ORIGINAL ARTICLE: Clinical Endoscopy

EUS-guided gallbladder drainage versus laparoscopic cholecystectomy for acute cholecystitis: a propensity score analysis with 1-year follow-up data

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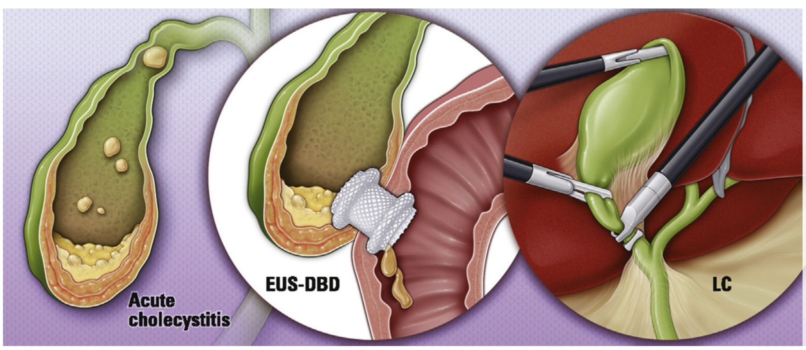
GRAPHICAL ABSTRACT



Comparison on clinical outcomes of the two procedures

	EUS-GBD n = 30	LC n = 30	*P* value
Technical success (%)	30 (100)	30 (100)	-
Clinical success (%)	28 (93.3)	30 (100)	1
Length of hospital stay (days)	6.8 (8.1)	5.5 (2.7)	1
30-day adverse events (%)	4 (13.3)	4 (13.3)	1
30-day mortality (%)	2 (6.7)	0 (0.0)	1
Recurrent cholecystitis (%)	1 (3.3)	0 (0.0)	0.168
Recurrent biliary events (%)	3 (10.0)	3 (10.0)	0.784
Re-interventions (%)	4 (13.3)	3 (10.0)	1
Unplanned readmissions (%)	3 (10.0)	3 (10.0)	0.784

Background and Aims: EUS-guided gallbladder drainage (EUS-GBD) is a safe alternative to percutaneous cholecystostomy (PT-GBD) for acute cholecystitis. How the procedure compares with laparoscopic cholecystectomy (LC) is uncertain. The aim of the current study is to compare the outcomes of EUS-GBD with LC for acute cholecystitis.

Methods: This was propensity score analysis of all patients admitted for acute cholecystitis between 2012 and 2018. Consecutive patients who received EUS-GBD or LC were included. Patients were matched for age, sex, and age-adjusted Charlson score. Outcome measurements included 30-day adverse events, mortality, recurrent cholecystitis, recurrent biliary events, reinterventions, and readmissions.

Results: During the study period, 60 patients were selected (30 EUS-GBD vs 30 LC) after propensity score matching. Technical success rates (100% vs 100%), clinical success rates (93.3% vs 100%, $P = 1$), lengths of hospital stay (6.8 [8.1] vs 5.5 [2.7], $P = 1$), 30-day adverse events (4 [13.3%] vs 4 [13.3%], $P = 1$), and mortality rates (2 [6.7%] vs 0 [0%], $P = .492$) were similar. The rates of recurrent biliary events (3 [10%] vs 3 [10%], $P = .784$), reinterventions (4 [13.3%] vs 3 [10%], $P = 1$), and unplanned readmissions (3 [10%] vs 3 [10%], $P = .784$) in 1 year were also similar.

Conclusions: The outcomes of EUS-GBD for acute cholecystitis were comparable with LC with acceptable rates of recurrent acute cholecystitis. These results support the role of EUS-GBD as an alternative to LC in patients who may or may not be surgically fit to undergo definitive cholecystectomy. (Gastrointest Endosc 2021;93:577-83.)

(footnotes appear on last page of article)

EUS-guided gallbladder drainage (EUS-GBD) is gaining popularity as the procedure of choice to drain the gallbladder in patients with acute cholecystitis who are at very high-risk for cholecystectomy.[1-17] The procedure is associated with reduced adverse events, shorter hospital stays, fewer reinterventions, and unplanned readmissions. The gallbladder could also be cleared of gallstones endoscopically by interventions through the stent placed during EUS-GBD. Long-term follow-up of these patients showed a low risk of recurrent acute cholecystitis, suggesting long-term efficacy.[3] However, how the procedural outcomes of EUS-GBD compare with the criterion standard of treatment, laparoscopic cholecystectomy (LC), is unexplored.

In the current study, we aimed to compare the outcomes of EUS-GBD and LC in the treatment of acute cholecystitis using propensity score analysis. We hypothesize that EUS-GBD is associated with comparable outcomes with LC.

METHODS

This was a propensity score analysis of a retrospective database that included all patients with acute cholecystitis who received EUS-GBD or LC as a definitive management between 2012 and 2018 at the Prince of Wales Hospital in Hong Kong. During the study period, EUS-GBD was first introduced and offered to patients who were at very high risk for cholecystectomy, and LC was offered to patients who were surgical candidates in the same time period. Because the 2 groups differ significantly in premorbid status, propensity score matching was used to match several parameters to make the 2 groups more comparable. Diagnosis and severity of acute calculous cholecystitis were defined according to the 2018 Tokyo guidelines.[18]

Procedures were performed after informed consent was obtained from the patients. All authors had access to the study data and reviewed and approved the final manuscript before submission.

Inclusion and exclusion criteria for the study arms

EUS-guided GBD. The inclusion and exclusion criteria for EUS-GBD were previously described.[15,19] Patients who were at very high risk for cholecystectomy and received EUS-GBD as a definitive treatment were included. Patients were deemed very high risk for cholecystectomy if they satisfied 1 or more of the following criteria: age ≥80 years, American Society of Anesthesiology grade 3 or above, age-adjusted Charlson comorbidity index >5, and/or Karnofsky score <50.[20] Elderly patients who had acute cholecystitis but refused operations were also included. The surgeon and anesthesiologist jointly made the decision regarding which patients were deemed to be at very high risk for cholecystectomy.

Laparoscopic cholecystectomy. Patients who were surgically fit and presented with fewer than 7 days of pain who received LC within 24 hours after diagnosis were included.[21-23] Those patients who received interval cholecystectomy with or without prior percutaneous cholecystostomy gallbladder drainage (PT-GBD) were not included. Patients were also excluded if they had prior abdominal surgery that rendered LC more difficult.

Study interventions

Before the procedures, patients were kept fasted for 6 hours and were given intravenous antibiotics (second-generation cephalosporin or equivalent). After the study interventions, antibiotics were continued for up to 1 week after the procedure or longer, depending on the clinical course of the patient.

EUS GBD. All procedures were performed by 1 of 2 endosonographers (A.Y.T. and S.M.C.) within 6 to 8 hours after diagnosis. The gallbladder was identified by a linear echoendoscope (GF-UTC 260; Olympus Co Ltd, Tokyo, Japan), and a suitable puncture site in the stomach or the duodenum without intervening blood vessels was located. EUS-GBD was performed by either the conventional or direct method. In the conventional method, the gallbladder was punctured with a 19-gauge needle, and the position was confirmed by aspiration of bile and/or minimal contrast injection. A .025-inch or .035-inch guidewire was passed through the needle and looped in the gallbladder. The delivery system of the cautery-enhanced lumen-apposing metal stent (LAMS; Axios; Boston Scientific, Marlborough, Mass, USA) was inserted. In the direct method, the delivery system of the stent was directly inserted into the gallbladder without prior needle insertion. A 10 mm × 10 mm stent system was used if the largest gallstone was smaller than 10 mm in size and a 15 × 10 mm stent was used if the largest gallstone was larger than 10 mm. The distal flange of the stent was deployed under EUS guidance, followed by deployment of the proximal flange under endoscopic guidance. Once deployed, the gallbladder was completely emptied by suction and irrigation until the effluent through the stent was clean (Fig. 1A). An additional double-pigtail plastic stent was inserted through the LAMS if there was concern that the gallstones could block the stent.

Laparoscopic cholecystectomy. LC was performed using the standard 4-port technique.[21] A 10-mm subumbilical port was inserted with the open Hasson's technique for insertion of the laparoscope under CO_2 pneumoperitoneum. Two 5-mm and one 10-mm ports were used as working ports. The gallbladder was retracted and the Calot's triangle exposed. The cystic artery and duct were isolated and individually ligated with clips. The gallbladder was then removed from the liver bed. In the event when dissection of the Calot's triangle was difficult, the gallbladder was removed by a fundus-first approach. Closed suction drains were inserted through the subcostal port

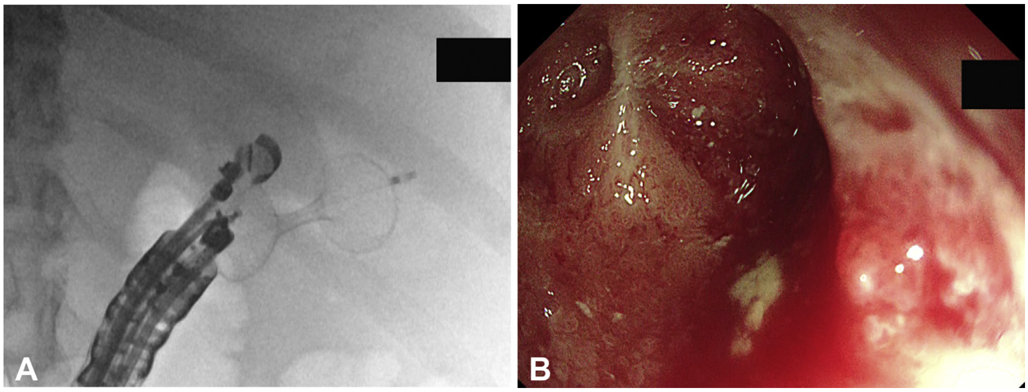


Figure 1. A, Radiographic imaging of EUS-guided gallbladder drainage after stent placement. **B,** Cholecystoscopic image showing a scarred gallbladder consistent with chronic cholecystitis changes.

to drain the subhepatic space at the end of the procedure. If the surgical anatomy was unclear or if the dissection was too difficult, the laparoscopic procedure was converted to an open subcostal approach.

Postprocedural management

Oral diets were resumed when the patient was afebrile and had presence of flatus or bowel output. The patients in the EUS-GBD arm were monitored for signs of improving or worsening sepsis. If resolution of signs and symptoms was not reached after 96 hours, then patency of stents was checked with endoscopy. If sepsis still failed to resolve, CT of the abdomen was performed to look for potential adverse events resulting from acute cholecystitis or the procedure. In the LC arm, patients were monitored for presence of postoperative adverse events. When an adverse event was suspected, a CT of the abdomen was performed to look for potential adverse events resulting from the procedure; these were then managed accordingly.

Follow-up interventions

Patients who received EUS-GBD were scheduled for a follow-up peroral cholecystoscopy 1 month after the procedure to check for clearance of stones.[24] The procedure was performed with the patient under conscious sedation. A regular endoscope was inserted through the gallbladder stent into the gallbladder to check for presence of gallstones (Fig. 1B). If all gallstones were cleared, the LAMSs were removed with rat-tooth forceps (FG-42L-1; Olympus Co Ltd) and replaced with 1 permanent 7F double-pigtail plastic catheter. If stones could not be completely cleared, patients were scheduled for another follow-up cholecystoscopy 1 month afterward. This was repeated until all stones were removed and the LAMS was removed. Gallbladder stents were placed permanently in patients who were too old or frail to undergo additional endoscopic procedures.

Outcome measurements

Outcome measurements included technical success, clinical success, 30-day adverse events, 30-day mortality, recurrent cholecystitis, recurrent biliary events, reinterventions and readmissions up to 1 year after the procedure, or death. Technical success was defined as the ability to access and drain the gallbladder by placement of a stent and maintenance of good drainage in the EUS-GBD group, whereas it was defined as the ability to perform a total cholecystectomy by laparoscopic or open means in the LC group. Clinical success was defined as improvement in clinical symptoms and laboratory tests. Only biliary tract–related adverse events after the 30-day period were recorded. The number of unplanned admissions because of gallstone-related disease or of study interventions was recorded up to 1 year.

Propensity score matching

As mentioned, patients who underwent EUS-GBD and LC differed significantly in premorbid status. To make the 2 groups more comparable, propensity score matching was used.[25] The propensity score was estimated using multivariable logistic regression with covariates age, sex, and age-adjusted Charlson score. Patients were individually matched on a 1:1 basis using a caliper width equal to .2 of the standard deviation of the logit of the propensity score, and 60 patients were identified (30 in each group).

Statistical analyses

We intended to show an equivalence between EUS-GBD and LC at a 2-sided significance level of .05, with an equivalence margin of 10%.[26] Bonferroni correction was used to adjust for multiple testing. Statistical analyses were performed using SPSS 20.0 statistical software (SPSS, Chicago, Ill, USA) and R software version 3.6.0, Free Software Foundation (Boston, Mass, USA). Comparisons were made by the χ^2 or Fisher exact test for categorical data and the Mann-Whitney U test or *t* test for continuous data, where appropriate.

RESULTS

During the study period, 144 patients were identified (74 EUS-GBD and 70 LC). Patients were matched by age,

TABLE 1. Comparison of outcomes between EUS-guided gallbladder drainage and laparoscopic cholecystectomy

	EUS-guided gallbladder drainage (n = 74)	Laparoscopic cholecystectomy (n = 70)	*P* value
Before propensity score matching			
Age, y	82.11 (9.66)	76.49 (4.71)	<.001
Sex, M/F	41/33	42/28	.615
Age-adjusted Charlson score	5.86 (1.79)	5.06 (1.03)	<.001
	EUS-guided gallbladder drainage (n = 30)	**Laparoscopic cholecystectomy (n = 30)**	***P* value**
After propensity score matching			
Age, y	78.0 (12.2)	76.4 (5.4)	.152
Sex, M/F	17 / 13	18 / 12	1
Age-adjusted Charlson score	4.5 (1.0)	4.4 (1.2)	.837

Values are mean (SD).

sex, and age-adjusted Charlson score with propensity score matching, and 60 patients were selected (30 EUS-GBD vs 30 LC). Table 1 shows the 3 parameters before and after matching. Before matching, age ($P < .001$) and age-adjusted Charlson scores ($P < .001$) were significantly different. After matching, the parameters were not significantly different.

The comparison in background demographics between the 2 groups after matching is shown in Table 2. There were no significant differences except that patients in the EUS-GBD group had longer durations of follow-up (571.9 days [475.6] vs 264.4 days [362.1], $P = .002$). The mean age-adjusted Charlson scores were 4.5 (standard deviation, 1.0) for EUS-GBD and 4.4 (standard deviation, 1.2) for LC ($P = .837$). Most patients had grades 1 and 2 acute cholecystitis.

The outcomes of the 2 procedures (EUS-GBD vs LC) are shown in Table 3. Technical success rates (100% vs 100%), clinical success rates (93.3% vs 100%, $P = 1$), hospital length of stay (6.8 days [8.1] vs 5.5 days [2.7], $P = 1$), 30-day adverse events (4 [13.3%] vs 4 [13.3%], $P = 1$), and 30-day mortality (2 [6.7%] vs 0 [0%], $P = 1$), although very similar, were unable to show equivalence between the 2 groups. Two patients in the EUS-GBD group did not achieve clinical success. Both patients died, 1 because of aspiration pneumonia and 1 because of uncontrolled sepsis. Apart from these 2 patients, 2 other patients had 30-day adverse events in the EUS-GBD group. One patient had upper GI bleeding requiring endoscopic hemostasis, and the other had a blocked stent because of gallstones requiring endoscopic insertion of an additional double-pigtail stent through the LAMS. In the LC group, 1 patient had intra-abdominal collections requiring percutaneous drainage. One patient had multiorgan failure requiring treatment in the intensive care unit. Another patient had upper GI bleeding requiring endoscopic hemostasis, and finally 1 patient had a chest infection that required prolonged antibiotic treatment. None of the patients in the LC group required conversion to open surgery, and none died.

The rates of recurrent biliary events (3 [10%] vs 3 [10%], $P = .784$), reinterventions (4 [13.3%] vs 3 [9.7%], $P = 1$), and unplanned readmissions (3 [10%] vs 3 [10%], $P = .784$) were also similar but again did not show equivalence. Three patients in the EUS-GBD and the LC group had recurrent biliary events, and all were because of the presence of common bile duct stones. These stones were not suspected on preprocedural imaging. These events all resulted in unplanned admissions, and the stones were removed by ERCP.

DISCUSSION

The current study is the first to compare the outcomes of EUS-GBD with LC after propensity score analysis. Although equivalence in the outcomes cannot be concluded because of lack of power, in the short term, the 30-day adverse event rate and mortality appeared to be comparable. In the longer term, recurrent biliary events and cholecystitis rates were also comparable between the groups. This suggests that EUS-GBD may reduce the risk of gallstone-related adverse events, and this may be a potential option in the group of patients who do not want to undergo cholecystectomy.

EUS-GBD is gaining popularity as an option of draining the gallbladder in patients at very high risk of cholecystectomy.[1-17] In a recently completed randomized controlled trial of EUS-GBD and percutaneous cholecystostomy, EUS-GBD was associated with reduced 1-year adverse events (25.6% vs 77.5%, $P < .001$), 30-day adverse events (12.8% vs 47.5%, $P = .010$), reinterventions after 30 days (2.6% vs 30%, $P = .001$), number of unplanned readmissions (15.4% vs 50%, $P = .002$), and recurrent cholecystitis (2.6% vs 20%, $P = .029$). Postprocedural pain scores and analgesic requirements were also lower ($P = .034$).[27]

TABLE 2. Comparison in background demographics between the 2 groups

	EUS-guided gallbladder drainage (n = 30)	Laparoscopic cholecystectomy (n = 30)	*P* value
Age, y	78.0 (12.2)	76.4 (5.4)	.152
Sex, M/F	17/13	18 / 12	1
Age-adjusted Charlson score	4.5 (1.0)	4.4 (1.2)	.837
White blood cell counts on admission, g/dL $\times 10^9$	16.0 (8.8)	18.8 (6.5)	.101
Severity of acute cholecystitis, I/II/III	12/16/2	9/18/3	.689
Mean follow-up duration, days (standard deviation)	571.9 (475.6)	264.4 (362.1)	.002

Values are mean (SD).

TABLE 3. Comparison of clinical outcomes of the 2 procedures

	EUS-guided gallbladder drainage (n = 30)	Laparoscopic cholecystectomy (n = 30)	*P* value
Technical success	30 (100)	30 (100)	
Clinical success	28 (93.3)	30 (100)	1
Length of hospital stay, days (mean ± SD)	6.8 (8.1)	5.5 (2.7)	1
30-day adverse events	4 (13.3)	4 (13.3)	1
30-day mortality	2 (6.7)	0 (0)	1
Recurrent cholecystitis	1 (3.3)	0 (0)	.168
Recurrent biliary events	3 (10.0)	3 (10.0)	.784
Reinterventions	4 (13.3)	3 (10.0)	1
Unplanned readmissions	3 (10.0)	3 (10.0)	.784

Values are n (%) unless otherwise indicated.

These findings were in line with a meta-analysis that included 495 patients.[28] EUS-GBD had fewer adverse events (odds ratio [OR], .43; 95% confidence interval [CI], .18-1.00; $P = .05$), shorter hospital stays (pooled standard mean difference, –2.53; 95% CI, –4.28 to –.78; $P = .005$), fewer reinterventions (OR, .16; 95% CI, .04-.042; $P < .001$), and fewer unplanned readmissions (OR, .16; 95% CI, .05-.53; $P = .003$). In a 3-way comparison of EUS-GBD, PT-GBD, and endoscopic transpapillary drainage, EUS-GBD was associated with shorter hospital stay and less additional surgical interventions.[14] Hence, EUS-GBD should be the preferred method of draining the gallbladder in patients provided the expertise is available. Furthermore, the gallbladder can be cleared of all gallstones by peroral cholecystoscopy performed through the stent after EUS-GBD.[29] A stone clearance rate of 88% after a mean number of 1.25 sessions (standard deviation, .46) of cholecystoscopy was reported. This may further reduce the risk of recurrent cholecystitis as compared with other methods of draining the gallbladder.

On the other hand, the outcomes of percutaneous cholecystostomy were compared with LC in several studies.[30,31] In a propensity score analysis comparing PT-GBD with LC using U.S. Medicare data, patients with PT-GBD had higher 30-day, 90-day, and 2-year mortality. Hospital stays were significantly longer, and readmissions were also higher at 30 days and 2 years. In another randomized study between LC and PT-GBD, PT-GBD was associated with significantly higher rates of major adverse events (65% vs 12%, $P < .001$), reinterventions (66% vs 12%, $P < .001$), recurrent biliary disease (53% vs 5%, $P < .001$), and longer hospital stays (9 days vs 5 days, $P < .001$). Thus, it remains intriguing as to whether EUS-GBD could result in comparable outcomes with LC, given that the approach provides significant advantages as compared with PT-GBD. The current study provides some initial data in support of EUS-GBD.

However, to make EUS-GBD a more acceptable option in surgical candidates, several important questions need to be answered, such as the feasibility of performing cholecystectomy after EUS-GBD and whether prior EUS-GBD would make subsequent cholecystectomy more difficult. In the only study comparing cholecystectomy after EUS-GBD and PT-GBD, cholecystectomy was possible in all patients.[32] The rates of conversions were similar between the 2 groups (15.38% vs 16.05%, $P = 1$), whereas the operative times were significantly longer in the PT-GBD groups ($P = .01$). The issue with EUS-GBD for cholecystectomy is that the drainage site needs to be closed during the operation, and it is suggested that a transgastric drainage would be easier for the surgeon to close.

There are several limitations to the current study. First, the current study has a small sample size and prone to Type II error. We attempted to make the 2 distinct populations more comparable by propensity score matching, but inherent bias can still exist. Furthermore, although EUS-GBD can treat acute cholecystitis and clear the gallbladder of all gallstones, the risk of recurrent gallstones remains. Hence, the need for subsequent cholecystectomy remains present in the next 5 to 10 years. However, in a 10-year study assessing the need for cholecystectomy after PT-GBD and successful percutaneous cholecystolithotomy, it was noted that only 20.9% of 182 patients eventually required cholecystectomy.[33] This suggests that although gallstone recurrence is common, most patients were still asymptomatic and did not require a cholecystectomy.

In conclusion, although this propensity score analysis was unable to demonstrate equivalence in outcomes between the 2 procedures because of a lack of power, the numbers still suggest that the outcomes of EUS-GBD and LC were comparable. The results support the role of EUS-GBD as an alternative to LC in patients who may or may not be surgically fit to undergo definitive cholecystectomy. Future studies with larger sample size and longer follow-up are required to confirm the efficacy.

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Abbreviations: EUS-GBD, EUS-guided gallbladder drainage; LAMS, lumen-apposing metal stent; LC, laparoscopic cholecystectomy; PT-GBD, percutaneous cholecystostomy gallbladder drainage.

DISCLOSURE: *The following authors disclosed financial relationships: A. Y. B. Teoh: Consultant for Boston Scientific, Cook, Taewoong, and Microtech Medical. All other authors disclosed no financial relationships.*

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