

GUIDELINE



American Society for Gastrointestinal Endoscopy guideline on the role of therapeutic EUS in the management of biliary tract disorders: summary and recommendations

Prepared by American Society for Gastrointestinal Endoscopy Standards of Practice Committee

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This clinical practice guideline from the American Society for Gastrointestinal Endoscopy provides an evide-based approach for the role of therapeutic EUS in the management of biliary tract disorders. This guideline was developed using the Grading of Recommendations Assessment, Development and Evaluation framework and addresses the following:

1: The role of EUS-guided biliary drainage (EUS-BD) versus percutaneous transhepatic biliary drainage (PTBD) in resolving biliary obstruction in patients after failed ERCP.

2: The role of EUS-guided hepaticogastrostomy versus EUS-guided choledochoduodenostomy in resolving distal malignant biliary obstruction after failed ERCP.

3: The role of EUS-directed transgastric ERCP (EDGE) versus laparoscopic-assisted ERCP and enteroscopyassisted ERCP (E-ERCP) in resolving biliary obstruction in patients with Roux-en-Y gastric bypass (RYGB) anatomy.

4: The role of EUS-BD versus E-ERCP and PTBD in resolving biliary obstruction in patients with surgically altered anatomy other than RYGB.

5: In patients with acute cholecystitis who are not candidates for cholecystectomy, how does EUS-guided gallbladder drainage (EUS-GBD) compare with percutaneous gallbladder drainage and endoscopic transpapillary transcystic gallbladder drainage in resolving acute cholecystitis? (Gastrointest Endosc 2024; ■:1-13.)

This guideline was prepared by the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy using the best available scientific evidence and considering a multitude of variables including but not limited to adverse events, patient values, and cost implications. The purpose of these guidelines is to provide the best practice recommendations, which may belp standardize patient care, improve patient outcomes, and reduce variability in practice. We recognize that clinical decisionmaking is complex. Guidelines, therefore, are not a substitute for a clinician's judgment. Such judgements may, at times, seem contradictory to our guidance because of many factors that are impossible to fully consider by guideline developers. Any clinical decisions should be based on the clinician's experience, local expertise, resource availability, and patient values and preferences. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating for, mandating, or discouraging any particular treatment. Our guidelines should not be used in support of medical complaints, legal proceedings, and/or litigation, because they were not designed for this purpose. ERCP is currently the first-line therapy for the management of both benign and malignant biliary tract obstruction^{1,2} with a reported biliary cannulation rate >90%³⁻⁵ and significantly lower morbidity compared with surgical approaches.⁶⁻⁸ However, in addition to failed selective biliary cannulation, ERCP may fail because of an altered anatomy or an inability to access the major papilla (eg, gastric outlet obstruction, severe duodenal diverticulosis, papillary deformity).

Traditionally, percutaneous transhepatic biliary drainage (PTBD) has served as the second-line approach for biliary drainage in the setting of ERCP failure. Although PTBD is widely available and has high technical and clinical success rates, it is associated with higher rates of adverse events (AEs) such as bleeding, tube dislodgment, and peritonitis.⁹ Thus, there is an unmet need for alternative methods of biliary drainage after failed ERCP.

Therapeutic EUS offers high-resolution imaging of previously inaccessible anatomic regions and combines the advantages of ERCP and percutaneous biliary drainage approaches without the inconvenience and discomfort of external catheters. EUS has emerged as a minimally invasive alternative for biliary drainage, allowing access to the obstructed biliary tree from the GI lumen (most often the stomach or duodenum) based on biliary anatomy, stricture location, prior upper GI surgery, and endoscopist preference. Additionally, therapeutic EUS techniques have been adapted to perform EUS-guided gallbladder drainage (EUS-GBD) in patients with acute cholecystitis who are deemed inappropriate candidates for cholecystectomy.¹⁰ Increasingly, studies have demonstrated that therapeutic EUS can be performed safely and effectively to manage biliary tract disorders, but formal guidance regarding its usage is lacking.^{11,12} The aim of this guideline is to provide evidence-based recommendations for the use of therapeutic EUS techniques in the management of biliary tract disorders.

METHODS

This guideline was prepared by the American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee and used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach throughout its preparation.¹³ The recommendations in this summary document were carefully crafted and informed by best available evidence. Evidence profiles were created by GRADE methodologists. Evidence was reviewed and recommendations generated by a panel of stakeholders and content experts over a meeting held virtually on January 18, 2023. When developing recommendations, we took into consideration multiple factors, including the overall certainty in the evidence, potential benefits and harms of varying approaches, feasibility of implementation, patient values and preferences, direct costs, cost-effectiveness, and impact on health equity. The final wording of our recommendations was approved by all members of the panel and the ASGE governing board. Stronger recommendations are represented using statements such as "we recommend...," whereas weaker recommendations are represented by statements such as "we suggest...." This article, subtitled "Summary and Recommendations," provides our final recommendations as well as a high-level summary of the evidence-based guideline process that was followed by the ASGE in preparing this document.

This guideline addresses the following clinical questions using the GRADE format:

- In patients with biliary obstruction and failed ERCP, how does EUS-guided biliary drainage (EUS-BD) compare with PTBD in resolving biliary obstruction?
- In patients with malignant distal biliary obstruction and failed ERCP, how does EUS-guided hepaticogastrostomy (EUS-HGS) compare with EUS-guided choledochoduo-denostomy (EU-CDS) in resolving biliary obstruction?
- In patients with Roux-en-Y gastric bypass (RYGB) surgery needing biliary drainage, how does EUS-directed transgastric ERCP (EDGE) compare with laparoscopicassisted ERCP (LA-ERCP) and enteroscopy-assisted ERCP (E-ERCP) in achieving successful biliary cannulation and resolving biliary obstruction?
- In patients with biliary obstruction and non–gastric bypass surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunos-tomy, pancreaticoduodenectomy, or Billroth II reconstruction), how does EUS-BD compare with E-ERCP or PTBD in resolving biliary obstruction?
- In nonsurgical patients with acute cholecystitis, how does EUS-guided gallbladder drainage (EUS-GBD) compare with percutaneous gallbladder drainage (PT-GBD) and endoscopic transpapillary transcystic gallbladder drainage (ET-GBD) in resolving acute cholecystitis?

Further details on methodology and the evidence synthesis process are provided in the accompanying article subtitled "Methodology and Review of Evidence." Details of the literature searches, data analyses, pooled-effects estimates, evidence profiles, forest plots, and panel deliberation for each outcome can also be found in that article. Terms and definitions used throughout this guideline can be found in Table 1.

RESULTS AND SUMMARY OF RECOMMENDATIONS

A summary of recommendations for each question is provided in Table 2. To accompany and support these recommendations, algorithms were prepared with additional details to guide decisions based on various clinical scenarios. These algorithms are provided in Figures 1 to 3. In general, the interventions considered in this guideline require specific expertise. As with all guidelines, decisions should be based on the local expertise, resource availability, and patient safety, values, and preferences.

TABLE 1. Terms and definitions use	d throughout this guideline
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Term	Definition
EUS-guided biliary drainage	Biliary drainage using EUS to puncture the intra- or extrahepatic ducts. The 4 techniques described under this category are the EUS-guided rendezvous procedure, EUS-CDS, EUS-HGS, and EUS- guided antegrade interventions.
EUS-guided rendezvous procedure	The biliary duct is punctured by using an FNA needle from the upper GI tract under EUS guidance followed by guidewire placement into the duodenum through the needle. After exchanging the endoscope with the ERCP duodenoscope, biliary cannulation is then reattempted either over or alongside the EUS-placed guidewire.
EUS-CDS	Stents are placed to connect the extrahepatic bile duct to the duodenum.
EUS-HGS	Stents are placed to connect the liver and intrahepatic ducts to the stomach
EUS-guided antegrade interventions	A stent is passed through the stomach (intrahepatic biliary access) or the duodenal bulb (extrahepatic biliary access) to bypass the biliary stricture and drain using the ampullary orifice.
EUS-guide gallbladder drainage	A stent is placed into the gallbladder from within the lumen of the GI tract (duodenum or stomach),
Endoscopic transpapillary transcystic gallbladder drainage	Stents are placed through the cystic duct into the gallbladder during ERCP.
EUS-directed transgastric ERCP	A lumen-apposing metal stent is placed between the gastric pouch or jejunum and the excluded stomach to facilitate anterograde duodenoscope advancement to the duodenum.

EUS-HGS, EUS-guided hepaticogastrostomy; EUS-CDS, EUS-guided choledochoduodenostomy.

Question 1: In patients with biliary obstruction and failed ERCP, how does EUS-BD compare with PTBD in resolving biliary obstruction?

Recommendation 1: In patients with biliary obstruction and failed ERCP, the ASGE suggests EUS-BD over PTBD to resolve biliary obstruction.

(Conditional recommendation, low quality of evidence)

General concepts:

- The EUS-guided rendezvous procedure is preferred over EUS-CDS or EUS-HGS in suspected benign disease.
- Transmural drainage can be performed with multidisciplinary input and patient counseling.
- PTBD preferred in patients who are hemodynamically unstable, cannot tolerate general anesthesia, or have suspected malignancy as the cause of the obstruction or if EUS-BD is not available (because of lack of expertise or training).

Summary of the evidence. We performed a systematic review of studies comparing EUS-BD and PTBD for the management of benign or malignant biliary obstruction after a failed ERCP in patients with normal anatomy. EUS-BD interventions included the EUS-guided rendezvous procedure, EUS-CDS, and EUS-HGS.

We identified 13 full-text studies comparing EUS-BD with PTBD (2 randomized controlled trials [RCTs] and 11 observational cohort studies).¹⁴⁻²⁶ In the identified studies,

the definition of failed ERCP included instances where selective biliary cannulation could not be accomplished and/ or access to the major papilla could not be reached because of gastric or duodenal obstruction. In total, 379 patients underwent EUS-BD and 376 underwent PTBD. Outcomes of interest included 30-day mortality, technical success, clinical success, AEs, need for reintervention (both total and unplanned), and length of hospital stay.

EUS-BD was associated with higher odds of clinical success in 10 observational studies (odds ratio [OR], 2.53; 95% confidence interval [CI], 1.22-5.28).^{16-19,21-26} However, based on the 2 RCTs, there was no difference in clinical success between the 2 modalities (OR, .86; 95% CI, .24-3.17).^{14,20} Additionally, EUS-BD was associated with lower rates of AEs in the 2 RCTs $(OR, .29; 95\% CI, .09-.91)^{14,20}$ and in the 10 observational studies (OR, .26; 95% CI, .12-.56).^{15-19,22-26} Need for reintervention was significantly less frequent in EUS-BD compared with PTBD in both RCTs (OR, .27; 95% CI, .09-.78)^{14,20} and observational studies (OR, .07; 95% CI, .04-.14).15-17,19,21,23,25 One observational study demonstrated that the hospital length of stay was significantly shorter for patients undergoing EUS-BD compared with those undergoing PTBD (11.54 days vs 15.68 days, P < .05).¹⁸ No differences were found between the 2 modalities in technical success (OR, 1.39; 95% CI, .55-3.48)¹⁴⁻²⁶ or 30-day mortality (OR, .34; 95% CI, .09-1.19).^{14-17,20,23,25,26}

We identified 5 studies (1 RCT and 4 observational) that evaluated cost differences in patients undergoing EUS-BD and PTBD.^{14,17-19,26} The RCT found no significant difference in cost in EUS-BD and PTBD (\$5673 vs \$7570, P = .39).¹⁴ However, the 4 observational studies identified significant

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Role of therapeutic EUS in biliary tract disorder management

TABLE 2. Summary of r	recommendations
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Recommendation	General concepts	Strength of recommendation	Quality of evidence
1. In patients with biliary obstruction and failed ERCP, the ASGE suggests EUS- guided biliary drainage over percutaneous biliary drainage to resolve biliary obstruction.	The EUS-guided rendezvous procedure is preferred over EUS-CDS or EUS-HGS in suspected benign disease. Transmural drainage can be performed with multidisciplinary input and patient counseling.	Conditional recommendation	Low
	Percutaneous transhepatic gallbladder drainage is preferred in patients who are hemodynamically unstable, cannot tolerate general anesthesia, or have suspected malignancy as the cause of the obstruction.		
 In patients with distal malignant biliary obstruction and failed ERCP, the ASGE suggests either EUS-HGS or EUS-CDS should be performed to resolve biliary obstruction. 	EUS-CDS is preferred if cancerous involvement of the stomach compromises puncture sites for EUS- HGS. EUS-HGS is preferred if cancerous involvement of the duodenum or a pre-existing enteral stent compromises puncture sites for EUS-CDS or gastric outlet obstruction proximal to the pylorus and a proximal/hilar biliary obstruction is present.	Conditional recommendation	Low
3. In patients with Roux-en-Y gastric bypass surgery needing biliary drainage, the ASGE suggests EDGE over E- ERCP or LA-ERCP in resolving biliary obstruction.	EDGE is preferred in patients with a suspected ampullary lesion, with malignant disease, or needing repeat ERCP. LA-ERCP may be preferred in patients who require surgery in the near future (eg, cholecystectomy).	Conditional recommendation	Low
4. In patients with biliary obstruction and non-gastric bypass surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction), the ASGE suggests E-ERCP as an initial approach. If unsuccessful, the ASGE suggests EUS-guided biliary drainage or percutaneous biliary drainage.	Review the operative report to identify the length of the Roux limb (if feasible).	Conditional recommendation	Very low
 5a. In nonsurgical patients with acute cholecystitis, the ASGE suggests EUS-GBD over PT-GBD in resolving acute cholecystitis. 5b. In nonsurgical patients with acute cholecystitis, the ASGE suggests EUS-GBD over ET-GBD to resolve acute cholecystitis. 	EUS-GBD is preferred in patients for whom the major papilla cannot be accessed and those with an indwelling metal stent occluding the cystic duct and large stone burden within gallbladder. PT-GBD is preferred in patients with gallbladder perforation, emphysematous cholecystitis, clinical instability, or inability to tolerate more than moderate sedation. ET-GBD is preferred in patients with ascites, malignant gallbladder infiltration, or severe coagulopathy; who have refused rescue surgery; liver transplant candidates; and patients who are not surgical candidates at the time of intervention but may be in the future.	Conditional recommendation	Moderate

ASGE, American Society for Gastrointestinal Endoscopy; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-CDS, EUS-guided choledochoduodenostomy; EDGE, EUS-directed transgastric ERCP; *E-ERCP*, enteroscopy-assisted ERCP; *LA-ERCP*, laparoscopic-assisted ERCP; *EUS-GBD*, EUS-guided gallbladder drainage; *PT-GBD*, percutaneous gallbladder drainage; *ET-GBD*, endoscopic transpapillary transcystic gallbladder drainage.

cost savings associated with EUS-BD compared with PTBD.^{17-19,26} One study evaluating procedural fees, medications, facility costs, and hospital stay found EUS-BD to be less costly than PTBD (\$1440.15 vs \$2165.87, P = .03).²⁶ A second study looking at hospital costs found EUS-BD to be

less costly than PTBD (\$3439 vs \$4798; P < .05).¹⁸ Additionally, a third study also identified EUS-BD as being a less costly option compared with PTBD (\$5439 vs \$9987, P < .001).¹⁷ Another study evaluating costs associated with both the index procedure and reinterventions found EUS-BD to be



Figure 1. Proposed algorithm for the approach to biliary drainage after failed ERCP. Please note that the decision to pursue transmural EUS-BD in patients with benign disease should be made after a multidisciplinary evaluation and counseling with the patient. Factors to consider before the interventions include patient age, comorbidities, prior adverse events from percutaneous drains, location of the gastric outlet obstruction, hemodynamic instability, and presence of ascites. Consider EUS-guided gallbladder drainage if the biliary obstruction is clearly occurring below the cystic duct insertion. *EUS-BD*, EUS-guided biliary drainage; *CDS*, EUS-guided choledochoduodenostomy; *EUS-GBD*, EUS-guided gallbladder drainage; *HGS*, EUS-guided hepaticogastrostomy; *RV*, EUS-guided rendezvous procedure; *PTBD*, percutaneous biliary drainage.



Figure 2. Proposed algorithm for the approach to biliary drainage in patients with RYGB. *RYGB*, Roux-en-Y gastric bypass; *EDGE*, EUS-directed transgastric ERCP; EUS-GBD, EUS-guided gallbladder drainage; *LA-ERCP*, laparoscopic-assisted ERCP.

less costly than PTBD (\$9072 vs \$18,261, P = .003).¹⁹ We did not identify studies evaluating cost-effectiveness in patients undergoing EUS-BD or PTBD. When discussing patient values, our patient advocate described difficulties in managing external drains and concerns regarding the possible need to be hospitalized for drains that become dislodged, blocked, or kinked.

Overall, the evidence was noted to be of low to moderate quality. The panel acknowledged that most studies reporting on the efficacy of EUS-BD and PTBD originated from tertiary

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Figure 3. Proposed algorithm in nonsurgical candidates with acute cholecystitis who require gallbladder drainage. *EUS-GBD*, EUS-guided gallbladder drainage; *PT-GBD*, percutaneous gallbladder drainage; *GB*, gallbladder; *ET-GBD*, endoscopic transpapillary transcystic gallbladder drainage.

care centers that have a high volume of ERCP cases. The panel discussed that it is important for clinicians who have less experience in ERCP and with patients who have failed biliary cannulation to refer these patients to more experienced biliary endoscopists to reattempt biliary cannulation before performing EUS-BD or PTBD. The panel expressed concern regarding the limited availability of clinicians who regularly perform EUS-BD compared with the relative ubiquity of radiologists available to perform PTBD. Thus, the panel emphasized that if personnel who can perform interventional EUS techniques are unavailable, clinicians should still consider radiologically guided percutaneous interventions for management of biliary obstruction. Additionally, the panel expressed concerns about the ramifications of future surgical interventions when EUS-BD is used. In patients who may require future surgical interventions, endoscopists are encouraged to discuss drainage options with the surgical team before attempting EUS-BD. The panel discussed the need for more clinicians to be trained in EUS-BD in light of the evidence and recommendations being made. Additionally, the panel highlighted the following considerations:

- 1. In patients with ascites, percutaneous drainage of the ascitic fluid should be considered before or at the time of PTBD or EUS-BD.
- 2. In patients who are hemodynamically unstable, PTBD may be preferred over EUS-BD.
- 3. In patients who cannot tolerate general anesthesia, PTBD may be preferred over EUS-BD.

Overall, the panel made a conditional recommendation for EUS-BD compared with PTBD in the setting of failed ERCP and provided suggestions about the use of particular techniques based on different clinical situations (Fig. 1).

Question 2: In patients with malignant distal biliary obstruction and failed ERCP, how does EUS-HGS compare with EUS-CDS in resolving biliary obstruction?

Recommendation 2: In patients with distal malignant biliary obstruction and failed ERCP, the ASGE suggests either EUS-HDS or EUS-CDS should be performed to resolve biliary obstruction.

(Conditional recommendation, low quality of evidence)

General concepts:

- EUS-CDS is preferred if cancerous involvement of the stomach compromises puncture sites for EUS-HGS.
- EUS-HGS is preferred if cancerous involvement of the duodenum or a pre-existing enteral stent compromises puncture sites for EUS-CDS and if gastric outlet obstruction proximal to the pylorus and a proximal/ hilar biliary obstruction is present.

Summary of the evidence. For this question, we performed a systematic review of studies comparing EUS-HGS with EUS-CDS in patients with distal malignant biliary obstruction. Our review identified 13 full-text studies (2 RCTs and 11 observational studies) totaling 281 patients who underwent CDS and 267 patients who underwent HGS.²⁷⁻³⁹ Outcomes of interest were technical success, clinical success, AEs, and need for reintervention. No significant differences were found between the 2 modalities in technical success (OR, 1.35; 95% CI, .56-3.29), clinical success (OR, 1.31; 95% CI, .63-2.72), AEs (OR, .76; 95% CI, .35-1.63), or need for reintervention (OR, 1.83; 95% CI, .86-3.87).²⁷⁻³⁹

We did not identify any studies that compared cost or costeffectiveness of the 2 modalities. The panel considered the increasing use of cautery-enhanced lumen-apposing metal stents (LAMSs) and the availability of smaller-caliber LAMSs, which have generally made EUS-CDS technically easier to perform in a single-step procedure.⁴⁰ In contrast, no such device is currently available in the United States for EUS-HGS, and thus it was believed that clinicians in the United States may be more comfortable performing EUS-CDS over EUS-HGS.

Again, the panel expressed concerns about the ramifications of future surgical interventions when EUS-BD is used. Specifically, in patients who may require a Whipple procedure in the future, performing EUS-CDS can result in inflammation around the porta hepatis area, which can complicate surgical interventions in the area. In such patients, endoscopists are encouraged to discuss drainage options with the surgical team before attempting EUS-BD.

The evidence was noted to be low to moderate. Additionally, the panel noted the following considerations:

- 1. EUS-CDS maybe preferred if cancerous involvement of the stomach or interfering vasculature compromises the puncture sites for HGS.
- 2. EUS-HGS maybe preferred if
 - a. A surgical intervention is planned where surgeon preference is to not use the duodenum.
 - b. Cancerous involvement of the duodenum compromises the puncture sites for EUS-CDS.
 - c. A enteral stent interferes with EUS-CDS.
 - d. A proximal/hilar biliary obstruction is present.
 - e. If gastric outlet obstruction is proximal to the pylorus.

Overall, the panel voted for a conditional recommendation based on similar clinical and technical success rates and comparable AE rates.

Question 3: In patients with RYGB surgery needing biliary drainage, how does EDGE compare with LA-ERCP and E-ERCP in achieving successful biliary cannulation and resolving biliary obstruction?

Recommendation 3: In patients with RYGB surgery needing biliary drainage, the ASGE suggests EDGE over E-ERCP or LA-ERCP in resolving biliary obstruction.

(Conditional recommendations/very low quality of evidence)

General concepts:

- EDGE is preferred in patients with a suspected ampullary lesion, with malignant disease, or needing repeat ERCP.
- LA-ERCP may be preferred in patients who require surgery in the near future (eg, cholecystectomy).

Summary of the evidence. For this question, we performed a systematic review of studies comparing EDGE versus E-ERCP and EDGE versus LA-ERCP for the management of biliary obstruction in patients with an RYGB. The EDGE procedure involves the placement of a LAMS between the gastric pouch (or jejunum) and the excluded stomach to allow the duodenoscope to advance into the duodenum and access the major papilla. The gastrogastrostomy is created in the first procedure, and ERCP is performed through it as a second procedure after the tract has matured.

Four observational studies met the selection criteria.⁴¹⁻⁴⁴ No RCTs were identified. Two studies compared EDGE, LA-ERCP, and E-ERCP,^{43,44} whereas 1 study compared E-ERCP and EDGE⁴¹ and another LA-ERCP and EDGE.⁴² In total, 176 patients underwent EDGE, 396 patients underwent LA-ERCP, and 172 patients underwent E-ERCP. Outcomes of interest were technical success, clinical success, AEs, need for reintervention (both total and unplanned), and mean procedure time.

When compared with E-ERCP, EDGE had higher odds of technical success (OR, 28.01; 95% CI, 5.17-151.6) and clinical success (OR, 26.30; 95% CI, 1.52-453.0) with lower rates of AEs (OR, 32; 95% CI, .11-.93) and reinterventions (OR, .05; 95% CI, .01-.35).^{41,43 44} Additionally, EDGE had shorter procedure times than E-ERCP (mean difference, 34.4 minutes; 95% CI, 17.5-51.3).^{41,43} There was no difference between EDGE and LA-ERCP in rates of technical success (OR, 1.09; 95% CI, .01-5.55), clinical success (OR, .90; 95% CI, .11-7.53), or AEs (OR, .62; 95% CI, .17-2.29).⁴²⁻⁴⁴ When compared with LA-ERCP, EDGE had shorter procedure times with a mean difference of 95.1 minutes (95% CI, 63.8-126.5).^{42,43}

A theoretical concern after EDGE because of the intentional creation of a gastrogastric fistula is weight gain because of persistent gastrogastric or gastrojejunal fistulas. Two studies demonstrated that at 52 weeks and 28 weeks after EDGE, patients lost 6.3 pounds and 6.6 pounds, respectively.^{42,45} Additionally, only 9% of EDGE patients had a persistent fistula at a mean of 182 days of followup.⁴⁶ Therefore, the panel concluded that weight gain is not a significant concern for this population.

Regarding cost analyses, LA-ERCP (\$20,000) had higher direct healthcare costs compared with EDGE (\$11,300) and E-ERCP (\$13,000).⁴⁴ A cost-effectiveness analysis demonstrated that EDGE was cost-saving with a higher effectiveness when compared with LA-ERCP and E-ERCP.⁴⁷ When discussing patient values, our patient advocate described a preference for endoscopic biliary interventions (such as EDGE) that could help avoid surgical operations (such as LA-ERCP).

The panel suggested EDGE as the favored option, given that EDGE was superior to E-ERCP in all outcomes and equivalent to LA-ERCP with patient values and costeffectiveness. This was a conditional recommendation, given the low quality of evidence (Fig. 2). The panel also recognized the following scenarios where 1 modality could be preferred over the other:

1. In patients with a suspected ampullary lesion, with malignant disease, or needing a repeat ERCP, EDGE is superior to LA-ERCP (given the anticipated need for repeated interventions).

- 2. In patients who require surgery (ie, cholecystectomy), LA-ERCP is suggested over EDGE because all interventions can be combined in a single anesthetic session.
- 3. In patients in whom a safe window for EDGE is not found, either LA-ERCP or E-ERCP can be considered.

Question 4: In patients with biliary obstruction and non-gastric bypass surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction), how does EUS-BD compare with E- ERCP or PTBD in resolving biliary obstruction?

Recommendation 4: In patients with biliary obstruction and non–gastric bypass surgically altered anatomy (specifically, patients who have undergone prior Roux-en-Y hepaticojejunostomy, pancreaticoduodenectomy, or Billroth II reconstruction), the ASGE suggests E-ERCP as the initial approach. If unsuccessful, the ASGE suggests EUS-BD or percutaneous biliary drainage.

(Conditional recommendation, low quality of evidence)

General concept:

• Review the operative report to identify the length of the Roux limb (if feasible).

Summary of the evidence. For this question, we performed a systematic review of studies comparing EUS-BD with E-ERCP and EUS-BD with PTBD for the management of biliary obstruction in patients with surgically altered anatomy, specifically post-Whipple anatomy, Roux-en-Y hepaticojejunostomy, or Billroth II anatomy. EUS-BD interventions in the extracted studies included the EUS-guided rendezvous procedure, EUS-HGS, and EUS-guided antegrade interventions.

Our review identified 15 observational studies.⁴⁸⁻⁶² No RCTs were identified. Three studies compared E-ERCP and EUS-BD directly, whereas 12 studies that reported outcomes for EUS-BD and PTBD separately were used for indirect comparison. Two hundred ninety-nine patients underwent EUS-BD, 92 patients underwent E-ERCP, and 89 patients underwent PTBD. Outcomes of interest for this question were technical success, clinical success, AEs, and need for repeat intervention (both total and unplanned).

Compared with E-ERCP, EUS-BD had better technical success (OR, 5.56; 95% CI, 1.04-9.16) and clinical success (OR, 4.08; 95% CI, 1.82-9.16) but had higher rates of AEs (OR, 3.24; 95% CI, 1.33-7.90).⁴⁸⁻⁵⁰ This was primarily related to

an increase in mild to moderate AEs related to EUS-guided antegrade interventions, including the advancement of a peroral cholangioscope through an HGS tract. Comparing EUS-BD and PTBD showed similar pooled rates of technical success (92.9% vs 87.6%, P = .26), clinical success (87.6% vs 80.8%, P = .44), need for reintervention (18.8% vs 29%, P = .63), $\frac{52,55,56,58,61}{52,55,56,58,61}$ and AEs (18.8% vs 29%, P = .11). $\frac{51-62}{52}$

Data on cost, cost-effectiveness, or patient values were not available. The patient advocate on the panel was in favor of the less-invasive approach irrespective of cost.

Overall, based on the evidence described above, the panel voted that E-ERCP should be the preferred initial approach. Despite the lower rates of technical success and clinical success of E-ERCP, its lower rate of AEs and potential success in patients with shorter pancreaticobiliary limbs was noted. If E-ERCP failed, the panel suggested either EUS-BD or PTBD because of comparable outcomes. The panel recognized the importance of reviewing imaging to assess for presence of dilated left hepatic ducts and verifying limb lengths using the operative reports when feasible to decide on the optimal strategy of biliary drainage. The panel also noted that these procedures are technically complex and may be best managed at tertiary referral centers.

Question 5: In nonsurgical patients with acute cholecystitis, how does EUS-GBD compare with PT-GBD and ET-GBD in resolving acute cholecystitis?

Recommendation 5a: In patients with acute cholecystitis who are not candidates for cholecystectomy, the ASGE suggests EUS-GBD over PT-GBD in resolving acute cholecystitis.

(Conditional recommendation/moderate quality of evidence)

General concepts:

- EUS-GBD is preferred in patients for whom the major papilla cannot be accessed and those with an indwelling metal stent occluding the cystic duct and large stone burden within gallbladder.
- PT-GBD is preferred in patients with gallbladder perforation, with emphysematous cholecystitis, who are not surgical candidates at the time of intervention but may be in the future, are clinical instability, are unable to tolerate more than moderate sedation, or when EUS-GBD is no available (because of lack of expertise or training).
- Avoid EUS-GBD in patients who may be liver transplant candidates.

Summary of the evidence. For this question, we performed a systematic review and meta-analysis comparing EUS-GBD and PT-GBD for the management of acute

cholecystitis in poor surgical candidates. Five studies were identified, of which 1 study was a multicenter RCT.⁶³⁻⁶⁷ In aggregate, 475 patients were analyzed, of which 199 patients underwent EUS-GBD and 276 patients underwent PT-GBD. Outcomes of interest were 30-day mortality, technical success, clinical success, AEs, reintervention (both total and unplanned), recurrent acute cholecystitis, hospital readmission, and future need for cholecystectomy.

EUS-GBD was associated with a lower odds of reintervention (OR, .14; 95% CI, .04-.55),^{64,67} readmission (OR, .07; 95% CI, .01-.44),⁶⁶ and future need for cholecystectomy (OR, .15; 95% CI, .04-.58)^{64,65,67} when compared with PT-GBD. Furthermore, the included RCT demonstrated that EUS-GBD had significantly lower AEs (OR, .10; 95% CI, .04-.28)⁶³ and recurrent cholecystitis (OR, .11; 95% CI, .01-.89)⁶³ compared with PT-GBD.

Four observational studies showed that technical success was significantly lower with EUS-BD compared with PT-GBD (OR, .19; 95% CI, .04-.81).⁶⁴⁻⁶⁷ There was no difference between EUS-GBD and PT-GBD in 30-day mortality (OR, .75; 95% CI, .16-3.59),⁶³ overall mortality (OR, .75; 95% CI, .16-3.59),⁶⁴⁻⁶⁷ clinical success (OR, 1.09; 95% CI, .49-2.44),⁶³⁻⁶⁷ AEs (OR, .53; 95% CI, .20-1.45), or rates of recurrent cholecystitis (OR, .63; 95% CI, .25-1.60).⁶³⁻⁶⁷

Regarding cost analyses, a Korean study compared the total cost of a hospital stay for patients undergoing EUS-GBD and PT-GBD and found that EUS-GBD (\$1678) was more expensive than PT-GBD (\$969, P < .001).⁶⁴ We did not find any studies that evaluated cost-effectiveness in patients undergoing EUS-GBD or PT-GBD. Also, we found no data on patient values, and the patient advocate did not add to this discussion. Previous concerns regarding external drains and possible subsequent issues, such as dislodgment requiring possible repeat intervention, are still pertinent in this scenario.

The panel was concerned that seeking expertise in EUS-GBD may result in a delay of care because of limited availability of therapeutic endoscopists nationwide that can perform EUS-GBD, whereas radiologists performing PT-GBD are more widely available, particularly in community centers Additionally, the panel discussed that in certain situations, such as potential liver transplant candidates, EUS-GBD may complicate future surgery and surgeons may prefer PT-GBD. The panel also discussed that some patients who are not surgical candidates at the time of intervention may be planned for surgical cholecystectomy after improvement in their clinical status. In such patients, PT-GBD is the preferred modality because EUS-GBD may complicate future surgery. Overall, the panel made a conditional recommendation favoring EUS-GBD (when available) over PT-GBD with acute cholecystitis as the initial therapy of choice in patients who are not surgical candidates.

The role of antibiotic therapy alone as a management strategy for nonsurgical patients with acute cholecystitis is outside the scope of this question. However, evidence from large cohorts indicates that antibiotic therapy alone may be considered in patients who cannot undergo surgery. However, in such cases, hospital readmission rates are >50% in addition to elevated mortality rates at 1 year compared with other gallbladder interventions for cholecystitis.⁶⁸

Recommendation 5b: In patients with acute cholecystitis who cannot undergo cholecystectomy, the ASGE suggests EUS-guided gallbladder drainage over endoscopic transpapillary transcystic gallbladder drainage to resolve acute cholecystitis.

(Conditional recommendation/very low quality of evidence)

General concepts:

- ET-GBD is preferred in patients with ascites, malignant gallbladder infiltration, and severe coagulopathy or when EUS-GBD is not available (because of lack of expertise or training).
- Avoid EUS-GBD in patient who may be liver transplant candidates.

Summary of the evidence. For this question, we performed a systematic review and meta-analysis comparing EUS-GBD and ET-GBD for the management of acute cholecystitis in patients who are not candidates for cholecystectomy. Three observational studies were identified that addressed this question.⁶⁹⁻⁷¹ In aggregate, 311 patients were analyzed, of which 148 patients underwent EUS-GBD and 163 patients underwent ET-GBD. Outcomes of interest were 30-day mortality, technical success, clinical success, AEs, reintervention (both total and unplanned), recurrent acute cholecystitis, hospital readmission, and future need for cholecystectomy.

EUS-GBD had better technical success rates (OR, 11.26; 95% CI, 2.99-42.48), higher clinical success rates (OR, 8.20; 95% CI, 2.75-24.49),⁶⁹⁻⁷¹ lower rates of postprocedural pancreatitis (OR, .11; 95% CI, .01-.91), and a decreased risk of recurrent cholecystitis (OR, .23; 95% CI, .08-.66) when compared with ET-GBD.⁶⁹⁻⁷¹ There was no difference in 30-day mortality for patients undergoing EUS-GBD compared with ET-GBD (OR, 2.53; 95% CI, .10-64.36).⁶⁹ Additionally, there was no difference between EUS-GBD and ET-GBD in AEs (OR, .87; 95% CI, .26-2.86), need for reintervention (OR, .51; 95% CI, .15-1.80), or future need for cholecystectomy (OR, .19; 95% CI, .01-3.41).^{69,71}

No studies evaluating differences in cost or costeffectiveness for EUS-GBD and ET-GBD were identified. Our patient advocate noted no preference for either endoscopic modality if both were effective.

Overall, the evidence was noted to be of low quality. The panel made a conditional recommendation suggesting EUS-GBD over ET-GBD if both were available. The panel recognized the risk of selection bias inherent in retrospective studies, which were analyzed in formulating this recommendation. Also, as described previously, the panel again emphasized that if personnel trained in endoscopic gallbladder drainage techniques are unavailable, then clinicians should still refer their patients for radiology-guided percutaneous drainage of the gallbladder.

The panel also recognized the following scenarios where 1 modality could be preferred over the other:

- 1. ET-GBD is the preferred option in patients with ascites, malignant gallbladder infiltration, severe coagulopathy, liver transplant candidates, or future surgical candidates or if ERCP is performed for other indications (ie, choledocholithiasis).
- 2. ET-GBD should be avoided in patients with gastric outlet obstruction or large stone burden within the gallbladder.
- 3. PT-GBD is preferred in patients with gallbladder perforation, emphysematous cholecystitis, gangrenous cholecystitis, or an inability to tolerate more than moderate sedation.

Based on the recommendations from the panel for questions 5a and 5b, an additional flowchart was created to help guide clinicians regarding interventions based on specific clinical scenarios (Fig. 3).

FUTURE DIRECTIONS

Our systematic literature reviews highlighted several areas that require additional study to better elucidate the role of therapeutic EUS in the management of biliary tract disorders. Additionally, although many observational studies were identified in our systematic reviews, RCTS were notable lacking that assessed therapeutic EUS techniques.

Future studies should address the following:

- 1. In patients with benign disease for whom ERCP failed, how do different EUS-BD techniques (ie, EUS-guided rendezvous procedure and EUS-guided transmural drainage of the bile duct) compare with one another in regards to technical success, clinical success, and AEs?
- 2. In patients who undergo EUS-GBD for the management of acute cholecystitis, what follow-up should patients receive? Specifically, in those patients for whom LAMSs are placed, do the LAMSs need to be removed and when? What are the consequences of leaving LAMSs in place? Should LAMSs be replaced with 1 or more plastic double-pigtail stents?
- 3. In patients with a high gallbladder stone burden for whom EUS-GBD is performed, does endoscopic lithotripsy and removal of stones improve long-term outcomes and decrease the risk of recurrent cholecystitis? Additionally, in patients who have undergone prior PT-GBD and have persistent cystic duct obstruction at follow-up, is there a role for EUS-GBD to improve quality of life?
- 4. What are the impacts of therapeutic EUS techniques on future surgery? Specifically, does transluminal drainage using EUS negatively impact the technical and clinical success of future surgical interventions?

- 5. For all questions addressed in this summary article, what are the cost and cost-effectiveness benefits of therapeutic EUS when compared with other treatment modalities?
- 6. What training is required for clinicians to perform the therapeutic EUS procedures described in this article and to maintain high levels of technical and clinical success and with minimal rates of AEs?
- 7. The panel also encourages endoscopy manufacturers to develop dedicated, single-step stent delivery systems for performing transluminal drainage procedures as well as devices to steer guidewires in the desired direction for antegrade and rendezvous procedures.

WHAT IS NEW

These guidelines highlight existing data to suggest EUS-BD over PTBD when ERCP fails in biliary obstruction, EUS-CDS or EUS-HGS when ERCP fails in distal malignant biliary obstruction, EDGE over LA-ERCP or E-ERCP in biliary drainage in RYGB, E-ERCP initially over EUS-BD or PTBD in biliary obstruction in non-RYGB surgically altered anatomy, and EUS-GBD over PTBD or ET-ERCP in patients with acute cholecystitis for whom cholecystectomy is not an option.

GUIDELINES UPDATE

ASGE guidelines are reviewed for updates approximately every 5 years or if new data may influence a recommendation. Updates follow the same ASGE guideline development process.

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Abbreviations: AE, adverse event; ASGE, American Society for Gastrointestinal Endoscopy; CI, confidence interval; E-ERCP, enteroscopyassisted ERCP; EDGE, EUS-guided transgastric ERCP; ET-GBD, endoscopic transpapillary transcystic gallbladder drainage; EUS-BD, EUS-guided biliary drainage; EUS-CDS, EUS-guided choledoduodenostomy; EUS-GBD, EUSguided gallbladder drainage; EUS-HGS, EUS-guided bepaticogastrostomy; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; LA-ERCP, laparoscopic-assisted ERCP; LAMS, humen-apposing metal stent; OR, odds ratio; PTBD, percutaneous transbepatic biliary drainage; PT-GBD, percutaneous transbepatic gallbladder drainage; RCT, randomized controlled trial; RYGB, Roux-en-Y gastric bypass.

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