



Digestive Endoscopy

International collaborative study on EUS-guided gallbladder drainage: Are we ready for prime time?[☆]



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ABSTRACT

Background: Cholecystectomy remains the gold standard treatment of cholecystitis. Endoscopic treatment of cholecystitis includes transpapillary gallbladder drainage. Recently, endoscopic ultrasound-guided transmural drainage of the gallbladder (EUS-GBD) has been reported. This study reports the cumulative experience of an international group performing EUS-GBD.

Methods: Cases of EUS-GBD from January 2012 to November 2013 from 3 tertiary-care institutions were captured in a registry. Patient demographics, disease characteristics, procedural and clinical outcomes were recorded.

Results: 35 patients (15 malignant, 20 benign) were included. Median age was 81 years (SD = 13.76 years), sixteen (46%) were males. Median follow-up was 91.5 days (SD = 157 days). Transmural access was obtained from the stomach ($n=17$) or duodenum ($n=18$). Stents placed included plastic ($n=6$), metal ($n=20$), or combination ($n=7$). Technical success was achieved in 91.4% ($n=32$). Immediate adverse events (14%) included: bleeding, stent migration, cholecystitis and hemoperitoneum. Delayed adverse events (11%) included abscess formation and recurrence of cholecystitis. Long-term clinical success rate was 89%. Stent type and puncture site were not associated with immediate ($p=0.88$, $p=0.62$), or long-term ($p=0.47$, $p=0.27$) success.

Conclusions: EUS-GBD appears to be feasible, safe, and effective. Prospective studies are needed to confirm these findings and identify the best technique to use.

Clinical trial registration: NCT01522573.

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1. Introduction

Acute cholecystitis results from obstruction to the cystic duct secondary to multiple causes, of which cholelithiasis is the most common (90–95% of the cases) followed by benign or malignant biliary strictures [1,2]. It affects nearly 500,000 Americans annually and 6.0% of cases can be complicated with multiple organ failure

[1,3]. Cholecystectomy is the gold standard treatment of acute cholecystitis [3,4]. However, some patients have significant comorbidities, are at high risk for surgical intervention, have limited life expectancy secondary to advanced malignancy and thus are not candidates for surgery. Non-surgical gallbladder drainage in these cases is the only available lifesaving treatment [3–5]. Percutaneous gallbladder drainage (PTGBD) has been used for years with reported good outcomes. However, it carries risks of liver injury, pneumothorax, tube malfunction, bile leak, skin site infection and is associated with a decrease in the quality of life [3,5,6]. The complication rate of PTGBD can reach up to 12% [5]. Use of PTGBD is also limited in patients with massive ascites, coagulopathy or an intervening loop of bowel between the diaphragm and the liver. Transpapillary drainage of the gallbladder is another available

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option. It can be limited by technical difficulties due to biliary or pancreatic malignancies or previously placed metallic stents [3–5]. Recently, the growing experience with endoscopic ultrasound-guided drainage of pancreatic pseudocysts and other EUS guided procedures has led endoscopists to adopt a new approach: endoscopic ultrasound guided transenteric gallbladder drainage (EUS-GBD) [6]. This study reports the cumulative experience of an international collaborative group performing EUS-GBD.

2. Materials and methods

2.1. Patient selection

Patients undergoing endoscopic ultrasound guided gallbladder drainage from three international tertiary-care institutions between January 2012 and November 2013 were captured in a dedicated registry (IRB approval 11/2011, NCT01522573). A total of 35 cases of EUS-GBD were included and reviewed retrospectively. Thirty-one patients were poor surgical candidates because they were either diagnosed with unresectable cancer or had many comorbidities that precluded surgery; and four refused any surgical intervention. Fourteen patients required gallbladder drainage due to malignant disease. Risks, benefits and alternatives were explained and written informed consents were obtained from all patients before the procedure. Cases were performed by advanced endoscopists with extensive EUS and endoscopic retrograde cholangiopancreatography (ERCP) experience.

2.2. Data collection

The following variables were collected: age, sex, prior ERCP with transcystic drainage, prior percutaneous drainage, benign or malignant disease, altered anatomy, puncture site, type of stent, immediate and final outcome, immediate and delayed complications. Immediate complications was defined as complications occurring within 30 days of procedure, while delayed complications were defined as complications occurring from 30 days to 90 days post procedure.

2.3. Procedural technique

None of the patients were managed conservatively once they were diagnosed with acute cholecystitis.

Prior to endoscopic drainage, all patients were placed on IV antibiotic therapy.

EUS-GBD was performed using the curved linear array echoendoscopes and under fluoroscopic guidance. Punctures were performed using either 19-gauge EUS needles or direct cautery access with needle-knives or cystotome, depending on operator's preference. After needle access, the puncture tract was serially dilated prior to stent insertion using cystotomes or balloon dilators. Access to the gallbladder was obtained either from the antrum or the duodenal bulb. After obtaining access to the gallbladder three different types of stents were deployed: self-expandable metal stent (SEMS), lumen apposing metallic stent (LAMS) (Axios, Xlumen, Mountain View, CA) or double-pigtail plastic stent. All stents were inserted under direct fluoroscopic and EUS control to monitor proper placement and facilitate drainage. The size of the stents used was estimated by approximation to the transmural distance (between gallbladder and enteral lumen).

2.4. Definitions and primary outcomes

The following primary outcomes were measured (1) technical success, (2) clinical success and (3) adverse events. Technical success was defined as the ability to access and drain the gallbladder.

Table 1
Patient characteristics (n = 35).

Age	81 ± 13.7
Males	46% (16)
Diagnosis	
Benign	57% (20)
Malignant	43% (15)
Prior procedures	
ERCP with transcystic drain attempt	57% (20)
Percutaneous drainage	26% (9)
Indication	
Poor surgical candidate	89% (31)
Refused surgical treatment	11% (4)
Puncture site	
Stomach	66% (23)
Duodenum	31% (11)
Stomach and duodenum	3% (1)
Puncture instrument	
Endoscopic ultrasound (EUS) needle	32% (11)
Needle knife	26% (9)
Cystostome	40% (14)
Anatomy	
Normal	91% (32)
Altered anatomy (Roux-en-Y, other)	9% (3)
Stent type	
Lumen-apposing metal stent	42% (14/33)
Self-expandable metal stents	39% (13/33)
Plastic	18.5% (6/33)
Combination	21% (7/33)

Clinical success was defined as complete resolution of symptoms with normalization of laboratory test data. Adverse events were defined as any procedure related event occurring during or after the procedure, such as bleeding, stent migration, bile leak, hemoperitoneum, abscess formation and/or recurrence of cholecystitis.

2.5. Statistical analysis

Descriptive statistics were calculated for all demographic, imaging, and clinical variables and reported as mean + standard deviation (S.D.) or as a proportion. Univariate analysis was performed using Chi-square test and Fisher's exact test for categorical variables and student's *t*-test for continuous variables or Mann-Whitney as required. Multivariate analysis was performed using logistic regression to evaluate the factors influencing the success of the EUS-GBD. All statistical analysis was conducted using STATA 13.0. A *p*-value of <0.05 was considered significant.

All authors had access to the study data, and reviewed and approved the final manuscript.

3. Results

A total of 35 patients underwent EUS-GBD. Indications for the procedure included patients with acute cholecystitis who were unsuitable for surgery due to malignancy (*n* = 15) and/or multiple comorbidities (*n* = 31). All patients had acute cholecystitis based on the clinical criteria that included right upper quadrant pain, fever, positive Murphy's sign, and leukocytosis and associated with radiologic findings confirming the diagnosis and feasibility of drainage i.e.: distended gallbladder, thickened gallbladder wall with eventual pericholecystic fluid without sign of perforation. The median age was 81 (SD = 13.76 years). There were 16 men (46%) and 19 women (54%) (Table 1). The median follow up period was 91.5 days (SD: 157 days).

3.1. Procedure

The initial access was obtained using the transgastric route in 17 patients and transduodenal in 18 patients. The puncture was made using EUS needles in 10/35 patients (29%), needle knife in

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