## How to perform EUS-guided biliary drainage

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## ABSTRACT

EUS-guided biliary drainage (EUS-BD) has recently gained widespread acceptance as a minimally invasive alternative method for biliary drainage. Even in experienced endoscopy centers, ERCP may fail due to inaccessibility of the papillary region, altered anatomy (particularly postsurgical alterations), papillary obstruction, or neoplastic gastric outlet obstruction. Biliary cannulation fails at first attempt in 5%–10% of cases even in the absence of these factors. In such cases, alternative options for biliary drainage must be provided since biliary obstruction is responsible for poor quality of life and even reduced survival, particularly

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due to septic cholangitis. The standard of care in many centers remains percutaneous transhepatic biliary drainage (PTBD). However, despite the high technical success rate with experienced operators, the percutaneous approach is more invasive and associated with poor quality of life. PTBD may result in long-term external catheters for biliary drainage and carry the risk of serious adverse events (SAEs) in up to 10% of patients, including bile leaks, hemorrhage, and sepsis. PTBD following a failed ERCP also requires scheduling a second procedure, resulting in prolonged hospital stay and additional costs. EUS-BD may overcome many of these limitations and offer some distinct advantages in accessing the biliary tree. Current data suggest that EUS-BD is safe and effective when performed by experts, although SAEs have been also reported. Despite the high number of clinical reports and case series, high-quality comparative studies are still lacking. The purpose of this article is to report on the current status of this procedure and to discuss the tools and techniques for EUS-BD in different clinical scenarios.

Key words: acute cholecystitis, ERCP, EUS, EUS-guided biliary drainage, EUS-guided gallbladder drainage, obstructive jaundice

## **INTRODUCTION**

Biliary drainage procedures are usually undertaken in patients with symptomatic biliary obstruction. Various techniques and interventions that allow extraction of bile duct stones, dilatation of benign biliary strictures, and placement of stents across malignant stenosis are available. EUS has the ability to perform a detailed assessment of adjacent organs before accurately targeting and guiding needle passage into obstructed bile ducts under real-time vision. Echoendoscopes with large channels that allow passage of stents and other accessories have transformed EUS from a pure imaging modality into an interventional therapeutic tool with respect to the biliary system. EUS-guided procedures for peripancreatic fluid collections have been shown to be superior to percutaneous and surgical techniques in terms of morbidity, length of hospital stay, and costs.<sup>[1,2]</sup> A novel technique that has recently been introduced in clinical practice is the motorized spiral enteroscopy (MSE), which facilitates access to the papillary region in the majority of cases that present with anatomical alterations, including Billroth's and Whipple's resection.

More recently, EUS-guided biliary drainage (EUS-BD) has become available. Drainage techniques and types of devices vary according to indications, biliary anatomy, and local preferences.<sup>[3]</sup>

The aim of this article is to describe how to perform EUS-BD with a focus on the technical aspects to perform these procedures in clinical practice successfully. The different techniques are shown in Figures 1-12.

## **BASIC PRINCIPLES OF EUS-BD**

#### EUS-BD generally consists of four steps:

1. Transmural puncture of a specific site of the biliary system under EUS with confirmatory

cholangiography in selected cases -direct access technique with an electrocautery stent delivery system may be used for EUS-choledochoduodenostomy (EUS-CD) or EUS-gallbladder drainage (EUS-GBD)

- 2. Placement of a guidewire (not obligatory for EUS-CD or EUS-GBD)
- 3. Creation of a fistula between the enteral tract and bile duct
- 4. Stabilization of the fistula through the placement of a stent.

## TRANSMURAL PUNCTURE OF THE BILIARY TREE ("CLASSIC" OR TRADITIONAL TECHNIQUE)

EUS is used to detect a dilated bile duct; color Doppler helps to avoid vascular structures. Subsequently, transmural (transgastric, transduodenal, or transjejunal) puncture is performed with a needle that allows a 0.035-inch guidewire to be passed through the needle into the bile duct. In most cases, this will be a 19-G aspiration needle. Dedicated puncture needles, which are sharp with the stylet in place but become blunt after stylet removal, are also available to prevent shearing off the wire during manipulation. After puncture, aspiration of bile is frequently possible to demonstrate correct placement within the bile duct as well as to obtain a specimen for culture, if indicated. Contrast injection will demonstrate the patient's biliary anatomy and further confirm the appropriate position of the needle.

In unaltered anatomy, the biliary puncture site in more than 90% of the cases is either transgastric, to reach an intrahepatic duct of the left liver lobe (segment 2 or 3) or transduodenal, to reach the common bile duct from the bulb. In patients with altered anatomy (e.g., postsurgical reconstruction), the transgastric approach is still feasible and frequently allows EUS-guided biliary access and drainage.

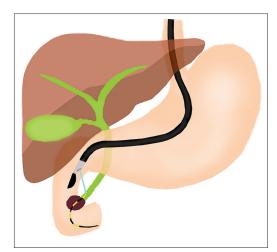


Figure 1. Normal anatomy – Rendezvous

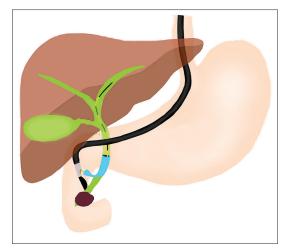


Figure 3. Normal anatomy – CDS retrograde. CDS: Choledochoduodenostomy

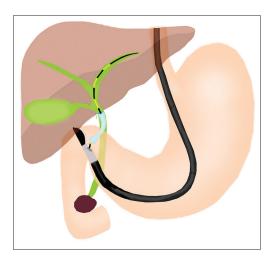


Figure 5. Normal anatomy - CDS retrograde. CDS: Choledochoduodenostomy

With hilar obstruction, the transgastric approach offers the option of successful drainage, while in

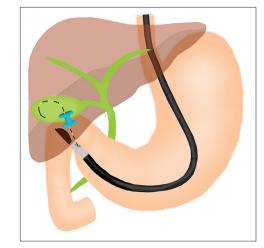


Figure 2. Normal anatomy - Gallbladder drainage

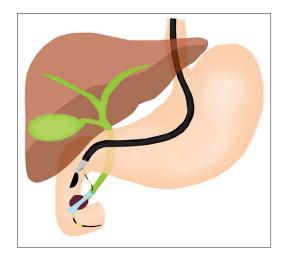


Figure 4. Normal anatomy – CDS antegrade. CDS: Choledochoduodenostomy

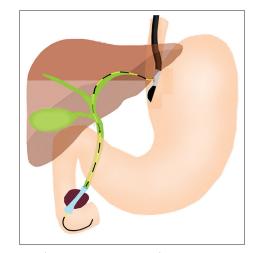


Figure 6. Normal anatomy - HGS antegrade. HGS: Hepaticogastrostomy

patients with distal obstruction, both approaches could be used. From both positions, the endosonographer aims the needle and the wire in

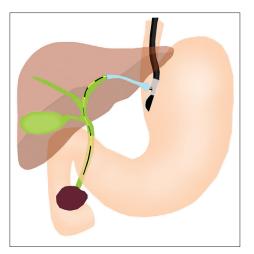


Figure 7. Normal anatomy - HGS retrograde. HGS: Hepaticogastrostomy

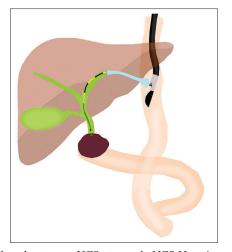
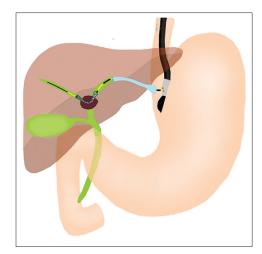


Figure 9. Altered anatomy - HGS retrograde. HGS: Hepaticogastrostomy

the preferred direction, which is either toward the liver (retrograde) or toward the papilla (antegrade). However, the patient's anatomy and the site of the stenosis may still preclude the passage of the wire in some cases. Nevertheless, the appropriate choice of the access tract as close as possible to the axis of the targeted bile duct allows guidewire manipulation in the correct direction in most instances. Steerable needles are currently under investigation.<sup>[4,5]</sup> Intrahepatic bile ducts with a diameter of at least 3 mm can be punctured in most cases.

In cases with external PTBD in place and intended internalization, EUS-BDD can be difficult due to a decompressed biliary system. Either stopping the drainage the day before or filling with saline solution via PTBD (up to 100 ml) can be helpful in these patients.

Puncturing from the stomach below the cardia is potentially challenging. First, a transmediastinal access



**Figure 8.** Normal anatomy – Bridging and HGS retrograde. HGS: Hepaticogastrostomy

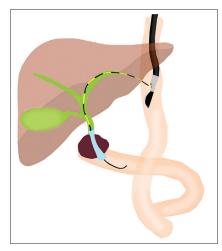
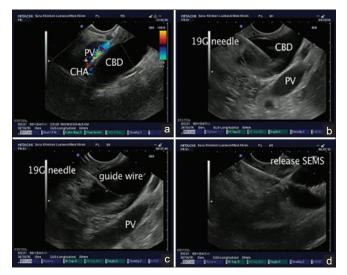


Figure 10. Altered anatomy - HGS antegrade. HGS: Hepaticogastrostomy

should be avoided, though it may seem attractive when relying solely on the EUS view and in trying to avoid an acute puncturing angle. With the EUS scope at the esophagogastric junction, segment 2 of the liver is visible above and segment 3 is visible below the left hepatic vein. Endoscopic confirmation is required to ensure puncture below the esophagogastric junction. Second, respiratory movement results in constant movement of the target. Third, dilated bile ducts may be difficult to access due to interposing accompanying vessels. Finally, the choice of the puncture site may be influenced by the aim of the procedure. Close to the hilum, the intrahepatic ducts are wider, but the placement of fully covered stents in the hilar area may block stent insertion into other ducts and should be avoided. Conversely, if the tract through the liver parenchyma is <2.5 cm, the risk of bile leak increases.<sup>[6]</sup> Following biliary puncture and aspiration, the next step of the procedure is to attempt gentle advancement of the guidewire. If there is resistance, the



**Figure 11.** EUS-CDS. Anatomy dilated CBD (a), puncture (b), guidewire placement (c), and stent placement (d). CBD: common bile duct; CHA common hepatic artery; PV portal vein; SEMS self expanding metal stent; CDS: Choledochoduodenostomy

needle is repositioned. If the guidewire passes without resistance in an appropriate configuration, a cystotome is passed and then contrast is injected to opacify the biliary system if not done with the puncture needle. A needle with a blunt tip after removing the sharp stylet is preferable for challenging maneuvers with the guidewire. A newly designed access needle with a bendable and rotatable tip may facilitate the advancing of the wire in the desired direction.<sup>[4]</sup> After a successful puncture, contrast injection should demonstrate an appropriate position and clarify the biliary anatomy. Injection of air bubbles or an extravasation of contrast should be avoided as this can hinder further attempts by overlying bubbles or contrast medium and compression of the puncture site. An initial saline injection before using contrast agent can be helpful to maintain visualization of the targeted structures. When the common bile duct is dilated, transduodenal drainage is easier than transgastric, but the advancement and deployment of the stent can be challenging due to the twisted and angulated position of the endoscope.

## PLACEMENT OF A GUIDEWIRE

A standard ERCP 0.025/0.035 inch guidewire that is at least three times the length of an endoscope (420 cm) together with an appropriate working length (approximately 30 cm) is necessary, for example, Jagwire® (Boston Scientific, Natick, MA, USA) or Visiglide® (Olympus Cooperation, Tokyo, Japan). The guidewire can be directed towards either the liver hilum or the papilla by carefully choosing the puncture axis. Further maneuvers should be reduced to a minimum if a sharp needle tip is in place as its sharp edges could cut the flexible tip of the wire or shear its outer coat. After removal of the needle further maneuvers to redirect the guidewire and pass the stenosis can be attempted through the accessory used to create the fistula, which is part of the next step. If passage of the guidewire across the obstruction is not possible after the first few attempts, the wire is coiled safely in the enlarged prestenotic bile duct, and a fistula is created.

## CREATION OF A FISTULA BETWEEN GASTROINTESTINAL LUMEN AND BILE DUCT

In the next step, a fistulous tract is created to place the stent. The tract must allow an available stent delivery system to be passed. Most currently available self-expanding metal stents (SEMS) delivery systems are 8 F in size, while 7 F delivery systems are now available (DEUS Bonastent®, MTW, Wesel, Germany). Thus, a diathermic ring knife/cystotome of 6F will be sufficient. If the wire has not been passed through the stenosis yet, this can be re-attempted using the ring knife/cystotome as a catheter allowing to better directing the wire. Of note, in one study, the use of a needle-knife for obtaining primary access was found to be a risk factor for adverse events.<sup>[7]</sup> Alternatively, the fistula can be enlarged using a dilatation balloon (4 mm- 8 mm) or by mechanical dilatators with increasing diameters (6-10 F). The latter, however, requires cumbersome instrument exchanges with high risk of dislodgement.

## STENT PLACEMENT

With respect to gastro-hepatic stent placement, simple SEMS can migrate with potentially fatal outcomes due to biliary peritonitis developing from a bilio-peritoneal fistula. Therefore, strategies to ensure proper positioning and to avoid stent migration are necessary. First, a sufficient length of the stent is necessary to allow an appropriate biliary and luminal position. The luminal portion should protrude at least 2 cm into the stomach or intestine. Endoscopic hemostatic clips can be placed at the luminal end of the stent after placement, to help prevent dislodgment. To overcome the risk of stent migration, new stent systems have been developed, that are discussed in the following chapters. For the transgastric approach, partially covered stents with flared ends to prevent migration can be used, for example, Giobor® (Taewoong,

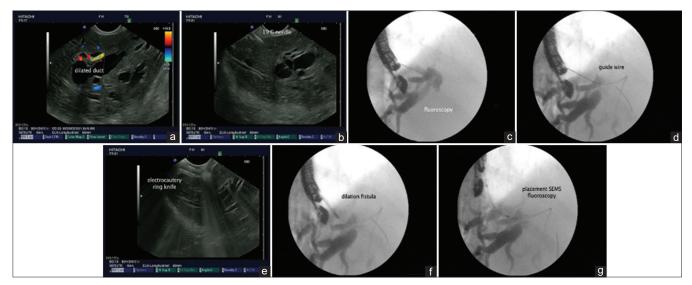


Figure 12. HGS. Dilated intrahepatic duct segment 2 (a). Needle (b). Dilated intrahepatic duct segment 2, fluoroscopy (c). Guidewire (d). Electrocautery ring knife (e). Dilation fistula (f). Placement SEMS retrograde (g). HGS: Hepaticogastrostomy

Korea) or Hanarostent® (M. I. Tech, Korea). These stents are partially covered, with an uncovered portion placed in the intraductal part to avoid the obstruction of the biliary side branches; a long covered part bridges the hepatic parenchyma to the gastrointestinal (gastric, duodenal or jejunal) wall, ending with a long intragastric portion to prevent bile leakage into the peritoneal cavity. On the other hand, with the transduodenal route it is ideal to use lumen apposing metal stents (LAMS), for example, the "HotAxios® "(Boston Scientific, USA), or other LAM-devices such as the "Hot Spaxus" LAMS (Taewong, Korea). The LAMS is mounted on a delivery system that includes diathermy, thereby allowing a one-step approach without the need for needle puncture, contrast injection, and guidewire placement. By using diathermy, the device can be directly advanced inside the biliary system under EUS guidance and theoretically deployed without the need for fluoroscopic guidance.

Alternatively, less expensive double pigtail plastic stents can be placed. However, plastic stents are associated with a higher risk of bile leaks since there is no tight closure of the access tract with plastic stents. In general, after a few days, a stable fistula is established, which allows stent exchange or other biliary interventions to be performed.

## COMPLICATED BILE DUCT STONE DISEASE AND OTHER BENIGN INDICATIONS

In cases of biliary obstruction due to choledocholithiasis with unaltered anatomy, ERCP is the method of choice for biliary cannulation, sphincterotomy/balloon dilatation (sphincteroplasty) and stone extraction (with or without mechanical or laser lithotripsy). If ERCP fails, a EUS-guided rendezvous maneuver is currently the method of choice [Figure 1]. A wire is placed through the stomach or duodenal wall via EUS-guided needle puncture and advanced into the biliary system. From here, the guidewire is subsequently passed antegrade through the papilla. If EUS succeeds using this guidewire, conventional ERCP can then be performed with a duodenoscope by grabbing the wire with a snare (rendezvous maneuver), or simply cannulating next to the guidewire. Removal of biliary stones through a transhepatic access is technically challenging but could be successful in selected cases. In patients with altered anatomy, an antegrade dilation of the biliodigestive anastomosis through a transhepatic access followed by a maneuver to push the stones inside the digestive track can be performed. Increasingly, the techniques of EUS-guided bile duct drainage are also used to create a hepatoenteric tract in order to treat strictures of enterobiliary anastomoses and complicated bile duct disease, for example, using cholangioscopy-assisted antegrade interventions.[8-10]

## MALIGNANT STENOSIS

In cases of malignant biliary stenosis, the procedure begins as described above. Insurmountable stenosis is diagnosed if the wire cannot be passed through the stenosis even after creation of the bilioenteric fistula and use of a needle knife/sphincterotome/ring knife/cystotome as a guiding catheter. A sphincterotome allows angulation of the tip to better direct guidewire direction.

If the stenosis is passed, one can proceed towards a rendezvous maneuver. This is theoretically simpler and if the guidewire easily passes through the papilla, there is no need for subsequent fistula creation. However, caution is needed since rendezvous techniques are prone to technical errors and are frequently challenging. Moreover, the papillary region may be inaccessible due to tumor infiltration or gastric outlet obstruction. A preferable alternative in these situations is the antegrade placement of a conventional SEMS across the stricture, which is pushed through the gastrointestinal wall and liver parenchyma to end inside the bile duct, either transpapillary or not, depending on the site of the stricture [Figures 4, 6 and 10]. The gastro-(enterohepatic-) biliary fistula is allowed to spontaneously close although some endoscopists temporarily place a plastic stent across the stricture.

If the stenosis cannot be traversed during the procedure, the creation of a fistula for retrograde drainage of the bile into the stomach, duodenum, or jejunum is necessary [Figures 3, 5, 7-9]. An experienced investigator may also consider this approach if this would provide better or safer results in a specific clinical situation. For any level of obstruction, a hepatico-gastrostomy/enterostomy fistula can be created with a flared-end-stent inserted from the stomach. In distal obstructions (prepapillary or intrapancreatic), a LAMS can provide a quicker approach for the creation of a choledocho-duodenostomy fistula. Frequently, a direct diathermy approach without needle and guidewire (and X-ray) is possible with the cautery enhanced LAMS.

## NEEDLES AND GUIDEWIRES

Transluminal access can be obtained in the vast majority of cases by using standard 19-or 22-gauge fine-needle aspiration needles (available from many manufacturers) with no objectively proven significant benefit of one over the others. In this respect, needles composed of cobalt-chromium as opposed to stainless-steel alloys bring greater tensile properties and hardness, generally resulting in a superior needle penetration, even from oblique angles. Only one needle specially designed for transluminal access is available, the 19-gauge Echotip® Ultra HD Ultrasound Access Needle (Cook Medical, Bloomington, IN, USA), featuring a sharply beveled stylet to allow needle penetration, housed within a blunt needle sheath, developed to reduce the incidence of guidewire shearing during its manipulation. The 19-gauge needles can accommodate 0.035-inch guidewires that guarantee better stability during subsequent interventional maneuvers, including scope exchange. A 19-gauge flexible needle (Expect<sup>™</sup> 19 Flex, Boston Scientific Corp., Marlborough, MA, USA),<sup>[11]</sup> or a thinner 22-gauge needle,<sup>[12]</sup> which both possess greater flexibility, can be used in challenging situations, such as with a hard fibrotic liver parenchyma or when the echoendoscope is in a tightly bent position in the duodenum.<sup>[13-15]</sup> However, 22-G needles allow only 0.018-0.025 inch wires. A newly designed steerable access needle device (18.5-gauge, 90°, Beacon EUS access system; Covidien, St Louis, Mo, USA) allows bending the needle tip to 90° on withdrawal of the sharp stylet and can be manually rotated.<sup>[4]</sup> The Olympus needle 19G EZshot 3 with a metal outer sheet has also a bending possibility (180°) and should be mentioned as well. Guidewires play an essential role in stabilization to pass strictures and the ampulla to reach the duodenum. An angled-tip and thin hydrophilic guidewire are helpful in negotiating tight or tortuous strictures, while a stiffer guidewire is better in maintaining access and completing a safe and effective therapeutic EUS procedure. A disadvantage of coated 0.035-inch guidewires is the risk of shearing-off when manipulated to-and-fro into a beveled-tip needle.<sup>[16]</sup> The use of thinner guidewires within a 19-gauge needle may result in a decreased rate of such incidents.<sup>[17]</sup> Conversely, thinner wires have poorer fluoroscopic visibility, kink more easily, and lack the stiffness of the 0.035-inch wire. An exception is represented by the 0.025-inch VisiGlide<sup>TM</sup> guidewire (Olympus Corp., Tokyo, Japan), which possesses rigidity and fluoroscopic visibility not inferior to that of 0.035-inch guidewires to allow transmural stent placement and traversing biliary stenoses.[18]

## EUS-GUIDED HEPATICOGASTROSTOMY/ HEPATICOJEJUNOSTOMY

## Review of the literature

Small case series in EUS-guided hepaticogastrostomy (HGS) were first published between 2003 and 2007.<sup>[19,20]</sup> This approach is used for patients with a dilated intrahepatic biliary tree in the setting of failed ERCP, as an alternative to PTBD also for rendezvous maneuver. HGS is particularly suitable for cases where EUS-choledochoduodenostomy (EUS-CDS) is not feasible (surgically altered anatomy, inaccessible duodenum due to gastric outlet obstruction or hilar

strictures). When the clinical conditions allow for both techniques, the decision often depends on local expertise. Most studies comparing EUS-HGS vs. EUS-CDS failed to show differences in clinical success and adverse events.<sup>[21-23]</sup> A recently published meta-analysis revealed technical success rates for EUS-HGS and EUS-CDS of 93.7% and 94.1%, respectively.<sup>[22]</sup> Clinical success was achieved in 84.5% of cases for EUS-HGS and in 88.5% of cases for EUS-CDS, with no difference in adverse events between the two techniques (odds ratio [OR] = 0.97, 95% confidence interval [CI] = 0.60-1.56). However, most reviewed studies did not reveal any specific information about the type of stents used, so the effect of stent type could not be taken into account.<sup>[22]</sup> Paik et al. reviewed 29 studies examining EUS-HGS and found an 18% overall serious adverse event (SAE) rate.<sup>[24]</sup> The main SAEs were bile leaks, bleeding/ hemobilia, distal stent migration or stent dysfunction, and infectious complications. Though not proven in any prospective blinded head-to-head study, EUS-HGS may produce fewer complications than PTBD with similar efficacy.<sup>[25]</sup> In addition, compared to PTBD, EUS-HGS is associated with a lower number of re-interventions and results in higher quality of life by avoiding external drainage,<sup>[25]</sup> which still needs to be left in place in a significant proportion of patients. These advantages of EUS-HGS over PTBD, initially described in the setting of distal malignant biliary obstruction, have recently also been reported in cases of hilar stenosis or postsurgical anatomy.<sup>[26]</sup> However, high-quality comparative studies in this respect are still lacking.

## Technique

Due to the complexity of the procedure, HGS/ hepaticojejunostomy (HJS) is reserved for centers with appropriate expertise and should be performed only by endoscopists with sufficient experience in interventional EUS.<sup>[27,28]</sup> To expand the clinical role of EUS-HGS/ HJS, development of dedicated devices is crucial; such devices should be comparable to the LAMS that are used for EUS-CDS.<sup>[29,30]</sup> To date, plastic stents, as well as fully covered and partially covered SEMS, have been used for EUS-HGS/HJS. Plastic stents carry a high risk of bile leak and biliary peritonitis, which is primarily due to the gap between the newly formed fistula and the stent.<sup>[31]</sup> Another disadvantage is the limited patency of stents in this setting, resulting in frequent reinterventions. Therefore, SEMS has become the standard treatment in many centers. Insertion of fully

covered SEMS for EUS-HGS was reported as safe and effective with high clinical and technical success rates of up to 100% and 95%.[32] However, fully covered SEMS include the risk of internal stent migration, which may occur even after the fistula is "mature" in up to 20% of cases.<sup>[32]</sup> Moreover, the insertion of a fully covered SEMS into a major biliary duct could also result in the exclusion of branches draining proximally to the entry point, resulting in cholangitis. These limitations can be overcome by using partially covered SEMS that were specifically designed such as Giobor® (Taewoong, Korea), the Hanarostent<sup>®</sup> (Olympus, Tokyo, Japan), the DEUS-Stent (DEUS Bonastent; Standard Sci Tech Inc), or the Hybrid stent (Standard Sci-Tech, Seoul, South Korea).<sup>[33]</sup> The long, covered part with a flange at the gastric end prevents biliary leakage and migration in the liver. The uncovered intrahepatic end stabilizes and maintains the correct position of the stent inside the intrahepatic biliary tract while avoiding blockage of side branches.

In a retrospective study, De Cassan *et al.* reported technical success rates for partially covered SEMS of 90.2%.<sup>[31]</sup> Infections, like mild cholangitis, are the most frequently early complications.<sup>[31,32]</sup> Stent patency in EUS-guided biliary drainage is reported to be significantly longer than in ERCP stents (85% *vs.* 49% after 6 months).<sup>[34]</sup> This advantage may be greater for EUS-HGS than for EUS-CDS due to a lower risk of tumor ingrowth because the stents are placed distant to the malignant stricture. One retrospective study revealed that EUS-HGS had longer stent patency compared to EUS-CDS in patients with malignant duodenal stenosis in part II or III of the duodenum (133 *vs.* 37 days, P = 0.045).<sup>[35]</sup> However, no electrocautery-enhanced LAMS were used in the EUS-CDS group.

## **EUS-CHOLEDOCHODUODENOSTOMY**

## Review of the literature

EUS-CDS aims at creating a direct communication between the common bile duct and the duodenum. It was the first EUS-BD technique described in 2001,<sup>[36]</sup> when transduodenal biliary access was obtained with a needle knife followed by placement of a metal stent. Since then, various other techniques have been described, all requiring a dilated common bile duct as a prerequisite for a successful procedure. The proximity of the EUS probe within the duodenum and the retroperitoneum, and the relatively fixed position of the common bile duct renders it an attractive drainage site even in patients with ascites.<sup>[37]</sup> Of particular note, the extrahepatic bile ducts are anatomically larger than the intrahepatic ones; therefore, EUS-CDS can be performed even when the latter is not particularly dilated.

Recent systematic reviews have assessed the safety and efficacy of EUS-CDS, reporting technical success in 90%–95% of cases, clinical success in 85%–90% of cases, and SAEs in 9%–20% of cases.<sup>[22,38,39]</sup> Technical and clinical success rates of EUS-CDS in comparative studies<sup>[40-42]</sup> and meta-analyses<sup>[22,38,39]</sup> are similar to those reported for EUS-HGS. Evidence suggests that, at least during the learning curve, EUS-HGS is associated with more adverse events than EUS-CDS.<sup>[43]</sup> A recent consensus paper involving endoscopists experienced in EUS-BD showed that the majority of respondents (30% *vs.* 23%) preferred EUS-CDS to EUS-HGS.<sup>[17]</sup>

Comparative analyses between the different techniques of accessing the extrahepatic bile duct (see below) have not revealed any significant differences regarding safety or efficacy.<sup>[44,45]</sup> Therefore, the choice of the approach is mainly determined by the experience and preference of the operator. It must be taken into account that EUS-HGS is the only option for patients with hilar obstruction or after bile duct surgery. Importantly, insertion of a duodenal metal stent to palliate duodenal stenosis, when present, can be performed after EUS-CDS, even in the same endoscopic session.<sup>[46]</sup>

Although EUS-CDS has been performed for almost 20 years, many controversial issues remain, reflecting the lack of properly designed studies. The electrocautery-enhanced LAMS has revolutionized this procedure allowing free-hand (needle-and wire-less) single-step access to the common bile duct and fluoro-less delivery of the stents under EUS control. Many retrospective studies have examined this approach after failed ERCP, while trials are currently underway investigating EUS-CDS as a competitor modality to ERCP for biliary drainage in the setting of malignant distal obstruction.

LAMS, which were initially developed for drainage of pancreatic fluid collections, are available in smaller sizes and can be used for the creation of choledocho-duodenal anastomoses.<sup>[46]</sup> The development of electrocautery-enhanced delivery systems (The HotAXIOS Electrocautery Enhanced Delivery System<sup>TM</sup>; Boston Scientific Corp., Marlborough, MA, US and the Niti-S<sup>™</sup> HOT SPAXUS<sup>™</sup> device, Taewong, Goyang, Republic of Korea) allows for a one-step procedure without the need for prior needle puncture and guidewire insertion into the CBD. Moreover, the stent can be released completely under EUS guidance without the need for an endoscopic view and/or fluoroscopy use,<sup>[47]</sup> facilitating the procedure and shortening its duration. In a retrospective study on 57 patients who underwent EUS-CDS with the HotAxios<sup>TM</sup> stent, the procedure-related SAE rate was 7% with no mortality, while the reintervention rate was 9.3%, mainly due to stent dysfunction.<sup>[48]</sup> Another retrospective study involving 6 centers reported on outcomes following 67 attempted EUS-CDS procedures using cautery-enhanced LAMS. EUS-CDS was technically successful in 95.5% of patients and clinically successful in 100% of the 40 patients with technical success who were followed up for more than 4 weeks.<sup>[49]</sup> In this study, a plastic or tubular SEMS was placed inside the LAMS in 78% of the cases to avoid a perpendicular position of the LAMS in respect to the CBD. Reintervention rates were significantly higher in the LAMS alone arm (50% vs. 5%). The overall rate of adverse events for electrocautery-enhanced LAMS was only 6.3%, and all were managed conservatively.<sup>[49]</sup> In a recent systematic literature review comprising seven studies and 284 patients who underwent EUS-CDS with a LAMS, the pooled rates of technical and clinical success, as well as of postprocedural adverse events were 95.7% (95% CI 93.2-98.1), 95.9% (95% CI 92.8-98.9), and 5.2% (95% CI 2.6-7.9), respectively, with no statistically significant differences in the rates reported for tubular SEMS.<sup>[50]</sup> In the same analysis, the pooled rate of recurrent jaundice induced by stent dysfunction or migration was 8.7% (95% CI 4.5-12.8), although this increased to 11.3% (95%) CI 6.9-15.7) on sub-group analysis applied to electrocautery-enhanced LAMS. Their short length, full silicone membrane coverage, and large flanges allowed lumen-to-lumen anchorage with reduced migration rates while remaining easily removable if needed. They allow another plastic or metal tubular stent to be placed within their lumen when necessary and even offer the possibility for passage of a slim forward-viewing endoscope to perform direct intraluminal interventions such as cholangioscopy and biopsy or stone fragmentation.

## EUS-GUIDED GALLBLADDER DRAINAGE

#### Review of the literature

Acute cholecystitis in patients at high risk for surgery due to advanced age, frailty, and severe comorbidities is often managed by percutaneous gallbladder drainage (PT-GBD). Recently, endoscopic methods of draining the gallbladder have gained popularity over PT-GBD, as this may be technically easier and less invasive from the patient's perspective. Endoscopic gallbladder drainage can be performed by either endoscopic transpapillary gallbladder drainage (ETP-GBD) or EUS-GBD. ETP-GBD is performed in a similar manner as ERCP. After transpapillary selective cannulation of the cystic duct, a double pigtail stent is placed into the gallbladder. In EUS-GBD, a transmural stent is placed from the antrum or duodenum into the gallbladder under EUS guidance.<sup>[51,52]</sup> In the only international, multicenter, randomized controlled trial to date,<sup>[53]</sup> EUS-GBD significantly improved the outcome in high-risk surgical patients compared to PT-GBD. The 30-day adverse event rate (12.8% vs. 47.5%, P = 0.01) and the 1-year adverse event rate (25.6% vs. 77.5%, P < 0.001) were considerably reduced in the EUS-GBD group. Re-intervention (2.6 vs. 30%, P = 0.001), re-admission (15.4% vs. 50%, P = 0.002), and recurrent cholecystitis (2.6% vs. 20%, P = 0.029) occurred less frequently. The technical success, clinical success, and 30-day mortality rates were statistically similar, which is consistent with a previous trial.<sup>[54]</sup> The findings of this randomized trial were consistent with those of a meta-analysis that mostly included retrospective comparative studies comparing EUS-GBD with PT-GBD.<sup>[55]</sup> EUS-GBD had fewer adverse events than PT-GBD (OR 0.43, 95%CI 0.18-1.00; P = 0.05), required shorter hospital stays with a pooled standard mean difference of-2.53 (95%CI-4.28 to-0.78; P = 0.005), and required significantly fewer re-interventions (OR 0.16, 95%CI 0.04-0.042; P < 0.001) resulting in significantly fewer unplanned readmissions (OR 0.16, 95%CI 0.05-0.53; P = 0.003). When comparing all 3 modalities for the treatment of acute cholecystitis, a network meta-analysis showed that PT-GBD and EUS-GBD had the highest likelihood of technical success and clinical success. EUS-GBD was associated with the lowest risk of recurrent cholecystitis. PT-GBD had the highest risk of unplanned readmissions, while ETP-GBD drainage was associated with the lowest mortality rate.<sup>[56]</sup> The authors concluded that in centers with expertise in endoscopic gallbladder drainage, EUS-GBD was preferable to the other two modalities in patients for whom cholecystectomy was not planned. In addition, some patients may improve sufficiently following EUS-GBD to be considered surgical candidates again.

It is important to consider the question of whether laparoscopic cholecystectomy is still possible after EUS-GBD. This was addressed in a retrospective study by Saumov et al. comparing the outcomes of cholecystectomy after EUS-GBD vs. PT-GBD.<sup>[57]</sup> The authors found no difference in conversions rates, blood loss, and postoperative adverse events between the groups but the operative time was significantly shorter in the EUS arm. The results suggested that after EUS-GBD, cholecystectomy is still possible and did not result in worse outcomes. Finally, an intriguing question is whether the outcomes of EUS-GBD could be comparable to laparoscopic cholecystectomy. After EUS-GBD, peroral cholecystoscopy can be performed with complete stone clearance achieved in up to 88% of patients, thereby reducing the risk of recurrent cholecystitis.<sup>[58]</sup> In a propensity score analysis comparing the outcomes of EUS-GBD with laparoscopic cholecystectomy with a 1-year follow-up, there were no significant differences in technical success rates (100% vs. 100%), clinical success rates (93.3% vs. 100%, P = 1), length of hospital stay (6.8 [8.1] vs. 5.5 [2.7], P = 1), 30-day adverse events (4 [13.3%] vs. 4 [13.3%], P = 1), and mortality rates (2 [6.7%] vs. 0 [0%], P = 0.492).<sup>[59]</sup> There was also no difference in rates of recurrent biliary events (3 [10%] vs. 3 [10%], P = 0.784), re-intervention (4 [13.3%] vs. 3 [10%], P = 1), and unplanned readmission (3 [10%] vs. 3 [10%], P = 0.784). These results provide some initial data in support of the role of EUS-GBD as an alternative to laparoscopic cholecystectomy in patients who may or may not be surgically fit to undergo definitive cholecystectomy.

## Technique

The gallbladder can be accessed from the distal antrum or the duodenal bulb. In general, the position with the best sonographic imaging, lack of interposing vessels, stability, and maximal apposition of gallbladder and gastrointestinal wall should be selected. The duodenum should be preferred over the antrum for drainage to avoid the risk of food impaction in the gallbladder and the risk of "buried stent syndrome". As with other EUS-BD techniques, the gallbladder can be drained endosonographically using needle puncture followed by guidewire insertion, tract dilatation (or diathermy), and stent placement or by direct access using an electrocautery-enhanced LAMS, allowing for one-step, freehand and fluoro-less drainage. SEMS was once preferred to plastic stents for EUS-GBD due to their superior stent patency. However, pneumoperitoneum, bile leak, biliary peritonitis, bleeding, stent migration, and stent dysfunction are common SAEs of EUS-GBD with SEMS. The rate of SAEs has been reduced by the introduction of single-step electro-cautery enhanced LAMS<sup>[60]</sup> which represent the new standard of care in this setting. Other centers have reported excellent clinical results in patients with transmural gallbladder stents. No LAMS-related adverse events were reported beyond the 1<sup>st</sup> year after stent deployment, and only 4.5% of the patients needed readmission due to gallstone-related problems.<sup>[61]</sup> After percutaneous cholecystostomy, conversion and internalization to EUS-GBD may be performed to remove the external drains and avoid recurrence. Importantly, cholecystectomy can still be performed at a later stage after EUS-GBD, if the patient's fitness for surgery improves. In critically ill patients, EUS-GBD can also serve as a bridge to surgery. Finally, EUS-GBD can also be used as a salvage technique after failed ERCP and/or EUS-BD. If the gallbladder has an open connection via the cystic duct to the prestenotic bile duct, EUS-GBD can provide retrograde biliary decompression for palliation.

#### **CONCLUSION**

EUS-BD has become feasible as a viable minimally invasive modality for resolving biliary obstruction. It can be employed either when ERCP fails, or as an alternative to percutaneous drainage, or when a surgical procedure is considered to put the patient at high risk. There is an increasing interest in applying EUS-BD as a primary method of biliary drainage and not just as an alternative when conventional methods fail. The technical details on how to perform EUS-BD are reported and discussed in detail in this comprehensive paper.

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## Conflicts of interest

Siyu Sun is the Editor-in-Chief of the journal; Christoph F. Dietrich is the Co-Editor-in-Chief; Paolo Giorgio Arciadacono and Adrian Săftoiu are Associate Editors; Manoop S. Bhutani and Pietro Fusaroli are Senior Associate Editors; Michael Hocke, Christian Jenssen, Alberto Larghi, and Anthony Yuen Bun Teoh are Editorial Board Members. This article was subject to the journal's standard procedures, with peer review handled independently of the editors and their research groups.

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