrival of new tools and devices should increase safety and efficacy of those procedures.

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Conflicts of interest

Michel Kahaleh has done consulting work for Boston Scientific, Interscope Med, and Abbvie. He is the CEO and Founder of Innovative Digestive Health Education & Research Inc, Therapeutic Endoscopic Ultrasound Society and Obesity Coalition Inc. He is the CEO and Co-Founder of Clinical Research Directory Inc. Monica Gaidhane has done consulting work for Interscope Med. She is the COO of Therapeutic Endoscopic Ultrasound Society, Innovative Digestive Health Education & Research Inc. & Obesity Coalition. She is the Co-CEO of Clinical Research Directory Inc. Martin Freeman is Consultant for Abbvie Inc. Travel support from Wilson Cook Inc. Rajeev Attam received travel support from Olympus.

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