Article published online: 2023-04-24

Society of Gastrointestinal Endoscopy of India Consensus Guidelines on Endoscopic Ultrasound-Guided Biliary Drainage: Part II (Technical Aspects)

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J Digest Endosc 2023;14:74–87.

Abstract

Endoscopic management of bile duct obstruction is a key aspect in gastroenterology practice and has evolved since the first description of biliary cannulation by McCune et al in 1968. Over many decades, the techniques and accessories have been refined, and currently, the first-line management for extrahepatic biliary obstruction is endoscopic retrograde cholangiopancreatography (ERCP). However, even in expert hands, the success rate of ERCP reaches up to 95%. In almost 4 to 16% cases, failure to cannulate the bile duct may necessitate other alternatives such as surgical bypass or, more commonly, percutaneous transhepatic biliary drainage (PTBD). While surgery is associated with high morbidity and mortality, PTBD has a very high reintervention and complication rate (~80%) and poor quality of life. Almost parallelly, endoscopic ultrasound (EUS) has come a long way from a mere diagnostic tool to a substantial therapeutic option in various pancreaticobiliary diseases. Biliary drainage using

Keywords
- biliary drainage
- endoscopic ultrasound
- obstructive jaundice

article published online
April 24, 2023

DOI https://doi.org/10.1055/s-0043-1768043.
ISSN 0976-5042.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

EUS-guidance (EUS-BD) has gained momentum since the first report published by Giovannini et al in 2001. The concept of accessing the bile duct through a different route than the papilla, circumventing the shortcomings of PTBD, and sometimes bypassing the actual obstruction have enthused a lot of interest in this novel strategy. The three key methods of EUS-BD entail transluminal, antegrade, and rendezvous approach. Over the past decade, with growing experience, EUS-BD has been found to be equivalent to ERCP or PTBD for malignant obstruction with better success rates. EUS-BD, however, is not devoid of adverse events and can carry fatal adverse events. However, neither the technique of EUS-BD nor the accessories and stents for EUS-BD have been standardized. Additionally, different countries and regions have different availability of the accessories, making generalizability a difficult task. Thus, technical aspects of this evolving therapy need to be outlined. For these reasons, Society of Gastrointestinal Endoscopy of India (SGEI) deemed it appropriate to develop technical consensus statements for performing safe and successful EUS-BD.

Introduction

Endoscopic management of bile duct obstruction is a key aspect of gastroenterology practice and has evolved since the first description of biliary cannulation by McCune et al[1] in 1968. Over many decades, the techniques and accessories have been refined, and currently, the first line of management of extrahepatic biliary obstruction is endoscopic retrograde cholangiopancreatography (ERCP). However, even in expert hands, the success rate of ERCP reaches up to 95%.[2] In almost 4 to 16% of cases, failure to cannulate the bile duct may necessitate other alternatives, such as surgical bypass or, more commonly, percutaneous transhepatic biliary drainage (PTBD).[3] While surgery is associated with high morbidity and mortality, PTBD has a high reintervention and complication rate (20–77%) and poor quality of life.[4] Almost parallelly, endoscopic ultrasound (EUS) has come a long way from a mere diagnostic tool to a substantial therapeutic option in various pancreaticobiliary diseases. Biliary drainage using EUS guidance (EUS-BD) has gained momentum since the first report by Giovannini et al[5] in 2001. The concept of accessing the bile duct through a different route than the papilla, circumventing the shortcomings of PTBD and sometimes bypassing the actual obstruction, has enthused much interest in this novel strategy. The three key methods of EUS-BD entail transluminal, antegrade, and rendezvous approaches. Over the past decade, with growing experience, EUS-BD has been found to be equivalent to ERCP or PTBD for malignant obstruction with better success rates.[6–8]

EUS-BD is not devoid of adverse events and can carry fatal ones. However, neither the technique of EUS-BD nor the accessories and stents for EUS-BD have been standardized.

Additionally, different countries and regions have different availability of the accessories, making generalizability a difficult task. Thus, technical aspects of this evolving therapy need to be outlined. For these reasons, the Society of Gastrointestinal Endoscopy of India (SGEI) deemed it appropriate to develop technical consensus statements for performing safe and successful EUS-BD.

Aims

The aim of this study is to discuss and develop consensus statements/recommendations on the key technical aspects of EUS-BD to optimize performance, including the choice of scope, needle, wire, and other accessories used, as well as certain EUS-BD technique–specific nuances.

Methods

In 2022, the SGEI board convened the SGEI EUS-BD Consensus Working Group comprising experts in therapeutic endosonography who are involved in training. Topic-specific tasks were assigned to the working group members, and clinical key questions were generated for discussion in the consortium. Searches were performed on Medline and the Cochrane Library till March 2022. The level of evidence for each statement was graded as per the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system.[9] Recommendations were drafted, and the strength was ascertained based on the level of evidence (►**Supplementary Table S1**, available in the online version only). The members of the expert group met in person to discuss and vote on the recommendations. Voting was done by electronic keypads. Statements with more than 80% total or partial agreement were accepted, while those with major disagreements were discarded or modified after discussion. A second and final round of voting was done to record all statements finally agreed upon. The recommendations developed by this expert group were divided into two parts: (1) general guidance on indications and outcomes, and (2) the technical aspects of "how to do" EUS-BD. This manuscript represents the outcome of the Delphi process resulting in the development of technical guidelines on how to perform EUS-BD.

General Technical Aspects of EUS-BD

EUS-BD encompasses a multitude of approaches and techniques, including transluminal, antegrade, and rendezvous techniques. The transluminal approach involves the creation of a permanent new bilioenteric fistula between the biliary system and the stomach, i.e., hepaticogastrostomy (EUS-HGS), or the duodenum, i.e., choledochoduodenostomy (EUS-CDS) and hepaticoduodenostomy (EUS-HDS). The antegrade technique (EUS-AG) entails the placement of transpapillary stents after gaining transgastric access to the proximal biliary system in the liver. In the rendezvous technique (EUS-RV), the biliary system is accessed using EUS guidance via transgastric or transduodenal routes. First, a guidewire is negotiated across the papilla and then used to perform an ERCP conventionally. This technique is also known as the EUS-guided biliary access procedure. Depending on the type of access approach, EUS-BD can be performed via the intrahepatic route (EUS-HGS, EUS-AG, EUS-RV, EUS-HDS) or the extrahepatic route (EUS-CDS, EUS-RV).

Nevertheless, all the various techniques are performed using common basic tools such as scope, needle, wire, and accessories used for tract dilation.

Recommendation 1

SGEI recommends that a therapeutic linear echoendoscope is suitable for EUS-BD procedures. A forward-viewing echoendoscope may be used for EUS-CDS

Agreement: 92.7%. Level of evidence: III. Grade of recommendation: C.

Echoendoscopes are broadly of two major types: radial and curvilinear. Radial echoendoscopes are used for diagnostic purposes, while oblique-viewing curvilinear echoendoscopes are used for biopsies and therapeutic procedures. Irrespective of the manufacturer, a therapeutic curvilinear echoendoscope with a working channel of 3.7-mm diameter is routinely preferred for all therapeutic EUS-guided procedures, including EUS-BD.[10] A 3.7-mm working channel can allow passage of 10-Fr accessories, compared with the thinner 2.8-mm working channel scopes that can accommodate only 7-Fr accessories, and is hence preferred.

A relatively newer echoendoscope is the forward-viewing curvilinear array echoendoscope (FV-CLA). Although the scanning view is limited to 90 degrees, this scope has the advantages of offering a forward endoscopic view, lack of the "push-back" phenomenon on the scope by the advancing needle, and better transmission of the force.[11] Of late, FV-CLA has been used for various therapeutic procedures, including EUS-BD.[12] FV-CLA has been used to perform EUS-CDS[13] and EUS-HGS successfully.[14,15] During EUS-CDS, the endoscopic images become indispensable for safely placing the proximal part of the stent, as the proximal duodenum has limited space for any scope manipulation. In this scenario, an FV-CLA has an expectedly better safety profile due to superior endoscopic view and has reported high technical success.[13] Thus, an FV-CLA can be used as an alternative for performing EUS-CDS wherever available.

Recommendation 2

SGEI recommends that a 19-G needle is the preferred choice for biliary puncture. However, a 22-G needle can be used in the setting of a nondilated biliary system.

Agreement: 100%. Level of evidence: III. Grade of recommendation: C.

Most studies report using a 19-G fine needle aspiration (FNA) needle for EUS-BD. A needle of 19 G allows both 0.025- and 0.035-inch guidewire, which are easier to manipulate than a 0.018-inch guidewire. However, it might be difficult to maneuver standard 19-G steel needles in difficult angulated positions such as the duodenum. Nitinol needles are more flexible and less prone to bending. Moreover, the coil sheath possesses higher lumen retention than the plastic sheath. As a result, these "flexible" nitinol needles may be preferred in difficult scope positions during EUS-BD.[16]

Although 19 G is the preferred needle size, it can be technically difficult to use in a nondilated ductal system. A 22-G needle with an 0.018-inch guidewire can be used in such situations. Recent studies have shown that this strategy is equally effective for EUS-BD.[17–20] In fact, a recent prospective comparative study using a 19-G needle for a duct diameter of >1.5 mm and a 22-G needle for a duct diameter of <1.5 mm showed similar technical success (100 vs 89%) of the two needles.[21] Thus, for a nondilated system, a 22-G needle with 0.018-inch guidewire is a viable alternative. Tract dilation, however, is technically difficult with 0.018-inch guidewire, and hence, novel thin mechanical dilators have been designed for the same (not available in India).[19]

Recommendation 3

SGEI recommends that a 0.025- to 0.035-inch guidewire with a hydrophilic tip is preferred. Short wires may be used if expertise is available.

Agreement: 92.8%. Level of evidence: III. Grade of recommendation: C.

High-performance guidewires with good torque ability, pushability, and tip flexibility are needed for navigation

across strictures. Both 0.025- and 0.035-inch guidewires are equally effective and commonly used for EUS-BD. Thinner wires can get damaged easily and are unsuitable for tract dilation or stent placement.

Although standard long wires (400 cm) are used, efficacy data on using shorter (280 cm) hydrophilic guidewires exist.[22,23] The completely hydrophilic wire can have better efficacy in negotiating strictures and papilla. However, saline must be pushed through the needle hub during needle exchange to "float" the wire and maintain its position.[23] Thus, centers or endoscopists with adequate expertise may use these short wires (280 cm).

Recommendation 4

SGEI recommends that for tract dilation, a coaxial cautery device is preferred. Mechanical dilators may also be used. Lumen-apposing metal stents (LAMS) may be placed without tract dilation.

Agreement 100%. Level of evidence: III. Grade of recommendation: C.

After guidewire negotiation, tract dilation is a crucial step in EUS-BD. The tract dilatation can be done by electrocautery, mechanical, or balloon dilators. Electrocautery dilators include coaxial diathermy catheters: (1) 6-Fr cystotome with diathermic tip (ENDO-Flex GmbH, Voerde, Germany) and (2) Fine 025 (Medico's HIRATA Inc, Osaka, Japan) with 3-Fr metal tip. Mechanical dilators include (1) bougie dilator, Soehendra (Cook Medical, Bloomington, IN, United States) or (2) ultratapered (2.5 Fr) mechanical dilator (ES dilator, Zeon Medical Co., Tokyo, Japan). Balloon dilators include (1) Hurricane Rx Balloon – 4 mm (Boston Scientific, Natick, MA, United States) or (2) REN, 0.025 sharp tip – 4 mm (Kaneka Medix Corporation, Japan). The dilation devices available in India are cystotome, Soehendra bougie, and balloon dilators.

While coaxial dilation devices are preferred, needle-knife sphincterotome should not be used as it is associated with higher adverse events.[24,25]

Of the coaxial dilators, electrocautery and mechanical can both be used for EUS-BD. However, there are certain caveats to using mechanical dilators, such as the following: (1) inadequate penetration ability across a tough tract with fibrotic or hard tissues because of nonsharp tip; (2) long length of the tract to be dilated, more for procedures such as EUS-HGS and EUS-AG; and (3) inadequate force transmission through a nonaligned oblique-viewing curvilinear scope, which might be in an unstable position in a large stomach. Thus, dedicated thin mechanical dilators with sharp tips would be required to overcome these concerns,[26] which are currently unavailable in India. Cautery dilators, on the other hand, have been shown to shorten procedure time for draining pancreatic fluid collection[27] and EUS-BD.[26] Hence, they might be preferred over mechanical dilators as of now. In addition, cautery devices have been reported to have early and late "burn effects," but these can be mostly managed conservatively. Similarly, cautery-mounted LAMS are single-step devices designed to dilate the tract and place the stent with the same catheter. Thus, they usually do not require additional tract dilation.

EUS-Guided Choledochoduodenostomy: Technical Aspects

EUS-CDS is the technique of creating a fistula between the duodenum and the bile duct and bridging it with a stent. With a technical success rate of 90 to 95% and adverse event rate of 12 to 20%, EUS-CDS is considered technically easier compared with other EUS-BD procedures.[28] The basic steps entail puncturing the bile duct from the duodenum, negotiating the guidewire up the hilum, dilating the tract, and placing the stent. However, the lack of intervening hepatic parenchyma and angled scope poses some challenges during EUS-CDS. Therefore, the key aspects of this procedure were discussed in the consensus meeting, and four statements were proposed.

Recommendation 5

SGEI recommends that a long or intermediate scope position in the duodenal bulb is preferred. The needle direction should be toward the liver hilum.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

In EUS-CDS, the echoendoscope is positioned in the duodenum, and the common bile duct (CBD) is interrogated in a long position to assess the severity of dilation and the location of the obstruction. The proximity of the CBD to the duodenal bulb and the retroperitoneal position of the CBD make CDS an attractive therapeutic option. Thus, the scope needs to be placed in the duodenal bulb. The procedure is performed with the scope in the long or intermediate position, enabling scope stability. Moreover, as the guidewire needs to be directed toward the hilum, the scope tip should be positioned toward the hilum. This echoendoscope shape should be confirmed on fluoroscopy.[29] The patient position during CDS can be either supine, prone, or left lateral, although the ductal anatomy on cholangiogram may be better delineated under fluoroscopy in the supine or prone position.

Akin to the scope position, the needle, too, should be directed toward the hilum. The wire can be easily negotiated to the hilum when the FNA needle comes out nearly parallel to the CBD axis on EUS imaging. Specialized needles, such as the steerable access needle, can help manipulate the wire in the desired direction after the puncture. In this needle, the

access catheter is blunt-tipped and rotatable and can assume a preset curvature (90 or 135 degrees) once the sharp stylet is removed. Ryou et al[30] evaluated this needle in 22 EUS-BD cases, including 7 EUS-CDS, and found it to be a useful device for selective positioning and advancement of wire.

Recommendation 6

SGEI recommends that needle puncture be done preferably from the duodenal bulb, avoiding double duodenal folds.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

One of the technical steps of EUS-CDS is puncturing the CBD from the duodenum. Sometimes, a double duodenal mucosal fold can interrupt the needle path leading to perforation or bleeding.[31] This double mucosal puncture can be avoided using the water-filling technique,[32] wherein intraluminal water instillation flattens out the duodenal folds. Additionally, Matsumoto et al[33] have shown that one of the risk factors of double mucosal puncture was using an oblique-viewing echoendoscope. This can be avoided by using a forward-viewing echoendoscope, which can be opposed to the puncture site and, thus, prevent double puncture. However, since a forward-viewing echoendoscope is not frequently used or may not be available in all centers, using the water-filling technique and careful assessment of the duodenal wall anatomy on EUS before puncture is essential to avoid this complication.

Recommendation 7

SGEI recommends that a fully covered self-expanding metal stent (FC-SEMS) or an LAMS is the stent of choice in EUS-CDS.

Agreement: 100%. Level of evidence: III. Grade of recommendation: C.

The choice of the stent for EUS-CDS is a cardinal step to prevent adverse events. While plastic and metal stents can be placed for EUS-CDS, plastic stents are a significant predictor of peritonitis.[33] The relatively narrower diameter of the plastic stent predisposes to bile leakage between the stent and the created fistula. Therefore, plastic stents should not be placed for EUS-CDS.

Generally, FC-SEMS are used for EUS-CDS. They are either braided or laser-cut.[29] One of the key risks of FC-SEMS is stent migration. While laser-cut may have a lower migration rate, it can be complicated by kinking of the stent. Cho et al[34] have evaluated a partially covered stent or hybrid stent with proximal and distal anchoring flaps to prevent migration. Their study on 33 EUS-CDS cases did not have any migration. Ogura et al[35] found that a double-bared stent with low axial force has less stent dysfunction due to kinking than FC-SEMS.

LAMS, first reported in 2011,[36] have high appositional force and adhere the gastrointestinal lumen with the target area. Thus, the issue of stent migration can be avoided. With the advent of the electrocautery-enhanced LAMS delivery system (ECE-LAMS), other tract dilations and accessories exchange were avoided, reducing adverse event rates and procedure time.[37] Jacques et al[38] evaluated the utility of ECE-LAMS using the "recommended" technique of direct fistulotomy with pure cut current and a 6- or 8-mm stent. They found a very high technical success rate of 97.1%. While performing EUS-CDS using ECE-LAMS, the preferred diameter of CBD is >10 mm,[37] and a protective guidewire may be considered in case the CBD ≤ 10 mm. A recent meta-analysis showed that ECE-LAMS have a pooled technical success rate of 95.7% and an adverse events rate of 5.6%.[39] Comparison of LAMS with SEMS showed that both were equally effective for EUS-CDS with similar adverse event rates.[40]

Since the distal flange of the stent is in the lumen, food/residue impaction is quite common. In a multivariate analysis, Matsumoto et al[33] demonstrated that stent opening toward the oral side posed a greater risk for stent dysfunction than the anal side. However, more data are needed to prove this important hypothesis. Additionally, the presence of significant gastric outlet obstruction may pose added risk of stent dysfunction for EUS-CDS and might warrant using other modalities of biliary drainage.

The placement of coaxial plastic stents through the LAMS/SEMS has the theoretical advantage of preventing stent migration and avoiding recurrent biliary obstruction due to stent blockage. El Chafic et al[41] showed that coaxial plastic stents could significantly reduce the need for biliary interventions. However, other studies failed to show any difference.[42,43] A large multicenter randomized controlled trial is underway to answer this question better.[44] A coaxial plastic stent may be placed in EUS-CDS, depending on the endoscopist's discretion.

Recommendation 8

SGEI recommends that intrachannel stent deployment is suggested for the distal end of the stent.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

After tract dilation, the stent is deployed. While the proximal part of the stent is deployed inside the CBD under

fluoroscopic guidance, releasing the stent in the duodenal lumen can be tricky. Duodenum, unlike the stomach, has little space; thus, maneuvering the scope for distal stent release under endoscopic visualization is difficult. As a result, there can be accidental migration of the stent into the abdominal cavity, or the scope may rapidly fall back into the stomach, risking the unintentional pullout of the whole stent along with it inside the lumen. To avoid this, intrachannel deployment of the stent seems a good strategy.[29,45] The distal end of the stent is deployed inside the channel of the echoendoscope, and then gradually, the stent is pushed out of the channel while withdrawing the scope. Maintaining the guidewire access till the last step is key to troubleshooting in cases of stent maldeployment. The delivery catheter may be exchanged over the guidewire after stent deployment, keeping the guidewire in place till the stent position has been confirmed on endoscopy/fluoroscopy. In case of maldeployment of the stent, this guidewire access can then be used to place a second stent to bridge the tract created and complete the procedure.

EUS-Guided Hepaticogastrostomy: Technical Aspects

EUS-HGS, first described by Burmester et al,[46] involves the creation of a fistula between the stomach and the left ductal system and bridging it with a stent. The pooled technical success rate of EUS-HGS is 96.6%, with an adverse events rate of 17.5%.[47] The key technical aspects of EUS-HGS determining the procedure's success include the following: (1) puncture of the appropriate segment; (2) guidewire manipulation, the most crucial step; (3) choice of the stent; and (4) stent deployment strategy. The working group discussed the various aspects and developed four main technical recommendations for EUS-HGS.

Recommendation 9

SGEI recommends that segment 3 duct is the preferred access site for EUS-HGS.

Agreement: 100%. Level of evidence: III. Grade of recommendation: C.

Recommendation 10

SGEI recommends that a tubular, partially covered metal stent is used for HGS.

Agreement: 100%. Level of evidence: III. Grade of recommendation: C.

Access to the left ductal system from the stomach can be achieved by puncturing the B2 or B3 segment. While no head-to-head trial exists between the two approaches, the preferred approach used by most studies is the B3 segment. Guidewire manipulation is easier after a B2 puncture, but the puncture can sometimes be from the esophagus. The transesophageal approach can lead to mediastinal emphysema, mediastinitis, and pneumothorax.[48] Even if the puncture is just below the gastroesophageal junction (GEJ), the deployed stent might be directed toward the oral side, leading to adverse events.[49] Although a recent study has evaluated the technique of B2 puncture for HGS using a forward-viewing scope, the authors have used a clip to landmark the GEJ on fluoroscopy to prevent esophageal puncture.[15] To avoid this inadvertent esophageal puncture, it is recommended that the puncture be made into the B3 segment. The scope tip can be angled only to around 170 degrees when in the esophagus but to 90 degrees when in the stomach, and this shape can be double-checked on fluoroscopy to ensure the puncture site.

Guidewire manipulation toward the hilum is the most critical step in HGS, and the angle of the puncture becomes an important determinant. Ogura et al[50] have shown that an angle of $>$135 degrees (obtuse angle) between the FNA needle and the echoendoscope on fluoroscopy was an independent predictor of successful guidewire negotiation. Various techniques have been described to facilitate guidewire manipulation, such as the "liver impaction" technique to prevent wire shearing,[51] the "moving endoscope" technique to change the needle-scope angle,[52] the "jumping technique" of guidewire manipulation,[53] and the physician-controlled guidewire manipulation.[54] A few other factors, such as the minimum ductal diameter and optimum hepatic parenchyma length, have been systematically evaluated during the ductal puncture. A study of 174 HGS cases noted that a ductal diameter of $\leq$5 mm was associated with low technical success.[55] While Oh et al[55] suggested that hepatic parenchyma length of 1 to 3 cm was optimum, Yamamoto et al[56] recently showed that hepatic portion length of $\leq$2.5 cm was an independent risk factor for biliary peritonitis. Thus, more data are needed to opine the optimum hepatic parenchyma length. One study by Ishiwatari et al[57] has shown that aspiration of the bile ($>$10 mL) during HGS reduces the risk of adverse events, primarily postprocedure cholangitis and bile leak.

The choice of the stent is crucial for the procedure's success and for avoiding complications. FC-SEMS and partially-covered self-expanding metallic stents (PC-SEMS) have been used. FC-SEMS can lead to segmental cholangitis by blocking the peripheral branches. PC-SEMS essentially has two features: (1) uncovered part to prevent obstructive cholangitis and (2) covered portion placed across the liver parenchyma and the tract into the stomach. The uncovered part of the stent additionally acts as an anchor inside the biliary system.[29] Hence, the use of a tubular PC-SEMS is advocated. The risk, however, is the accidental deployment of the uncovered portion outside the liver parenchyma, leading to a bile leak.

The various kinds of stents evaluated for EUS-HGS have been briefed in ►**Table 1**. Dedicated stents and accessories for EUS-HGS are limited; thus, newer devices are being evaluated to get the best answer. Park et al[58] evaluated, in a randomized controlled trial, a one-step EUS-BD device with a 3-Fr catheter and a 4-Fr tapered metal tip for placement of stent without the need for additional dilation. This stent system showed significantly lower procedure time and the need for further fistula dilation. The stent also had four flaps at the distal end to prevent migration. Cho et al evaluated another hybrid stent (Standard Sci Tech Inc, Seoul, South Korea) with antimigratory anchoring flaps at the two ends of the covered portion.[34] They found that none of the stents had migration. However, these stents, as mentioned earlier, are not currently available in India.

Plastic stents are usually not advocated for use in EUS-HGS. This procedure entails tract dilation between two mobile organs (stomach and liver) and bridging it with a stent. Thus, currently available plastic stents are not designed to serve this purpose and bear a high risk for bile leakage, peritonitis, stent migration, etc.

Table 1 Characteristics of specific stents used for EUS-guided biliary drainage

Stent	Manufacturer	Diameter	Length	Special features
EUS-HGS				
Giobor Stent	Taewoong Medical, South Korea	8, 10 mm	8, 10 cm	Covered:uncovered, 50:50 and 70:30 Flared end at gastric side Delivery system: 8.5 Fr
SPAXUS-MG	Taewoong Medical, South Korea	8, 10 mm	6, 8, 10 cm	Uncovered segment with marker 15 mm Marker for gastric segment 20 mm Delivery system: 8.5 Fr Proximal anchoring flange: 20 mm
Hybrid Stent[a]	Standard Sci Tech, South Korea	8, 10 mm	5–10 cm	Distal silicone covered: 3.5 cm Antimigration flaps: 4 Proximal uncovered: 1.5–5 cm
Hanarostent BPD	MI Tech, Seoul, South Korea	10 mm	8, 10 cm	Uncovered part: 30 mm Delivery system: 8.5 Fr Flared gastric flap (20 mm) with lasso
DEUS delivery system[a]	Standard Sci Tech, South Korea	6 mm	5–10 cm	Covered:uncovered: 85:35 3-Fr/4-Fr tapered pentagonal metal tip Delivery catheter: 7 Fr Single one-step stenting device Proximal anchoring flaps; funnel-shaped uncovered wire mesh
Spring Stopper[a]	Taewoong Medical, South Korea			1.5–2 cm uncovered part Stopper on stomach side
BileRush Advance[a]	Piolax Medical, Kanagawa, Japan	8 mm	9, 10, 12 cm	2 cm uncovered part Delivery system: 7 Fr with tapered tip (no need for tract dilation) Flared end on stomach side
Laser-cut stent with anchoring hook[a]	Zeon Medical, Tokyo, Japan	8 mm	10 cm	1 cm uncovered part Delivery system: 7.2 Fr with tapered tip 3 hooks on the stomach side
EUS-CDS				
Hot-AXIOS	Boston Scientific, USA	6, 8 mm	8 mm	LAMS designed for EUS-CDS CBD diameter should be $\geq$ 1.5 cm
Double bare covered stent, EGIS	S&G Biotech, South Korea	10 mm	6 cm	8-Fr delivery catheterLower axial force
Covered BileRush[a]	Piolax Medical, Kanagawa, Japan	6 mm	6 cm	7.5-Fr delivery catheter Laser-cut nitinol wire 5 mm at the proximal end uncovered 10 m flare at both ends

Abbreviations: CBD, common bile duct; EUS-CDS, endoscopic ultrasound-guided choledochoduodenostomy; EUS-HGS, endoscopic ultrasound-guided hepaticogastrostomy; LAMS, lumen-apposing metal stents.
[a]These stents are not available in India.

Furthermore, plastic stents have been found to be a significant predictor of adverse events after EUS-HGS.[25] A dedicated EUS-HGS plastic stent (15-cm effective length; single pigtail; four flanges with apertures; tapered tip) is available in Japan[59] and is technically feasible, although more data are needed.

Recommendation 11

SGEI recommends an intragastric stent length of 3 to 5 cm is recommended to prevent proximal stent migration.

Agreement: 100%. Level of evidence: III. Grade of recommendation: C.

One of the dreaded complications of EUS-HGS is stent migration. Extraluminal migration can lead to an open bile leakage and biliary peritonitis requiring surgery. Thus, measures to prevent stent migration are key. While various antimigratory flaps and flares are present in different designs of stents, the length of the stent, both intragastric and overall, is an important parameter. Nakai et al found that a total stent length $\geq$ 10 cm has no migration risk.[60] While long intragastric stent length can help prevent stent migration, too long an intraluminal segment can make reintervention difficult. Thus, an optimum intraluminal length of the stent is required. An intragastric stent length of $\geq$3 cm has been shown to have lower stent migration[61] and longer stent patency.[62] Thus, a minimum length of 3 cm is desired in the stomach. Additionally, too long a stent segment can make reintervention difficult as the distal stent end would drop into the stomach. Hence, the consensus proposed that an intragastric length of 3 to 5 cm would be optimum for preventing migration and gaining access for reintervention.

Recommendation 12

SGEI recommends that for EUS-HGS, intrachannel stent deployment is suggested.

Agreement :100%. Level of evidence: III. Grade of recommendation: C.

Stent deployment is a final cardinal step, and inappropriate placement can lead to stent migration and other complications. There are two techniques for the distal deployment of EUS-HGS stents: (1) within the channel (intrachannel) deployment or (2) deployment under endoscopic vision. The intrachannel deployment showed higher technical success with lower adverse events.[63] Additionally, objective assessment has shown that the hepatic parenchyma–stomach distance is shorter during intrachannel deployment compared with extrachannel deployment.[45] This translates to a lower incidence of "candy" signs and other adverse events. Thus, it is recommended that the stent be deployed within the channel and then pushed out using endoscopic and fluoroscopic guidance. As discussed earlier, maintaining the guidewire access till the last step is key to troubleshooting in cases of stent maldeployment. In case of maldeployment of the stent, this guidewire access can then be used to place a second stent to bridge the tract created and complete the procedure. Once the distal flange has been deployed inside the biliary system, one should maintain controlled traction on the delivery catheter during the deployment of the rest of the stent. This is a key step to avoid the separation of the liver and stomach, leading to a "candy sign."

EUS-Guided Antegrade Intervention: Technical Aspects

EUS-AG is useful for establishing physiological bile flow across an inaccessible papilla.[64] Additionally, this technique can be used for benign diseases with altered anatomy. However, this is a technically challenging procedure with a lower success rate of 77% and adverse events rate of 5%.[65] The rate-limiting step is the guidewire negotiation across the papilla. While most steps are similar to EUS-HGS, additional technical aspects include delineation of the lower-end biliary stricture, position of papilla, and stent placement. The consensus has recommended three main technical recommendations for EUS-AG.

Recommendation 13

SGEI recommends that needle puncture through segment 3 is preferred for EUS-AG as it allows conversion to EUS-HGS in case of failure of antegrade guidewire manipulation.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

As discussed, the B2 segment puncture can help get a relatively straighter course to the papilla. Additionally, the force transmission to the devices is better, enabling tight stricture/neoplastic lesion negotiation[66] with B2 puncture. However, the inability to pass the wire across the papilla might require converting the intended EUS-AG procedure to EUS-HGS. However, as discussed earlier, EUS-HGS would be risky from the B2 segment. Therefore, the consensus

committee has recommended a B3 puncture so that EUS-HGS can be completed lest the wire does not cross the papilla.

Recommendation 14

SGEI recommends that an ERCP cannula or a 6-Fr cystotome allows better control during guidewire manipulation with the possibility of performing a cholangiogram to delineate the stricture.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

While systematic data do not exist for guidewire manipulation techniques of EUS-AG, it is imperative that guiding the wire all the way down across the papilla from the intrahepatic puncture site is not feasible with the FNA needle. Thus, an ERCP cannula or a 6-Fr cystotome is recommended as an effective approach for guidewire manipulation.[66] This enables better pushability and torquing for the guidewire. Additionally, the catheter can be used for obtaining a cholangiogram, delineating the anatomy of the stricture and marking the papilla's exact location on fluoroscopy.

Recommendation 15

SGEI recommends that uncovered SEMS may be preferred in EUS-AG for malignant biliary obstruction.

Agreement: 100%. Level of evidence: II. Grade of recommendation: C.

In patients with distal malignant bowel obstruction (MBO) undergoing EUS-AG, the stent placed across the papilla cannot be removed through the fistula created. Any need for reintervention would entail fresh puncture and access to the biliary system such as the index procedure. The choice of the stent type (covered or uncovered) depends on multiple factors. The two main concerns of EUS-AG are bile leak from the puncture site and pancreatitis due to the stent placed across the papilla. Surprisingly, pooled data do not show bile leak as the major adverse effect. The commonest adverse effect is pancreatitis.[67] Pancreatitis can be avoided by placing the stent proximal to the papilla. However, that might not be feasible in EUS-AG for MBO as the obstruction might not be far from the papilla. Moreover, the stent not being placed across the papilla might not decrease the intrabiliary pressure adequately and can lead to an increased risk of bile leak from the puncture site. Thus, a stent has to be placed across the papilla.

Looking at ERCP data of covered versus uncovered SEMS across the papilla, one can observe no difference in the pooled incidence of pancreatitis.[68] However, the scenario is slightly different for EUS-AG as sphincterotomy is not feasible in EUS-AG. A prospective study showed that the rate of pancreatitis in EUS-AG with uncovered SEMS was 15%, mild in intensity.[69] Another multicenter study showed that hyperamylasemia was noted in 8.1% of cases without clinical pancreatitis[70] with uncovered SEMS. In contrast, a recent study on EUS-AG with covered SEMS showed that 24% of patients developed mild pancreatitis.[71] Although there is no head-to-head trial, this hints that covered SEMS might have a slightly higher risk of postprocedure pancreatitis in EUS-AG.

While covered SEMS have low tissue ingrowth, they have higher tissue overgrowth and higher stent migration rates than uncovered ones[68] with similar stent patency rates. Covered SEMS have a theoretical risk of acute cholecystitis from cystic duct block, although there are insufficient data to say that. Moreover, the delivery system of uncovered SEMS is thinner, allowing easy passage across the fistula tract without the need for greater dilation. Thus, considering multiple factors, the working group suggested using uncovered SEMS for MBO in EUS-AG. However, additional stent properties may be preferred, such as those with lower foreshortening postdeployment.

EUS-Guided Rendezvous: Technical Aspects

Of all the EUS-guided biliary access techniques, EUS-RV is an EUS-assisted technique that facilitates subsequent ERCP in a previously failed case by passing a guidewire across the papilla. Thus, it is theoretically one of the safest EUS-BD techniques with a relatively lower pooled technical success rate of 86.1% and adverse events rate of 14%.[72] The two key technical steps for EUS-RV are the site of puncture and the strategy for cannulation attempt after scope exchange. The working group has recommended three main technical aspects to be considered while performing EUS-RV.

Recommendation 16

SGEI recommends that performing the EUS-extrahepatic approach may be preferred over the intrahepatic approach when both are technically feasible.

Agreement: 100%. Level of evidence: III. Grade of recommendation: C.

The biliary system can be accessed in EUS-RV by the intrahepatic approach from the stomach or the extrahepatic

approach from the duodenum. The scope position in the transgastric intrahepatic approach is stable, with the needle pointing toward the hilum. Still, the distance from the papilla is long and may have difficult wire manipulation. On the other hand, the extrahepatic transduodenal approach has two scope positions: (1) shortened echoendoscope placed in the duodenum D2—relatively unstable scope position with the needle pointing toward the papilla and the shortest distance from the papilla; ii) semi-long scope stably positioned in D1 junction with the needle often pointing away the papilla, sometimes pointing toward hilum. As highlighted, each of these positions has its specific pros and cons.

Dhir et al[73] have systematically evaluated the intrahepatic and extrahepatic approaches and found the intrahepatic approach to be associated with higher postprocedure abdominal pain, longer procedure time, and longer hospital stay. Other studies have also voiced that the extrahepatic route has better technical success and lower adverse events than the intrahepatic route.[74–76] Overall, the technical success of the extrahepatic approach is 87% compared with 65% of the intrahepatic approach. The adverse events rate was also higher in the intrahepatic route (17 vs 8%). The logistic regression analysis has shown that the choice of the access route is an important predictor of adverse events.[77] Therefore, the consensus group has opined that the extrahepatic approach should be the preferred route for EUS-RV.

Recommendation 17

SGEI recommends that for the transhepatic approach, a segment 3 puncture is appropriate. For the transduodenal approach, the puncture should be from the D1–D2 area, with the needle directed toward the papilla.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

As highlighted earlier, puncturing the B2 segment for the intrahepatic approach makes guidewire negotiation straightforward. However, in the unusual circumstance of failure to negotiate across the papilla, a salvage HGS cannot be performed from a B2 segment puncture. Hence, the working group agreed that the first approach should be a B3 segment access.

Among the two stations of transduodenal extrahepatic access, the D2 station with shortened scope has been shown to have better technical success than the semi-long D1 position.[76,78] Iwashita et al have proposed an algorithm for performing EUS-RV wherein the first strategy is the extrahepatic short-scope D2 station approach, followed by D1 and then intrahepatic.[78] This algorithmic approach had a success rate of 80%. Thus, the puncture should be from D2 with the needle directed toward the papilla to optimize the technical success.

Recommendation 18

SGEI recommends that once the ERCP scope is at the papilla, cannulation should be first attempted by the side of the guidewire exiting the papilla.

Agreement: 100%. Level of evidence: IV. Grade of recommendation: D.

There are various techniques for cannulating the papilla once a guidewire has been passed through it. The traditional "over the wire" rendezvous technique entailed grasping the guidewire with a snare or foreign body and pulling inside the biopsy channel of the duodenoscope. The wire is then gradually pulled out of the channel while simultaneously pushing the guidewire at the mouth to minimize resistance. Once the guidewire is pulled out of the channel, a cannula or sphincterotome is guided, and the papilla is cannulated over the exiting wire. However, this is cumbersome and time-consuming. An easier alternative is to cannulate the papilla by the side of the exiting wire ("along the wire"). As the wire passes out of the papilla, it straightens the intramural segment of the papilla, and thus, passing a cannula parallel to this wire becomes easy. Sometimes fluoroscopy can be used to align the axis of the cannula/sphincterotome to the exiting guidewire.[79] There are no comparative data between the two techniques. Most studies have described the "over the wire" technique, while some have described the "along the wire" technique.[80,81] The working group opine that for cannulation in EUS-RV, the "along the wire" technique should be attempted first as it is easy and succeeds most of the time.

A novel "hitch and ride" technique for cannulation was also described, wherein a handmade catheter with a slit at the tip was designed. The slit helped in the anchorage of the catheter over the wire ("hitch") and then glid the catheter ("ride") over the exiting wire.[82]

Summary

This technical review and the statements have been framed to give general guidance for the practicing endosonologists for performing EUS-BD. The recommendations have been summarized in ►**Table 2**. There is a lack of sufficient high-quality data to guide the day-to-day practice of these procedures. Hence, a lot of these techniques are yet to be standardized. SGEI acknowledges that with the fast-changing scenario of therapeutic EUS, continued efforts must be made to update and modify these statements as more high-quality data get generated. High-quality multicenter data are needed to fill up our knowledge gaps.

Table 2 Summary of recommendations on the technical aspects of endoscopic ultrasound-guided biliary drainage

Recommendation	Level of evidence	Grade of recommendation	Agreement
General technical aspects			
Recommendation 1: A therapeutic linear echoendoscope is suitable for EUS-BD procedures. A forward-viewing echoendoscope may be used for EUS-CDS.	III	C	92.7%
Recommendation 2: A 19-G needle is the preferred choice for biliary puncture. However, a 22-G needle can be used in the setting of a nondilated biliary system.	III	C	100%
Recommendation 3: A 0.025- to 0.035-inch guidewire with hydrophilic tip is preferred. Short wires may be used if expertise is available.	III	C	92.8%
Recommendation 4: For tract dilation, a coaxial cautery device is preferred. Mechanical dilators may also be used. Lumen-apposing metal stents may be placed without tract dilation.	III	C	100%
EUS-guided choledochoduodenostomy			
Recommendation 5: A long or intermediate scope position in the duodenal bulb is preferred. The needle direction should be toward the liver hilum.	IV	D	100%
Recommendation 6: Needle puncture be done preferably from the duodenal bulb, avoiding double duodenal folds.	IV	D	100%.
Recommendation 7: A fully covered self-expanding metal stent (FC-SEMS) or a lumen-apposing metal stent is the stent of choice in EUS-CDS.	III	C	100%
Recommendation 8: Intrachannel stent deployment is suggested for the distal end of the stent.	IV	D	100%
EUS-guided hepaticogastrostomy			
Recommendation 9: Segment 3 duct is the preferred access site for EUS-HGS.	III	C	100%
Recommendation 10: A tubular, partially covered metal stent should be used for HGS.	III	C	100%
Recommendation 11: An intragastric stent length of 3–5 cm is recommended to prevent proximal stent migration.	III	C	100%
Recommendation 12: For EUS-HGS, intrachannel stent deployment is suggested.	III	C	100%
EUS-guided antegrade intervention			
Recommendation 13: Needle puncture through segment 3 is preferred for EUS-AG as it allows conversion to EUS-HGS in case of failure of antegrade guidewire manipulation.	IV	D	100%
Recommendation 14: An ERCP cannula or a 6-Fr cystotome allows better control during guidewire manipulation with the possibility of performing a cholangiogram to delineate the stricture.	IV	D	100%
Recommendation 15: Uncovered SEMS may be preferred in EUS-AG for malignant biliary obstruction.	II	C	100%
EUS-guided rendezvous technique			
Recommendation 16: Performing EUS-extrahepatic approach may be preferred over intrahepatic approach when both are technically feasible.	III	C	100%
Recommendation 17: For transhepatic approach, a segment 3 puncture is appropriate. For transduodenal approach, the puncture should be from D1–D2 area, with the needle directed toward the papilla.	IV	D	100%
Recommendation 18: Once the ERCP scope is at the papilla, cannulation should be first attempted by the side of the guidewire exiting the papilla.	IV	D	100%

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; EUS-AG, EUS-guided antegrade intervention; EUS-BD, EUS-guided biliary drainage; EUS-CDS, EUS-guided choledochoduodenostomy; ESU-HGS, EUS-guided hepaticogastrostomy; SEMS, self-expanding metal stents.

Conflict of Interest
None declared.

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