



# Safety of EUS-guided gallbladder drainage using a lumen-apposing metal stent in patients requiring anticoagulation

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**Background and Aims:** EUS-guided gallbladder drainage (EUS-GBD) can be used to treat acute cholecystitis in patients with medical comorbidities that prevent definitive operative management. Historically, nonsurgical management of cholecystitis was achieved by way of percutaneous gallbladder drainage.

**Methods:** We examined the periprocedural bleeding rate of EUS-GBD for acute cholecystitis using lumen-apposing metal stents in 5 high-surgical-risk patients requiring anticoagulation. Data on 5 nonoperative candidates with acute cholecystitis who underwent EUS-GBD were studied retrospectively.

**Results:** There were no immediate or delayed postprocedure adverse events, including bleeding.

**Conclusions:** Although further study is needed, EUS-GBD appears safe in patients who require periprocedural anticoagulation. (VideoGIE 2020;5:500-3.)

EUS-guided gallbladder drainage (EUS-GBD) can be used to treat acute cholecystitis in patients with medical comorbidities that prevent definitive operative management. Historically, nonsurgical management of cholecystitis was achieved by way of percutaneous gallbladder drainage (PTGBD). However, the percutaneous approach involves a number of potential adverse events, including bile leak, bowel perforation, catheter dislodgement, and bleeding in those on anticoagulation or with underlying coagulopathy.<sup>1-3</sup>

EUS-GBD has emerged as an alternative method of gallbladder decompression, with several studies demonstrating superior outcomes with EUS-GBD when compared with PTGBD.<sup>4-8</sup> As opposed to more-established endoscopic procedures, there are no guidelines on the optimal management of anticoagulation in these patients.<sup>7,9-12</sup> EUS-GBD is purported to carry a potential reduced risk of bleeding given that the tract to the bowel is less vascular than the liver, the vascular supply of the gallbladder is located along the posterior wall, and the lumen-apposing metal stent (LAMS) routinely used for EUS-GBD may act as a tamponade.<sup>9</sup>

We report on 5 patients who underwent EUS-GBD while on long-term anticoagulation and the procedural outcomes.

## METHODS

From a prospectively maintained EUS-GBD database (December 2018 to February 2020) including 21 patients, 5 required long-term anticoagulant therapy (23.8%). Long-term anticoagulation users included those on warfarin, unfractionated heparin, low-molecular-weight heparin, fondaparinux,

or direct oral anticoagulants with a clear indication (atrial fibrillation, acute coronary syndrome, deep vein thrombosis, or a hypercoagulable state). Patients were diagnosed with acute cholecystitis based on Tokyo criteria and deemed nonoperative candidates after surgical consultation. Technical success was defined as appropriate stent placement into the gallbladder through the duodenum or stomach. Clinical success was defined as resolution of symptoms and/or laboratory or radiographic evidence of improvement. Adverse events were characterized as early (<14 days) or late (>14 days). A retrospective review of demographic, clinical, procedural, and outcome data was performed. Institutional review board approval was obtained before retrospective chart review.

All procedures were performed with patients under monitored anesthesia care, using a curvilinear array echoendoscope that was advanced into the antrum or duodenal bulb. Transduodenal or transgastric access was obtained after sonographic visualization of the gallbladder, with a measured distance between the gallbladder and enteric wall of <10 mm in each case. A freehand technique was used to perform drainage with a cautery-enhanced LAMS (The AXIOS Stent and Delivery System and the AXIOS Electrocautery Enhanced Stent and Delivery System; Boston Scientific Corporation, Marlborough, Mass). Stent position was confirmed under endoscopic and endosonographic guidance. No dilation of the LAMS after deployment was performed (Video 1, available online at [www.VideoGIE.org](http://www.VideoGIE.org)). Procedures were performed by 2 endoscopists (P.C. and T.S.) with >10 years of experience in therapeutic EUS and without trainee involvement.

**TABLE 1. Case descriptions**

Characteristics	Case 1	Case 2	Case 3	Case 4	Case 5
Age, y	75	69	71	40	92
Sex	F	M	M	M	M
Underlying cancer	Endometrial cancer	None	None	Non-small cell lung cancer	None
Comorbid conditions	MI, CHF, DM, PE, HIT	MI, CHF, CKD, pAF	MI, PVD, dementia, DM, pAF	DVT	MI, COPD, pAF, CVA, DVT, DM
AC	Bivalirudin/warfarin	Heparin	Heparin	Heparin	Heparin
Reason for AC	PE, HIT	MI, pAF	pAF, possible cardiac thrombus	DVT	DVT, pAF
Hb preprocedure	10.7	11.5	11.7	8.1	15.2
Hb postprocedure	10.6	12.9	11.6	8.8	14.2
INR	1.8	1.1	1.2	1.2	1.2
PTT	n/a	61.3	54.9	56.7	64.6
Platelet count	182	241	307	243	174
Albumin	2.8	3.1	2.0	2.9	3.0
PPI use	No	No	Yes	No	Yes
Hours AC held preprocedure	23	24	6	12	7
Hours AC held postprocedure	24	48	48	24	9
Hospital LOS, d	8	28	4	5	5

AC, Anticoagulant; CHF, congestive heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; DM, diabetes; DVT, deep vein thrombosis; HIT, heparin-induced thrombocytopenia; INR, international normalized ratio; LOS, length of stay; MI, myocardial infarction; pAF, paroxysmal atrial fibrillation; PE, pulmonary embolism; PPI, proton pump inhibitor; PVD, peripheral vascular disease.

**RESULTS**

Five patients underwent EUS-GBD while on anticoagulation. The Tokyo score defining severity of cholecystitis for each patient was calculated retrospectively. The majority of the patients were grade III severity (60%), with the remaining 2 patients categorized as grade I severity. See Tables 1 and 2 for further information on baseline characteristics and procedural details.

Technical and clinical success was achieved in 100%. There were no immediate or delayed postprocedure adverse events. Three patients died within 3 months of the procedure because of underlying metastatic solid tumor malignancy or chronic medical issues.

**CASE REPORTS**

**Patient 1**

A 75-year-old woman with metastatic endometrial cancer, bilateral pulmonary emboli, left ventricular mural thrombus, and heparin-induced thrombocytopenia presented with acute abdominal pain, elevated transaminases, and leukocytosis concerning for acute cholecystitis. The patient was on coumadin (international normalized ratio 1.8) before the EUS-GBD. Bivalirudin and warfarin were started 24 hours postprocedurally. She was discharged on postprocedural day 6, with improvement in symptoms and no adverse events. Three months postoperatively,

the patient developed respiratory arrest related to a thromboembolic event.

**Patient 2**

A 69-year-old man with paroxysmal atrial fibrillation presented with non-ST elevation myocardial infarction, necrotizing gallstone pancreatitis, and acute cholecystitis. Heart catheterization showed severe multivessel coronary disease, and cardiac bypass was deferred until after management of acute cholecystitis. Heparin was held 24 hours before EUS-GBD. Therapeutic heparin was resumed on postprocedural day 2 at the time of coronary artery bypass grafting. Follow-up endoscopy performed 2 months postprocedurally revealed spontaneous expulsion of the LAMS with near closure of the tract. The patient underwent laparoscopic cholecystectomy 4 months after the initial EUS-GBD. The operation revealed a persistent pinpoint cholecystogastric fistula, which required takedown and closure. He remains asymptomatic at 9-month follow-up.

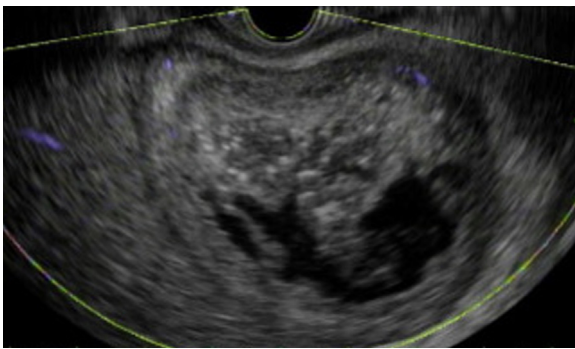
**Patient 3**

A 71-year-old man with a history of atrial fibrillation with possible thrombus on echocardiogram presented with septic shock related to calculous cholecystitis. The patient was placed on heparin. Given hemodynamic instability and active anticoagulation (partial thromboplastin time 54.9), the patient underwent transduodenal EUS-GBD with a LAMS (Figs. 1, 2, and 3). The LAMS was removed 1

**TABLE 2. Procedural details by case**

Details	Case 1	Case 2	Case 3	Case 4	Case 5
Procedure time, min	15	6	17	12	9
Axios position	Stomach	Duodenum	Duodenum	Stomach	Duodenum
LAMS diameter/length, mm	10/10	10/10	10/15	10/10	10/10
Technical success	Yes	Yes	Yes	Yes	Yes
Clinical success	Yes	Yes	Yes	Yes	Yes
Time to clinical response, d	1	1	1	1	1
Stent dwell time, mo	n/a	2	1	n/a	n/a
Bleeding events	None reported	None reported	None reported	None reported	None reported
Thrombotic events	None reported	None reported	None reported	None reported	None reported
Alive/deceased	Deceased 3 mo postprocedurally	Alive	Alive	Deceased 1 mo postprocedurally	Deceased 3 mo postprocedurally

LAMS, Lumen-apposing metal stent.



**Figure 1.** EUS image of a calculous, distended gallbladder.



**Figure 2.** EUS-guided lumen-apposing metal stent deployment.

month later, and a 7F double-pigtail stent was left across the fistula indefinitely. The patient remained asymptomatic at 1-year follow-up and has not required cholecystectomy.

#### Patient 4

A 40-year-old man with a medical history significant for metastatic non-small cell lung cancer, neutropenia related to cancer chemotherapy, and acute deep vein thrombosis presented with abdominal pain and imaging findings consistent with acalculous cholecystitis. The patient was continued on heparin until 12 hours before transgastric EUS-GBD and resumed heparin within 24 hours. There were no immediate adverse events. The patient was discharged to hospice care and died 1 month after the procedure from an underlying malignancy.

#### Patient 5

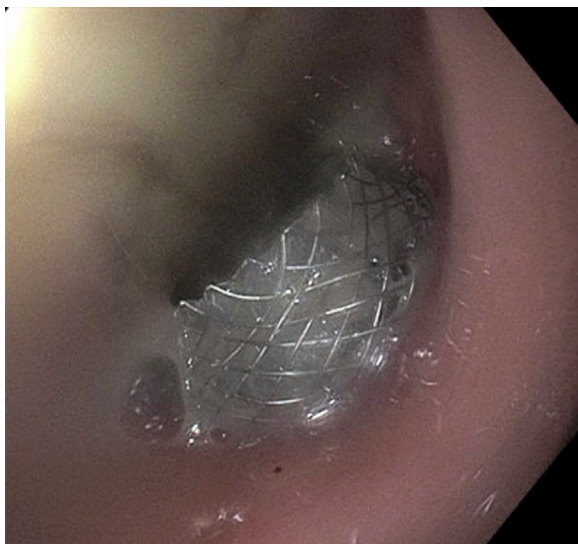
A 92-year-old man with a history of coronary artery disease, chronic obstructive pulmonary disease, atrial fibrillation with history of stroke, and deep vein thrombosis presented with confusion, fever, and abdominal pain. He was diagnosed with cholecystitis. Percutaneous cholecystostomy was considered, but given colonic interposition between the abdominal wall and gallbladder, it was not

deemed feasible. A heparin drip was held for 7 hours, and he underwent transduodenal EUS-GBD. Heparin was resumed 9 hours after the procedure. The patient was discharged on postprocedural day 3 in stable condition. Given his age and comorbidities, the LAMS was left in place indefinitely. The patient died 3 months after the procedure from underlying medical issues.

## CONCLUSIONS

We report a series of successful EUS-GBD procedures in patients requiring anticoagulation. All stents were placed with quick resumption of anticoagulation and without evidence of bleeding during the index hospitalization. The long-term data of this study are limited because the average follow-up duration postprocedurally was 6.25 months. Efforts were made to withhold anticoagulation in line with society guidelines for invasive endoscopic procedures.<sup>13</sup>

EUS-GBD is an emerging therapy in the management of cholecystitis in nonsurgical patients, and several retrospective and randomized controlled trials demonstrated superiority of



**Figure 3.** Luminal view of the lumen-apposing metal stent within the duodenum with purulent drainage.

EUS-GBD over PTGBD.<sup>4-7</sup> However, current data do not provide clarity on the safest noninvasive modality to treat cholecystitis in those on anticoagulation, and there are no guidelines on this subject. Tokyo Guidelines recommend PTGBD as an initial approach in all nonsurgical patients with cholecystitis, but endoscopic means of drainage may be considered in high-volume centers with skilled endoscopists.<sup>14</sup> Anderloni et al<sup>12</sup> describe 4 cases of EUS-GBD with LAMS enhanced with cautery in patients who were actively receiving anticoagulants or coagulopathic. They had technical and clinical success similar to that in our current case series and did not find any procedural or postprocedural bleeding.<sup>12</sup>

This case series provides a thorough review of the clinical and technical success of EUS-GBD in patients requiring anticoagulation and adds to the limited number of cases reported in the literature. From our experience, EUS-GBD appears to be safe in anticoagulated patients with guideline-directed brief holding of anticoagulation; however, more data are needed pertaining to the different anticoagulants and their periprocedural management before a definitive conclusion can be drawn (Supplementary Figs. 1 and 2, available online at [www.VideoGIE.org](http://www.VideoGIE.org)).

## DISCLOSURE

*All authors disclosed no financial relationships.*

*Abbreviations: EUS-GBD, EUS-guided gallbladder drainage; LAMS, lumen-apposing metal stent; PTGBD, percutaneous gallbladder drainage.*

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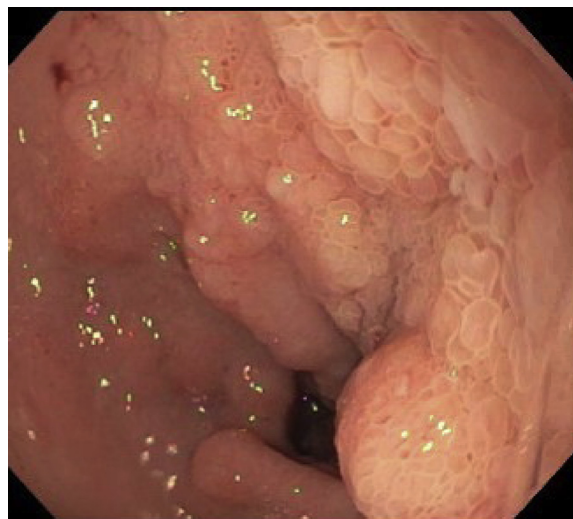
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**Supplementary Figure 1.** Shows a CT abdomen with cholecystoduodenostomy stent in place 1 month postprocedure.



**Supplementary Figure 2.** Reveals that subsequent EGD performed 2 months postprocedure showed spontaneous expulsion of the lumen-apposing metal stent in the region of prior stent placement.