Endoscopic Ultrasound-Guided Gallbladder Drainage Versus Percutaneous Drainage in Patients With Acute Cholecystitis Undergoing Elective Cholecystectomy

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INTRODUCTION: **Cholecystectomy (CCY) is the gold standard treatment of acute cholecystitis (AC). Nonsurgical management of AC includes percutaneous transhepatic gallbladder drainage (PT-GBD) and endoscopic ultrasound-guided gallbladder drainage (EUS-GBD). This study aims to compare outcomes of patients who undergo CCY after having received EUS-GBD vs PT-GBD.**

METHODS: **A multicenter international study was conducted in patients with AC who underwent EUS-GBD or PT-GBD, followed by an attempted CCY, between January 2018 and October 2021. Demographics, clinical characteristics, procedural details, postprocedure outcomes, and surgical details and outcomes were compared.**

RESULTS: **One hundred thirty-nine patients were included: EUS-GBD in 46 patients (27% male, mean age 74 years) and PT-GBD in 93 patients (50% male, mean age 72 years). Surgical technical success was not significantly different between the 2 groups. In the EUS-GBD group, there was decreased operative time (84.2 vs 165.4 minutes, $P < 0.00001$), time to symptom resolution (4.2 vs 6.3 days, $P = 0.005$), and length of stay (5.4 vs 12.3 days, $P = 0.001$) compared with the PT-GBD group. There was no difference in the rate of conversion from laparoscopic to open CCY: 5 of 46 (11%) in the EUS-GBD arm and 18 of 93 (19%) in the PT-GBD group (P value 0.2324).**

DISCUSSION: **Patients who received EUS-GBD had a significantly shorter interval between gallbladder drainage and CCY, shorter surgical procedure times, and shorter length of stay for the CCY compared with those who received PT-GBD. EUS-GBD should be considered an acceptable modality for gallbladder drainage and should not preclude patients from eventual CCY.**

KEYWORDS: EUS gall bladder drainage; percutaneous; cholecystectomy; cholecystitis; EUS-GBD

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INTRODUCTION

The gold standard treatment of acute cholecystitis (AC) remains cholecystectomy (CCY) (1).However, not all patients with AC are candidates for surgery. Current nonsurgical options for the management of AC include percutaneous transhepatic gallbladder drainage (PT-GBD), endoscopic ultrasound-guided gallbladder drainage (EUS-GBD), and endoscopic transpapillary gallbladder drainage (ETP-GBD) (2). PT-GBD involves the placement of an external drain through a pigtail catheter (or multiple catheters) into the gallbladder; EUS-GBD involves the placement of a transluminal stent from the gastrointestinal lumen into the gallbladder; and ETP-GBD involves the placement of a transpapillary stent from the cystic duct into the gallbladder during endoscopic retrograde cholangiopancreatography.

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EUS-GBD can be performed by using either a transgastric or transduodenal approach. During the transgastric approach, the gallbladder is accessed at its body from the antrum, whereas the transduodenal approach provides access to the gallbladder neck from the duodenal bulb. Although the transduodenal approach is theoretically easier, because the duodenum is less mobile and provides a more stable position, with less chance for stent migration or tissue overgrowth around the stent, the transgastric approach provides the advantage of easier closure of the fistula after stent removal, which may be beneficial in patients who may become a potential candidate for surgery in the future (3).

EUS-GBD has been proven to be superior to PT-GBD for 30-day and long-term adverse events, including cholecystitis recurrence, and is nowadays accepted as an upfront therapeutic option for nonsurgical patients with AC (4). However, in patients who are anticipated to later become surgical candidates, PT-GBD has traditionally been viewed as the preferred method of gallbladder drainage because of a presumed increased operative complexity during the subsequent CCY after EUS-GBD (5). A small study has previously demonstrated the feasibility of CCY after EUS-GBD (6). This study aims to expand on that feasibility by comparing clinical outcomes of patients who undergo EUS-GBD vs PT-GBD, followed by CCY.

METHODS

A multicenter international cohort study was conducted across 9 academic centers in 5 countries. From January 2018 to October 2021, patients with AC who underwent EUS-GBD or PT-GBD, followed by an attempted or completed elective or semielective CCY, were included in a dedicated retrospective chart review registry (NCT05051358). Inclusion criteria included all patients deemed unfit for surgery but requiring gallbladder drainage for sepsis, pain, or impeding cholecystitis. Any patient with a suspected gallbladder wall perforation based on imaging underwent percutaneous drainage and was excluded from this study.

Demographics; Charlson Comorbidity Index; procedural details for EUS-GBD, PT-GBD, and CCY; and postprocedural outcomes and adverse events were captured (i.e., bleeding, perforation, migration, bile leakage, infection and occlusion). Results are reported as mean ± SD or median (interquartile range) for quantitative variables and percentages for categorical variables.

The EUS-guided approach was performed with cautery-enhanced lumen-apposing metal stents (LAMS) (Axios, Boston Scientific, Natick, MA) of 8, 10, or 15-mm diameter were used; a free hand technique was offered, as well as a Seldinger technique with the placement of a guidewire. Balloon dilation performed after LAMS deployment was left at the discretion of the endoscopist, as well as pigtail stent placement. For the percutaneous approach, most procedures were performed with ultrasound or fluoroscopy assistance using a transhepatic or transabdominal approach; the range of catheter size was between 7 and 10 Fr.

Most EUS-GBD stents were placed from the gallbladder to the stomach (n = 37, 80%) and the remainder from the duodenum (n = 9, 20%). Forty-four of EUS-GBD stents (96%) were LAMS of varying diameters: 10 mm (n = 31, 73.9%), 15 mm (n = 9, 20%), or 20 mm (n = 4, 9%). One patient had a 10-mm fully covered self-expanding metal stent placed in primary drainage. Catheters used in the PT-GBD group were 8 French (n = 33, 35.5%) and 10 French (n = 60, 64.5%).

Technical success was defined as successful stent or catheter placement with visible drainage for EUS-GBD and PT-GBD and as successful removal of the gallbladder for CCY. Clinical success was defined as resolution of symptoms (i.e., resolution of sepsis and/or pain after drainage).

The primary outcome of the study was the rate of technical success of CCY after either procedure. Secondary outcomes were operative procedure time, rate of conversion from laparoscopic to open CCY, operative adverse events, length of stay after CCY, and time to symptom resolution after CCY.

Data were compared using the Student *t* test for independent means and a χ^2 test (or Fisher exact test, if required) for categorical variables. The Mann-Whitney *U* test was used to conduct comparison for ordinal data. Two-sided P values < 0.05 were considered statistically significant. All descriptive and statistical analyses were conducted using MedCalc V18.9 (MedCalc Software, Ostend, Belgium).

RESULTS

A total of 139 patients were included in this study. EUS-GBD was performed in 46 patients (27% male, mean age of 74 years), and PT-GBD was performed in 93 patients (50% male, mean age of 72 years). Within the EUS-GBD group, 6 patients from Rutgers Robert Wood Johnson Medical School; 39 patients from Instituto Ecuatoriano de Enfermedades Digestivas, Guayaquil, Ecuador; and 1 patient from Methodist Dallas were included. Within the PT-GBD group, 44 patients from Robert Wood Johnson Medical School; 3 patients from Deenanath Mangeshkar Hospital, Pune, India; 11 patients from Instituto Ecuatoriano de Enfermedades Digestivas, Guayaquil, Ecuador; 37 patients from San Raffaele, Milan Hospital, Milan, Italy; and 2 patients from Hospital das Clinicas da FMRPUSP, Sao Paulo, Brazil, were included. There were no significant differences in patient demographics and Charlson Comorbidity Index between the 2 groups (Table 1). The etiology of cholecystitis was primarily due to gallstones in both groups (78% vs 81%), followed by acalculous cholecystitis (17% vs 14%) and malignancy (4% vs 5%).

EUS-GBD and PT-GBD outcomes

Technical success was high in both groups: 98% (n = 45) in the EUS-GBD group and 100% (n = 93) in the PT-GBD group. One patient in the EUS-GBD group had a misdeployed stent that was unable to be salvaged, after which the fistula site was closed, and the patient went for CCY. Clinical success was 91% (n = 42) in the EUS-GBD group vs 86% (n = 80) in the PT-GBD group.

Patients who underwent EUS-GBD had a shorter mean time to symptom resolution compared with patients in the PT-GBD arm (1.5 vs 2.4 days, $P = 0.0006$). Hospital length of stay was shorter in patients who underwent EUS-GBD compared with patients who underwent PT-GBD (2.4 vs 11.6 days, $P < 0.00001$). The rate of hospital readmission was also lower in the EUS-GBD arm compared with the PT-GBD arm (9% vs 37%, $P = 0.0003$). Procedural adverse events were comparable between the 2 arms (28.3% vs 36.6%) (Table 1). Four of the adverse events in the EUS-GBD group required urgent CCY.

Cholecystectomy outcomes

The mean time interval between procedural gallbladder drainage and CCY was shorter after EUS-GBD compared with PT-GBD (38 vs 70 days, $P = 0.007$). In the EUS-GBD group, the drainage stent was removed in all patients before surgery and closure was performed with an over-the-scope clip (Ovesco Endoscopy USA, Cary, NC).

Table 1. Clinical characteristics

	Endoscopic ultrasound-guided Gallbladder drainage (N = 46)	Percutaneous gallbladder drainage (N = 93)	*P* value	95% CI
Age, mean (SD) (y)	73.7 (7.9)	71.7 (15)	0.4250	−6.7456 to 2.8592
Sex, n males (%)	27 (58.7)	51 (53.8)	0.6663	
Charlson Comorbidity Index, mean (SD)	3.9 (0.5)	4.3 (2.1)	0.1584	−0.1830 to 1.1115
Etiology of cholecystitis, n (%)			0.8463	
Gallstone	36 (78.3)	75 (80.7)		
Acalculous	8 (17.4)	13 (14.0)		
Malignancy	2 (4.4)	5 (5.4)		
Procedure duration, mean (SD) (min)	39.6 (24.5)	31.0 (9)	0.0072	−14.9341 to −2.3865
EUS puncture site, n (%)				
Stomach	37 (80.4)			
Duodenum	9 (19.6)			
Technical success, n (%)	45 (97.8)	93 (100)	No *P* value	
Adverse events, n (%)	13 (28.3)	34 (36.6)	0.330,487	
	Bleeding	3	Bleeding	4
	Stent misplacement	3	Catheter migration/malfunction	20
	Peritonitis	1	Pneumoperitoneum	1
	Pain	3	Sepsis and hypotension	3
	Gastric ulcers	2	Skin infection	4
	Nausea and vomiting	1	Worsening of acute cholecystitis	2
Clinical resolution of symptoms, n (%)	42 (91.3)	80 (86.0)	0.37104	
Time to resolution of symptoms, mean (SD) (d)	1.5 (0.5)	2.4 (1.3)	0.00003	0.4987 to 1.3655
Hospital readmission, n (%)	4 (8.7)	35 (37.6)[a]	0.0003	
Length of stay, mean (SD) (d)	2.4 (1.2)	11.6 (7.8)	<0.0001	6.8360 to 11.6669
Time interval to CCY, mean (SD) (d)	38 (9.3)	69.6 (78)	0.0079	8.5165 to 55.2878

CCY, cholecystectomy; EUS, endoscopic ultrasound.
[a]Most common etiology was due to drain malfunction.

Technical success was high in both groups: 93.5% (n = 43, EUS-GBD group) vs 98% (n = 91, PT-GBD group). Two patients in the PT-GBD group were found to have severe, persistent inflammation and bowel adhesions during laparoscopy, for which the surgery was aborted. Three patients in the EUS-GBD group had aborted surgery, 2 for persistent inflammation and 1 for diagnosis of peritoneal carcinomatosis.

The rate of open CCY was not statistically significantly different in the EUS-GBD group (11/46, 24%) compared with the PT-GBD group (8/93, 9%) ($P = 0.068$) (Table 2). The rate of conversion from laparoscopic to open CCY was not significantly different between the 2 groups: 5 of 46 (11%) in the EUS-GBD arm and 18 of 93 (19%) in the PT-GBD group (*P* value 0.2324). Operative time was shorter in the EUS-GBD arm compared with the PT-GBD arm (84.2 vs 165.4 minutes, $P < 0.00001$). Operative adverse events were similar in both arms (19.5% vs 23.6%). Total length of hospital stay for CCY was shorter in the EUS-GBD arm compared with the PT-GBD arm (5.4 vs 12.3 days, $P = 0.001$). The mean follow-up time was 21 weeks in the EUS-GBD group and 39 weeks in the PT-GBD group ($P = 0.0039$).

DISCUSSION

Current nonoperative management techniques for AC include PT-GBD, EUS-GBD, and ETP-GBD. PT-GBD has the advantage of requiring only local anesthesia (7), but is associated with a higher rate of complications such as catheter migration or dislodgement (8). The formation of biofilm within the percutaneous drain is a well-described event that can increase the risk of recurrent cholecystitis (9). EUS-GBD was first demonstrated in 2007 and subsequently has been shown to be safe and efficacious when performed by a skilled operator (10,11). The placement of a large-diameter LAMS allows for drainage of biliary fluid and larger gallstones, eventually also allowing direct per-oral endoscopic cholecystoscopy and cholecystolithotomy (12,13). These

Table 2. Surgical outcomes

Surgical outcomes	Endoscopic ultrasound-guided Gallbladder drainage (N = 46)	Percutaneous gallbladder drainage (N = 92)	*P* value	95% confidence intervals
Type of cholecystectomy, n (%)				
Laparoscopic	30 (65.2)	66 (71.7)	0.07	
Open	11 (23.9)	8 (8.7)	0.07	
Laparoscopic-to-open	5 (10.9)	18 (19.6)	0.08	
Technical success, n (%)	43 (93.5)	90 (97.8)	0.08	
Procedure time, mean (SD) (min)	84.2 (7.7)	165.4 (77.8)	<0.00001	48.0553–114.3543
Adverse events, n (%)	9 (19.6)	22 (23.9)	0.09	
	Bleeding	2	Bleeding	4
	Septic shock	1	Peritonitis	1
	Biliary leak	3	Biliary leak	4
	Cutaneous infection	3	Cutaneous infection	4
			Cystic duct injury	2
			Atrial fibrillation	3
			Cholestasis	3
			Hypoxia	1
Clinical resolution of symptoms, n (%)	44 (95.7)	88 (95.7)	0.07	
Time to symptom resolution, mean (SD) (d)	4.2 (1.3)	6.3 (4.8)	0.005	12.5913–55.4687
Hospital readmissions (recurrent AC or procedure-related complication), n (%)	8 (17.4)	15 (16.3)	0.09	
Total length of stay, mean (SD) (d)	5.4 (1.9)	12.3 (13.8)	0.001	13.8850–53.4903
Longest follow-up time, mean (SD) (w)	20.7 (4.4)	39 (27)	0.0039	3.9737–20.2601

AC, acute cholecystitis.

stents are also equipped with proximal and distal flanges to prevent migration or dislodgement, although anastomotic leaks are a possible but rare complication (14). Studies comparing EUS-GBD with PT-GBD have demonstrated similar rates of technical success and clinical success (15–17).

Compared with ETP-GBD, EUS-GBD has been shown to have fewer adverse events, decreased length of stay, and significantly lesser rates of readmissions and reinterventions (18). Recently, a randomized control trial by Teoh et al confirmed the safety of EUS-GBD when compared with PT-GBD (4). In this study, similar trends were identified with patients with EUS-GBD having a lower rate of adverse events, lesser time to symptom resolution, lower readmission rate, and shorter length of stay.

One concern limiting widespread adoption of EUS-GBD is the unknown feasibility of performing subsequent CCY in patients who clinically improve enough to become surgical candidates. EUS-GBD could theoretically increase surgical complexity because of the anastomosis between the gastrointestinal lumen and the gallbladder, potentially increasing procedure time, operative adverse events, and rates of conversion to open CCY. A study by Saumoy et al that included 13 patients who underwent EUS-GBD, followed by CCY, did not confirm these concerns (6). In this larger, international study, we also confirmed the lack of validity of these theoretical concerns. In this study, 44 of 46 patients who underwent EUS-GBD were able to successfully undergo CCY and there was no difference in technical success whether patients underwent PT-GBD vs EUS-GBD. The operative time for CCY in the EUS-GBD group was less than that in the PT-GBD group by nearly half (84.2 vs 165.4 minutes, $P < 0.00001$), and the rate of conversion from laparoscopic to open CCY was not different between the groups, suggesting no difference in surgical complexity. The operative adverse event rate was also similar between the groups. In surgical literature, the critical view of safety during laparoscopic CCY refers to optimal visualization of the structures at the Calot triangle to avoid iatrogenic biliary injuries. When there is active or recent inflammation, the structures may not be visualized adequately and conversion to an open procedure is considered a safer alternative (19). Because the drainage of the gallbladder obtained during EUS-GBD achieves faster resolution of cholecystitis, it is expected that dissection of the gallbladder and surrounding structures would be simpler and faster than that after PT-GBD, even after factoring the reversal of the cholecystogastric or cholecystoduodenal fistula. This concept would explain why the operative time was significantly shorter in the EUS-GBD group. This parallels studies on patients with PT-GBD demonstrating that patients who underwent earlier drainage had

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lower rates of laparoscopic-to-open conversion compared with patients who had a late drainage of the gallbladder (9). Although not statistically significant, it is notable that the rate of open CCY was higher in the EUS-GBD group compared with the PT-GBD group. However, the modality of CCY was at the sole discretion of the surgeon, and some surgeons may have been reluctant to opt for an initial laparoscopic approach after EUS-GBD drainage.

Although CCY after EUS-GBD seems safe and without increased complexity based on our study findings, the ideal preoperative management of patients after EUS-GBD remains unknown. In this study, 80% of the LAMS (n = 37) were deployed from the stomach because initial data suggest that most surgeons prefer a gastric site of drainage compared with a duodenal site (6). In addition, in our study, all LAMS were removed and the fistulas were closed endoscopically before CCY. Further studies are needed to elucidate the benefit of presurgical vs intraoperative stent removal with or without endoscopic fistula closure.

Limitations of this study include possible selection bias toward EUS-GBD because randomization was not performed. Only 2 centers performed both EUS and percutaneous transhepatic-guided drainage while other centers performed either EUS or percutaneous drainage, resulting in selection bias. Selection bias could explain the differences in time to CCY and the differences in length of stay.

In conclusion, consistent with prior studies, EUS-GBD is safe and efficacious and is associated with shorter length of stay and fewer postprocedure readmissions compared with PT-GBD. In patients who later become surgical candidates, patients who received EUS-GBD had a significantly shorter interval between gallbladder drainage and CCY, a shorter surgical procedure time, no difference in the rate of conversion from laparoscopic to open CCY, a shorter length of stay after CCY, and no difference in surgical-related adverse events compared with those who received PT-GBD. As such, in tertiary centers offering therapeutic endosonography, EUS-GBD should be considered an acceptable nonoperative treatment of cholecystitis in patients awaiting surgery and should not preclude patients from eventual CCY. Further randomized controlled trials are needed to clarify this paradigm.

CONFLICTS OF INTEREST

Guarantor of the article: Michel Kahaleh, MD.

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Study Highlights

WHAT IS KNOWN

- ✓ Cholecystectomy (CCY) is the gold standard treatment of acute cholecystitis.
- ✓ Nonsurgical management of acute cholecystitis includes percutaneous transhepatic gallbladder drainage and endoscopic ultrasound-guided gallbladder drainage (EUS-GBD).

WHAT IS NEW HERE

- ✓ Patients who received EUS-GBD had a significantly shorter interval between gallbladder drainage and CCY, shorter surgical procedure times, and shorter length of stay for the CCY compared with those who received percutaneous transhepatic gallbladder drainage.
- ✓ EUS-GBD should be considered an acceptable modality for gallbladder drainage and should not preclude patients from eventual CCY.

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