



Endoscopic Methods for Gallbladder Drainage

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Key points

- Endoscopic gallbladder drainage is a feasible and efficacious alternative to percutaneous drainage in the management of acute cholecystitis for high-risk surgical candidates.
- EUS-guided gallbladder drainage and per-oral cholecystoscopy are facilitated by the use of lumen-apposing metal stents.
- Multidisciplinary collaboration with IR and surgery is paramount in the care of these patients.
- Choosing the optimal drainage method is dependent on individual patient characteristics.

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Keywords Acute cholecystitis · EUS · ERCP · Per-oral cholecystoscopy · Gallbladder drainage

Abbreviations *CCY* Cholecystectomy · *CT* Computed tomography · *EUS-GBD* Endoscopic ultrasound-guided gallbladder drainage · *ET-GBD* Endoscopic transpapillary gallbladder drainage · *Fr* French · *LAMS* Lumen-apposing metal stent

Abstract

Purpose of review Acute cholecystitis is conventionally managed with cholecystectomy; however, when this occurs in the non-operative patient, it requires consideration for alternative means of gallbladder drainage (GBD).

Recent findings Suitable endoscopic methods for GBD include transpapillary cystic duct stent or endoscopic ultrasound (EUS)-guided transmural stent placement. Importantly, patients who undergo endoscopic GBD have comparable outcomes to those who undergo placement of percutaneous transhepatic catheters by interventional radiology (IR).

Summary There is evolving evidence to support endoscopic gallbladder drainage by EUS or ERCP with transpapillary stenting for patients who are non-operative candidates. There appear to be advantages over percutaneous drainage in terms of lower rates of recurrent cholecystitis, faster clinical resolution of symptoms, and omission of external drain-

related complications. However, careful consideration of individual characteristics is warranted in the care of these complicated patients. The technical and clinical considerations for endoscopic methods of GB drainage are discussed in this review article.

Introduction

Background

Acute cholecystitis is a common condition with a rising incidence in the USA [1]. Laparoscopic cholecystectomy is the definitive and standard treatment [2••]; however, patients may be deemed inoperable when presenting with concomitant acute medical illness or chronic comorbidities. Without a timely intervention, these patients can succumb to serious infectious complications including sepsis and death. Endoscopic gallbladder drainage (GBD) procedures via transpapillary or EUS-guided approach have established a foundational role in the management of acute cholecystitis in high-risk surgical candidates.

Placement of a percutaneous transhepatic gallbladder drain (PT-GBD) is the most common, non-operative

method for GB decompression. PT-GBD was first described in the 1970s and has an established body of evidence to support use in non-surgical candidates [3–5]. Drain-related complications often prompt subsequent endoscopic procedures to internalize drainage [6]. ERCP with transpapillary cystic duct stenting (ET-GBD) and endoscopic ultrasound (EUS)-guided (EUS-GBD) gallbladder drainage procedures can be safely and effectively employed in the care of these complex patients. This chapter provides an overview of each endoscopic technique, clinical considerations for use, and comparative outcomes.

Endoscopic techniques for drainage

Historical development of endoscopic GBD

Endoscopic GBD has evolved since 1984 when Kozarek first described accessing the cystic duct during ERCP with placement of a nasobiliary drainage catheter [7•]. Subsequent studies confirmed the efficacy of this drainage modality [8–11]. Randomized trials comparing nasobiliary drain placement to ERCP with transpapillary cystic duct stenting demonstrated similar technical and clinical success rates, but nasobiliary drainage is limited by cumbersome drain maintenance, risk of dislodgement, and postprocedure pain [12–14].

Transpapillary GBD

Transpapillary drainage (ET-GBD) is performed by cystic duct cannulation during endoscopic retrograde cholangiopancreatography (ERCP). Guidewire access of the gallbladder is obtained over which a double pigtail plastic biliary stent can be placed. There are inherent challenges to this approach including negotiating the cystic duct which may be tortuous or occluded by stone, stricture, or tumor. Cystic duct access may not be feasible if there is an indwelling metal biliary stent [2••, 15]. Transpapillary stents may require exchanging in patients with high stone burden who present with stent occlusion and

recurrent cholecystitis. These stents can be left indefinitely for non-operative candidates [16] or removed at the time of cholecystectomy. An advantage of this approach over EUS-GBD is the preservation of normal anatomy for surgical candidates.

EUS-guided GBD

The first reported case of EUS-GBD was in 2007 in a patient with unresectable hilar cholangiocarcinoma with acute cholecystitis who was successfully drained with transmural 7Fr double pigtail plastic biliary stent. [17•] Subsequent trials using fully covered tubular metal biliary stents were published [18]; however, these stents were prone to migration, risk of contralateral GB wall injury, or stent occlusion due to excessive length. Lumen-apposing stents (LAMS) (e.g., Axios, Boston Scientific) have proved to be an ideal stent for EUS-GBD [19] as these bi-flanged stents were shorter in length, with larger diameters through which per-oral cholecystoscopy could be performed for obliteration of gallstones [20]. While multiple LAMS have been released worldwide for commercial use, only one type of LAMS is currently available in the USA.

Per-oral cholecystoscopy

Placement of a 15 mm diameter LAMS for EUS-GBD facilitates access to the GB lumen to directly address gallbladder pathology including large volume cholelithiasis [21]. Stones can be obliterated using a variety of means including direct extraction with retrieval devices, electrohydraulic lithotripsy or Holmium laser lithotripsy. For poor operative candidates, cholecystoscopy can also be used to address other forms of GB pathology including polyps, workup abnormal imaging findings, and provide advanced imaging for neoplastic disease. Limited case series suggest that these interventions are safe and efficacious [22].

Technical considerations

Transpapillary GBD

ERCP with biliary sphincterotomy is required for both nasobiliary and transpapillary cystic duct stenting. This procedure is optimally performed using a standard duodenoscope to obtain guidewire access of the cystic duct which is then coiled within the gallbladder lumen, followed typically by a 7Fr by 15 cm double pigtail plastic biliary stent which can then be deployed with the proximal pigtail within the gallbladder lumen and the distal end of the stent left in a transpapillary position within the duodenum (Fig. 1).

EUS-guided GBD

EUS-GBD is conventionally performed using a LAMS with a 10.5 French catheter-based delivery system. (Fig. 1) These are fully covered nitinol-braided stents with bilateral anchor flanges with dimensions: 10 mm in saddle length, inner diameter of 10, 15, or 20 mm, and outer flange of 21, 24, or 29 mm diameter (Axios, Boston Scientific). To safely accommodate the 10 mm saddle length of the stent, the measured distance between the enteral puncture site and the lumen of the gallbladder should be < 10 mm.

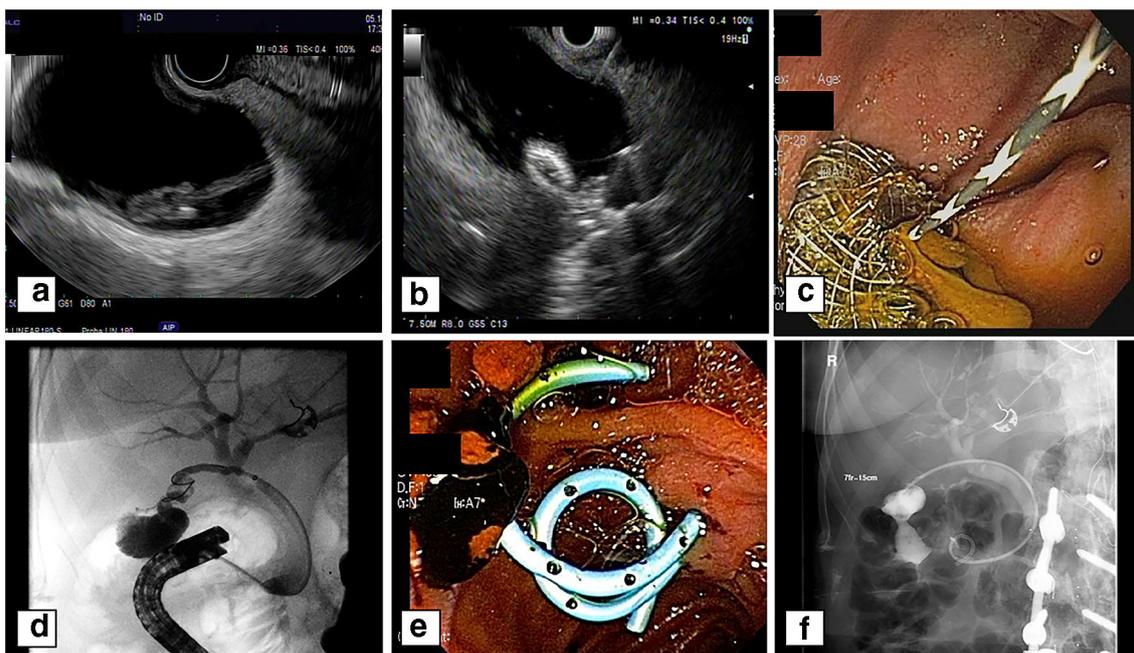
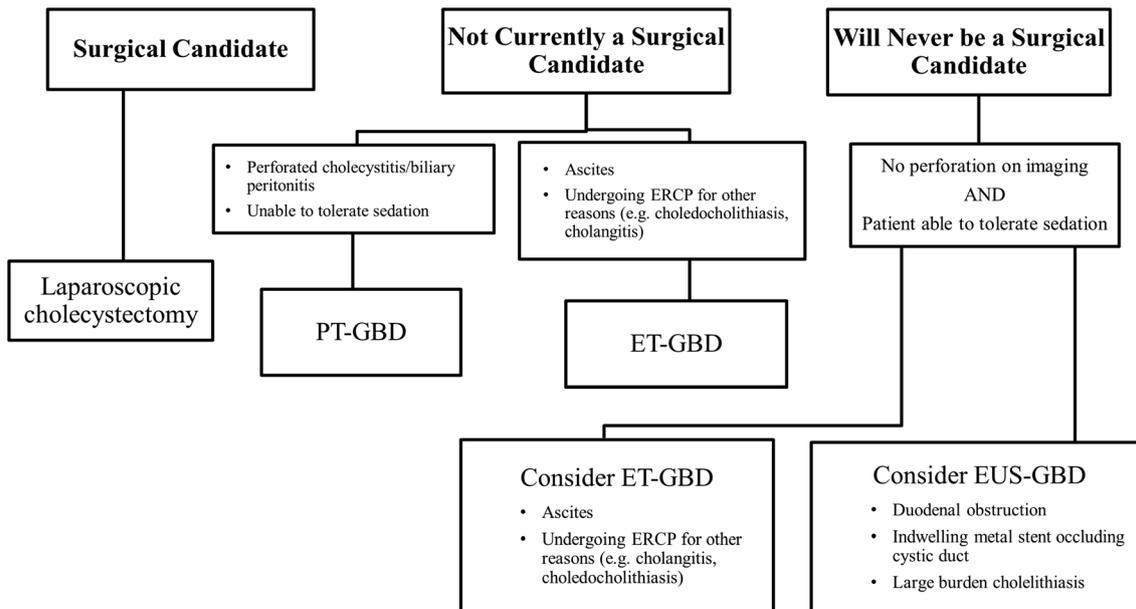


Fig. 1. Endoscopic and fluoroscopic images of EUS and endoscopic transpapillary gallbladder drainage. **a** EUS view of gallbladder filled with stones and sludge, **b** Gallbladder flange of the LAMS deployed under EUS view, **c** Endoscopic view of transduodenal LAMS placed with drainage of purulent bile, **d** Fluoroscopic view of guidewire access of the cystic duct using an extraction balloon, **e** Transpapillary stent placed after common bile duct stones removed, **f** Fluoroscopic image of transpapillary 7French \times 15 cm double pigtail stent.

First, a 19-gauge FNA needle is used to puncture the GB through which a guidewire can be advanced into the lumen. Bile can be aspirated or a cholecystogram obtained if needed to confirm placement. The non-cautery-enhanced LAMS has to be placed over a guidewire with tract dilation followed by stent deployment. The cautery-enhanced LAMS placement involves transmural puncture from the duodenum or distal stomach into the gallbladder body using a pure-cut current. An over-the-wire technique may reduce risk of stent misdeployment and should be considered for patients with difficult anatomy, unstable scope position, or a contracted GB. A direct method, without guidewire, can be safely employed in a distended, (largely) stone-free gallbladder. The gallbladder flange is deployed under EUS guidance, proximal traction applied to appose the lumen to the duodenal or gastric wall followed by the deployment of the enteral flange under either EUS or endoscopic view [23]. Placement of a 7Fr \times 3 cm double pigtail plastic biliary stent across the stent may mitigate contralateral wall injury from the stent and food occlusion of the LAMS, particularly for transgastric stents.



Key: ERCP = endoscopic retrograde cholangiopancreatography, ET-GBD = endoscopic transpapillary gallbladder drainage, EUS-GBD = endoscopic ultrasound gallbladder drainage, PT-GBD = percutaneous transhepatic gallbladder drainage

FIG. 2. Flowchart for gallbladder drainage for the treatment of acute cholecystitis, based on operative candidacy.

Clinical considerations

Patient selection

Endoscopic GBD should be considered in all patients who are high risk for surgery, without evidence of free GB perforation, and sufficient sedation/anesthesia tolerance. (Fig. 2) There is a compelling argument for initial consideration of ET-GBD in those already requiring ERCP for other reasons, or for potential future surgical candidates [7•, 15]. Furthermore, this method of endoscopic drainage is particularly useful in patients with coagulopathy, large volume abdominal ascites, or comorbidities that may preclude optimal percutaneous drain placement. An advantage of ET-GBD over EUS-GBD is the preservation of normal anatomy for surgery [24]. Cholecystectomy with fistula repair appears to be safe and feasible based on EUS-GBD series [25], however, does carry the potential risk for a postoperative leak. Therefore prior to endoscopic drainage, discussion with the surgeon is appropriate to clarify potential future surgical candidacy. Specific indications for EUS-GBD over ET-GBD include indwelling metal biliary stents obstructing the cystic duct takeoff or patients with large volume cholelithiasis or other clinical indications for cholecystoscopy.

Contraindications

EUS-GBD is ill-advised if there is evidence of gallbladder perforation and biliary peritonitis. Patient intolerance to sedation or general anesthesia serves as a contraindication to all forms of endoscopic GBD as well. Discussion with a surgeon about potential future surgical candidacy is important to elucidate preference for preservation of normal anatomy (with transpapillary stenting and ERCP) over transmural stenting that would require repair at the time of cholecystectomy [26, 27].

Informed consent

When counseling patients and their families about endoscopic GBD, an informed discussion of the risks, benefits, and alternative treatment options are paramount. In addition to the standard endoscopic procedural risks, there are specific endoscopic GBD-related adverse events including puncture-induced hemorrhage and bile leak (with resultant biliary peritonitis), risk of GB or cystic duct perforation, and stent migration [24]. Potential late adverse events include relapsing cholecystitis in the case of stent migration or occlusion.

Outcomes of endoscopic gallbladder drainage

Endoscopic vs. percutaneous GBD

PT-GBD for non-operative candidates persists as the most commonly employed method of GBD particularly due to the ubiquity of procedural expertise. Despite limitations of drain-related dyscosmesis and maintenance issues, there exists an extensive body of literature to support its use, and until recently, there was a paucity of compelling evidence to support endoscopic alternatives. Available systematic reviews of EUS-GBD report rates of technical success in the range of 93–95.2% and clinical success in the range 92.5–97% [3, 28–31]. Aggregate analyses are more limited for ET-GBD; however, one review reported composite technical and clinical success rates at 83% and 93% respectively [28]. Percutaneous drainage technical and clinical success rates have been reported as high as 98% and 97% [32•]. Despite comparable technical and clinical success rates for drainage by an EUS vs. percutaneous approach [23, 33, 34•, 35], patients managed with PT-GBD are subject to longer hospital length of stay (16 vs. 19 days, $p = 0.01$), and higher procedure reintervention rates (1 vs. 2, $p = 0.001$) [4, 36]. Recurrent acute cholecystitis can occur in up to 15.4% of the patients after percutaneous drainage [5].

Recent multi-center data found that PT-GBD is associated with higher post-procedure pain scores (6.5 vs. 2.5, $p < 0.05$) with a trend toward higher adverse events at 30 days (32% vs 11%, $p = 0.065$) compared with EUS-GBD [14, 23]. Lower postprocedure pain scores following EUS-GBD likely accounts for the shorter postintervention hospital stay. Another study detected significant differences in rates of adverse events and hospital readmission for re-intervention at 1-year post-procedure [33, 37]. Readmission rates for the PT-GBD group were due to drain-related leak, obstruction, or dislodgement.

Table 1. Outcomes for technical success, clinical success and adverse event rate for comparative studies of EUS and transpapillary gallbladder drainage

	GBD procedure by type, (n/total)	Technical success, % (n)	Clinical success, % (n)	Adverse events, % (n)
Higa et al. [38], USA	EUS—40/78	97.5 (39/40)	95.0 (38/40)	17.9 (7)
	ET—38/78	84.2 (32/38)	76.3 (29/38)	9.4 (3)
Oh et al. [34], Korea	EUS—76/172	98.8 (82/83)	98.8 (82/83)	7.1 (6)
	ET—96/172	83.3 (80/96)	82.3 (79/96)	19.3 (9)
Siddiqui et al. [32], USA	EUS—102/372	94 (96/102)	90 (92/102)	11.8 (12)
	ET—124/372	88 (109/124)	80 (99/124)	7.2 (9)
	Perc—146/372	98 (143/146)	97 (141/146)	4.1 (6)

EUS EUS-guided gallbladder drainage, *GBD* gallbladder drainage, *Perc* percutaneous gallbladder drainage, *ET* transpapillary gallbladder drainage

Transpapillary vs. EUS-guided GBD

Recently data is emerging that may suggest superiority of one endoscopic modality over the other. One recent multicenter study comparing ET vs. EUS vs. PT-GBD found significantly lower technical and clinical success rates in the transpapillary drainage arm [32•] (Table 1). In the single US-based series comparing ET- to EUS-GBD, clinical success was higher in the EUS drainage arm with a trend toward higher technical success rates as well (95.0% vs. 76.3% (adjusted OR 7.14; 95% CI 1.32–38.52)) [38]. Cystic duct occlusion is the primary reason for technical failures with ET-GBD and inability to gain cystic duct access due to obstruction by uncovered metal biliary stent, tumor, or stone. Lower rates of recurrent cholecystitis following EUS-drainage have been reported (12.4% vs. 3.2% (HR 3.01; 95% CI 0.73–12.9)) [34]. Postprocedure pain scores and 30-day adverse event rates appear comparable based on limited data.

Long-term outcomes

Many favor leaving the LAMS in permanently for very frail patients and in those who do not want to undergo a second procedure. In a study reporting the long-term outcomes of EUS-GBD, late adverse events were low at 7.1%, and the 3-year stent patency was 86%, making this a reasonable approach as well [39]. Alternatively once the GB is cleared, exchanging the LAMS for plastic pigtail stents might maintain the cholecysto-intestinal fistula and potentially reduce the risks associated with a long-term, indwelling LAMS including bleeding and stent migration. With regard to long-term transpapillary stents, currently available studies support permanent stent placement for the bile wicking factor which can maintain GB decompression, even in the case of stent occlusion [16].

Conclusions

There is an established role for endoscopic GBD in patients with acute cholecystitis who are high-risk operative candidates. Determining which method of endoscopic drainage is most appropriate requires consideration of

comorbidities, potential future surgical candidacy, presence of ascites, and observation of local practices. Data based determinants for which endoscopic method to employ is subject to current debate and can depend on the patient's anatomy (GB position, cystic duct characteristics, indwelling metal biliary stent), comorbidities like ascites or coagulopathy, and potential future surgical candidacy. ET-GBD should be prioritized for patients who require ERCP for alternative reasons and patients for whom endoscopic GBD is a known temporizing measure. Conversely, EUS-GBD is preferred for patients who are poor candidates for repeat intervention, those with indwelling metal biliary stents covering the cystic duct and/or high volume cholelithiasis which is preferably addressed using per-oral cholecystoscopy. Both stents can be left long-term; however, transpapillary stents have a higher likelihood of occluding and requiring reintervention. Ultimately, more randomized and prospective data are needed to compare ET- and EUS-GBD outcomes, including formal cost-analysis.

Compliance with ethical standards

Conflict of interest

Jennifer T. Higa declares that she has no conflict of interest.
Shayan S. Irani declares that he has no conflict of interest.

Human and animal rights and informed consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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