Thieme

Endoscopic ultrasound-guided gallbladder drainage reduces adverse events compared with percutaneous cholecystostomy in patients who are unfit for cholecystectomy

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Bibliography

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ABSTRACT

Background and study aim There are no data comparing endoscopic ultrasound (EUS)-guided gallbladder drainage (EGBD) with percutaneous cholecystostomy as a treatment for patients with acute cholecystitis.

Patients and methods This was a 1:1 matched cohort study of all patients who were unfit for cholecystectomy and underwent EGBD or percutaneous cholecystostomy instead for the treatment of acute cholecystitis. The outcomes were matched for age, sex, and American Society of Anesthesiologists grade. Outcome measures included the technical and clinical success rates, adverse events, hospital stay, the number of unplanned admissions, and mortality.

Results Between November 2011 and August 2014, a total of 118 patients were included in the study (59 EGBD, 59 percutaneous cholecystostomy). Technical and clinical success rates were similar. In the EGBD group, significantly fewer patients suffered from overall adverse events (19 [32.2%] vs. 44 [74.6%]; $P<0.001$) and serious adverse events (14 [23.7%] vs. 44 [74.6%]; $P<0.001$) compared to the percutaneous cholecystostomy group. Patients in the EGBD group required fewer unplanned admissions (4 [6.8%] vs. 42 [71.2%]; $P<0.001$), which were due to problems related to the cholecystostomy tube in 95.2%. The 30-day adverse event rates were similar between the groups (17 [28.8%] vs. 10 [16.9%]; $P=0.13$). For instance, recurrent acute cholecystitis occurred in 0 patients in the EGBD group and in 4 (6.8%) patients in the percutaneous cholecystostomy group ($P=0.12$). The 30-day mortality rates were non-significantly higher in the EGBD group (5 [8.5%] vs. 1 [1.7%]; $P=0.21$).

Conclusions EGBD and percutaneous cholecystostomy were both effective means of achieving gallbladder drainage. EGBD may be a promising alternative to percutaneous cholecystostomy for treatment of acute cholecystitis in patients who are unfit for surgery, provided that experienced endosonographers are available.

Introduction

Laparoscopic cholecystectomy is the gold standard for the treatment of acute cholecystitis [1]. In patients who are high-risk surgical candidates, percutaneous cholecystostomy is a valuable treatment option. Percutaneous cholecystostomy is safe, and is associated with high rates of technical and clinical success [2–6]. However, tube-related problems have been observed in up to 16.2% of patients and recurrent acute cholecystitis has been reported in 15.4% of patients [6].

Recently, the technique of endoscopic ultrasound (EUS)-guided gallbladder drainage (EGBD) has been described [7–16]. The procedure avoids the risk of tube-related problems. Furthermore, the cholecysto-enteric stoma created allows luminal access to the gallbladder for removal of gallstones. This may reduce the risk of recurrent cholecystitis. However, it is unclear how EGBD compares with percutaneous cholecystostomy. The aim of the current study was to compare EGBD with percutaneous cholecystostomy as a definitive management approach for acute cholecystitis in patients who are unfit for surgery.

Patients and methods

This was a retrospective 1:1 matched cohort study of all patients with acute calculous cholecystitis who were unfit for cholecystectomy. The study was approved by the ethical committees of the respective hospitals.

The diagnosis of acute cholecystitis was made according to the revised Tokyo guidelines [17]. All patients were considered unfit for cholecystectomy if they satisfied at least one of the following criteria: age ≥80 years, American Society of Anesthesiologists (ASA) grade 3 or above, age-adjusted Charlson Comorbidity Index score ≥4 and/or Karnofsky score <50 [18–21]. The anesthesiologists and surgeons of the respective hospitals jointly made the treatment decisions.

Patients underwent either EGBD or percutaneous cholecystostomy for acute cholecystitis between November 2011 and August 2014 in two university affiliated hospitals (one in Hong Kong and one in Spain). None of the patients received interval cholecystectomy. Percutaneous cholecystostomy was the standard treatment for these patients in each hospital initially. EGBD was introduced gradually from November 2011 and became the standard procedure in each of the hospitals during the later part of the study. For comparison, consecutive patients who underwent EGBD were matched by age (to within 5 years), sex, and ASA grade to another group of patients who received percutaneous cholecystostomy for acute cholecystitis in the hospital from Hong Kong during the same period. These patients were selected as they followed a postdrainage protocol, allowing objective comparison.

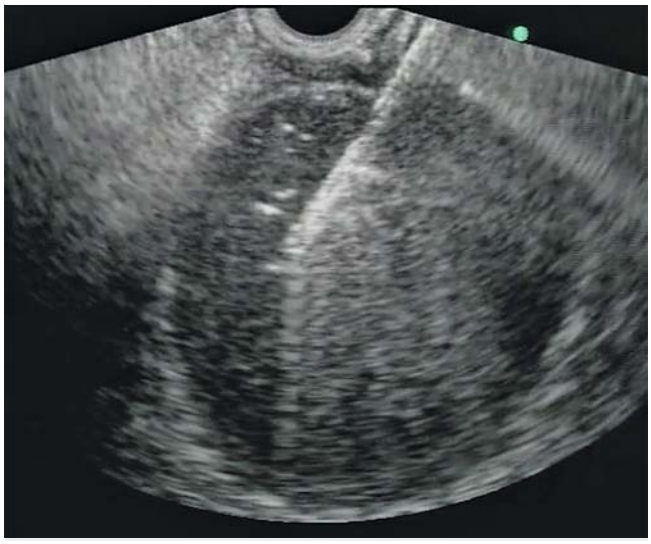
Study interventions

In patients with organ dysfunction (Tokyo guidelines grade 3), urgent interventions were performed as soon as possible within a few hours after the diagnosis was made. In patients with no organ dysfunction (Tokyo guidelines grade 2), drainage was performed within 24 hours after admission [17]. The patients were kept fasted for 6 hours and given intravenous antibiotics (second-generation cephalosporin or equivalent) before the procedure. After the procedure, antibiotics were continued for 1 week or longer, depending on the clinical course of the patient. The procedures are described below.

EGBD

All procedures were performed under conscious sedation or monitored anesthesia by dedicated endosonographers in the respective hospitals. The procedures were performed by one expert endosonographer in each hospital who had performed more than 50 pancreatic fluids collections and 50 bile duct drainage procedures under EUS guidance.

The gallbladder was identified using 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. The gallbladder was punctured with a 19-gauge needle, and the position was confirmed by the aspiration of bile or contrast injection (to avoid flare up of sepsis) and visualized using fluoroscopy (▶ **Fig. 1**, ▶ **Video 1**). A 0.025- or 0.035-inch guidewire was passed through the needle and looped within the gallbladder (▶ **Fig. 2**). Two versions of the lumen-apposing stent were used in the study. Initially, the cold AXIOS stent was used (Boston Scientific, Marlborough, Massachusetts, USA). The needle track was dilated by a 6-Fr cystotome (Endo-flex GmbH, Voerde, Germany), and a 4-mm biliary balloon (Hurricane RX dilation balloon; Boston Scientific). The



▶ **Fig. 1** The gallbladder was punctured with a 19-gauge needle.

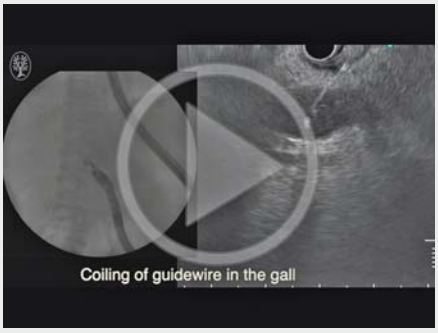
delivery system for the AXIOS stent was then inserted. From December 2013, a newer version of the lumen-apposing stent – the hot AXIOS – became available. The device is equipped with a cautery device at the tip of the delivery system and thus allows insertion of the system without prior dilation [7].

A 10×10 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 and the proximal flange was released under endoscopic guidance (▶ **Fig. 3**, ▶ **Fig. 4**). Once deployed, the gallbladder was completely emptied by suction and irrigation until the effluent through the stent was clean.

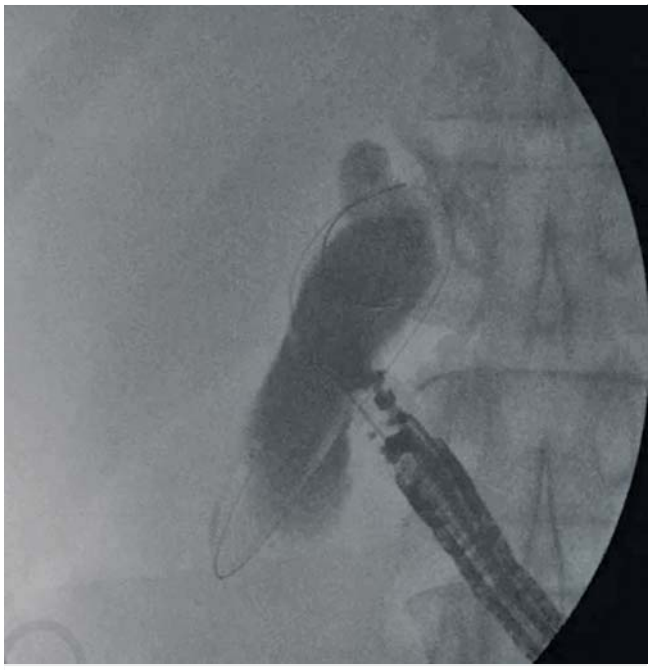
Percutaneous cholecystostomy

Four experienced specialist interventional radiologists who were certified for the procedure in the Hong Kong hospital performed the procedures under local anesthesia. Percutaneous cholecystostomy was performed under real-time ultrasound

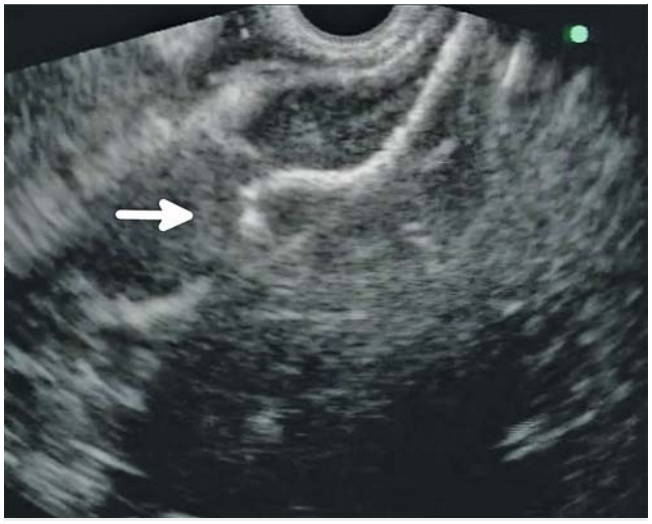
VIDEO 1



▶ Video 1: Endoscopic ultrasound-guided gallbladder drainage using a lumen-apposing stent.



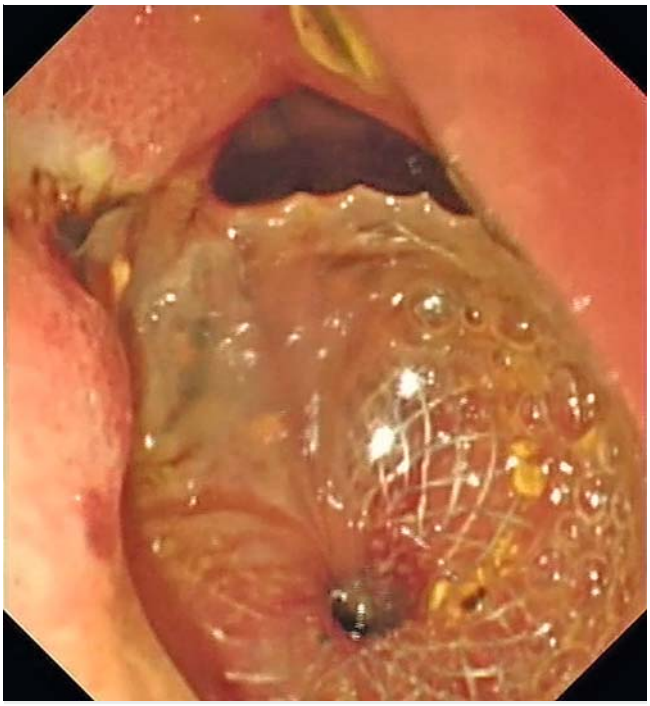
▶ **Fig. 2** Looping of the guidewire in the gallbladder.



▶ **Fig. 3** Deployment of the distal flange (arrow) under endoscopic ultrasound guidance.

and fluoroscopic guidance via a transhepatic or transperitoneal approach. A transhepatic approach was preferred, but the decision of the approach depended on user preferences, the best ultrasound view available, and patient factors (including presence of ascites or uncorrected coagulopathy).

The gallbladder wall was punctured using an 18-gauge needle (Cook Medical, Bloomington, Indiana, USA) under direct ultrasound visualization. Confirmation of correct needle tip position within the gallbladder lumen was ascertained by aspiration of bile. The gallbladder lumen was then opacified by injecting small amounts of contrast medium (Omnipaque 300 mg I/mL; GE Healthcare, Shanghai, China) under fluoroscopy. A 0.035-inch Amplatz guidewire (Argon Medical Devices Inc., Plano, Texas, USA) was inserted through the needle and securely coiled inside the gallbladder lumen. This was followed by serial tract dilations. Once the tract had been adequately dilated, a suitable size of pigtail drainage catheter (6- to 10-Fr; Bard Angiomed, Karlsruhe, Germany) was inserted into the gallbladder lumen over the guidewire.



▶ **Fig. 4** Deployment of the proximal flange under endoscopic visualization.

Postprocedural management

Patients were monitored after the procedure, and fluid diets were resumed the next day if patients were afebrile and had presence of flatus or bowel output. Diets were then stepped up to a regular low-fat diet if the fluid diet had been tolerated.

A positive response to drainage was defined as resolution of signs, reduction in temperature to less than 37.5 °C, and reduction in white cell counts by ≤ 25 % or < 10×10^3/mm within 72 hours of drainage. If a positive response was not observed within 72 hours, patients were assessed for potential complications resulting from acute cholecystitis or the procedure. Patients were discharged if they were afebrile and had decreasing white cell counts.

Follow-up interventions

EGBD patients

Patients who underwent EGBD were scheduled for a follow-up cholecystoscopy 12 weeks after the procedure to check for clearance of stones. All peroral cholecystoscopies were performed under carbon dioxide insufflation with a 9.8-mm magnifying endoscope equipped with water-jet irrigation (GIF-

H290Z; Olympus) (▶ **Video 2**). In patients with stones that were too large to pass out spontaneously, basket mechanical lithotripsy (BML-110A-1; Olympus) was employed to break down the stones, followed by laser lithotripsy (VersaPulse PowerSuite; UHS, Minneapolis, Minnesota, USA) if this was not successful. In patients with suspected concomitant common bile duct (CBD) stones, a cholecystogram was performed by injection of contrast through the cystic stump opening under flouroscopy. Endoscopic retrograde cholangiopancreatography was performed during the same session for removal for CBD stones. Patients were then scheduled for another follow-up cholecystoscopy 1 month later. The procedure was repeated until all stones had been removed. If gallstones were absent from the gallbladder, the AXIOS stent was removed using rat tooth forceps (FG-42L-1; Olympus). In patients who refused further endoscopic procedures because of their co-morbid condition, the gallbladder stents were left in place permanently.

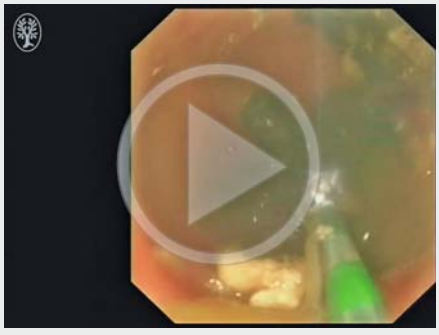
Percutaneous cholecystostomy patients

Patients in the percutaneous cholecystostomy group received a tube cholecystogram 6 – 8 weeks after the procedure to check the patency of the cystic duct. If the duct was patent, the cholecystostomy tubes were either removed or plugged with a spigot and left in situ. If the cystic duct was obstructed, long-term cholecystostomy tube drainage to a bag was arranged.

Outcome measures

The outcome measures included the technical and clinical success rates, adverse event rates, hospital stay, the number of unplanned admissions, and mortality. Technical success was defined as the ability to access and drain the gallbladder by placement of a drainage tube or stent with immediate drainage of bile. Clinical success was defined as improvement in clinical symptoms and decreasing white cell counts within 5 days after the procedure. Only biliary tract-related adverse events after the 30-day period were recorded, as many of the patients had other co-morbidities that were likely to require frequent hospital admission. The severity of adverse events was graded according to the lexicon of endoscopic adverse events [22].

VIDEO 2



▶ Video 2: Peroral cholecystoscopy laser lithotripsy of a gallstone.

Statistical analyses

Statistical analyses were performed using SPSS statistical software version 20.0 (IBM Corp., Armonk, New York, USA). Comparisons were made by McNemar's test for categorical data, and Wilcoxon signed-rank test for nonparametric continuous data. Predictors of adverse events were analyzed using Cox proportional hazards regression using the enter method by stratifying the model based on a variable that identified the matched pairs. A two-sided P value of <0.05 was considered to be significant.

Results

A total of 118 patients were included in the study (59 EGBD, 59 percutaneous cholecystostomy). There were no significant differences in the background demographic details between the two groups of patients, except for the duration of follow-up (▶ **Table 1**). In the EGBD group, the gallbladder was drained from the antrum of the stomach in 36 patients and from the first part of the duodenum in the remaining patients. In the percutaneous cholecystostomy group, 45 patients had their gallbladders drained transperitoneally, and the remaining patients underwent a transhepatic approach. Some of the results from these patients have been presented previously in another study [16].

Technical and clinical success

The technical success (96.6 % vs. 100 %; $P=0.15$) and the clinical success (89.8 % vs. 94.9 %; $P=0.30$) were comparable between the two groups (▶ **Table 2**).

EGBD was technically and clinically unsuccessful in two patients: a safe site to puncture the gallbladder could not be identified in one patient, and another patient suffered from peritonitis after EGBD as a result of stent migration. In the percutaneous cholecystostomy group, three patients did not achieve clinical success: one patient died 1 day after the procedure as a result of severe sepsis that led to acute renal failure and death; and in two patients, blocked or dislodged cholecystostomy tubes required reintervention within 5 days after the index procedure.

Adverse events

The overall adverse event rates were significantly higher in patients who underwent percutaneous cholecystostomy (19 [32.2 %] vs. 44 [74.6 %]; $P<0.001$) (▶ **Table 2**, ▶ **Table 3**). No differences in the intraprocedural adverse event rates were observed between the two groups (3 [5.1 %] vs. 0 [0 %]; $P=0.24$). In the EGBD group, two patients suffered from self-limiting pneumoperitoneum and were treated conservatively. One patient suffered from progressive abdominal pain with peritonitis after the EGBD. Emergency surgery was offered and the distal flange was noted to have migrated outside the gallbladder. The patient died after the surgery. All intraprocedural adverse events occurred in the first 20 procedures performed by the institution.

▶ **Table 1** Comparison of the background demographic data between the two groups.

	EGBD n = 59	Percutaneous cholecystostomy n = 59	*P* value
Age, mean (SD), years	82.7 (7.9)	81.2 (10.4)	0.71
Sex, M/F, n	30/29	30/29	1
ASA grading (I/II/III/IV), n	1/9/30/19	1/9/29/20	1
Age-adjusted CCI, mean (SD)	5.6 (1.9)	5.8 (1.7)	0.24
Size of gallbladder, mean (SD), cm	8.4 (2.2)	8.8 (2.1)	0.65
Size of gallstones, mean (SD), mm	14.2 (9.4)	13.9 (6.9)	0.81
Duration of follow-up, mean (SD), days	450.7 (343.1)	834.1 (416.6)	<0.001

EGBD, endoscopic ultrasound-guided gallbladder drainage; ASA, American Society of Anesthesiologists; CCI, Charlson Co-morbidity Index.

▶ **Table 2** Comparison of the clinical outcomes between the two groups.

	EGBD n = 59	Percutaneous cholecystostomy n = 59	*P* value
Technical success, n (%)	57 (96.6)	59 (100)	0.15
Clinical success, n (%)	53 (89.8)	56 (94.9)	0.30
30-day mortality, n (%)	5 (8.5)	1 (1.7)	0.21
Overall adverse events, n (%)	19 (32.2)	44 (74.6)	<0.001
Intraprocedural adverse events, n (%)	3 (5.1)	0 (0)	0.24
30-day adverse events, n (%)	17 (28.8)	10 (16.9)	0.13
Severe adverse events, n (%)	14 (23.7)	44 (74.6)	<0.001
Unplanned admissions related to the intervention, n (%)	4 (6.8)	42 (71.2)	<0.001
Recurrent acute cholecystitis, n (%)	0 (0)	4 (6.8)	0.12

EGBD, endoscopic ultrasound-guided gallbladder drainage.

There were also no significant differences in the 30-day adverse event rates (17 [28.8%] vs. 10 [16.9%]; $P=0.13$), and the observed difference in adverse events occurred during the subsequent follow-up period. Serious adverse events were more frequent in the percutaneous cholecystostomy group (14 [23.7%] vs. 44 [74.6%]; $P<0.001$). Patients who underwent percutaneous cholecystostomy had significantly more unplanned admissions related to the intervention (4 [6.8%] vs. 42 [71.2%]; $P<0.001$) (▶ **Table 2**, ▶ **Table 4**). Problems related to the cholecystostomy tube were responsible for 95.2% of the admissions. Tube dislodgement occurred in 17 patients, obstruction in 12 patients, and wound infection or peritubal leak in 6 patients (▶ **Table 4**). A total of 16 patients had more than one unplanned admission for problems related to the cholecystostomy tube that required reintervention or treatment.

30-day mortality

The 30-day mortality rates were higher in the EGBD group but the difference was not statistically significant (5 [8.5%] vs. 1 [1.7%]; $P=0.21$). In the EGBD group, two deaths were due to uncontrolled sepsis and multiorgan failure after the drainage procedure, one was due to pneumonia, one was due to acute coronary syndrome, and one was due to a migrated stent, as mentioned above. In the percutaneous cholecystostomy group, one death was due to acute renal failure. These cases were all counted as clinical failure.

Recurrence of cholecystitis

The rate of recurrent acute cholecystitis was similar between the two groups (0% vs. 6.8%; $P=0.12$). A total of 17 patients (28.8%) in the EGBD group had their stents removed at 3 months, after cholecystoscopy through the stent confirmed absence of stones. In the remaining patients, the gallbladder stents were left in place permanently.

In the percutaneous cholecystostomy group, tube cholecystogram at 6–8 weeks demonstrated a patent cystic duct in 28 patients (47.5%). These patients had their cholecystostomy tubes either removed or plugged with a spigot. Among the four patients who developed recurrent cholecystitis in the percutaneous cholecystostomy group, cholecystogram showed a patent cystic duct in two patients and their cholecystostomy were plugged initially. In the other 2 patients, the cholecystostomy tubes had become dislodged.

▶ **Table 3** The 30-day adverse events in both groups.

30-day adverse events, n	EGBD n = 59	Percutaneous cholecystostomy n = 59	*P* value
Patients with ≥ 1 adverse event, n (%)[1]	17 (28.8)	10 (16.9)	0.13
Intraprocedural adverse events	3	0	
Multiorgan failure	3	0	
Pericholecystic collection	2	2	
Acute coronary syndrome	2	2	
Congestive heart failure	0	1	
Atrial fibrillation	0	2	
Hypotension	0	2	
Pulmonary embolism	0	1	
Pneumonia	3	1	
Acute renal failure	0	3	
Bleeding	2	0	
Urinary tract infection	2	0	
Tube dislodgement	0	1	
Stent obstruction	1	0	

EGBD, endoscopic ultrasound-guided gallbladder drainage.
[1] Some patients had more than one adverse event.

▶ **Table 4** Reasons for unplanned admissions in the percutaneous cholecystostomy group.

	n = 42
Tube dislodgement	17
Tube obstruction	12
Recurrent acute cholecystitis	4
Wound infection	4
Peritubal bile leak	2
Acute cholangitis	1
Miscellaneous causes	2

Subgroup analyses

Subgroup analyses compared the differences in outcomes based on the type of AXIOS stent used, the institution, and the location of the puncture site for drainage in patients who underwent EGBD. EGBD was performed with the cold AXIOS stent in 49 patients and the hot AXIOS stent in 10 patients (▶ **Table 5**). There were no significant differences in the technical and clinical success rates, 30-day mortality, and the overall and intraprocedural adverse event rates. Similarly, no differences in the outcomes of EGBD were observed based on the institution (▶ **Table 6**) or the puncture site (▶ **Table 7**).

Predictors of adverse events

The predictors of overall adverse events were analyzed by Cox's proportional hazards regression (▶ **Table 8**). Only the use of percutaneous cholecystostomy was a significant predictor (hazard ratio 5.19, 95 %CI 2.23 – 12.08; $P < 0.001$).

Discussion

In the current study, EGBD was comparable to percutaneous cholecystostomy in terms of technical and clinical success rates. Overall adverse events, serious adverse events, and unplanned admissions were significantly higher in patients who underwent percutaneous cholecystostomy, mainly as a result of problems related to the cholecystostomy tube. The use of percutaneous cholecystostomy was the only significant predictor for overall adverse events. No differences in the outcomes of EGBD were observed based on the institution, puncture site, or the type of stent used.

Percutaneous cholecystostomy is the gold standard for gallbladder drainage in high-risk patients who cannot undergo cholecystectomy [2, 3]. However, the procedure is associated with potential adverse events in 0 % – 25 % of patients, including intrahepatic hemorrhage, pneumothorax, and biliary peritonitis [4]. In addition, percutaneous cholecystostomy has several other disadvantages. The catheter for drainage has to remain in place until a mature percutaneous tract is created or until interval cholecystectomy can be performed. Inadvertent tube removal and tube migration occurs in 8.6 % of patients (range 0 % – 25 %), ne-

▶ **Table 5** Comparison of the clinical outcomes of endoscopic ultrasound-guided gallbladder drainage between the cold and hot AXIOS stents.

	Cold AXIOS[1] n = 49	Hot AXIOS[1] n = 10	*P* value
Technical success, n (%)	47 (95.9)	10 (100)	1
Clinical success, n (%)	43 (87.8)	10 (100)	0.58
30-day mortality, n (%)	5 (10.2)	0 (0)	0.58
Overall adverse events, n (%)	17 (34.7)	2 (20)	0.48
Intraprocedural adverse events, n (%)	3 (6.1)	0 (0)	1
30-day adverse events, n (%)	16 (32.7)	1 (10)	0.25

[1] AXIOS stent, Boston Scientific, Marlborough, Massachusetts, USA.

▶ **Table 6** Comparison of the clinical outcomes of endoscopic ultrasound-guided gallbladder drainage based on institution.

	Hospital 1 n = 24	Hospital 2 n = 35	*P* value
Technical success, n (%)	24 (100)	33 (94.3)	0.51
Clinical success, n (%)	22 (91.7)	31 (88.6)	1
30-day mortality, n (%)	2 (8.3)	3 (8.6)	1
Overall adverse events, n (%)	11 (45.8)	8 (22.9)	0.09
Intraprocedural adverse events, n (%)	2 (8.3)	1 (2.9)	0.56
30-day adverse events, n (%)	9 (37.5)	8 (22.9)	0.25

▶ **Table 7** Comparison of the clinical outcomes of endoscopic ultrasound-guided gallbladder drainage based on puncture site.

	Antrum n = 36	Duodenum n = 23	*P* value
Technical success, n (%)	34 (94.4)	23 (100)	0.52
Clinical success, n (%)	31 (86.1)	22 (95.7)	0.39
30-day mortality, n (%)	4 (11.1)	1 (4.3)	0.64
Overall adverse events, n (%)	12 (33.3)	7 (30.4)	1
Intraprocedural adverse events, n (%)	3 (8.3)	0 (0)	0.27
30-day adverse events, n (%)	11 (30.6)	6 (26.1)	0.78

▶ **Table 8** Predictors of overall adverse events, analyzed by Cox's proportional hazards regression.

Parameter	Univariate analysis		Multivariate analysis	
	P value	HR (95 %CI)	*P* value	HR (95 %CI)
Age	0.13	1.20 (0.99 – 1.05)	0.68	1.00 (0.97 – 1.04)
Sex	0.27	0.74 (0.43 – 1.26)	0.32	0.74 (0.41 – 1.34)
ASA ≥ 3	0.97	1.02 (0.46 – 2.24)	0.37	0.67 (0.27 – 1.62)
Age-adjusted CCI	0.19	1.11 (0.95 – 1.29)	0.30	1.10 (0.92 – 1.31)
Technical success	0.04	8.84 (1.11 – 70.14)	0.41	0.32 (0.02 – 4.75)
Clinical success	0.31	1.48 (0.69 – 3.16)	0.47	1.41 (0.55 – 3.63)
Intraprocedural complications	0.02	4.09 (1.22 – 13.70)	0.63	0.67 (0.14 – 3.30)
Underwent percutaneous cholecystostomy	< 0.001	5.01 (2.43 – 10.33)	< 0.001	5.19 (2.23 – 12.08)

HR, hazard ratio; CI, confidence interval; ASA, American Society of Anesthesiologists; CCI, Charlson Co-morbidity Index.

cessitating repeated admissions and procedures [3]. Furthermore, the external catheter is associated with discomfort, pain, and cosmetic disfigurement, and continuous care of the cholecystostomy tube is required. Thus, there is a need for a better alternative to achieve gallbladder drainage in these patients.

EUS-guided transmural gallbladder drainage was first described in 2007 [8, 9]. In the initial studies, a transmural nasobiliary drainage tube or plastic stent was inserted under EUS-guidance in 12 patients with acute cholecystitis who were unsuitable for cholecystectomy. Technical and functional success rates of 100 % were reported, with adverse events occurring in two patients (minor bile leak and pneumoperiotoneum). These studies were then followed by a randomized study comparing EUS-guided transmural drainage using a nasocystic catheter with percutaneous cholecystostomy as intermediate treatments before cholecystectomy [10]. Both methods showed high rates of technical (97 % vs. 97 %) and clinical (100 % vs. 96 %) success, and there were no difference in morbidities. However, the pain scores at 24 hours in the EUS group were significantly lower compared with those in the percutaneous cholecystostomy group. The study concluded that both techniques were comparable in terms of technical feasibility and there were no differences in safety. The naso-gallbladder drain may also have an added advantage for irrigation of the gallbladder in patients with empyema of the gallbladder.

Recently, several studies have described the use of EUS-specific metallic stents for EGBD [7 – 11, 16]. These stents possess unique properties that could address the drawbacks associated with nasobiliary or plastic stents for transmural drainage. These stents have been designed with antimigratory properties, are fully covered to prevent bile or intestinal content leakage, and some possess features designed to facilitate organ lumen apposition [23].

In two previous studies, 18 patients with acute cholecystitis underwent EGBD with the AXIOS stent [12, 13]. The AXIOS stent is a biflanged covered metallic stent that claims lumen-apposing properties. Technical success was achieved in 16 patients (88.9 %) and clinical success was achieved in all patients. Adverse events occurred in one patient (bleeding) and this was managed conservatively. In seven patients (38.9 %), gallstones were removed from the gallbladder. In another study, three patients with acute cholecystitis underwent drainage with the SPAXUS stent (Niti-S; Taewoong, Ilsan, South Korea) [14]. The SPAXUS stent is a biflanged stent that folds onto itself to bring about lumen apposition. All stents were successfully placed and none of the patients suffered from adverse events.

To assess the long-term outcomes of EGBD in patients who are unsuitable for surgery, our group recently conducted a prospective multicenter study of 30 patients who underwent EGBD with the AXIOS stent [16]. The technical success rate was 90 % and the clinical success rate was 100 %. Stent-related adverse events occurred in four patients (15 %; one mucosal gangrene of the gallbladder, one hemobilia, one sepsis, and one aspiration pneumonia). The stent was removed in 15 patients after a mean (SD) of 91 (24) days, after cholecystoscopy showed no residual stones in the gallbladder. Similarly, Choi et al. reported on the long-term outcomes after EGBD in 63 patients [15]. Late adverse events developed in four patients (7.1 %): stent migration in two patients and recurrent acute cholecystitis due to stent occlusion in another two patients. The cumulative stent patency rate was 86 % at 3 years. These studies demonstrate that EGBD may serve as a definitive procedure for the treatment of acute cholecystitis in high-risk patients. And indeed, a lower rate of recurrent acute cholecystitis was observed in the EGBD group in the current study.

The current study has several limitations. First, patients who underwent percutaneous cholecystostomy were followed up for longer periods of time, as more patients received EGBD in the later part of this study. This may result in lead-time biases, exaggerating the adverse event rate of percutaneous cholecystostomy. To take into account the difference in the duration of follow-up, the Cox proportional hazards regression was used to adjust for time-dependent variables. Only the treatment group was a significant predictor, and patients in the percutaneous cholecystostomy group were 5 times more likely to suffer from an adverse event. Second, patients selected for percutaneous cholecystostomy in the historical cohort may have been more severely ill at presentation and there may be potential for selection bias. Furthermore, a number of anatomical factors may limit the technical feasibility of EGBD. These include the thickness of tissue between the gallbladder and the duodenum or stomach, the distensibility of the gallbladder, and the presence of a contracted or fibrotic gallbladder. In addition, one patient in the EGBD group died after a mis-deployed stent was not detected during the procedure. This serves as a caution, as an unsuccessful EGBD procedure may lead to disastrous outcomes, and it is important that the endoscopist recognizes any adverse events promptly and manages them accordingly. A higher mortality rate was also observed in the EGBD group, although the difference did not reach statistical significance.

In conclusion, EGBD and percutaneous cholecystostomy were both effective means of draining the gallbladder in patients who were unfit for cholecystectomy. EGBD reduced the overall adverse event rate, serious adverse event rate, and the number of unplanned admissions. EGBD may be a promising alternative to percutaneous cholecystostomy as the treatment of choice in patients who are unfit for surgery, provided that experienced endosonographers are available.

Competing interests

None

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