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EUS-Guided Choledochoduodenostomy With Lumen-Apposing Metal Stents: A Recommendation From an Expert Delphi Consensus

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ABSTRACT

Background and Aims: Endoscopic ultrasound-guided choledochoduodenostomy with a lumen apposing metal stent (EUS-CDS-L) is an increasingly utilized therapeutic option for biliary drainage. However, numerous procedural and periprocedural

The first two authors contributed equally to this article.

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factors may influence technical and clinical outcomes. The aim of this study was to develop an expert consensus on key recommendations for EUS-CDS-L.

Methods: Thirty-two international experts in EUS-CDS-L contributed to this Delphi process over two rounds by voting anonymously on 28 statements using a five-point Likert scale. Statements were accepted in the first round or revised in the second round based on an agreement level of $\geq$ 80%, with a median $\geq$ 4, and an interquartile range (IQR) $\leq$ 1.

Results: 28 statements were initially circulated, 2 were removed, and 26 were considered for final consensus. A consensus was achieved for 24 of 26 (92.3%) statements after two voting rounds across the three domains, with the first focusing on indications: (1) the preference for EUS-CDS-L in distal malignant biliary obstruction (DMBO) without gastric outlet obstruction (GOO); (2) the inclusion of EUS-CDS-L as a therapeutic option in benign biliary obstruction, and (3) the performance of EUS-CDS-L in patients scheduled for upfront surgery. A second domain focused on procedural considerations: (1) the preferred cutoff of common bile duct (CBD) diameter for safe EUS-CDS-L, and (2) the lack of evidence for antibiotic prophylaxis, and several technical steps in the recommended deployment process.

Conclusion: This modified Delphi consensus provides international expert panel agreement on several key aspects of EUS-CDS-L, while also highlighting areas that require further research.

1 | Introduction

Endoscopic ultrasound-guided choledochoduodenostomy with lumen apposing metal stents (EUS-CDS-L) has become an established, effective and safe modality for biliary drainage in cases of failed endoscopic retrograde cholangiopancreatography (ERCP) due to distal malignant biliary obstruction (DMBO) [1]. Growing evidence also supports its use as a first-line therapeutic option in patients with DMBO [2]. EUS-CDS involves transmural drainage through the duodenal wall to bypass the obstruction site. For many years, EUS-CDS has been performed using plastic stents and fully covered self-expandable metal stents (FC-SEMS), adopting a multi-step technique, and carrying a higher risk of bile leak and peritonitis [3, 4]. However, since the introduction of lumen-apposing metal stents (LAMS) in 2014, EUS-CDS-L has been increasingly adopted and has recently emerged as one of the most important interventional EUS-guided procedures [5]. Despite its widespread adoption, considerable variability persists in procedural and periprocedural practices, resulting in varying applicability and outcomes and underscoring the need for procedure standardization. Although here are several consensus publications on EUS-guided biliary (BD) drainage [6, 7], they cover the broader aspects of EUS-BD procedures, and do not specifically address EUS-CDS-L. This modified Delphi project aims to provide expert consensus on the indications, optimal technique, safety, and post-procedural management of EUS-CDS-L.

2 | Methods

2.1 | Study Design and Panel Recruitment

This study used the modified Delphi Methodology [8] to develop expert recommendations for EUS-CDS-L, characterized by an anonymous assessment of statements by a panel of experts through two voting rounds. A steering committee (TK, AL, RIO, BN) invited 29 internationally renowned experts in interventional EUS and LAMS procedures. Three experts in interventional EUS (TK, AL, BN) on the steering committee who participated in the voting rounds designed the study and its scope and formulated the Delphi statements, while RIO supervised data collection and analysis, and did not contribute to the voting rounds. The Delphi technique was chosen to systematically collect and refine expert opinions through iterative, anonymized voting rounds using a predefined study design.

2.2 | Expert Panel Selection

Experts were identified through a center volume, guidelines participation from professional societies, and PubMed search of authorship publications on EUS-guided drainage using LAMS, specifically EUS-CDS-L. Invitations were sent by email, and efforts were made to ensure a balanced geographic distribution. Of 36 invited experts, 32 agreed to participate, forming the final Delphi panelists from multiple institutions and countries.

2.3 | Developments of Statements

The steering committee developed the initial statements based on a comprehensive review of the available summary of evidence and clinical experience. Statements were grouped into predefined domains, including indications, procedural and technical considerations, and post-procedural management. Each statement was paired with the corresponding paragraph in the technical review, and a detailed PICO table was shared with panelists for comments before the Delphi voting rounds began to ensure that all aspects of EUS-CDS-L would be covered before voting began. A 30-day period was given to the panelists to submit their comments before the voting round began.

2.4 | Delphi Process

The Delphi course included two voting rounds conducted via an anonymous online survey platform, Google Forms. Panelists were subsequently invited to vote anonymously on a five-point Likert scale (1 = completely disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree) with a free-text feedback box for comments, personal experiences, and preferences, and to propose modifications and revisions.

A "consensus" threshold was set a priori as agreement when $\geq$ 80% of panelists rated a statement as "agree" or "strongly agree" (Likert score 4 or 5), with a median $\geq$ 4 indicating a major agreement, and an interquartile range (IQR) $\leq$ 1

Key Summary

- Summarise the established knowledge on this subject
  - Endoscopic ultrasound-guided choledochoduodenostomy with a lumen apposing metal stent (EUS-CDS-L) is one of the most applicable therapeutic options after failed ERCP in distal malignant biliary obstruction
  - Still, the pre-, post-, and procedural aspects of EUS-CDS-L are not fully harmozined and standardized
- What are the significant and/or new findings of this study?
  - We developed a Delphi consensus among 32 leading international experts who voted on 26 statements addressing all aspects of the EUS-CDS-L procedure
  - This Delphi set a practical evidence based and expert opinion platform for accurate consideration of EUS-CDS-L, while providing a clear recommendation on the technical details of performing EUS-CDS-L
  - Still, few periprocedural considerations, specifically the use of double plastic pigtail stent within the lumen apposing metal stents, and the contraindications of EUS-CDS-L should be more explored in further studies

reflecting stronger consensus. The agreement was further categorized as very strong ($\geq$ 90%) or strong (80%–89%).

Statements that met the consensus threshold in the first round were accepted without further modifications. Statements that achieved $<$ 80% consensus, regardless of their median and IQR values, were revised by the steering committee based on feedback, then sent to the panelists for further edits and comments and finally resubmitted for the second round of voting. The same consensus thresholds from Round 1 were applied. Panelists were given 2 weeks to complete the online survey. A 90% participation rate was required for the second voting round. If, after 7 days, this rate was below 90%, an individualized reminder email was sent to the panelists to encourage them to complete the voting process.

2.5 | Data Analysis

A descriptive analysis was conducted using Excel. For each statement, the proportion of panelists who rated "4 = agree" or "5 = strongly agree" across all voting rounds was calculated. Agreement rates were reported as numbers and percentages. Responses in which panelists selected more than one option on the Likert scale (1–5) or wrote free text without selecting a value on the Likert scale were excluded from analysis of that specific statement. No regression analyses were conducted.

2.6 | Assessment of Evidence Quality

The level of evidence was assessed using the Oxford Center for Evidence-Based Medicine Levels of Evidence, defined as: (1) Level 1a (systematic review/meta-analysis of randomized controlled trials (RCTs)); (2) Level 1b (individual high-quality RCT); (3) Level 2a (systematic review of prospective cohort studies); (4) Level 2b (individual cohort study, prospective studies, and low-quality RCT); (5) Level 3a (systematic review of non-randomized or indirect case-control studies); (6) Level 3b (individual case-control studies including retrospective studies); (6) Level 4 (case series); and, (7) Level five (expert opinion and Delphi consensus). Levels 1a-1b reflected high-quality evidence, levels 2a-2b moderate-quality evidence, levels 3a-3b low-quality evidence, and levels 4–5 very low-quality evidence. When a guideline was cited, the guideline's strength level was reported.

An assessment of evidence quality using the Oxford Center for Evidence-Based Medicine Levels of Evidence was conducted to contextualize expert consensus statements within the existing literature and to distinguish expert agreement from the strength of the available empirical evidence, not to generate a graded recommendation.

3 | Results

3.1 | Participants

Thirty-two experts participated in each voting round, including 30 interventional advanced endoscopists and two hepato-pancreato-biliary surgeons. Three invited experts declined to participate in this study, and one did not respond to the invitation. All invited experts (n = 32, 100%) completed the first and second voting rounds. Twenty-five of the 32 experts were from Europe (78.1%), 5 from Asia (15.6%), 1 from North America (3.1%), and 1 from South America (3.1%).

3.2 | Statements Summary

A flowchart summary of the Delphi consensus from both rounds is presented in Figure 1.

Initially, 28 statements were proposed and circulated to all experts, including 12 on preprocedural considerations (indications, contraindications, and eligibility for EUS-CDS-L), 14 on procedural and technical considerations (setup, preparation, techniques), and 2 on post-procedural management (diet and surveillance). Of the 28 statements, 20 were approved in the first voting round achieving consensus $>$ 80%, with a median $\geq$ 4, and an IQR $\leq$ 1. Two statements were removed, that is (1) [EUS—gallbladder drainage (GBD) might be considered as a rescue modality in case of failed ERCP and EUS-BD in patients with a patent cystic duct] as it was out of scope for our Delphi, and (2) [It is recommended to correct coagulopathy, avoid large intervening vessels, and perform paracentesis in severe ascites before EUS-CDS-L], as this statement was redundant according to panelists' comments. In the second round, the steering committee discussed 6 statements, revised them to address major comments, and then submitted them for voting. Of these, 4 statements met the above-mentioned criteria, while 2 failed to reach the predefined consensus and were finally rejected.

3.3 | Preprocedural Considerations

Table 1 Among the 12 statements in the preprocedural considerations domain, 2 were deleted as mentioned above. In the first voting round, 7 statements were approved, 2 were approved in the second voting round, and 1 was rejected.

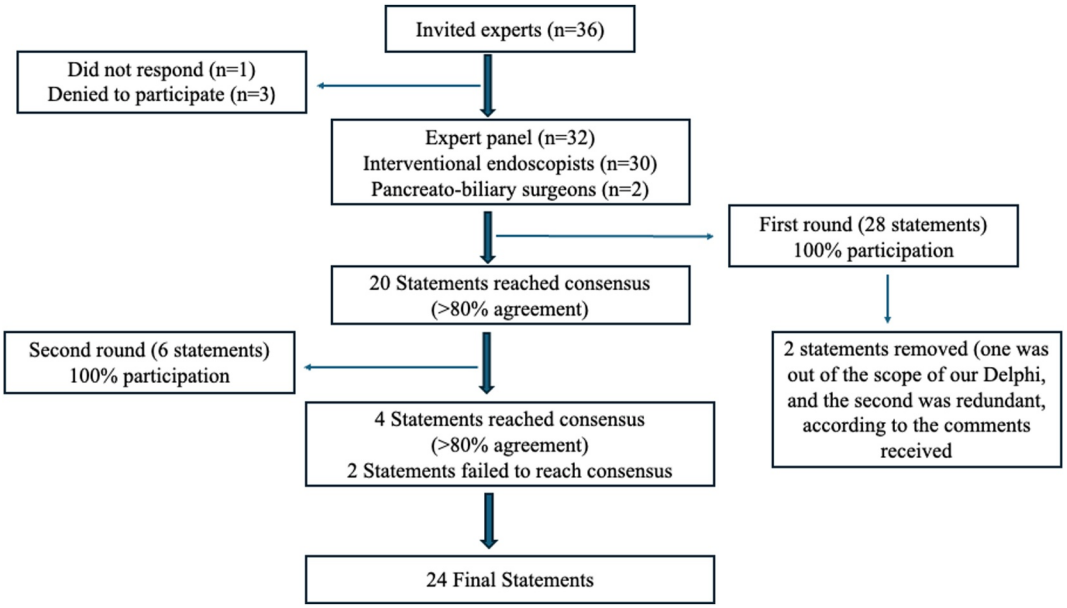

FIGURE 1 | Delphi process methodology flowchart.

Regarding procedural indications, most panelists agreed that EUS-CDS-L should be preferred over percutaneous drainage after failed ERCP in DMBO patients (*Statement 1*), and that primary EUS-CDS-L can be considered over ERCP for selected patients with DMBO (*Statement 6*). Moreover, among patients with DMBO and gastric outlet obstruction, most experts preferred EUS-hepaticogastrostomy (HGS) over EUS-CDS-L (*Statement 3*), secondary to evidence that duodenal stenosis is the most significant risk factor for LAMS dysfunction. Conversely, there was agreement that EUS-CDS-L is recommended over EUS-HGS in DMBO patients without GOO (*Statement 2*).

For benign biliary obstruction, the panelists agreed that the data remain limited for EUS-CDS-L; however, in the second round, they agreed that EUS-CDS-L should be included in the therapeutic armamentarium after multidisciplinary discussion (*Statements 4-5*). Given the potential for severe adverse events, and an agreement was reached that prerequisite expertise in EUS and ERCP is needed before performing EUS-CDS-L (*Statement 7*) and that this expertise should begin with pancreatic fluid collection drainage using LAMS under expert supervision (*Statement 8*). Finally, the consequence of EUS-CDS-L on upfront surgery was discussed, and agreement was reached that, according to the limited available evidence and expert opinion, EUS-CDS-L did not affect resectability and did not alter future pancreaticoduodenectomy outcomes (*Statement 9*).

3.4 | Procedural Considerations

Table 1 Among the 13 statements, 11 achieved consensus in the first voting round, and two achieved consensus in the second voting round.

Patient positioning was left to the operators' discretion (*Statement 10*). However, the panelists favored a standardized fluoroscopy-friendly position (either prone or supine). There was strong discussion of the minimum common bile duct (CBD) diameter required for EUS-CDS-L, with many experts agreeing that $\geq$ 15 mm was the safest cutoff, yielding 90.6% agreement (*Statement 13*). Some experts proposed a cutoff value $\geq$ 12 mm, as more patients could benefit from the therapeutic option (*Statement 14*). There was strong consensus on several technical considerations, with $>$ 90% agreement. Smaller-caliber LAMS (6–8 mm and 8-8 mm) were preferred by most experts (*Statement 15*). The use of pure cutting current (*Statement 18*), free-hand technique (*Statement 16*), and intra-channel proximal flange release (*Statement 19*) were preferred techniques and acceptable to most panelists. Additionally, given the potential adverse events related to EUS-CDS-L, most experts agreed that endoscopists must be experienced in salvage techniques (*Statement 20*), and that fluoroscopy is needed to assist in key procedural steps and to handle potential intraprocedural adverse events (*Statement 21*). There was strong discussion about the need for antimicrobial prophylaxis, as high-quality data remain lacking, with panelists questioning the usefulness of routine antimicrobial prophylaxis, specifically when complete biliary drainage was obtained (*Statement 11*). Moreover, there was a strong agreement of 96.9% on the use of LAMS over FC-SEMS in patients with dilated CBD, acknowledging that LAMS are more attractive given the ease of placement and lower risk of stent migration (*Statement 12*).

3.5 | Post-Procedural Management

Table 1 Two statements achieved agreement in the first voting round. Regarding resuming oral food intake, most experts agreed that a normal diet can be restarted within 24 hours of an uncomplicated EUS-CDS-L procedure (*Statement 23*), with some experts even suggesting resuming a normal liquid diet immediately after recovering from anesthesia. For LAMS surveillance, there was a strong agreement that routine LAMS surveillance and revision are unnecessary in most cases (*Statement 24*), given the oncological context.

TABLE 1 | Delphi statements with their corresponding agreements, medians and IQRs.

Statements	Valid responses (4–5)\overall voting's	Reached consensus at round	Agreement	Median	IQR
Preprocedural considerations					
1) EUS-CDS-L is recommended over PTBD after failed ERCP in suitable patients with distal malignant biliary obstruction (DMBO)	30/32	1	93.7% Very strong	5	0
2) EUS-CDS-L is recommended over EUS-HGS in DMBO in patients without gastric outlet obstruction syndrome (GOO)	25/31[a]	1	80.6% Strong	4	1
3) EUS-HGS is recommended over EUS-CDS-L in patients with DMBO and concomitant gastric outlet obstruction (GOO)	27/32	1	84.4% Strong	4	1
4) In case of benign biliary obstruction, there is insufficient evidence to recommend EUS-CDS-L over EUS-guided rendezvous, or antegrade stenting	27/32	1	84.4% Strong	4	1
Initial: EUS-CDS-L could be considered in benign biliary obstruction after failed ERCP, and EUS-guided rendezvous-approach	18/32	1	56.2%	4	1.25
5) Revised: In benign biliary obstruction and failed ERCP, EUS-CDS-L can be considered among the therapeutic options following multidisciplinary discussion	26/32	2	81.2% Strong	4	1
6) primary EUS-CDS-L can be considered over ERCP in selected cases, where expertise is available	25/31[b]	1	80.6% Strong	5	1
7) EUS-CDS-L should be performed by physicians trained in interventional EUS as well as ERCP	31/32	1	96.9% Very strong	5	0
Initial: Interventional EUS training should start from EUS-guided drainage of pancreatic fluid collections in referrals centers with available interventional radiology and surgery	24/31[c]	1	77.4%	4	1
8) Revised: Training in EUS-guided drainage of pancreatic fluid collections with LAMS under expert supervision is recommended prior to performing EUS-CDS-L	27/32	2	84.4% Strong	4.5	1
9) EUS-CDS-L can be considered in patients with DMBO regardless of tumor resectability	27/32	1	84.4% Strong	4	1
Procedural and technical considerations					
10) patient positioning and sedation modality for EUS-CDS-L should be based on operator preferences and local protocol	30/31[c]	1	96.8% Very strong	4	1
Initial: Broad spectrum antimicrobial prophylaxis should be considered in patients undergoing EUS-CDS-L	20/31[d]	1	64.5%	4	1
11) Revised: There is insufficient evidence to recommend broad spectrum antimicrobial prophylaxis in patients undergoing EUS-CDS-L	26/31[c]	2	83.9% Strong	4	1

(Continues)

TABLE 1 | (Continued)

Statements	Valid responses (4–5)\overall voting's	Reached consensus at round	Agreement	Median	IQR
Initial: Electrocautery-enhanced LAMS (EC-LAMS) in suitable cases should be recommended over FC-SEMS when both modalities are feasible	24/32	1	75%	4	1.25
12) Revised: In patients with DMBO, and sufficiently dilated common bile duct, electrocautery-enhanced LAMS (EC-LAMS) may be preferred over standard FC-SEMS due to its simplified single-step deployment and lower risk of stent migration	31/32	2	96.9% Very strong	5	1
13) EUS-CDS-L is recommended for patients with $\geq$ 15 mm common bile duct diameter	29/32	1	90.6% Very strong	4.5	1
14) EUS-CDS-L can be considered for patients with common bile duct diameter $\geq$ 12 mm and $<$ 15 mm in selected cases, when expertise is available	29/32	1	90.6% Very strong	4	0.25
15) Small caliber LAMS are recommended for EUS-CDS-L and should be tailored to CBD diameter	29/32	1	90.6% Very strong	5	1
16) free-hand insertion is recommended for EUS-CDS-L	29/32	1	90.6% Very strong	5	1
17) Selective over-the-wire LAMS release may be considered in challenging scenarios	29/32	1	90.6% Very strong	4	1
18) pure cutting current is recommended for EUS-CDS-L	31/32	1	96.9% Very strong	5	1
19) intra-channel release is recommended for LAMS proximal flange release	31/32	1	96.9% Very strong	5	1
20) endoscopists performing EUS-CDS-L must be familiar with salvage modalities and adverse event management	31/32	1	96.9% Very strong	5	0
21) fluoroscopy is recommended for EUS-CDS-L to facilitate adequate adverse event management	32/32	1	100% Very strong	5	0
22) In case of LAMS maldeployment, salvage should be individualized and should focus on securing adequate bile duct drainage with the lowest risk of adverse events	32/32	1	100% Very strong	5	1
Post-procedural management					
23) following uncomplicated EUS-CDS-L, oral intake can be initiated within 24 hours	31/32	1	96.9% Very strong	5	1
24) routine LAMS surveillance and revision is not recommended	30/32	1	93.7% Very strong	4	1

[a]One expert chose two options (disagree and neutral).
[b]One expert chose two options (agree and strongly agree).
[c]One expert chose two options (neutral and agree).
[d]One expert did not choose, only wrote free text.

3.6 | Rejected Statements

Table 2. Two statements were not accepted because they achieved $<$ 80% agreement, including (1) a strong discussion and various responses regarding contraindications to EUS-CDS-L, with some experts stating that uncorrected coagulopathy, intervening vessels, and ascites were contraindications according to the recent ESGE guideline [9], while other experts considered these criteria relative contraindications, noting that EUS-CDS-L can still be considered in uncorrected coagulopathy, specifically when percutaneous transhepatic biliary drainage

TABLE 2 | Rejected statements.

	Valid responses (4–5) \overall voting's	Consensus round	Agreement	Median	IQR
Initial: Relative contraindications to EUS-CDS-L are coagulopathy, intervening vessels or ascites	24/31	1	77.4%	4	0.5
Revised: Contraindications to EUS-CDS-L are uncorrected coagulopathy and the absence of a window without intervening vessels or ascites	25/32	2	78.1%	4	1
Initial: Double-pigtail plastic stent placement coaxial to the LAMS should be considered based on stent dysfunction risk	21/32	1	65.6%	4	1
Revised: Coaxial placement of a double-pigtail plastic stent within the LAMS can be considered to reduce the risk of stent dysfunction	24/31	2	77.4%	4	1

(PTBD) is the alternative, and that EUS-CDS-L can still be performed even if ascites is present, as most EUS-CDS-L procedures are performed through a retroperitoneal anastomosis, and (2) Double pigtail plastic stent (DPPS) placement through the LAMS, for which some experts referred to the recent "BAMPI-trial," reporting a significant decrease in recurrent biliary obstruction with the LAMS + DPPS placement versus LAMS alone [10], while other experts stated that this approach can be considered, and some experts reported that they never employed coaxial DPPS placement.

3.7 | Level of Evidence

Overall, 17 out of 24 statements (70.8%) were classified as very low- or low-quality evidence.

(*Statements: 2, 4, 5, 7, 8, 9, 11, 12, 15, 16, 17, 19, 20, 21, 22, 23, 24*). Four statements (16.7%) were classified as low-moderate quality evidence (*Statements 3, 13, 14, 18*), two statements (8.3%) as moderate quality evidence (*Statements 1, 10*), and 1 statement (4.2%) as high-quality evidence (*Statement 6*). Table 3 demonstrates the levels of evidence.

4 | Discussion

EUS-CDS-L is one of the therapeutic options for EUS-guided biliary drainage and has evolved into an effective and safe procedure in patients with DMBO. As its implementation in daily clinical practice increases, there is a need to standardize the procedure with respect to pre-procedural, technical, and post-procedural recommendations. This two-round modified Delphi consensus, involving 32 international experts, provides recommendations on key aspects of EUS-CDS-L (Figure 2). For 24 of 26 statements (92.3%), consensus was reached according to predefined criteria, with 16 of these 24 statements (66.7%) achieving very strong agreement (> 90%), including several landmark and key agreements in EUS-CDS-L. For pre-procedural considerations and indications: EUS-guided biliary drainage in DMBO without GOO, the data are controversial. A recent meta-analysis comparing EUS-BD with both EUS-CDS-L and EUS-CDS with FC-SEMS, compared to EUS-HGS, demonstrated that EUS-CDS-L has a shorter procedure time, a lower risk of side effects, easier puncture during the procedure, and a lower risk of recurrent biliary obstruction for EUS-CDS [11]. Although recent comparative studies have suggested that EUS-CDS and EUS-HGS achieve largely comparable performance when both procedures are technically feasible, the panel favored EUS-CDS-L given its greater technical simplicity, and widespread adoption among endosonographers. Accordingly, this recommendation should not be interpreted as a clear indication for EUS-CDS-L over EUS-HGS in all clinical scenarios. Rather, EUS-HGS remains an appropriate alternative in experienced hands and in situations where EUS-CDS is not feasible or is less suitable based on patient anatomy or disease characteristics.

Additionally, in the presence of concomitant GOO with DMBO, a recent multicenter study reported a dysfunction rate of 31.8% after a mean of 166 days, with duodenal obstruction as the only independent predictor of dysfunction [12]. A previous study by Ogura et al. suggested that in cases of obstructive jaundice with duodenal obstruction treated with duodenal stent, EUS-HGS may be a better option than EUS-CDS, with longer stent patency [13], which was later confirmed by retrospective and prospective evidence, also in the setting of EUS-guided gastroenterostomy [14, 15]. Moreover, although the interventional EUS training with available interventional radiology and surgery statement did not achieve a consensus at the first round, however, 77.4% of the panel agreed that EUS-CDS-L should be performed with multidisciplinary support, including hepato-pancreato-biliary surgery and interventional radiology. Notably, for primary EUS-CDS-L in DMBO, a recent randomized trials and a meta-analysis have shown that EUS-CDS-L achieved clinical success rates similar to ERCP, with a higher technical success rate, and lower rates of post-procedural pancreatitis and fewer reinterventions [2], supporting its use in selected patients when expertise is available. EUS-CDS-L appears to be safe in patients who are candidates for upfront surgery. Multicenter data suggest that EUS-CDS-L does not compromise the feasibility of pancreatoduodenectomy or increase the risk of major postoperative complications [16, 17].

Opinions differed widely regarding the role of EUS-CDS-L in benign biliary disease and the prerequisites for performing EUS-CDS-L, with consensus reached only in the second-round voting. However, most experts agreed that EUS-CDS-L should

TABLE 3 | Strength of evidence according to the Oxford Center for Evidence-Based Medicine Levels of Evidence.

Statements	Main evidence source	Evidence levels	Overall evidence
1) EUS-CDS-L is recommended over PTBD after failed ERCP in suitable patients with distal malignant biliary obstruction (DMBO)	Multicenter prospective (de Jong et al. [23]) Meta-analysis of RCTs (Lauri et al. [24]) ESGE guideline (van der Merwe et al. [1]) ASGE guideline (Pawa et al. [25])	2b	Moderate quality evidence
2) EUS-CDS-L is recommended over EUS-HGS in DMBO in patients without gastric outlet obstruction syndrome (GOO)	ESGE guideline (van der Merwe et al. [1]) Meta-analysis of RCT (Huh et al. [26]) Meta-analysis including prospective, retrospective and RCT (Yamazaki et al. [11]) Network meta-analysis of RCT (Lauri et al. [24])	2b	Moderate quality evidence
3) EUS-HGS is recommended over EUS-CDS-L in patients with DMBO and concomitant gastric outlet obstruction (GOO)	Multicenter prospective (Vanella et al. [12]) Multicenter retrospective (Vanella et al. [15]) Multicenter retrospective (Bronswijk et al. [27]) Multicenter retrospective (Fugazza et al. [28])	2–3b	Low-moderate quality evidence
4) In case of benign biliary obstruction, there is insufficient evidence to recommend EUS-CDS-L over EUS-guided rendezvous, or antegrade stenting 5) In benign biliary obstruction and failed ERCP, EUS-CDS-L can be considered among the therapeutic options following multidisciplinary discussion	Single center prospective (Fritzsche et al. [29]) ESGE guideline (van der Merwe et al. [1]) Case series (Knox et al. [30]) Prospective single center (Füldner et al. [31])	4–5	Very low-quality evidence
6) Primary EUS-CDS-L can be considered over ERCP in selected cases, where expertise is available	Multicenter RCT (Teoh et al. [32]) Multicenter RCT (Chen et al. [33]) Multicenter RCT (Anderloni et al. [34]) Meta-analysis of RCT (Khoury et al. [2])	1a-1b	High quality evidence
7) EUS-CDS-L should be performed by physicians trained in interventional EUS as well as ERCP 8) Training in EUS-guided drainage of pancreatic fluid collections with LAMS under expert supervision is recommended prior to performing EUS-CDS-L	ESGE-guideline (van Wanrooij et al. [9]) ESGE position statement (Johnson et al. [35])	3b	Low quality evidence
9) EUS-CDS-L can be considered in patients with DMBO regardless of tumor resectability	Multicenter retrospective (Janet et al. [16]) Multicenter retrospective (Fritzsche et al. [17])	3b	Low quality evidence
10) Patient positioning and sedation modality for EUS-CDS-L should be based on operator preferences and local protocol	Prospective multicenter (Fritzsche et al. [29]) Prospective single center (Fritzsche et al. [36]) National survey (Fabbri et al. [37])	2b	Moderate quality evidence
11) There is insufficient evidence to recommend broad spectrum antimicrobial prophylaxis in patients undergoing EUS-CDS-L	CDC guideline (Berríos-Torres et al. [38])	5	Very low-quality evidence
12) In patients with DMBO, and sufficiently dilated common bile duct, electrocautery-enhanced LAMS (EC-LAMS) may be preferred over standard FC-SEMS due to its simplified single-step deployment and lower risk of stent migration	Meta-analysis (Amato et al. [4]) Network meta-analysis (Lauri et al. [24]) Multicenter retrospective (da Silva et al. [3])	3a-3b	Low quality evidence
13) EUS-CDS-L is recommended for patients with $\geq$ 15 mm common bile duct diameter 14) EUS-CDS-L can be considered for patients with common bile duct diameter $\geq$ 12 mm and $<$ 15 mm in selected cases, when expertise is available	Multicenter prospective (Rimbaş et al. [21]) Multicenter retrospective (Jacques et al. [39]) Multicenter retrospective (Jacques et al. [18]) Multicenter retrospective (Beunon et al. [19])	2–3b	Low-moderate quality evidence

(Continues)

TABLE 3 | (Continued)

Statements	Main evidence source	Evidence levels	Overall evidence
15) Small caliber LAMS are recommended for EUS-CDS-L and should be tailored to CBD diameter	Multicenter retrospective (Beunon et al. [19]) Multicenter retrospective (Fugazza et al. [40]) Multicenter retrospective (Jacques et al. [39])	3a-3b	Low quality evidence
16) Free-hand insertion is recommended for EUS-CDS-L 17) Selective over-the-wire LAMS release may be considered in challenging scenarios	Multicenter retrospective (Jacques et al. [18]) Multicenter retrospective (Beunon et al. [19])	3b	Low quality evidence
18) Pure cutting current is recommended for EUS-CDS-L	ESGE-guideline (van Wanrooij et al. [9]) Single center prospective (Mangiavillano et al. [41])	2–3b	Low-moderate quality evidence
19) Intra-channel release is recommended for LAMS proximal flange release	Single center prospective (Mangiavillano et al. [41]) ESGE guideline (van Wanrooij et al. [9])	3b	Low quality evidence
20) Endoscopists performing EUS-CDS-L must be familiar with salvage modalities and adverse event management	Meta-analysis (li et al. [42]) Technical review (*Rana* et al. [43])	5	Very-low quality evidence
21) Fluoroscopy is recommended for EUS-CDS-L to facilitate adequate adverse event management	ESGE-guideline (van Wanrooij et al. [9]) ESGE-guideline (van der Merwe et al. [1])	3b	Low quality evidence
22) In case of LAMS maldeployment, salvage should be individualized and should focus on securing adequate bile duct drainage with the lowest risk of adverse events	Meta-analysis (Armellini et al. [44]) Multicenter retrospective (Rajadurai et al. [45]) Multicenter retrospective (On et al. [46]) Post hoc analysis of two RCTs (Chen et al. [20]) Multicenter retrospective (Beunon et al. [19])	3a-3b	Low quality evidence
23) Following uncomplicated EUS-CDS-L, oral intake can be initiated within 24 hours	Case reports (Elmassry et al. [47]) Single center retrospective (Mandai et al. [48]) RCT (Park et al. [49]) Consensus guideline (Marzioni et al. [6])	4–5	Very-low quality evidence
24) Routine LAMS surveillance and revision is not recommended	Meta-analysis of RCT (Khoury et al. [2]) Multicenter retrospective (Vanella et al. [12]) Expert commentary (Albouys et al. [50])	5	Very-low quality evidence

be included as a therapeutic option after multidisciplinary discussion in suitable cases of benign biliary obstruction.

Regarding the technical recommendations, there was strong agreement on most statements. For the recommended CBD diameter, EUS-CDS-L seems mostly suitable for a bile duct diameter $\geq$ 15 mm, while guidewire assistance is preferred when the CBD diameter is $<$ 15 mm [18–20]. CBD $\geq$ 12 mm could be considered feasible when advanced expertise is available [21].

Antibiotic prophylaxis was extensively debated within the Delphi consensus group, given the limited data supporting its routine use for EUS-CDS-L. European Society of Gastrointestinal Endoscopy (ESGE) Guideline on EUS-guided transluminal interventions suggest the utility of antibiotic prophylaxis in all transmural procedures, though evidence quality remains low [9]. Moreover, the question of whether EUS-CDS is performed with electrocautery (EC)-LAMS or FC-SEMS sparked debate among experts about whether LAMS should be preferred over a fully covered self-expandable metallic stent for EUS-CDS procedures. Some experts highlighted the relatively high dysfunction rate of EUS-CDS-L, with limited long-term data on stent patency [12]. A recent systematic review and meta-analysis comparing LAMS versus FC-SEMS for EUS-CDS reported a slight superiority of LAMS over SEMS, especially in terms of reinterventions, although not statistically significant [4]. Of note, we acknowledge that the strong expert agreement likely reflect accumulated clinical experience and perceived technical advantages and ease of EC-LAMS rather than high-quality comparative evidence, as the available evidence remains largely observational and comparative rather than randomized; therefore, further direct comparative trials are needed to confirm the superiority of either stent type in terms of long-term patency, cost-effectiveness, and adverse event profiles.

For the rejected statements, specifically, whether a DPPS should be inserted through the LAMS, a multicenter retrospective study of 41 patients found no statistically significant difference in clinical success, adverse event rate, or recurrent biliary obstruction between the LAMS alone group and the LAMS + DPPS group [22]. On the other hand, a recent multicenter RCT including 91 patients showed that the rate of recurrent biliary obstruction (but not reintervention rate) was significantly lower in the LAMS-DPPS group (9%) than in the LAMS group alone (30%) [10].

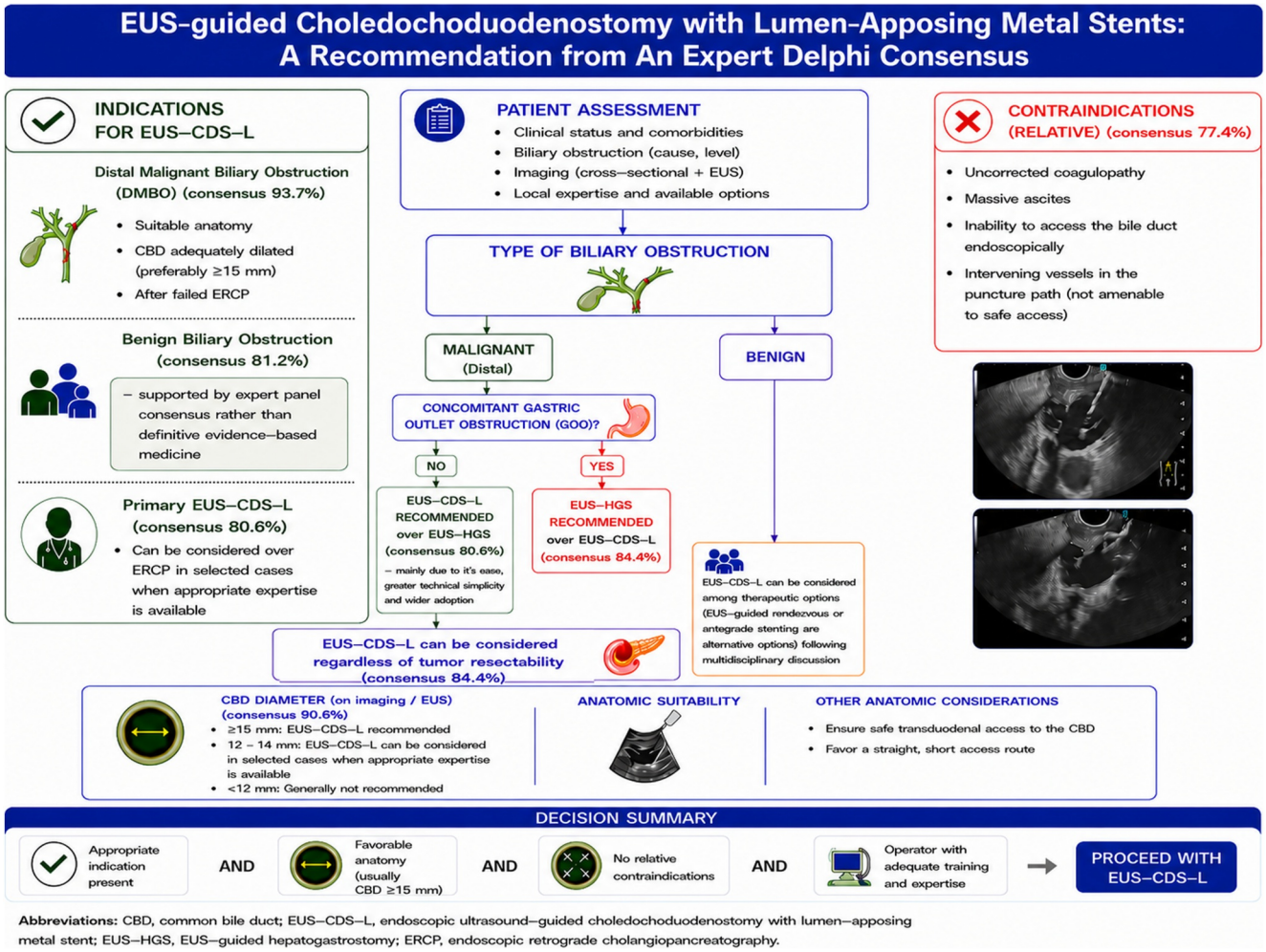

FIGURE 2 | An algorithm for patient selection and decision making.

Although the expert panel did not recommend the routine placement of DPPS through the LAMS, this recommendation should be interpreted in the context of the currently sparse evidence of a single randomized controlled trial. The panel's recommendation therefore is based on expert consensus. This position likely reflects concerns regarding the need for fluoroscopic guidance, longer procedure time, higher costs and the increased procedural complexity. Given this discrepancy between expert opinion and randomized evidence, the role of coaxial DPPS should be considered an important area for future investigation. Additional adequately powered multicenter randomized trials are needed to determine whether the reduction in recurrent biliary obstruction justifies the added procedural complexity and resource utilization, and to identify the patient populations most likely to benefit.

However, despite the RCT, endoscopists are not yet convinced that this is the way to go, probably due to the requirement of fluoroscopy, additional time or other factors that were not assessed in this Delphi.

Our study has several strengths. First, it included internationally renowned panelists with well-known expertise in EUS-guided LAMS procedures, and all panelists participated in both voting rounds at 100%. A second strength is its methodological robustness: it was conducted anonymously via an online platform with structured feedback that enabled panelists to share comments on each statement without affecting their peers' opinions. Third, the consensus statements were generated by the steering committee based on a comprehensive literature review, ensuring coverage of all aspects of EUS-CDS-L procedures, including pre-, intra-, and post-procedural considerations. Finally, our study used a modified Delphi methodology to assess expert agreement. The process was not designed to generate graded recommendations. However, the use of the Oxford Center for Evidence-Based Medicine framework was intended to enhance transparency by highlighting the variable quality of evidence supporting individual statements and acknowledging that our Delphi consensus reflects expert opinion rather than definitive comparative effectiveness data, as most of the statements (20/24, 83.3%) were ranked as low-moderate levels of evidence, and there are several statements (number: 7, 12, 15–17, 19, and 20–24) that achieved a very strong consensus ($\geq$ 90%), while only supported by very-low to low quality evidence reflecting expert consensus rather than definitive evidence-based recommendations.

Our study also has limitations. This consensus might underrepresent the opinions of experts from less-represented

regions, as 78.1% were from Europe. However, the most experienced experts from all regions were recruited for this Delphi consensus. There was an imbalance between interventional endoscopists and hepato-pancreato-biliary surgeons.

In conclusion, this Delphi consensus defines core principles for the EUS-CDS-L procedure and highlights areas of uncertainty that require further research. The accepted statements provide a practical guide to current best practice, aiming to optimize procedural safety and clinical outcomes.

Author Contributions

Tawfik Khoury contributed to the study concept. Tawfik Khoury, Andrea Lisotti, and Bertrand Napoleon contributed to study design and statement development. Tawfik Khoury, Wisam Sbeit, and Rares Ilie Orzan conducted database searches, data extraction, and data analysis. Tawfik Khoury wrote the initial manuscript draft. All authors approved the final version of the manuscript.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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