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The i-EUS consensus on EUS-guided gallbladder drainage: A 3-step modified Delphi approach

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ABSTRACT

Background and Objective: EUS-guided gallbladder drainage (EUS-GBD) has emerged as a viable alternative for patients with acute cholecystitis who are unfit for surgery. However, standardized guidelines for its indications, techniques, and management remain limited. The objective of this study is to develop evidence-based consensus recommendations for EUS-GBD in benign and malignant conditions, aimed at guiding clinical decision-making and improving patient outcomes.

Methods: A 3-step modified Delphi process was used by the Interventional Endoscopy and Ultrasound Group, involving multidisciplinary experts in gastroenterology, surgery, and radiology. Four task forces conducted systematic literature reviews and generated PICO (Patients, Interventions, Comparator, and Outcomes)–formatted clinical questions. Evidence was graded using the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system, and consensus was defined as ≥80% agreement among panelists.

Results: Twenty-two clinical questions were addressed, covering indications, timing, techniques, device selection, procedural aspects, and postprocedural care for EUS-GBD. Recommendations include the preferential use of EUS-GBD over percutaneous and transpapillary approaches in high-risk patients, early intervention in select cases, the use of lumen-apposing metal stents, and tailored postprocedural strategies. All recommendations were conditional, except for one strong recommendation in favor of EUS-GBD over other modalities, supported by moderate-quality evidence.

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Conclusions: This consensus offers a comprehensive, multidisciplinary guideline for the safe and effective use of EUS-GBD in clinical practice. These recommendations aim to standardize care and support future research in this rapidly evolving field.

Keywords: Endosonography; Gallbladder drainage; Percutaneous drainage; Lumen-apposing metal stents; EUS-guided gallbladder drainage

INTRODUCTION

Cholecystectomy remains the gold standard for managing acute cholecystitis (AC). However, in certain patients, particularly those with severe comorbidities or poor surgical candidacy, emergency cholecystectomy may pose significant risks, with morbidity rates reaching up to 41% and increased mortality.[1] When surgical intervention is not feasible, percutaneous gallbladder drainage (PT-GBD) offers an alternative for gallbladder decompression, utilizing ultrasound- or computed tomography–guided placement of a cholecystostomy tube. Although effective, PT-GBD has been associated with notable complications, including bleeding, bile leakage, pneumothorax, secondary infections, patient discomfort, and a risk of accidental catheter dislodgement.[2]

Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic transpapillary GBD (ET-GBD) provides an internal alternative for drainage, eliminating external tube-related complications. However, its success is hindered by technical challenges, particularly in cases of cystic duct obstruction, and a considerable risk of pancreatitis. On the other hand, EUS-guided GBD (EUS-GBD) has emerged as a minimally invasive, safe, and effective therapeutic option, especially with the advent of lumen-apposing metal stents (LAMSs), which have enhanced procedural efficiency and safety.[3,4] This paradigm shift necessitates well-defined evidence regarding the indications, standardization of techniques, and selection of rapidly evolving devices. Implementing novel approaches in routine clinical practice requires rigorous validation and standardization to ensure optimal outcomes.

The Interventional Endoscopy and Ultrasound Group (i-EUS) was established in 2017 as a collaborative network of Italian expert biliopancreatic endoscopists dedicated to data sharing, continuous updates, and education. The group aims to enhance procedural outcomes through methodical evaluation of execution techniques, clinical success, and long-term follow-up. Recognizing the absence of established guidelines in this domain, i-EUS has evolved into a multidisciplinary platform tasked with organizing consensus conferences to define indications, technical considerations, clinical management, and patient follow-up based on the best available evidence. The primary objective of these consensus guidelines is to provide evidence-based recommendations on EUS-GBD for both benign and malignant conditions. The primary audience for this document consists of clinicians involved in the management of patients with gallbladder disease.

METHODS

Organization

Four task forces were established, each comprising 4 experts in gallbladder disease management and led by a designated leader. The task forces conducted online meetings and formulated a series of clinical questions and statements based on systematic reviews and corresponding evidence tables. These focused on 4 key areas: EUS-GBD in AC and fragile patients, technical aspects of EUS-GBD, postprocedural considerations, and EUS-GBD as a rescue therapy or for other indications.

The proposed questions and statements were uploaded to a dedicated portal and reviewed twice by all experts, who provided feedback. Experts included gastroenterologists, surgeons, and radiologists. The revised statements were subsequently discussed in a face-to-face plenary session. Statements that failed to achieve at least 80% agreement were excluded. Those reaching consensus were further refined by the task force leaders (Table 1).

Grading of evidence

The task forces assessed the available evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to determine the quality of evidence and strength of recommendations (Supplementary Table 1, http://links.lww.com/ENUS/A378).[5,6]

Each clinical question was structured according to the PICO (Patients, Interventions, Comparator, and Outcomes) framework.

A systematic literature search was performed across major databases to identify relevant studies published in English from inception until April 2024, with a focus on meta-analyses and prospective studies.

The GRADE system was used to categorize the strength of recommendations as either strong or conditional, and the quality of evidence as high, moderate, low, or very low. Evidence derived from randomized controlled trials (RCTs) was initially classified as high quality, whereas evidence from nonrandomized studies was rated as low quality. The quality of evidence could be downgraded based on the presence of specific factors, including risk of bias, inconsistency, indirectness, imprecision, or publication bias.[7]

RESULTS

Question 1: Is there a validated definition of unfit-for-surgery patients?

i-EUS does not suggest one score over another among several validated ones to estimate the surgical risk; however, a multidisciplinary evaluation of surgical risk is recommended in patients with AC to stratify the prognosis, assess the preoperative risk of complications, and decide the optimal treatment strategy.

Conditional recommendation; low level of evidence. 98% agreement.

Frailty is characterized by a pathological decline in physiological reserve due to both age-related functional deterioration and pathological insults.[8] Currently, there is no universally accepted definition of frailty in the context of AC that reliably predicts patient outcomes. Despite this, frailty stratification is strongly recommended, as it influences therapeutic decision-making. Several scoring systems have been proposed to assess anesthesiology risk (American

Table 1

I-EUS statements.

Recommendations	Strength of recommendation	Quality of evidence	Agreement
1 i-EUS does not suggest one score over another among several validated ones to estimate the surgical risk; however, a multidisciplinary evaluation of surgical risk is recommended in patients with AC to stratify the prognosis, assess the preoperative risk of complications, and decide the optimal treatment strategy.	Conditional	Low	98%
2 i-EUS suggests gallbladder drainage in unfit-for-surgery patients with moderate to severe AC.	Conditional	Low	96%
3 i-EUS suggests early (<48 h) EUS-GBD in patients who do not respond to conservative therapy.	Conditional	Very low	94%
4 i-EUS recommends that EUS-GBD should be preferred over ET-GBD and/or PT-GBD in unfit-for-surgery patients with AC.	Strong	Moderate	100%
5 i-EUS suggests conversion of PT-GBD to EUS-GBD according to the patient's conditions and predicted risk of cholecystitis recurrence.	Conditional	Very Low	91%
6 i-EUS suggests same-session ERCP and ET-GBD for patients with concomitant AC and choledocholithiasis.	Conditional	Very Low	93%
7 i-EUS suggests using LAMSs for EUS-GBD.	Conditional	Low	100%
8 i-EUS suggests that ≥15-mm-diameter LAMSs could be preferred when cholecystoscopy is scheduled.	Conditional	Low	100%
9 i-EUS does not suggest a routine dilation of LAMSs for EUS-GBD.	Conditional	Low	100%
10 i-EUS suggests performing EUS-GBD in a fluoroscopy-equipped room.	Conditional	Low	98%
11 i-EUS suggests either transgastric or transduodenal route for EUS-GBD with LAMSs. The choice of the route should be personalized according to the EUS window, potential future surgical indication, and the expected duration of LAMS indwelling.	Conditional	Low	98%
12 i-EUS suggests that, in case of contracted gallbladder or difficult lumen visualization, saline injections can be attempted to obtain lumen distension.	Conditional	Very low	89%
13 i-EUS does not suggest routine antibiotic prophylaxis before EUS-GBD.	Conditional	Low	96%
14 i-EUS suggests managing antithrombotic therapy as for high-risk of bleeding endoscopic procedures. In those at high risk of bleeding conditions or if antithrombotic therapy cannot be discontinued, EUS-GBD can still be considered based on the clinical need of gallbladder drainage.	Conditional	Very low	98%
15 i-EUS does not suggest the routine use of any medical therapy following EUS-GBD.	Conditional	Very low	95%
16 i-EUS suggests early oral refeeding (<48 h) after uncomplicated EUS-GBD.	Conditional	Very low	100%
17 i-EUS suggests individualizing the timing for PT-GBD catheter removal based on the expected efficacy of the EUS-GBD.	Conditional	Very low	97%
18 i-EUS suggests that LAMS permanent indwelling should be individualized. LAMS exchange with double-pigtail plastic stents may be considered when long-term life expectancy is predicted.	Conditional	Low	98%
19 i-EUS suggests EUS-GBD after ERCP failure for distal malignant biliary obstruction when EUS-guided biliary drainage is not feasible.	Conditional	Low	86%
20 i-EUS does not suggest routine prophylactic EUS-GBD in patients who undergo ERCP with self-expandable metal stent placement for distal malignant biliary obstruction and tumor involvement across the orifice of the cystic duct.	Conditional	Low	83%
21 i-EUS does not suggest EUS-GBD in fit-for-surgery patients.	Conditional	Low	87%
22 i-EUS suggests that EUS-GBD does not increase the complexity of cholecystectomy compared with PT-GBD. iEUS suggests removing LAMSs before surgery.	Conditional	Low	98%

AC, acute cholecystitis; EUS-GBD, EUS-gallbladder drainage; ET-GBD, endoscopic transpapillary gallbladder drainage; PT-GBD, percutaneous gallbladder drainage; ERCP, endoscopic retrograde cholangiopancreatography; LAMSs, lumen-apposing metal stents.

Society of Anesthesiology—Physical Status), morbidity and mortality after surgery (Portsmouth Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity [P-POSSUM]), survival based on comorbidities (Charlson Comorbidity Index), and severity of critical illness (Acute Physiology and Chronic Health Evaluation). These tools have been validated primarily in preoperative settings but are increasingly being studied for nonsurgical candidates.[9–12]

Age is an independent risk factor for mortality in AC, with patients older than 80 years at a significantly higher risk of postoperative complications.[13] A simplified risk stratification model differentiates between elderly (65–79 years) and very elderly (>80 years) patients, revealing worse outcomes in the latter group.[14] The Clinical Frailty Score, a 9-point scale assessing overall patient fitness, has proven useful in determining eligibility for laparoscopic cholecystectomy *versus* minimally invasive drainage procedures such as PT-GBD.[15] A study on 344 patients with AC treated with percutaneous or surgical approach has shown lower predictive accuracy for morbidity in AC compared with the Tokyo Guidelines and American Society of Anesthesiology—Physical Status.[16,17]

A novel multivariate model, the Acute Cholecystitis Mortality Estimation, incorporates chronic obstructive pulmonary disease, dementia, age >80 years, and preoperative vasoactive amine use, achieving high mortality prediction accuracy (92%) across surgical and nonsurgical candidates.[18] The P-POSSUM score has demonstrated good predictive accuracy for AC outcomes, as shown by González-Muñoz et al., who identified independent predictors of mortality at the time of admission on 149 patients.[19]

More recently, the Chole-Risk score has been proposed for patients with AC, showing good predictive value for in-hospital mortality and 30-day mortality, in-hospital major morbidity, and 30-day

morbidity, based on 1429 patients.[20] Among the existing scoring systems, P-POSSUM demonstrated the highest predictive accuracy postoperatively, with an optimal cutoff of 25 for identifying high-risk patients (Supplementary Table 2, http://links.lww.com/ENUS/A378).

Given the absence of robust comparative studies, no single scoring system can be recommended as superior. However, risk stratification remains essential, and institutions should establish a standardized model for patient evaluation. Based on current evidence, a conditional recommendation with low level of evidence was provided.

Question 2: When is minimally invasive nonsurgical treatment indicated for AC in unfit-for-surgery patients?

i-EUS suggests GBD in unfit-for-surgery patients with moderate to severe AC.

Conditional recommendation; low level of evidence. 96% agreement.

Laparoscopic cholecystectomy remains the gold standard for AC treatment. However, patients with advanced age, frailty, or significant comorbidities may not be suitable surgical candidates. In severe AC cases with a high risk of systemic complications (sepsis, organ failure), GBD has been considered an effective alternative. The 2018 Tokyo Guidelines recommend PT-GBD as a bridge therapy for patients with potentially reversible comorbidities or unclear surgical risk, with reassessment at 4–6 weeks.[21–23]

However, emerging evidence has challenged this approach, suggesting that surgery may still be feasible in selected high-risk patients.[24] A multicenter RCT in 142 high-risk patients with AC was terminated early due to significantly higher major complication rates in the PT-GBD group (65% *vs.* 12% in the surgery group, Relative Risk, 0.19; 95% confidence interval [CI], 0.10–0.37; $P < 0.001$), with 66% requiring reintervention.[25]

When comparing PT-GBD and EUS-GBD in nonsurgical candidates, EUS-GBD demonstrated lower adverse event (AE) rates, fewer reinterventions, and lower recurrence of cholecystitis.[26,27] A meta-analysis of 6 studies reported comparable early AE rates but significantly lower delayed (odds ratio [OR], 0.21; 95% CI, 0.07–0.61; $P < 0.01$) and overall AEs (OR, 0.43; 95% CI, 0.30–0.61; $P < 0.01$) in the EUS-GBD group, along with a shorter hospital stay.[28] Furthermore, a propensity-score analysis comparing EUS-GBD and laparoscopic cholecystectomy in 60 patients demonstrated similar outcomes in terms of technical and clinical success, length of hospital stay, 30-day AEs, mortality, recurrent biliary events, reinterventions, and readmissions.[29] This suggests that EUS-GBD may be a viable alternative to surgery (Supplementary Table 3, http://links.lww.com/ENUS/A378).

Given the heterogeneity of available data and the indirect nature of interventions in included studies, a definitive recommendation on the optimal treatment for high-risk surgical patients is lacking. A stepwise, multidisciplinary approach tailored to individual cases is advised.[30] Due to these limitations, the panel downgraded the recommendation to conditional with low level of evidence.

Question 3: What is the optimal timing of EUS-GBD for AC?

i-EUS suggests early (<48 hours) EUS-GBD in patients who do not respond to conservative therapy.

Conditional recommendation; very low level of evidence. 94% agreement.

The ideal timing for nonsurgical, minimally invasive treatment of AC remains uncertain, with no trials specifically addressing the timing of EUS-GBD. Five studies compared early *versus* late PT-GBD in AC: 4 retrospective studies[31–34] and 1 comparative cross-sectional trial.[35] Early drainage was defined as occurring within 24 hours in 3 studies, within 48 hours in one, and within 72 hours in another.

Two studies reported lower drainage-related complications with early intervention, whereas 3 studies found a significant reduction in hospital stay. However, 2 studies showed no significant clinical benefit or reduction in morbidity and mortality.

Despite these conflicting findings, current guidelines recommend early minimally invasive drainage in patients unresponsive to conservative management.[8,36] The World Society of Emergency Surgery suggests PT-GBD or EUS-GBD after 48 hours in patients with persistent leukocytosis (>15,000 white blood cells/μL) and fever unresponsive to antibiotics at 24–48 hours.[36,37] Preliminary evidence supports performing EUS-GBD as soon as possible when laparoscopic cholecystectomy is not feasible.[38]

Given the absence of direct comparisons between early and late EUS-GBD and the extrapolation of evidence from other minimally invasive procedures, the panel downgraded the evidence to a conditional recommendation with very low level of evidence.

Question 4: Should EUS-GBD be preferred over ET-GBD or PT-GBD in unfit-for-surgery patients with AC?

i-EUS recommends that EUS-GBD should be preferred over ET-GBD and/or PT-GBD in unfit-for-surgery patients with AC.

Strong recommendation; moderate level of evidence. 100% agreement.

Laparoscopic cholecystectomy remains the gold standard for treating AC.[39] However, a subset of patients is unfit for surgery or presents contraindications at the time of diagnosis, necessitating alternative management strategies such as PT-GBD, ET-GBD, and EUS-GBD. Retrospective comparative studies yielded inconsistent findings. The only study comparing all 3 methods demonstrated significantly higher technical and clinical success for PT-GBD and EUS-GBD compared with ET-GBD.[40]

An RCT by Teoh et al. found that EUS-GBD with LAMSs was associated with lower AE rates, fewer episodes of recurrent cholecystitis, reduced reintervention, and fewer unplanned readmissions compared with PT-GBD, with similar technical and clinical success rates.[26]

Meta-analyses comparing EUS-GBD (using plastic, self-expandable metal stents, and LAMSs) to PT-GBD, revealed slightly higher technical success rates for PT-GBD but comparable clinical success. However, EUS-GBD was associated with a more favorable safety profile, lower recurrence rates of AC, and reduced need for reintervention.[41–43] A subgroup analysis focusing solely on EUS-GBD with LAMSs confirmed superior or comparable technical and clinical success rates (RR, 0.965; $P = 0.146$) to PT-GBD group (RR, 0.967; $P = 0.036$), with fewer AE rates (RR, 0.424 $P < 0.001$), and lower reintervention rates (RR, 0.244; $P < 0.001$).[27]

A pooled analysis by Mohan et al. found EUS-GBD to have significantly higher clinical success than ET-GBD and PT-GBD.[44] However, the all-cause mortality rate in the EUS-GBD group was unexpectedly high (26%) compared with ET-GBD (16.6%) and PT-GBD (11.2%, $P = 0.001$), likely due to selection bias, as EUS-GBD was frequently performed in patients with lower overall survival.

A network meta-analysis comparing the 3 drainage techniques demonstrated high clinical success and lower recurrence rates of cholecystitis in the EUS-GBD group.[45] ET-GBD was associated with the lowest rates of reintervention, unplanned readmissions, and mortality, whereas PT-GBD showed the highest technical success but was also linked to the highest rates of subsequent interventions and hospitalizations. The risk of AE was comparable across all 3 modalities (Supplementary Tables 4 and 5, http://links.lww.com/ENUS/A378).

Based on the available evidence, particularly the single RCT on the topic,[26] the panel issued a strong recommendation with a moderate level of evidence in favor of EUS-GBD with LAMSs as the preferred drainage modality for high-risk, unfit-for-surgery patients.

Question 5: Should conversion to EUS-GBD be preferred over conservative treatment in unfit-for-surgery patients with PT-GBD?

i-EUS suggests conversion of PT-GBD to EUS-GBD according to the patient's conditions and predicted risk of cholecystitis recurrence.

Conditional recommendation; very low level of evidence. 91% agreement.

There are no established guidelines for managing patients with AC who undergo PT-GBD and are unfit for subsequent interval cholecystectomy. PT-GBD maintenance is often challenging, and AC recurrence rates following catheter removal without surgery range from 22% to 45%.[46–48]

Recent studies have evaluated the feasibility of converting PT-GBD to ET-GBD or EUS-GBD in unfit-for-surgery patients.[49] Two case series demonstrated successful conversion to EUS-GBD using either LAMSs or double-pigtail plastic stents, reporting 100% technical success and up to 33% AE rates, with no recurrence of AC.[50,51] A retrospective study by Minaga et al. reported a 91% technical success rate in 21 patients undergoing EUS-GBD with either plastic stents or self-expandable metal stents, with 15% AE rate and AC recurrence in 2 patients.[52]

A comparative study by Chon et al. looked at the clinical outcomes of conservative treatment following PT-GBD removal *versus* conversion to ET-GBD.[53] The authors retrospectively analyzed 238 patients (63 endoscopic conversions, including 55 ET-GBD and only 8 EUS-GBD, and 175 conservative treatments). Patients who underwent conversion experienced significantly less frequent AC recurrence (5% *vs*. 18%, $P = 0.012$). The technical and clinical success rates of the conversion of PT-GBD to ET-GBD were 89% and 98%, respectively. Interestingly, the 8 EUS-GBD had 100% technical and clinical success. Procedure-related AE occurred in 3 patients (5%) who underwent ET-GBD (Supplementary Table 6, http://links.lww.com/ENUS/A378).

Endoscopic conversion of PT-GBD to either ET-GBD or EUS-GBD appears feasible and is associated with improved outcomes compared with conservative management after PT-GBD removal. However, further prospective studies with larger and more homogeneous patient cohorts are needed. Due to the heterogeneity of data, the panel issued a conditional recommendation with very low level of evidence.

Question 6: What is the optimal treatment for unfit-for-surgery patients with AC and concomitant choledocholithiasis?

i-EUS suggests same-session ERCP and ET-GBD for patients with concomitant AC and choledocholithiasis.

Conditional recommendation; very low level of evidence. 93% agreement.

Choledocholithiasis is present in approximately 15% of AC cases.[54,55] However, a subset of these patients is unsuitable for surgery due to significant comorbidities. Their optimal management remains unclear due to the lack of prospective RCT, with most available evidence derived from retrospective studies and lacking specific focus on high-risk populations.

Based on retrospective data, some general recommendations for unfit-for-surgery patients can be made.[56–58] First, it is generally agreed that cholecystitis should be managed within 72 hours of hospital admission. Second, ET-GBD is the preferred alternative to surgery. Third, ERCP is the standard treatment for clearing the common bile duct in case of biliary obstruction. Additionally, when ET-GBD fails, EUS-GBD combined with ERCP can be a valid rescue treatment that has comparable rates of technical and clinical success to EUS-GBD alone (Supplementary Table 7, http://links.lww.com/ENUS/A378).

Considering the available evidence, the panel provided a conditional recommendation with a low level of evidence in favor of a 1-stage procedure (simultaneous ERCP and ET-GBD), as it demonstrated similar efficacy and safety compared with a 2-stage approach, with organizational benefits.

Question 7: Do LAMSs improve the outcomes of EUS-GBD in comparison to other devices such as nasobiliary catheters, double-pigtail plastic stents, and self-expandable metal stents?

i-EUS suggests using LAMSs for EUS-GBD.

Conditional recommendation, low level of evidence. 100% agreement.

EUS-GBD had been traditionally performed using devices for other endoluminal procedures, including nasobiliary catheters, double-pigtail plastic stents,[59–62] and self-expandable metal stents.[63–65] However, double-pigtail plastic stents increased the risk of bile leakage and peritonitis due to small caliber and inadequate fistula sealing. Moreover, self-expandable metal stents had larger caliber and radial expansion to improve fistula sealing and reduce bile leakage but increased the risk of stent migration and contralateral wall injury. In comparison to the latter, antimigratory self-expandable metal stents showed higher technical and clinical success with favorable safety profiles.[66–68]

To overcome the limitations of the devices mentioned above and try to improve clinical outcomes, LAMSs were introduced for EUS-GBD. LAMSs have a large-bore, covered metal design with wide flanges to provide lumen-to-lumen apposition and prevent

migration, while minimizing the risk of extraluminal leakage[28,69,70] The electrocautery tip of LAMSs facilitates direct single-step deployment, eliminating the need for tract dilation and multiple device exchanges.[71]

No direct comparative trials have evaluated technical success, clinical efficacy, or AE between different stent types. However, a systematic review of 21 studies (166 patients) found similar technical (90%–100%) and clinical success rates for double-pigtail plastic stents, self-expandable metal stents, and LAMSs.[72] AE rates were 18% for double-pigtail plastic stents, 12% for self-expandable metal stents, and 10% for LAMSs. Moreover, a meta-analysis (27 studies, 1004 patients) demonstrated that antimigratory self-expandable metal stents and LAMSs significantly improved clinical success (OR, 2.16; 95% CI, 1.07–4.36) and reduced AEs (OR, 0.36; 95% CI, 0.14–0.98).[73]

Comparative data between LAMSs and antimigratory self-expandable metal stents are limited. A retrospective study (379 patients, 294 LAMSs, 85 antimigratory self-expandable metal stents) found no significant difference in technical or clinical success, but LAMSs had a higher 30-day AE rate (P = 0.045), whereas antimigratory self-expandable metal stents had more unplanned procedural events.[74] Another study (71 patients, 36 LAMSs, 35 antimigratory self-expandable metal stents) reported no significant differences in technical success (94% *vs.* 100%), clinical success (94% *vs.* 100%), procedure-related AE (0% *vs.* 2.9%), cholecystitis recurrence, or late stent-related complications.[66]

A meta-analysis (11 studies, 1155 patients) found no significant differences in technical or clinical outcomes between EUS-GBD and PT-GBD.[42] However, in a subgroup analysis of EUS-GBD performed with EC-LAMSs, there were lower rates of AE (P = 0.0006), recurrent cholecystitis (P = 0.02), and hospital readmissions (P = 0.03) compared with PT-GBD (Supplementary Table 8, http://links.lww.com/ENUS/A378).

Given the limited comparative data, the panel provided a conditional recommendation with low level of evidence in favor of LAMSs for EUS-GBD.

Question 8: Do LAMSs with a ≥ 15-mm-diameter improve the outcomes of EUS-GBD compared with smaller LAMSs?

i-EUS suggests that ≥15-mm-diameter LAMSs could be preferred when cholecystoscopy is scheduled.

Conditional recommendation; low level of evidence. 100% agreement.

LAMSs are available in diameters ranging from 6 to 20 mm, with 10- and 15-mm LAMSs being the most frequently used in clinical practice. However, comparative data evaluating outcomes between different LAMS sizes remain limited.[26,40] A meta-analysis of 13 studies suggested that larger-diameter LAMSs may facilitate better EUS-GBD by reducing the risk of stent obstruction due to thick bilious or purulent secretions.[75] However, this meta-analysis did not specifically focus on LAMS diameter comparison, potentially limiting its ability to detect significant differences. A multicenter study (102 patients) comparing 10-mm (n = 78) *versus* 15-mm (n = 24) LAMSs for EUS-GBD demonstrated high technical success rates in both groups, with no significant differences in clinical success or AE.[40]

The DRAC 1 trial and another study recommended 10-mm LAMSs for small gallbladder stones, and 15-mm LAMSs for larger stones.[26,29] The European Society of Gastrointestinal Endoscopy technical review suggested the same approach but did not give a specific recommendation.[76] An international consensus also advised using 15-mm LAMSs in cases of large gallbladder stones.[77] Additionally, some experts proposed 15- to 16-mm LAMSs to guarantee endoscopic access to the gallbladder for advanced interventions, such as lithotomy, gallbladder clearance, or polyp removal.[78]

Given the limited comparative data, the panel provided a conditional recommendation with low level of evidence in favor of ≥15-mm-diameter LAMSs for EUS-GBD.

Question 9: Does LAMS dilation improve the outcomes of EUS-GBD?

i-EUS does not suggest a routine dilation of LAMSs for EUS-GBD.

Conditional recommendation; low level of evidence. 100% agreement.

At the time of EUS-GBD, LAMSs do not reach their full caliber immediately postdeployment. Therefore, the lumen is initially limited to a few millimeters, restricting the passage of fluids (bile, pus) and gallstones. Over subsequent days, the radial expansion of the metal mesh gradually dilates the stent, optimizing drainage.

Endoscopic balloon dilation of LAMSs immediately after deployment has been proposed to enhance the effect of EUS-GBD and potentially reduce the risk of stone impaction. This technique is routinely used in other applications of LAMSs such as pancreatic fluid collection drainage (to facilitate direct endoscopic necrosectomy) and EUS-directed transenteric ERCP (to allow passage of the endoscope).

However, no dedicated studies have assessed the systematic impact of immediate LAMS dilation. A few retrospective studies reported high technical success (87%–100%), high clinical success (92%–100%), and moderate AE rates (0%–28%) with LAMSs for EUS-GBD, but they did not differentiate the outcomes according to LAMS dilation.[79–82]

Two case reports described immediate dilation of LAMSs for EUS-GBD to perform operative procedures inside the gallbladder (gallstone fragmentation and extraction).[83,84] A case series reported of 7 patients with AC, who had their LAMSs dilated 2 weeks after EUS-GBD to perform endoscopic gallstones extraction.[85] Although a long-term AE study included 14% of patients who underwent immediate LAMS dilation after EUS-GBD, their specific outcomes were not reported (Supplementary Table 9, http://links.lww.com/ENUS/A378).[58] On the other hand, a case series and a small prospective study (22 patients) explicitly reported not performing LAMS dilation after EUS-GBD.[86,87] Technical success (95.5%–100%) and clinical success (100%) were high, and AE rates (0%–4.5%) were low.

The evidence being based only on indirect comparisons, the panel provided a conditional recommendation with low level of evidence.

Question 10: Does fluoroscopy improve technical success and reduce the incidence of adverse events in patients undergoing EUS-GBD with LAMSs?

i-EUS suggests performing EUS-GBD in a fluoroscopy-equipped room.

Conditional recommendation; low level of evidence. 98% agreement.

Currently, no comparative data exist on the outcomes of EUS-GBD with LAMSs performed with or without fluoroscopy. International guidelines and expert consensus recommend performing interventional EUS-guided procedures under direct EUS view in facilities with fluoroscopy.[22] Access to interventional radiology and pancreatobiliary surgery for potential AE is also recommended.[77,88]

Although many studies on EUS-GBD included fluoroscopy availability, Lisotti et al. reported the outcomes of 34 cases performed without fluoroscopy, demonstrating comparable technical success (92%), clinical success (88%), and AE rate (16%).[89] Additionally, Vanella et al. suggested that fluoroscopy may not be necessary for some selected interventional EUS procedures, although it remains essential in complex cases.[90]

Fluoroscopy is particularly recommended in conversion of PT-GBD to EUS-GBD and in prophylactic EUS-GBD in patients with malignant cystic duct infiltration, after ERCP and self-expandable metal stent placement in the common bile duct.[52,91] Although rarely used, fluoroscopy is mandatory in the case of EUS-GBD using the Seldinger multistep technique.[69]

Given the lack of directly comparative studies, the panel provided a conditional recommendation with low level of evidence in favor of using fluoroscopy to enhance EUS-GBD safety and efficacy.

Question 11: Does the transduodenal route for EUS-GBD improve the outcomes over the transgastric approach?

i-EUS suggests either transgastric or transduodenal route for EUS-GBD with LAMSs. The choice of the route should be personalized according to the EUS window, potential future surgical indication, and the expected duration of LAMS indwelling.

Conditional recommendation; low level of evidence. 98% agreement.

Teoh et al. conducted a direct comparative analysis, revealing no statistically significant differences in technical and clinical success rates or intraprocedural and 30-day AE between the transgastric and transduodenal routes.[70] Other numerous retrospective studies, 2 prospective studies, 1 RCT, and 1 meta-analysis also failed to identify significant differences between these 2 routes (Supplementary Table 10, http://links.lww.com/ENUS/A378).[40,71,72,82,92–96]

The European Society of Gastrointestinal Endoscopy guidelines recommended the transduodenal over the transgastric route to minimize the risk of food impaction and buried LAMSs.[76] However, they were based on 3 retrospective studies without statistical inference, limiting the strength of this recommendation.[66,71,78] Moreover, a recent prospective study by Mangiavillano et al. that included 37 patients undergoing EUS-GBD for biliary drainage in distal malignant biliary obstruction (22 transduodenal, 15 transgastric) reported only 1 case of LAMS occlusion in the transgastric group, which was successfully managed endoscopically.[96] Based on their findings, a transgastric *versus* transduodenal route should be guided by echoendoscope stability, adequate gallbladder visualization, and the absence of interposed major vessels.

On the other hand, a retrospective study by Martinez-Moreno et al. followed 50 unfit-for-surgery patients for 3 years after EUS-GBD, reporting a significantly lower incidence of AE with the transduodenal route.[97] However, the sample size was limited, and data were incomplete, thereby reducing the study reliability. Notably, Teoh et al. performed independent gallbladder access via the stomach or duodenum,[70] whereas Martinez-Moreno et al. performed transgastric drainage only when transduodenal access was not feasible due to poor gallbladder visualization or unstable echoendoscope position.[97]

Given the lack of strong evidence and the potential for selection bias in retrospective studies, the panel issued a conditional recommendation with low level of evidence regarding the preference of a transduodenal over a transgastric route for EUS-GBD.

Question 12: Do gallbladder saline injections with a 19-gauge cytology needle allow better outcomes of EUS-GBD in case of contracted gallbladder or in case of difficult visualization of the gallbladder lumen?

i-EUS suggests that, in case of contracted gallbladder or difficult lumen visualization, saline injections can be attempted to obtain lumen distension.

Conditional recommendation; very low level of evidence. 89% agreement.

In patients with AC, the gallbladder typically presents with a thickened wall and a distended lumen containing bile and material of various densities due to the presence of pus, sludge, and stones. However, the gallbladder may not always be distended, such as in scleroatrophic chronic inflammation. Injections of saline mixed with iodine contrast through a 19-gauge fine-needle aspiration needle can obtain additional distension of the gallbladder and improve its visualization with EUS. Moreover, injections through the percutaneous tube to obtain an adequate distension of the gallbladder may facilitate conversion from PT-GBD to EUS-GBD.[51,52,98]

In a retrospective study on 51 patients, routine injections of the gallbladder were performed in all cases prior to LAMS deployment.[99] Notably, this procedure was carried out regardless of the gallbladder anatomical features. In another small retrospective study, saline injections were performed routinely to prevent bile leakage when fully covered self-expandable metal stents were used for EUS-GBD drainage (Supplementary Table 11, http://links.lww.com/ENUS/A378).[64]

Given the lack of comparative studies on this practice, the panel issued a conditional recommendation, with very low level of evidence, supporting injections of the gallbladder for EUS-GBD when there is inadequate lumen visualization.

Question 13: Does antibiotic prophylaxis reduce the incidence of AE in patients undergoing EUS-GBD for other indications than AC such as biliary drainage for malignant biliary obstruction and conversion of PT-GBD?

i-EUS does not suggest routine antibiotic prophylaxis before EUS-GBD.

Conditional recommendation, low level of evidence. 96% agreement

EUS-GBD is commonly performed in septic patients with AC who are under antibiotic therapy. On the other hand, patients undergoing

EUS-GBD for elective conversion of PT-GBD or palliation of malignant biliary obstruction may not receive antibiotic therapy. Data on the need for antibiotic prophylaxis before EUS-GBD are limited. Whereas some studies reported routine preprocedural administration of antibiotics,[87,91,100] others did not specify any given prophylaxis.[74,96] A retrospective multicenter study on 48 patients undergoing EUS-GBD for malignant biliary obstruction showed that only 39.6% of them received antibiotic prophylaxis. However, no significant impact on clinical outcomes and periprocedural AE was noted.[92]

The European Society of Gastrointestinal Endoscopy and the Asian EUS Group suggest considering broad-spectrum antibiotic prophylaxis in EUS-GBD.[76,88] Preferred drugs include second-generation cephalosporins or quinolones to target enteric gram-negative bacteria and enterococci. Prophylaxis is particularly important in high-risk patients, such as those with ascites, in whom sepsis and peritonitis have been reported after EUS-guided gastroenterostomy.[101–103] In such cases, a prolonged antibiotic course may be considered, although data on efficacy and optimal duration remain insufficient.[76]

Given the lack of clear evidence, a conditional recommendation with low level of evidence was provided for the management of antibiotics.

Question 14: What is the optimal management of antithrombotic therapy in patients undergoing EUS-GBD?

i-EUS suggests managing antithrombotic therapy as for high-risk of bleeding endoscopic procedures. In high-risk of bleeding conditions or if antithrombotic therapy cannot be discontinued, EUS-GBD can still be considered based on the clinical need of GBD.

Conditional recommendation; very low level of evidence. 98% agreement.

Antithrombotic therapy, including antiplatelets and anticoagulants, is commonly prescribed for elderly and oncological patients to prevent cardiovascular and cerebrovascular events. These medications increase the risk of bleeding during endoscopic procedures.[104]

A systematic review reported a 2% bleeding risk in patients undergoing EUS-GBD, which was higher compared with ERCP with transpapillary drainage.[105] However, due to the absence of specific studies on optimal antithrombotic management, a heterogeneous approach is observed, as evidenced by an Italian expert survey.[106] Case series have demonstrated that EUS-GBD can be successfully performed in patients with coagulopathy or antithrombotic therapy.[107,108] Lacking robust evidence, a conditional recommendation with very low quality of evidence was given for the management of antithrombotic agents in this context.

Question 15: Should patients receive any medical therapy after EUS-GBD?

i-EUS does not suggest the routine use of any medical therapy following EUS-GBD.

Conditional recommendation; very low level of evidence. 95% agreement.

There are limited data regarding medical therapy post–EUS-GBD, apart from antibiotics. In a multicenter study by Bazaga et al., proton pump inhibitors were investigated.[95] No significant correlation with AE after EUS-GBD was found including LAMS migration, bleeding, perforation, and recurrence of AC/cholangitis. An RCT by Teoh et al. on patients undergoing EUS-GBD for AC who received acetaminophen and intravenous tramadol for pain control showed inferior postprocedural pain compared with PT-GBD.[26]

According to a practical review, analgesic therapy should be provided for pain management, with no standardized protocol for the postprocedural care following EUS-GBD.[109] The use of opioids is controversial, as studies have shown both potential inhibitory effects on gallbladder motility and a relaxing effect on biliary pressure.[110,111] Given the lack of clear guidance, the recommendation was conditional, with very low level of evidence.

Question 16: When can patients resume oral feeding after EUS-GBD?

i-EUS suggests early oral refeeding (<48 hours) after uncomplicated EUS-GBD.

Conditional recommendation; very low level of evidence. 100% agreement.

Fragile individuals such as the elderly or the neoplastic patients are at nutritional risk. Therefore, appropriate nutritional support is crucial to improve clinical outcomes following EUS-GBD.[112,113] Early oral refeeding within 48 hours after EUS-GBD should be encouraged if not contraindicated, as it has been associated with better clinical outcomes.[69]

Although food impaction can potentially lead to recurrent AC, this AE has been reported to occur weeks after EUS-GBD.[96] As a result, it appears there is no need to delay refeeding in the absence of AE. Due to the lack of direct evidence, a conditional recommendation with very low level of evidence supported early oral refeeding following uncomplicated EUS-GBD.

Question 17: When should PT-GBD catheter be removed in patients undergoing conversion to EUS-GBD?

i-EUS suggests individualizing the timing for PT-GBD catheter removal based on the expected efficacy of the EUS-GBD.

Conditional recommendation; very low level of evidence. 97% agreement.

There are limited data regarding the optimal timing for PT-GBD removal following EUS-GBD as none of the available studies have assessed its impact on outcome measures. Of 7 patients who underwent EUS-GBD with LAMSs following PT-GBD, 4 had their catheter removed during the same session, whereas 2 had to wait for 12 and 30 days, respectively.[50] Another case series reported on 6 patients treated with EUS-GBD with double-pigtail plastic stents following PT-GBD, whose percutaneous catheter was removed after a median of 13 days (range, 2–72 days).[51] The maturity of the fistulous tract can be assessed using percutaneous cholangiography before removal, with well-formed tracts defined by an intact column of contrast material from the gallbladder to the skin, and poorly formed tracts showing spillage of contrast material.[114]

In a multicenter retrospective study, EUS-GBD was performed to replace indwelling PT-GBD in 21 patients, utilizing either plastic

or self-expandable metal stents.[52] After successful internal stent placement, the percutaneous catheter was clamped and temporarily left in place. The catheter was removed after a median of 7 days (range, 2–20 days) if no recurrence of AC or jaundice occurred. Two patients experienced AE, one dying prior to catheter removal and the other developing recurrent AC after catheter clamping.

Overall, there is lack of consensus on the timing of percutaneous catheter removal after EUS-GBD. A clinical review suggested that immediate removal of a mature tract (3–4 weeks after initial placement) may be considered following successful internal drainage but noted that the timing should be individualized based on treatment success, the duration of external catheter indwelling, and multidisciplinary consultation.[115]

Given the lack of definitive evidence, the recommendation for the timing of PT-GBD removal after EUS-GBD was conditional, with very low level of evidence.

Question 18: Should LAMSs be removed after EUS-GBD for AC?

i-EUS suggests that LAMS permanent indwelling should be individualized. LAMS exchange with double-pigtail plastic stents may be considered when long-term life expectancy is predicted.

Conditional recommendation; low level of evidence. 98% agreement.

After resolution of AC with EUS-GBD, LAMSs can be either removed/replaced or permanently left in place. In the former case, peroral cholecystoscopy at 4–6 weeks after EUS-GBD is done to assess complete stone clearance.[29] During this procedure, LAMSs can be exchanged for double-pigtail plastic stents to maintain a long-term fistula with a technical success rate up to 93%.[78] In the latter case, if patients are frail or unwilling to undergo another invasive procedure, LAMSs are left indefinitely in place.[23,76] There are no established guidelines either for the timing of LAMS removal or for the long-term implications of leaving a chronic fistula. Data on the long-term efficacy and safety of EUS-GBD with LAMSs are also limited.

Choi et al. reported long-term outcomes leaving LAMSs in situ; whereas 7% of patients experienced some late AE, 96% did not have recurrence of AC during follow-up.[116] The median stent patency was 458 days, with an 86% cumulative stent patency rate at 3 years, supporting this approach in selected high-risk patients. A multicenter retrospective study involving 116 patients found good safety and long-term patency, with 34.5% of patients having >1-year follow-up without LAMS removal.[69] A multicenter prospective observational study reported 1-year follow-up for 45 patients, who experienced AE in 15% of the cases and had 6% AC recurrence rate.[95]

These figures are not dissimilar from those of the DRAC 1 trial where cholecystoscopy and LAMS removal were scheduled for 1 month after EUS-GBD.[26] That trial reported 1-year AE rates up to 26%, including 10% recurrent biliary events. Another long-term study by Teoh et al. involving 60 patients with AC found a 10% rate of recurrent biliary events in patients treated with EUS-GBD, with reintervention and unplanned readmission rates of 13% and 10%, respectively.[29] Martinez-Moreno et al. conducted a study with 50 patients with a 3-year follow-up and found 18% of patients experienced AE in the first year, increasing to 26% by the third year, with stent migration in 14% (all asymptomatic).[97]

On the other hand, once the gallbladder is cleared of stones, it is hypothesized that LAMS removal may be appropriate in selected patients, although there is a 40% risk of recurrent cholelithiasis and AC.[117] Replacing LAMSs with double-pigtail plastic stents may help avoid gallbladder mucosal damage and stent food impaction. A retrospective study on 128 patients using LAMSs and self-expandable metal stents found that replacing LAMSs with 2 7F double-pigtail plastic stents after 4 weeks resulted in a mean stent patency of 421 days, with no recurrence of AC.[118] Based on the available evidence, the panel raised a conditional recommendation with low level of evidence for this topic.

Question 19: Can EUS-GBD after ERCP failure represent an alternative to EUS-guided biliary drainage in patients with distal malignant biliary obstruction?

i-EUS suggests EUS-GBD after ERCP failure for distal malignant biliary obstruction when EUS-guided biliary drainage is not feasible.

Conditional recommendation; low level of evidence. 86% agreement.

EUS-GBD has emerged as a potential rescue therapy for distal malignant biliary obstruction when ERCP fails. The safety and effectiveness of EUS-GBD using either fully covered self-expandable metal stents or LAMSs for patients with inoperable distal biliary malignancy after failed ERCP or EUS-guided biliary drainage have been demonstrated.[64,82]

A retrospective multicenter study compared EUS-GBD and EUS-guided choledochoduodenostomy in patients with distal malignant biliary obstruction after failed ERCP.[100] This study demonstrated comparable clinical success rates for EUS-GBD and EUS-guided choledochoduodenostomy (87.8% *vs.* 89.2%, $P = 0.8$). However, EUS-guided choledochoduodenostomy showed a higher AE rate, although the difference was not statistically significant (9.76% *vs.* 24.32%, $P = 0.128$). Notably, late AE rates (>24 hours postprocedure) were significantly higher with EUS-guided choledochoduodenostomy (21.6% *vs.* 7.5%, $P = 0.04$). The effectiveness of PT-GBD and EUS-guided biliary drainage in the context of distal malignant biliary obstruction has been extensively studied. A meta-analysis of 10 studies, including 5 RCTs, showed comparable clinical success of EUS-guided biliary drainage *versus* PT-GBD (90% *vs.* 88.7%, $P = 0.51$), but a significantly lower AE rate with EUS-guided biliary drainage (10% *vs.* 27.3%, $P = 0.01$).[119] Moreover, a pooled analysis. reported a clinical success rate of 85% (95% CI, 76%–91%) and an AE rate of 13% (95% CI, 7%–21%) of EUS-GBD for distal malignant biliary obstruction, similarly to EUS-guided biliary drainage and PT-GBD.[120] Furthermore, 4 retrospective studies involving 97 patients who were treated with the same technique showed a pooled clinical success of 88% and an AE rate of 11% (Supplementary Table 12, http://links.lww.com/ENUS/A378; Supplementary Figures 1 and 2, http://links.lww.com/ENUS/A379).[29,69,82,92]

When ERCP fails and EUS-guided biliary drainage is not feasible, a careful evaluation of the feasibility of EUS-GBD by assessing the patency of the cystic duct is crucial. However, there is currently no direct comparison between EUS-GBD and PT-GBD for the drainage of distal malignant biliary obstruction. A meta-analysis of various biliary drainage techniques (including EUS-guided biliary drainage, PT-GBD, and surgical hepaticojejunostomy) revealed that EUS-guided biliary drainage and EUS-GBD had similar

efficacy, whereas PT-GBD was associated with a trend toward higher AE rates compared.[121]

Given the current body of indirect evidence, the panel issued a conditional recommendation with low level of evidence for the use of EUS-GBD as an alternative for biliary drainage in this context.

Question 20: Is EUS-GBD indicated to prevent cholecystitis in patients with distal malignant biliary obstruction and tumor involvement across the orifice of the cystic duct undergoing self-expandable metal stent placement during ERCP?

i-EUS does not suggest routine prophylactic EUS-GBD in patients who undergo ERCP with self-expandable metal stent placement for distal malignant biliary obstruction and tumor involvement across the orifice of the cystic duct.

Conditional recommendation, low level of evidence. 83% agreement.

AC can occur after ERCP with self-expandable metal stent placement, with reported incidence rates ranging from 4.1% to 9.7%.[122] Studies have shown that tumor involvement across the cystic duct orifice is associated with an increased risk of cholecystitis, with rates ranging from 9.6% to 16.8% in this subgroup of patients.[123,124]

An RCT specifically addressed this high-risk group by comparing the rate of post-ERCP cholecystitis in patients with distal malignant biliary obstruction and tumor involvement across the cystic duct orifice.[91] The trial randomized 44 patients to undergo ERCP with self-expandable metal stent placement with or without prophylactic EUS-GBD. The results showed a significantly higher rate of post-ERCP cholecystitis in the control group without EUS-GBD (22.7%, 5/22) compared with the group with prophylactic EUS-GBD (0%). Despite the positive outcomes of this trial, it can be argued that EUS-GBD was still not necessary for most patients, and EUS-GBD can always be performed at a later stage, if post-ERCP cholecystitis develops. Furthermore, the AE rate of EUS-GBD performed in patients with a normal gallbladder is not negligible, with an approximate 13% incidence of peritonitis, bleeding, bile leakage, stent migration, and stent occlusion.[125]

Given its potential benefit in patients with tumor involvement across the cystic duct orifice, prophylactic EUS-GBD may be considered on a case-by-case basis, particularly in those with multiple risk factors for post-ERCP cholecystitis. However, the relatively low incidence of post-ERCP cholecystitis and the possible adverse effects of EUS-GBD in patients with a normal gallbladder should be carefully weighed. Therefore, the panel issued a conditional recommendation for prophylactic EUS-GBD, supported by low level of evidence.

Question 21: Can EUS-GBD be an alternative to laparoscopic cholecystectomy in symptomatic and fit-for-surgery patients with cholelithiasis?

i-EUS does not suggest EUS-GBD in fit-for-surgery patients.

Conditional recommendation, low level of evidence. 87% agreement.

EUS-GBD in fit-for-surgery patients in comparison to laparoscopic cholecystectomy has been investigated to a very limited extent. Teoh et al. conducted a propensity score–matched analysis to compare 30 patients in the EUS-GBD group with 30 patients in the laparoscopic cholecystectomy group for the treatment of AC.[29] The study found no significant differences in technical success, clinical success, length of hospital stay, or postprocedural morbidity and mortality. However, the study did not demonstrate equivalence due to a lack of statistical power. Importantly, the study remains biased as EUS-GBD was exclusively performed in unfit-for-surgery patients, whereas the LC group consisted only of fit-for-surgery patients.

Chan et al. reported, only in the abstract form so far, on 30 fit-for-surgery patients treated with EUS-GBD and compared them to retrospective data of 79 patients who underwent surgery.[126] The primary outcome, recurrent biliary events (including recurrent AC, acute biliary pancreatitis, cholangitis, common bile duct stones, and liver abscess), showed no significant differences between the 2 groups. Furthermore, technical success, clinical success, hospital stay, and 30-day AE rates were similar. However, EUS-GBD was associated with shorter procedural time, less blood loss, earlier resumption of diet, and fewer analgesic drugs. These findings, although promising, were limited by the small sample size.

The cost of the procedures has not been examined but might prove influential in the choice between EUS-GBD and laparoscopic cholecystectomy in fit-for-surgery patients. In fact, it was reported that EUS-GBD may be more expensive than surgery, particularly when considering the costs associated with the operating room, supplies, and anesthesia.[127,128] Given the limited data comparing EUS-GBD with laparoscopic cholecystectomy in fit-for-surgery patients and the potential bias in existing studies, the panel does not recommend EUS-GBD as a routine treatment in this group with conditional recommendation and low-quality evidence.

Question 22: Does EUS-GBD result in increased technical complexity versus PT-GBD during subsequent cholecystectomy?

i-EUS suggests that EUS-GBD does not increase the complexity of cholecystectomy compared with PT-GBD. I-EUS suggests removing LAMSs before surgery.

Conditional recommendation; low level of evidence. 98% agreement.

PT-GBD has traditionally been preferred for patients who are expected to undergo cholecystectomy at a later stage, due to concerns regarding the potential surgical complexity of subsequent cholecystectomy following EUS-GBD. However, there is limited literature on the feasibility and outcomes of performing cholecystectomy after EUS-GBD. In the largest study on this issue, EUS-GBD led to faster symptom resolution, a shorter hospital stay, and a reduced rate of readmission compared with PT-GBD.[79] The study found a nonsignificant trend toward a higher adoption of open cholecystectomy in the EUS-GBD group (24% *vs.* 9%, $P = 0.068$). However, there were no significant differences either in the conversion rate from laparoscopic to open surgery (11% *vs.* 19%, $P = 0.2$) or in technical success or AE. EUS-GBD patients had significantly shorter hospital stays (5.4 *vs.* 12.3 days, $P = 0.001$). Notably, 80% of patients in the EUS-GBD group underwent transgastric drainage, with LAMS removal before surgery and over-the-scope clip closure.

A similar study from the same authors supported these findings, demonstrating no major differences in cholecystectomy outcomes following EUS-GBD *versus* PT-GBD.[129]

A meta-analysis examined EUS-GBD and PT-GBD in the context of subsequent cholecystectomy.[42] Although the analysis did not focus specifically on this outcome, it found that the rate of second-stage cholecystectomy was significantly lower in the EUS-GBD group (14%) compared with the PT-GBD group (38%). The authors speculated that this may be due to the generally poorer outcomes associated with primary PT-GBD drainage, suggesting EUS-GBD as a more definitive solution. Some studies in the meta-analysis involved EUS-GBD with plastic stents or nasobiliary drainage tubes, which were excluded from further analysis, despite showing no increased rates of conversion from laparoscopic to open cholecystectomy.[130]

An abstract report described the largest experience with EUS-GBD using LAMSs as a bridge to interval cholecystectomy (n = 81).[131] The majority of procedures were performed transduodenally (68%), with a median interval of 99 days between drainage and surgery. The interval between LAMS removal and surgery was 4 days (interquartile range, 1; range, 0–35), and no endoscopic fistula closure was attempted in 86% of cases. The technical success rate of cholecystectomy was 100%, with a conversion rate to open surgery of 2.5% and surgery-related AE of 3.7% (including 2 postoperative collections and 1 transection of the common hepatic duct).

These findings suggest that, despite specific technical considerations (e.g., transgastric *vs*. transduodenal drainage), EUS-GBD does not significantly differ from PT-GBD in terms of the safety of subsequent cholecystectomy. However, EUS-GBD may offer advantages in terms of faster and more definitive resolution of the acute inflammatory event, potentially leading to a reduced need for subsequent cholecystectomy. Thus, the panel recommended EUS-GBD as a viable option for patients with AC who require a bridge to interval cholecystectomy, based on a conditional recommendation with low level of evidence.

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Not applicable.

Conflicts of Interest

Pietro Fusaroli is a Senior Associate Editor of the journal, and Manuel Perez-Miranda is an Editorial Board Member. The article was subjected to the standard procedures of the journal, with a review process independent of the editors and their research group. The other authors have nothing to declare.

Author Contributions

Antonio Facciorusso and Pietro Fusaroli wrote the final manuscript. All the other authors of the first group (all those listed between Facciorusso and Fusaroli) contributed to the writing of the statements, drafting of parts of text accompanying the statements, participated to the voting during the consensus session. The authors of the iEUS group voted during the consensus session and provided meaningful clinical comments for the revision of the statements.

Data Availability Statement

All data are available on published and supplementary online materials.

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