Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

ASGE American Society for Gastrointestinal Endoscopy

Endoscopic therapies for gallbladder drainage

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This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

Background and Aims: Endoscopic management of acute cholecystitis has expanded in patients who are considered nonoperative candidates. Traditionally managed with percutaneous cholecystostomy (PC), improvement in techniques and devices has led to increased use of endoscopic methods for gallbladder drainage. This document reviews technical aspects of endoscopic transpapillary gallbladder drainage (ET-GBD) and EUS-guided GBD (EUS-GBD) as well as their respective technical/clinical success and adverse event rates. Available comparative data are also reviewed among nonsurgical gallbladder drainage techniques (PC, ET-GBD, and EUS-GBD).

Methods: The MEDLINE database was searched through March 2021 for relevant articles by using keywords including "acute cholecystitis," "interventional EUS," "percutaneous cholecystostomy," "transpapillary gallbladder drainage," "EUS-guided gallbladder drainage," "lumen-apposing metal stent," "gallbladder stenting," and "endoscopic gallbladder drainage." The manuscript was drafted by 2 authors and reviewed by members of the American Society for Gastrointestinal Endoscopy Technology Committee and subsequently by the American Society for Gastrointestinal Endoscopy Governing Board.

Results: Multiple studies have demonstrated acceptable outcomes comparing PC and both endoscopic gallbladder drainage techniques, ET-GBD and EUS-GBD. Published data suggest that endoscopic gallbladder drainage techniques may be associated with lower rates of adverse events and improved quality of life. However, there are important clinical considerations for choosing among these treatment options, requiring a multidisciplinary and collaborative approach to therapeutic decision-making in these patients.

Conclusions: The implementation of EUS-GBD and ET-GBD in high-risk surgical patients with acute cholecystitis may result in favorable outcomes when compared with PC. Further improvements in techniques and training should lead to more widespread acceptance and dissemination of these treatment options. (Gastrointest Endosc 2021;94:671-84.)

The American Society for Gastrointestinal Endoscopy Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methods are used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a Manufacturer and User Facility Device Experience (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and web-based publications, proprietary publications, and informal communications with pertinent vendors. Technology status evaluation reports are drafted by 1 or 2 members of the American Society for Gastrointestinal Endoscopy Technology Committee, reviewed and edited

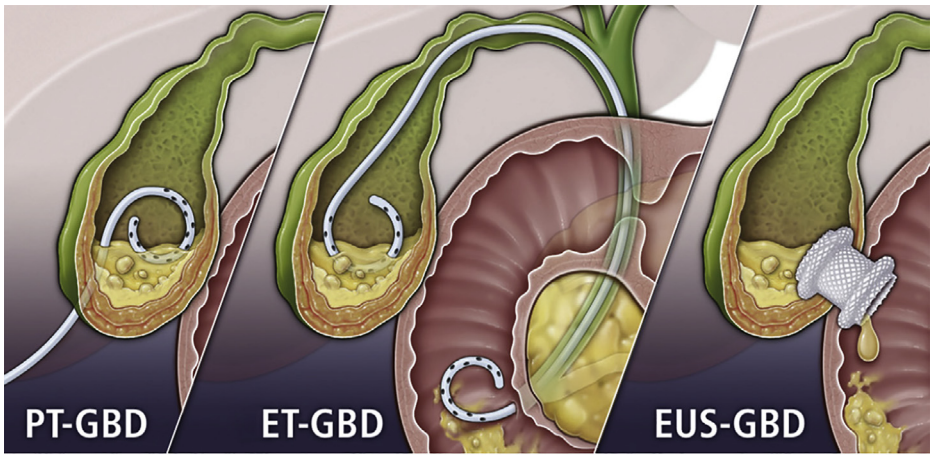

Figure 1. Gallbladder drainage procedures including percutaneous cholecystostomy (PC), endoscopic transpapillary gallbladder drainage (ET-GBD), and EUS-guided GBD (EUS-GBD). (Reprint with permission from Gastrointest Endosc 2021;93:797-804.)

by the committee as a whole, and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through March 2021 for articles related to gallbladder drainage by using additional relevant keywords such as "acute cholecystitis," "interventional EUS," "percutaneous cholecystostomy," "transpapillary gallbladder drainage," "EUS-guided gallbladder drainage," "lumen-apposing metal stent," "gallbladder stenting," and "endoscopic gallbladder drainage," among others. Technology status evaluation reports are scientific reviews provided solely for educational and informational purposes. Technology status evaluation reports on emerging technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

Laparoscopic cholecystectomy (CCY) is the criterion standard therapy for gallbladder disorders, particularly symptomatic cholelithiasis and acute cholecystitis.[1] However, management has evolved over the years based on clinical and patient factors.[2] Urgent CCY in patients with moderate and severe acute cholecystitis can be challenging because of the degree of inflammation as well as associated organ dysfunction and underlying comorbidities. These patients may benefit from a less invasive gallbladder drainage procedure.

The updated 2018 Tokyo guidelines for management of acute cholecystitis endorse percutaneous gallbladder drainage as the first-line alternative to surgery for high-risk surgical patients because of morbidity and mortality rates up to 40% and 5%, respectively.[3,4] Preoperative percutaneous cholecystostomy (PC) provides time for resolution of systemic illness and local inflammation, thus decreasing the rate of conversion from laparoscopic to open CCY.[5] Some patients remain at high risk for CCY requiring indefinite maintenance of a PC tube[6] with adverse events (AEs) requiring PC reintervention in 25% to 66% of patients.[1,7,8] Cholecystostomy tubes are also uncomfortable, adversely affect quality of life, and require tract maturation (typically 3-6 weeks) before removal.[1,8] Additionally, contraindications to PC, such as coagulopathy or ascites, may exist. Therefore, endoscopic approaches have emerged as alternative methods for gallbladder drainage in patients with moderate/severe acute cholecystitis, emphasizing reduction in tube-related AEs and maintenance of quality of life (Fig. 1). This document provides a review of the indications, technical aspects, and outcomes of these endoscopic procedures.

PATIENT AND PROCEDURE SELECTION CONSIDERATIONS

It is recommended that all patients considered for endoscopic gallbladder therapy receive multidisciplinary input with review of comorbidities, anesthesia risk, and clarification of the patient's candidacy for upfront or future CCY (Table 1). Endoscopic gallbladder drainage can be considered in patients without evidence of gallbladder perforation or biliary peritonitis. If a patient requires ERCP for other reasons (eg, cholangitis or choledocholithiasis), then endoscopic transpapillary gallbladder drainage (ET-GBD) is favored. Single-session EUS-guided GBD (EUS-GBD) combined with ERCP can also be considered, as a retrospective study did not demonstrate increased AEs of the same-session combined procedure compared with EUS-GBD alone.[9] EUS-GBD should also be considered in cases of cystic duct

TABLE 1. Overview of endoscopic gallbladder drainage procedures

Drainage procedure	Technique	Considerations for patient selection	Relative contraindications	Comments
ET-GBD	Gallbladder is drained by transcystic duct placement of plastic stent/drain across papilla	1. Patients who also require ERCP (cholangitis/ choledocholithiasis) 2. Contraindications for PC a. Coagulopathy or anticoagulation use b. Ascites 3. Potential candidate for future CCY 4. Other need to preserve anatomy (ie, liver transplant candidate)	1. Gallbladder perforation or biliary peritonitis 2. Altered anatomy 3. Cystic duct obstruction 4. Unable to tolerate sedation (consider PC)	ET-GBD can serve as a bridge to elective CCY by allowing recovery from sepsis and/or optimization of underlying comorbidities while not compromising the anatomy for subsequent gallbladder resection. Cost saving compared with EUS-GBD.
EUS-GBD	Transmural puncture of gallbladder via EUS with transenteric stent placement (either with a plastic stent, covered SEMS, or LAMS)	1. Altered anatomy 2. Duodenal obstruction 3. Cystic duct obstruction (ie, obstructing cholelithiasis or indwelling metal stent) 4. Large burden cholelithiasis 5. Considering cholecystoscopy	1. Gallbladder perforation or biliary peritonitis 2. Ascites 3. Coagulopathy 4. Unable to tolerate sedation (consider PC)	EUS-GBD creates a fistula from the stomach/duodenum to the gallbladder, which may interfere with future CCY or other planned abdominal surgeries. Requires additional endoscopic expertise/training.

ET-GBD, Endoscopic transpapillary gallbladder drainage; *EUS-GBD*, EUS-guided gallbladder drainage; *PC*, percutaneous cholecystostomy; *CCY*, cholecystectomy; *SEMS*, self-expanding metal stent; *LAMS*, lumen-apposing metal stent.
Courtesy of Dr Monica Saumoy, University of Pennsylvania, Philadelphia, Pa, USA, and Dr Julie Yang, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA.

obstruction or large-volume cholelithiasis, although significant stone burden may similarly interfere with the endosonographic approach.

Anesthesia considerations should influence procedure choice. Monitored anesthesia care or general anesthesia is preferred for ERCP and interventional EUS procedures.[10] However, for patients who cannot tolerate anesthesia, PC is favored because it can be performed with the patient under local anesthesia with or without minimal sedation.

Clarification of future surgical candidacy for CCY is also a key consideration. An advantage of ET-GBD over other nonsurgical gallbladder drainage modalities (PC and EUS-GBD) is preservation of gallbladder wall structural integrity. Therefore, ET-GBD serves as a bridge to elective CCY by allowing recovery from sepsis and/or optimization of underlying comorbidities while not compromising the anatomy for future CCY.

DESCRIPTION OF THE TECHNIQUES

Endoscopic transpapillary GBD

ET-GBD is an ERCP procedure whereby the gallbladder is drained by a transpapillary approach with placement of a plastic stent or a nasobiliary drain through the cystic duct with the proximal end placed into the gallbladder and the distal end into the duodenum (Fig. 2A and B). The mean procedure time for experienced endoscopists ranges from 22 to 36 minutes.[11-14] Sphincterotomy is not required but may be performed for concomitant treatment of choledocholithiasis, when cholangioscopy is used to identify the cystic duct orifice, and when parallel bile duct stent placement is warranted to preserve hepatic drainage through small ducts. Nasobiliary drainage can be used for irrigation and aspiration of the gallbladder after placement. Technical and clinical success rates are similar for both transpapillary drainage techniques, but nasobiliary drainage is less frequently used in current practice because of the need for oronasal transfer maneuvers, patient discomfort, intentional or inadvertent drain dislodgement, and acceptability for only short-term decompression.[13-15]

Challenges associated with ET-GBD are typically related to cannulation of the cystic duct and gallbladder, specifically difficulty in identifying the site of cystic duct insertion; long, narrow, tortuous cystic ducts; cystic duct inflammation; stone impaction within the cystic duct and/or gallbladder neck; gallbladder malignancy[16]; and large burden of gallbladder stones. Additionally, access into the cystic duct can be challenging if a transpapillary biliary uncovered self-expandable metal stent (SEMS) is already present.

Several methods have been used to improve technical success of ET-GBD, including the use of rotatable sphincterotomes for directed access and hydrophilic angled-tip

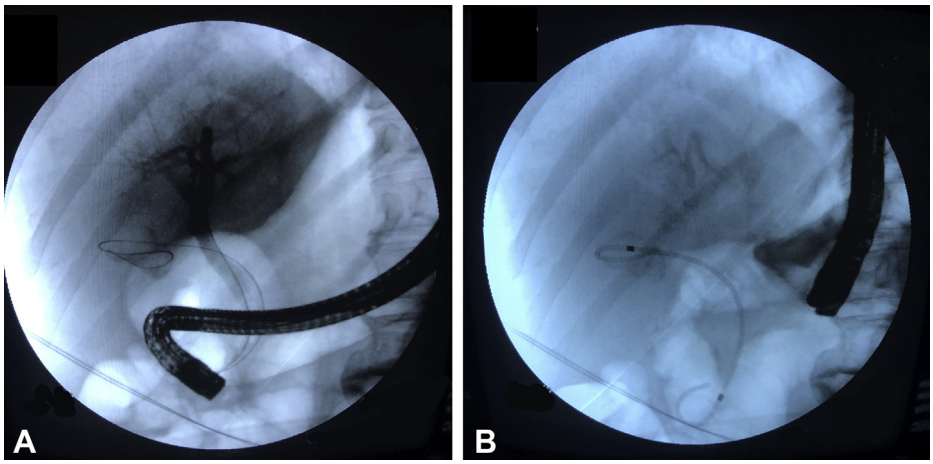

Figure 2. A, Endoscopic transpapillary gallbladder drainage (ET-GBD) with fluoroscopic view of wires in both the cystic duct coiled into the gallbladder and common bile duct. **B,** ERCP placement of a transpapillary plastic double-pigtail gallbladder stent. (Both A and B courtesy of Dr Monica Saumoy, University of Pennsylvania, Philadelphia, Pa, USA, and Dr Julie Yang, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA.)

guidewires.[17] Cholangioscopy can also be used to help identify the cystic duct orifice.[18-22] ET-GBD technical success rates can increase up to 22% with the addition of cholangioscopy after failed transcystic duct guidewire placement under fluoroscopic guidance.[22] Some investigators also recommend advancing a catheter/sphincterotome or a balloon/graduated dilator over the guidewire across the cystic duct and into the gallbladder to straighten and dilate the cystic duct before stent insertion.[14,16,23] Moreover, an existing PC can be converted to an ET-GBD whereby biliary guidewire access can be achieved from either an anterograde/rendezvous or retrograde approach.[24,25]

There is no consensus regarding the preferred stent selection for transpapillary gallbladder drainage. Gallbladder stents (GBSs) are typically double-pigtail plastic stents ranging from 5F to 10F diameter and are available in varying lengths, typically at least 12 cm. Alternative novel GBSs exist outside the United States, with a semicircular configuration to more closely mirror the anatomic curvature of the gallbladder and cystic duct. Varied stent designs include a spiral-shaped tip or smaller pigtail on the gallbladder end, straight distal tip with a single antimigratory flap at the duodenal end, and side holes throughout the entire length of the stent.[23,24]

Management of the transpapillary stent. It is uncertain whether ET-GBD can provide definitive long-term "destination" treatment for acute cholecystitis or symptomatic gallstone disease. Most studies of ET-GBD are limited by small sample size and short-term follow-up, although some groups have demonstrated absence of recurrent symptoms with GBSs up to 3 to 4 years.[11,24,26] One study specifically looked at GBSs as definitive treatment in an elderly population, defined as 65 years or older (mean age, 79.7) with comorbidities including dementia and stroke.[12] GBS placement was technically successful in 77.5% of patients who required emergency decompression and 100% technically successful in elective cases (conversion from PC). Recurrent cholecystitis did not occur during a mean follow-up of 31 months, with 2 late AEs including a liver abscess and stent migration. It is important to note that in this cohort of elderly patients with serious comorbidities, over 50% died because of nonbiliary issues.

It is unknown if GBS occlusion leads to recurrence of symptoms. Bile flow around the stent (providing a wick for biliary drainage) may be adequate to maintain functional patency. Therefore, stent exchanges in selected patients with significant comorbidities may be unnecessary and could be restricted to on-demand as needed for development of AEs. However, a recent study with a mean follow-up of 453 days did find a greater risk of recurrent cholecystitis in those individuals where the stent was removed.[27] Larger studies with longer follow-up are required to determine how long stents should be left in place in asymptomatic patients. Currently, there are no guidelines to recommend either stent removal or stent exchange.

EUS-guided transmural GBD

Before the advent of cautery-enhanced lumen-apposing metal stents (LAMSs), EUS-GBD was typically a 3-step process[28-31] of transmural puncture of the gallbladder, wire-guided access into the gallbladder with or without tract dilation, and stent deployment. The technique was initially described with a transenteric double-pigtail stent; however, the early experience was complicated by bile peritonitis because of leakage of bile through the gap between the intestinal lumen and gallbladder wall.[32] There was an evolution to covered SEMSs with antimigratory properties to prevent fistula tract leakage.[33] LAMSs have since emerged as the preferred stent given their ease of use and lower rate

of AEs. LAMSs have terminal flanges and a central tubular saddle in a dumbbell configuration with large luminal diameters and sufficient axial force to reduce physical separation of the gallbladder and bowel wall. These design considerations are intended to decrease the rate of leakage, perforation, and stent migration. The large luminal diameters minimize stent obstruction from sludge or stones and allow for additional diagnostic and intracholecystic therapeutic maneuvers (cholecystoscopy, narrow-band imaging, or confocal endomicroscopy of the gallbladder wall, polypectomy, stone extraction, and lithotripsy).[32,34,35]

Multiple covered biflanged metal LAMSs are available worldwide. In the United States, LAMS is U.S. Food and Drug Administration approved for drainage of symptomatic pancreatic pseudocysts and walled-off necrosis. Currently, LAMS use for gallbladder drainage remains off-label; however, a multicenter prospective trial using the Axios stent (Boston Scientific, Marlborough, Mass, USA) and electrocautery-enhanced delivery system for acute cholecystitis is currently under investigation (NCT03767881).

In this review, we have elected to describe the EUS-GBD technique using the electrocautery-enhanced LAMS because this technique is favored by most endoscopists. The electrocautery-enhanced LAMS eliminates the need for guidewire exchange and tract dilation before stent deployment. Additionally, this approach allows for procedure completion without the need for fluoroscopy, if preferred.

When performing EUS-GBD, the gallbladder is identified from the gastric antrum (cholecystogastrostomy) or duodenal bulb (cholecystoduodenostomy) using a therapeutic channel linear array echoendoscope. For those with altered surgical anatomy the anastomotic tract may be created between the jejunum and gallbladder (cholecystojejunostomy). The choice of puncture location depends on multiple factors, including absence of intervening blood vessels or other structures, distance between the intestinal lumen and the gallbladder to account for saddle length of the LAMS, and assessment of the patient's future candidacy for CCY. No current evidence demonstrates superiority of a particular puncture site, and therefore the decision is left to the discretion of the endoscopist.

Before puncturing the gallbladder, the endoscopist must consider the size of the desired stent. Biliary fully covered SEMSs have a maximal diameter of 10 mm. LAMSs are commercially available in 10-, 15-, and 20-mm saddle diameters with a common length of 10 mm and an additional option of a 15-mm diameter by 15-mm length stent. Case series have demonstrated high technical success rates with both the 10- and 15-mm diameter LAMS, with no reported differences in clinical success or AEs.[16]

Gallbladder access is obtained with or without guidewire assistance. With the guidewire approach, the gallbladder is punctured under EUS guidance with a 19-gauge needle or a cystotome followed by wire advancement through the needle and coiling into the gallbladder lumen, allowing exchange for the cautery-assisted LAMS delivery catheter.[36] Alternatively, the gallbladder can be punctured directly under EUS visualization with the electrocautery-enhanced LAMS delivery catheter (Fig. 3A).[37] The distal flange of the stent is deployed within the gallbladder under EUS imaging followed by deployment of the proximal flange into the intestinal lumen under endoscopic and/or fluoroscopic guidance (Fig. 3B). Subsequently, the lumen of the LAMS can be dilated, and plastic double-pigtail stents can then be deployed through the LAMS. The use of a coaxial plastic stent across the LAMS has been adapted from pancreatic fluid collection drainage procedures, but under this circumstance, it is uncertain whether the addition of a plastic stent decreases AEs.[38,39]

Management of the transenteric stent. The optimal duration of stent placement remains uncertain with a concern that removal of a transmural gallbladder LAMS will lead to spontaneous closure of the cholecystoenterostomy with resultant recurrent cholecystitis. The alternative of allowing the stent to remain in situ can be associated with a risk of stent migration or stent-induced gallbladder wall erosive injury and bleeding. A prospective long-term evaluation of EUS-GBD with LAMSs assessed outcomes among those patients with LAMSs left in place because of poor patient clinical condition and/or failure to consent to removal.[40] No LAMS-related AEs were observed during a mean stent dwell time of 364 days. Long-term stent placement, up to 3 years, has also been reported without stent-related AEs.[41] An alternative to indefinite LAMS placement is exchange with a double-pigtail stent to maintain cholecystoenterostomy patency. Because currently no optimally defined long-term strategy for stent management exists, the decision is left to the discretion of the endoscopist.

Interventions for gallstone removal. Cholecystoscopy and cholelithiasis extraction can be accomplished with a gastroscope advanced through the LAMS-created fistulous tract. Stone clearance can be achieved with extraction accessories, whereas larger stones may require fragmentation to facilitate removal. The need for oral cholecystoscopy and gallstone removal after EUS-GBD remains to be defined. In a retrospective study, 25 patients underwent per-protocol cholecystoscopy 1 to 3 months after initial EUS-GBD with LAMS placement. Fourteen patients (56%) had spontaneous stone passage and 8 of the remaining 11 had successful stone removal for an overall post EUS-GBD stone clearance rate of 88% after a mean number of 1.25 sessions.[42] However, currently no data suggest that cholecystoscopy and cholelithiasis extraction will change clinical outcomes.

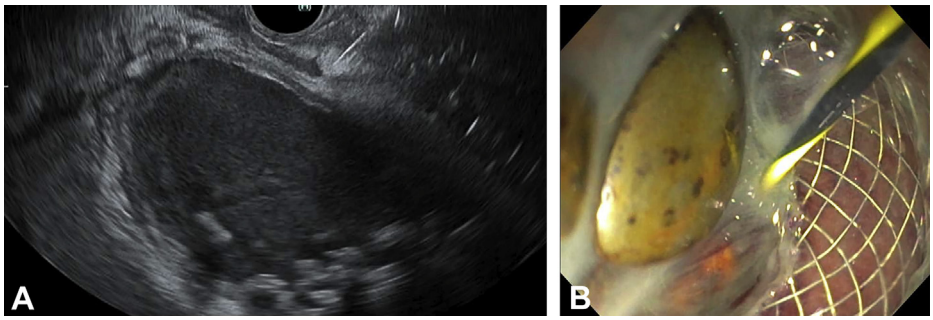

Figure 3. A, EUS view of gallbladder containing cholelithiasis with advancement of a cautery-assisted lumen-apposing metal stent (LAMS) in preparation for puncture. **B,** Endoscopic view after deployment of a LAMS with release of pus and cholelithiasis. (Both A and B courtesy of Dr Monica Saumoy, University of Pennsylvania, Philadelphia, Pa, USA, and Dr Julie Yang, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA.)

EFFICACY

Endoscopic transpapillary GBD

ET-GBD technical success rates range from 83% to 88% (Table 2).[15,16] Clinical success of transpapillary drainage, defined as resolution of symptoms and inflammatory markers, ranges from 80% to 100%.[15,16] A meta-analysis reported an overall weighted pool rate for technical success of 83% (95% confidence interval [CI], 78%-87%; Cochran *Q* test I^2 = 38%). Of those with technical success, the weighted pool rate for clinical success was 93% (95% CI, 89%-96%; Cochran *Q* test I^2 = 39%).[15] A second meta-analysis reported pooled technical and clinical success rates of 83% (95% CI, 80%-85%; I^2 = 29) and 88.1% (95% CI, 83.6%-91.4%; I^2 = 50), respectively.[43]

EUS-guided transmural GBD

EUS-GBD technical success rates range from 95% to 98%.[29,44-46] A multicenter, international registry of 379 patients who underwent EUS-GBD reported a technical success rate of 95.3%, clinical success rate of 90.8%, with a 30-day AE rate of 15.3% and 30-day mortality rate of 9.2%, the latter reflecting the serious comorbidities in this patient population.[45] Another meta-analysis (8 studies and 393 patients) of EUS-GBD with LAMSs reported a cumulative technical success rate of 94.9% and clinical success rate of 94.6%.[46] In this study, the rate of early AEs with LAMSs was 6.5% (95% CI, 4.2%-10%; I^2 = 1.2) and the rate of delayed AEs 8.3% (95% CI, 5.8%-11.9%; I^2 = 4.8).

COMPARATIVE STUDIES

Comparison of ET-GBD and PC

Two retrospective studies directly compared PC with ET-GBD for treatment of acute cholecystitis (Table 2).[47,48] One study demonstrated similar technical success rates, whereas the other noted a higher rate with PC (100% PC vs 77% ET-GBD, P = .004).[47] Both studies showed a higher absolute short-term rate of AEs with ET-GBD compared with PC, but the differences were not statistically significant (4.8% PC vs 12.1% ET-GBD, P = .20; PC 4.8% vs ET-GBD 8.2%, P = .08).[47,48] Long-term follow-up (median up to 485 days) demonstrated a higher rate of recurrent cholecystitis (17.2% PC group vs 0% ET-GBD group, P = .04) and increased length of hospitalization with PC.[24] Importantly, both PC and ET-GBD do not interfere with subsequent CCY. A comparative study following these approaches demonstrated no statistically significant difference in operative outcomes for subsequent CCY, including conversion to open surgery or severity of operative AEs.[49]

Comparison of ET-GBD and EUS-GBD

A single-center retrospective study compared transpapillary (n = 38) with transmural (n = 40) approaches for gallbladder drainage. First attempt technical success was 97.5% for EUS-GBD versus 84.2% for ET-GBD (odds ratio [OR], 9.83; 95% CI, .93-103.86). Clinical success was significantly higher with EUS-GBD compared with ET-GBD (95.0% vs 76.3%; OR, 7.14; 95% CI, 1.32-38.52).[50] A retrospective review of an endoscopic gallbladder drainage database demonstrated more favorable results for EUS-GBD compared with ET-GBD with higher technical success rates (99.3% vs 86.6%, P < .01) and clinical success rates (99.3% vs 86%, P < .01) as well as lower AE rates (7.1% vs 19.3%, P = .02).[41] The combined cholecystitis and cholangitis recurrence rate was also higher in the ET-GBD versus the EUS-GBD group (12.4% vs 3.2%; hazard ratio, 3.01; 95% CI, .73-12.9; P = .04).

A meta-analysis compared outcomes of patients undergoing EUS-GBD (n = 259) with those undergoing ET-GBD (n = 598). EUS-GBD was associated with higher technical (OR, 5.22; 95% CI, 2.03-13.44; P < .01; I^2 = 20%) and clinical success (OR, 4.16; 95% CI, 2.00-8.66; P < .01; I^2 = 19%). There was no statistically significant difference in the overall AE rate, although EUS-GBD was associated with a lower rate of recurrent cholecystitis (OR, .33; 95% CI, .14-.79; P = .01; I^2 = 0%).[51]

TABLE 2. Endoscopic gallbladder drainage studies

Drainage procedure	Study	Gallbladder drainage method	Study type	No. of patients	Technical success	Clinical success	Adverse effects	Additional information for the study
ET-GBD	Kjaer et al (2007)[72]	ET-GBD	Retrospective case series	ET-GBD: 34	ET-GBD: 70.6%	ET-GBD: 61.8%	ET-GBD: 8.8%	70% of clinically improved patients underwent elective cholecystectomy after ET-GBD
	Doi et al (2018)[64]	ET-GBD	Prospective case series	ET-GBD: 40	ET-GBD: 75%	ET-GBD: 96.6% of completed	ET-GBD: 5%	BLADE study: 5F nasocystic tube used for gallbladder lavage, then 5F trancystic stent placed. Elective cholecystectomy performed in 92.5% patients.
	Conway et al (2005)[63]	ET-GBD	Retrospective case series	ET-GBD: 29	ET-GBD: 90%		ET-GBD: 10.3%	ET-GBD in end-stage liver disease, 22% of which underwent successful liver transplant.
EUS-GBD	Song et al (2010)[32]	EUS-GBD	Retrospective case series	EUS-GBD: 8	EUS-GBD: 100%	EUS-GBD: 100%	EUS-GBD: 28.5%	EUS-GBD with 7F double-pigtail stent.
	Jang et al (2011)[33]	EUS-GBD	Prospective case series	EUS-GBD: 15	EUS-GBD: 100%	EUS-GBD: 100%	EUS-GBD: 0%	EUS-GBD with modified SEMS.
	Irani et al (2015)[36]	EUS-GBD	Retrospective case series	EUS-GBD: 15	EUS-GBD: 93%	EUS-GBD: 100%	EUS-GBD: 6.67%	EUS-GBD with modified LAMS.
	James et al (2019)[61]	EUS-GBD	Retrospective case series	EUS-GBD: 15	EUS-GBD: 93.3%	EUS-GBD: 93.3%	EUS-GBD: 13.3%	EUS-GBD with LAMS performed in Child-Pugh class A and B patients with 1 decompensation event.
Comparison studies	Itoi et al (2015)[13]	ET-GBD vs NBD	Randomized control trial	ET-GBD: 36 NBD: 37	ET-GBD: 86.1% NBD: 91.9%	ET-GBD: 90.3% NBD: 94.1%	ET-GBD: 2.78% NBD: 5.4%	
	Yang et al (2016)[14]	ET-GBD vs NBD	Randomized control trial	ET-GBD: 18 NBD: 17	ET-GBD: 88.9% NBD: 82.4%	ET-GBD: 93.8% NBD: 85.7%	ET-GBD: 17.6% NBD: 11.1%	CCY performed in 87 post-PC patients and 35 post–ET-GBD patients with no difference in intraoperative outcomes.
	Itoi et al (2017)[48]	ET-GBD vs PC	Retrospective cohort study	ET-GBD: 333 PC: 333	Study performed only on technically successful cases	ET-GBD: 87.6% PC: 89.2%	ET-GBD: 8.2% PC: 4.8%	Using propensity score matching, length of hospitalization was shorter for ET-GBD than PC.
	Kaura et al (2020)[49]	ET-GBD vs PC	Retrospective cohort study	ET-GBD: 52 PC: 140	ET-GBD: 91% PC: 100%	ET-GBD: 92.3% PC: 100%	Postoperative cholecystectomy AEs: ET-GBD: 30.7% PC: 43.5% $P = .07$	All patients underwent CCY. There was no difference in conversion to open cholecystectomy or severity of surgical adverse events in ET-GBD or PC patients.
	Khan et al (2017)[15]	ET-GBD vs EUS-GBD	Systematic review and meta-analysis	ET-GBD: 647 EUS-GBD: 162	ET-GBD: 83% EUS-GBD: 93%	ET-GBD: 93% EUS-GBD: 97%	ET-GBD: 10% EUS-GBD: 13%	Comparing any endoscopic GBD method vs PC: technical success pooled OR, .51; 95% CI, .09-2.88; $P = .23$; and adverse events: .33; 95% CI, .14-.8; $P = .31$.
	Mohan et al (2020)[43]	ET-GBD vs EUS-GBD vs PC	Systematic review and meta-analysis	ET-GBD: 1223 EUS-GBD: 557 PC: 13,351	ET-GBD: 83% EUS-GBD: 95.3% PC: 98.7%	ET-GBD: 88.1% EUS-GBD: 96.% PC: 89.3%	ET-GBD: 9.6% EUS-GBD: 12.4% PC: 15.1%	Pooled rates of recurrence of cholecystitis: ET-GBD, 4.6%; EUS-GBD, 4.2%; PC, 10.8%.
	Teoh et al (2020)[30]	EUS-GBD vs PC	Randomized control trial	EUS-GBD: 39 PC: 40	EUS-GBD: 97.4% PC: 100%	EUS-GBD: 92.3% PC: 92.5%	30-day AEs EUS-GBD: 12.8% PC: 47.5%	EUS-GBD with LAMS had fewer reinterventions after 30 days and less recurrent cholecystitis.
	Luk et al (2019)[56]	EUS-GBD vs PC	Systematic review and meta-analysis	EUS-GBD: 206 PC: 289	EUS-GBD vs PC: pooled OR .43; 95% CI, .12-1.58; $P = .21$	EUS-GBD vs PC: pooled OR 1.07; 95% CI, .36-3.16; $P = .90$	EUS-GBD vs PC: pooled OR .43; 95% CI, .18-1.00; $P = .05$	EUS-GBD had shorter length of stay: pooled standard mean difference of –2.53 (95% CI, –4.28 to –.78; $P < .01$.
	Jang et al (2012)[57]	EUS-GBD vs PC	Randomized control trial	EUS-GBD: 30 PC: 29	EUS-GBD: 97% PC: 97%	EUS-GBD: 100% PC: 96%	EUS-GBD: 7% PC: 3%	Postprocedure pain was lower in the EUS-GBD compared with PC. Twenty-three of 30 EUS-GBD patients and 26 of 39 PC patients underwent CCY, with similar operative outcomes.

ET-GBD, Endoscopic transpapillary gallbladder drainage; *EUS-GBD*, EUS-guided gallbladder drainage; *PC*, percutaneous cholecystostomy; *CCY*, cholecystectomy; *SEMS*, self-expanding metal stent; *LAMS*, lumen-apposing metal stent; *NBD*, nasobiliary drainage; *OR*, odds ratio; *CI*, confidence interval.
Courtesy of Dr Monica Saumoy, University of Pennsylvania, Philadelphia, Pa, USA, and Dr Julie Yang, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA.

Comparison of EUS-GBD and PC

Multiple retrospective cohort studies compared outcomes of PC with EUS-GBD.[22,24,25] Overall, EUS-GBD and PC demonstrated comparable technical and clinical success rates; however, patients who underwent PC had longer hospital stays and a higher number of procedure reinterventions.[52-55]

A meta-analysis compared outcomes after EUS-GBD (n = 206) and PC (n = 289) for high-risk surgical patients with acute cholecystitis and found no difference in

technical success (OR, .43; 95% CI, .12-1.58; $P = .21$; $I^2 = 0\%$) or clinical success (OR, 1.07; 95% CI, .36-3.16; $P = .90$; $I^2 = 44\%$).[56] However, patients undergoing EUS-GBD experienced fewer AEs compared with the PC group (OR, .43; 95% CI, .18-1.00; $P = .05$; $I^2 = 66\%$) and required significantly fewer reinterventions (OR, .16; 95% CI, .04-.042; $P < .001$; $I^2 = 32\%$), resulting in significantly fewer unplanned readmissions (OR, .16; 95% CI, .05-.53; $P = .003$; $I^2 = 79\%$). Moreover, patients undergoing EUS-GBD had shorter hospital stays, with a pooled standard mean difference of –2.53 (95% CI, –4.28 to –.78; $P = .005$; $I^2 = 98\%$). There was no difference in recurrent cholecystitis or disease-related mortality between the 2 groups.

A single-center randomized controlled trial compared EUS-GBD and PC for high-risk patients with acute cholecystitis failing to respond to nonoperative therapy.[57] EUS-GBD and PC showed similar technical success (97% vs 97%), clinical success (100% vs 96%), and AE rates (7% vs 3%, $P = .492$). However, the median postprocedure pain score was lower in the EUS-GBD group (score 1) compared with the PC group (score 5) ($P < .001$).[57] A second multicenter, randomized control trial compared EUS-GBD with PC as definitive therapy for high-risk acute cholecystitis patients.[58] There was no difference in technical (97.4% vs 100%, $P = .494$) or clinical success (92.3% vs 92.5%, $P = 1.0$). The 30-day mortality (7.7% vs 10%, $P = .68$) and median hospital stay (8 vs 9 days; $P = .18$) were also similar. However, EUS-GBD resulted in lower short-term (30-day) AEs (12.8% vs 47.5%, $P = .010$) and long-term (1-year) AEs (25.6% vs 77.5%, $P < .001$), fewer reinterventions after 30 days (2.6% vs 30%, $P = .001$), reduced number of unplanned readmissions (15.4% vs 50%, $P = .002$), and less-frequent recurrent cholecystitis (2.6% vs 20%, $P = .029$). Postprocedural pain scores and mean analgesic requirements were also significantly lower in the EUS-GBD group.[30]

Comparison of EUS-GBD and CCY

A single-center retrospective study compared outcomes of patients with acute cholecystitis when treated as primary therapy with EUS-GBD (n = 30) or CCY (n = 30).[58] By propensity score matching, there was no significant difference between the 2 groups in technical success (100% for both), clinical success (93.3% vs 100%, $P = 1.0$), length of hospital stay, 30-day AE and mortality rates, and rates of recurrent biliary events, reinterventions, and unplanned readmissions.

Comparison of ET-GBD, EUS-GBD, and PC

A network meta-analysis comprising 10 studies and totaling 1267 patients compared the 3 nonsurgical methods of gallbladder drainage for acute cholecystitis.[59] In the network ranking estimate, the endoscopic approaches were favored over PC. PC and EUS-GBD had the highest likelihood of procedural technical success (EUS-GBD vs PC vs ET-GBD = 2.00 vs 1.02 vs 2.98) and clinical success (EUS-GBD vs PC vs ET-GBD = 1.48 vs 1.55 vs 2.98). EUS-GBD had the lowest likelihood of recurrent cholecystitis (EUS-GBD vs PC vs ET-GBD = 1.089 vs 2.02 vs 2.89), whereas PC had the highest rate and ET-GBD the lowest rate of reintervention (EUS-GBD vs PC vs ET-GBD = 1.81 vs 2.99 vs 1.20), unplanned readmission (EUS-GBD vs PC vs ET-GBD = 1.58 vs 2.94 vs 1.47), and mortality (EUS-GBD vs PC vs ET-GBD = 2.62 vs 2.09 vs 1.29).

ADDITIONAL CLINICAL SCENARIOS

Cirrhosis and liver transplant candidates

Endoscopic gallbladder drainage can be performed to treat acute cholecystitis in cirrhotic patients and can serve as a bridge to liver transplantation. In a study of 34 decompensated cirrhotic patients with cholecystitis or symptomatic cholelithiasis, ET-GBD resulted in a technical success rate of 94%.[21] In those with GBSs, 88% had clinical improvement in biliary symptoms after 1 month and 72% remained asymptomatic during a median follow-up of 9 months. Thirty-three percent of patients underwent uncomplicated liver transplant, 20% died of progressive liver failure, and 47% continued on the waitlist with an improved model for end-stage liver disease score. A second study demonstrated similar results with resolution of symptoms in all patients after ET-GBD (57% were Child's class C), and 39% subsequently underwent successful liver transplantation, whereas 43% remained on the waitlist.[60]

Published experience is limited with EUS-GBD for patients with cirrhosis awaiting liver transplant. A retrospective series assessed outcomes of 15 cirrhotic patients (mean model for end-stage liver disease sodium of 15 ± 7; Child-Pugh class A [20%], class B [67%], and class C [13%]; international normalized ratio <1.5 in 53% and 1.5-2.5 in 47%) with acute cholecystitis treated by EUS-GBD.[61] The procedure was safe and efficacious with technical and clinical success rates of 93% resulting in 2 AEs (13%) of pancreatitis and stent maldeployment but no procedure-related bleeding. A case report described a pretransplant EUS-GBD that resulted in a periduodenal fistula and abscess formation after intraoperative LAMS removal from the cholecystoduodenostomy at the time of liver transplantation.[62]

Therefore, both ET-GBD and EUS-GBD drainage appear to be safe in high-risk cirrhotic populations.[21,60,61,63] However, in patients who are potential liver transplant candidates, ET-GBD may be preferred in an effort to preserve anatomy and prevent the potential of a persistent enteral fistula after LAMS removal.

CCY after endoscopic gallbladder drainage

As previously stated, multidisciplinary input is necessary to determine the optimal method of nonoperative gallbladder drainage, particularly if a patient is a candidate

for delayed CCY. A prospective multicenter study noted that ET-GBD did not interfere with subsequent surgical CCY. Forty patients with moderate severity cholecystitis underwent an attempted initial transcystic endoscopic nasobiliary (5F) catheter placement with lavage followed by exchange with a 5F stent. The technical success rate was 75%, and endoscopic failures were treated with subsequent PC. Thirty-seven of these 40 patients (92.5%) underwent successful elective laparoscopic CCY (2 patients refused and 1 was found to have metastatic ovarian cancer).[64] A small randomized study of 35 patients who underwent ET-GBD with either a GBS or nasobiliary drainage as a bridge to CCY did not find significant differences in clinical outcomes between the 2 patient groups.[14]

CCY in patients after EUS-GBD must include intraoperative closure of the enteral fistula to prevent a postoperative leak. Given the retroperitoneal location of the duodenum, fistula closure can be technically challenging compared with a gastric fistula. Despite these considerations, 2 small case series suggest that CCY after EUS-GBD is technically feasible with acceptable success rates and outcomes. A prospective randomized comparison of nonoperative management of acute cholecystitis reported successful subsequent CCY in 23 of 29 EUS-GBD patients (79%) and 26 of 27 PC patients (96%). Conversion rates from planned CCY to open CCY were similar in the 2 groups (9% vs 12%, $P = .99$).[57] It is important to note that the median time from drainage to surgery was only 5 to 6 days, a time interval inadequate to achieve a "mature" cholecystotomy tract. Surgical AE rates were similar between transgastric and transduodenal drainage sites. A small multicenter international study reported successful CCY in patients after gallbladder drainage procedures with no difference in conversion rates to open CCY between PC and EUS-GBD with LAMS.[65] CCY was performed on mature tracts ranging from 2 to 4 months after initial gallbladder drainage for transgastric (n = 9) and transduodenal (n = 4) GBS placement. Postsurgical AEs were similar between PC and EUS-GBD groups (23.8% vs 7.7%, $P = .23$). Further studies are needed to assess the safety and efficacy of CCY after EUS-GBD.

SAFETY AND PROCEDURE-RELATED AEs

Endoscopic transpapillary GBD

AEs associated with ET-GBD are inherent to ERCP, including pancreatitis, sphincterotomy-related bleeding, perforation, and cholangitis. AEs unique to ET-GBD are perforation of the cystic duct or gallbladder, GBS migration, recurrent biliary colic, and cholecystitis. Post-ERCP pancreatitis after transpapillary drainage occurs at rates comparable with standard ERCP (1%-2%)[15,16,66] Of note, most studies did not report if methods to reduce post-ERCP pancreatitis were used, such as prophylactic pancreatic duct stents or rectal indomethacin.[67] GBS migration or occlusion rates ranged from 2% to 12%,[11,16,21] some resulting in recurrent cholecystitis.[68]

A meta-analysis calculated the weighted pooled rates of AEs for transpapillary drainage techniques of 10% (95% CI, 7%-13%; $I^2 = 27\%$) with low rates of recurrent cholecystitis noted at 3% (95% CI, 1%-5%; $I^2 = 0\%$).[15] Other long-term AEs related to GBS migration include duodenal wall ulcer formation.[21]

EUS-guided transmural GBD

EUS-GBD–associated AEs are similar to other therapeutic EUS procedures and include pneumoperitoneum, bile peritonitis/bile leakage, stent migration, duodenal or gallbladder perforation, worsening cholecystitis because of stent occlusion, and bleeding. These AEs are encountered with all stents used for gallbladder drainage (plastic stents, fully covered SEMSs, and LAMSs).

A meta-analysis using LAMSs for EUS-GBD included 8 studies totaling 393 patients.[46] The pooled rate of AEs was 12.7% (95% CI, 8.4-18.7; $I^2 = 7.7$) with a rate of early AEs of 6.5% (95% CI, 4.2-10; $I^2 = 1.2$), and delayed AEs of 8.3% (95% CI, 5.8-11.9; $I^2 = 4.8$). Overall rates of AEs by subtype were bleeding (4.2%; 95% CI, 2.2-7.9; $I^2 = 31.8$), bile leak (2.4%; 95% CI, 1.1-5.1; $I^2 = 0$), stent occlusion (5.2%; 95% CI, 3-8.7; $I^2 = 0$), perforation (2.3%; 95% CI, 1.1-4.7; $I^2 = 0$), stent migration (3.2%; 95% CI, 1.8-5.8; $I^2 = 0$), recurrent cholecystitis and/or cholangitis (4.6%; 95% CI, 2.6-8.0; $I^2 = 0$), and death (5%; 95% CI, 2.6-9.5; $I^2 = 36.4$). Mortality was reported as the end patient outcome, which was primarily attributed to the underlying disease process and not a death event directly related to the endoscopic procedure.

A prospective randomized controlled trial of 80 patients undergoing minimally invasive gallbladder drainage procedures noted significantly reduced AE rates for EUS-GBD compared with PC,[30] with rates at 30 days of 12.8% versus 47.5% ($P = .010$) and 1 year of 25.6% versus 77.5% ($P < .001$). At 1 year, AEs in the EUS-GBD group included recurrent cholecystitis (2.6%), stent obstruction (2.6%), choledocholithiasis requiring ERCP (7.7%), and recurrent cholecystitis (2.6%). Additionally, tissue ingrowth and buried-stent syndrome have also been described.[69]

FINANCIAL CONSIDERATIONS

A decision analysis evaluated incremental cost and incremental effectiveness measured by the number of hospitalization days averted for the 3 gallbladder drainage treatment strategies (PC, ET-GBD, and EUS-GBD) in poor surgical risk patients with acute cholecystitis.[70] Endoscopic gallbladder drainage (ET-GBD and EUS-GBD) was overall more cost-effective than PC, mostly because of PC-related AEs. Compared with PC, ET-GBD was found to be cost-saving (lower cost and improved effectiveness),

whereas EUS-GBD was cost-effective compared with PC (higher cost and improved effectiveness). This study highlights that endoscopic drainage may be an economically favored option in patients who are not CCY candidates.

There are no specific current procedural terminology (CPT) codes for billing of ET-GBD and EUS-GBD. Related ERCP codes are frequently used for ET-GBD: 43274 (ERCP, with placement of endoscopic stent into biliary or pancreatic duct, including pre- and postdilation and guidewire passage, when performed, including sphincterotomy, when performed, each stent), 74328-26 (endoscopic catheterization of the biliary ductal system, radiologic supervision and interpretation), 43273 (endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s)) add-on code if cholangioscopy used, and 47999 (unlisted procedure, biliary tract).

For billing EUS-GBD, a service with fairly comparable work and time that might be provided to payers for an unlisted CPT code is 43240 (EGD, flexible, transoral; with transmural drainage of pseudocyst [includes placement of transmural drainage catheter[s]/stent[s], when performed, and EUS, when performed]), and CPT code 43247 (EGD with foreign body removal) can be used when the LAMS is endoscopically removed. An alternative is to report the most appropriate EUS code such as 43242 (EUS with FNA) and add an unlisted code for the additional biliary drainage. With sufficiently widespread use, the GI societies will likely submit applications for more specific CPT codes for endoscopic gallbladder interventions.

Of note, for unlisted CPT codes, information submitted to the insurance carrier should include a cover letter that provides a clear description of the nature, need, time required, and equipment necessary for the procedure as well as supporting medical literature. Additional information in the letter should state why billing cannot be addressed with the standard CPT codes and suggest a reasonably comparable CPT code based on work relative value units and/or percentage of a reasonably comparable CPT.

FUTURE AREAS FOR RESEARCH

Further research is needed to clarify which drainage procedure (PC, ET-GBD, or EUS-GBD) is most appropriate for carefully selected patient groups, such as those with decompensated cirrhosis/liver transplant candidates, the elderly, and metastatic cancer patients, as well as for specific indications. Future studies will require optimizing patient selection and standardization of drainage techniques and clinically relevant endpoints. Studies are also needed to elucidate the optimal stent characteristic (plastic vs LAMS vs SEMS), size (length and diameter), and duration of stent placement for optimal outcomes from transpapillary and transmural gallbladder drainage. Long-term follow-up and cost-effective analyses are necessary to guide post-GBS/LAMS management in prevention of AEs including recurrent biliary colic and cholecystitis.

TRAINING ISSUES AND ESTABLISHMENT OF COMPETENCY

Only limited information addresses optimal approaches to educate endoscopists and assess their competency for performance of endoscopic gallbladder drainage procedures. Transpapillary gallbladder drainage should mirror ERCP training and assessment of competency,[71] although an additional learning curve is unique to the complexity of negotiating a guidewire into the cystic duct and gallbladder. One group noted improvement in the success rate of placing a transpapillary GBS from 50% during the first 4 years to 89% during the subsequent 5 years of experience.[72]

Endoscopists acquiring skills in EUS-GBD with transmural LAMS placement are expected to have achieved competency in diagnostic EUS with fine-needle sampling techniques. With regard to procedural competency of EUS-GBD, 1 study compared outcomes for EUS-GBD performed by endoscopists with limited (<25 procedures) and greater experience (>25 procedures).[45] Outcomes were assessed with AEs, procedure time, and number of unplanned procedural events (defined as deviations from the planned procedural steps, ie, dislodged guidewire or stent misdeployment). Limited experience was associated with longer procedure time ($P = .006$), more unplanned procedural events ($P = .012$), and more 30-day AEs ($P = .031$). Another study performed a learning curve analysis of EUS-GBD with a mean procedure time of 41 minutes achieved after 19 cases.[73]

Additional studies are needed to further establish optimal training pathways and competency assessment for the individual gallbladder drainage procedures. Current educational approaches include simulators, "hands-on" endoscopy courses, vendor-supported training, and mentorship at specialized high-volume medical centers.

CONCLUSIONS

Nonsurgical gallbladder drainage is recommended for management of acute cholecystitis in patients deemed high risk for surgical CCY. Selection of the optimal technique (PC, ET-GBD, or EUS-GBD) should be individualized and determined using a multidisciplinary approach based on clinical determinants and available procedural expertise. In centers with proficiency in endoscopic gallbladder drainage, these techniques are becoming increasingly accepted treatment options. EUS-GBD and ET-GBD have high technical and clinical success rates with a low incidence of AEs, although EUS-GBD appears to provide superior results with these outcomes and lower rates of recurrent cholecystitis and reinterventions. Some patients

will not be candidates for EUS-GBD because of suboptimal anatomy secondary to a contracted gallbladder, lumen filled with stones, intervening ascites/varices, or insufficient proximity of the intestinal wall to the gallbladder. ET-GBD can be considered a preferred option in many of those patients, as well as those already undergoing ERCP to treat concomitant choledocholithiasis or cholangitis, nonsurgical candidates with a relative contraindication to EUS-GBD such as cirrhosis or coagulopathy, and where preservation of native biliary anatomy may favorably impact future surgical outcomes (ie, future CCY and liver transplant candidates). Future research will define the preferred technical approach for nonsurgical gallbladder drainage and the optimal duration of stent placement with respect to the goal of drainage as definitive therapy or as a bridge to CCY.

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Abbreviations: AE, adverse event; CCY, cholecystectomy; CPT, current procedural terminology; ET-GBD, endoscopic transpapillary gallbladder drainage; EUS-GBD, EUS-guided gallbladder drainage; GBS, gallbladder stent; LAMS, lumen-apposing metal stent; PC, percutaneous cholecystostomy; SEMS, self-expandable metal stent.

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