# Long-term results after EUS gallbladder drainage in high-surgical-risk patients with acute cholecystitis: A 3-year follow-up registry

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## ABSTRACT

**Background and study aims** Endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) has become the favorite drainage option for high surgical-risk patients with acute cholecystitis. However, data on long-term outcomes regarding efficacy and security over 1 year are scarce.

**Patients and methods** We performed a retrospective review of a prospectively maintained database to analyze the 3-year long-term outcomes of EUS-GBD with lumen apposing metal stents (LAMS) in high-surgical-risk patients with acute cholecystitis.

**Results** Fifty patients with acute cholecystitis who underwent EUS-GBD with LAMS and 3-year follow-up or until death were included in this study. No endoscopic revisions were scheduled unless an adverse event (AE) or suspected LAMS dysfunction occurred. AEs occurred in 18%, 20%, and 26% of patients in the first, second, and third years, respectively. Thirteen patients developed at least one AE, and six presented with a second AE during follow-up. Recurrence of cholecystitis occurred in two patients (4%). Seven stent migrations (14%) occurred but all were asymptomatic. Symptomatic LAMS-related AEs (LAMS-RAEs) (37.5%) were related to gastric location of the stent compared with duodenal location (66.7% vs. 12.5%, $P = 0.03$). No stent-related bleeding or stent-related mortality was observed.

**Conclusions** EUS-GBD with LAMS without scheduled removal is an effective and safe long-term treatment in high-surgical-risk patients with acute cholecystitis. Late LAMS-RAEs tend to be more asymptomatic over time. Symptomatic LAMS-RAEs are associated with gastric location, and overall, AEs tend to recur.

## Introduction

Laparoscopic cholecystectomy is the gold standard treatment for patients with acute cholecystitis (AC) [1]. However, not all patients are candidates for surgery during hospitalization for AC. Once the episode is resolved, the patient's baseline situation may improve, and cholecystectomy should be performed as a preventive measure against future biliary events. On the other hand, some patients are at high surgical risk due to comorbidities and high anesthetic risk, a situation which does not improve after the resolution of cholecystitis, and they will never be surgical candidates. The recommended treatment for patients at high surgical risk is currently percutaneous gallbladder drainage (PT-GBD), or endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) in specialized and experienced centers [2, 3].

Since the advent of EUS-GBD, there has been increasing evidence that it is a feasible, safe, and effective technique comparable to PT-GBD [4]. Recent data show that EUS-GBD results in fewer adverse events (AEs) than in patients undergoing PT-GBD, with the same rates of technical and clinical success; however, long-term safety data beyond 2 years are not available. Similarly, there is no evidence about the optimal follow-up strategy for these patients to achieve the minimum AE rate for biliary events, as well as possible long-term AEs associated with the stent.

Due to their design and ease of use, lumen apposing metal stents (LAMSs) allow EUS-GBD to be performed quickly and efficiently. Some authors advocate removing the LAMS weeks after EUS-GBD to avoid long-term AEs associated with LAMS [4], similar to studies using LAMS in pancreatic fluid collection. In contrast, other authors have suggested indwelling LAMS, given the fragility of these patients [5].

The aim of our study was to evaluate the very long-term efficacy and safety of EUS-GBD with LAMS in the treatment of high-surgical-risk patients with AC.

## Patients and methods

The present study was a single-center retrospective case series evaluating the long-term outcomes of consecutive patients who underwent EUS-GBD for AC. This study was approved by the local institutional review board (IRB). Patients were prospectively enrolled in a LAMS registry, which includes all LAMS deployed in our center. All patients or their legal representatives provided written informed consent.

All consecutive patients who underwent EUS-GBD for AC between September 2016 and April 2020 were eligible to participate in this study if data for a minimum of 3 years follow-up, or until their deaths, were available. All authors had access to the study data and reviewed and approved the final manuscript before submission.

### EUS-GBD

Procedures were performed by two expert endoscopists (BMM, JRA) in the endoscopy suite. Patients were sedated with intravenous administration of propofol by the endoscopy team or under general anesthesia by an anesthesiologist.

The gallbladder was imaged under EUS from the antrum or duodenal bulb using a therapeutic echoendoscope. Doppler was used to avoiding intervening vessels. In all cases, transduodenal drainage was attempted first. Transgastric drainage was performed only when transduodenal access was not possible, due to the absence of visualization of the gallbladder, vascular interposition, distance to the gallbladder, smaller target size or very unstable position of the echoendoscope.

The 10 × 10 or 15 × 10 mm LAMS (Hot Axios, Boston Scientific) was deployed directly using a freehand technique with pure cutting current (PureCut mode 100 W, effect 2, Olympus ESG 300). The distal flange of the stent was deployed under EUS guidance, followed by deployment of the proximal flange intrachannel. A coaxial 7F or 10F x 3 cm double-pigtail plastic stent (Boston Scientific) was inserted to prevent potential dislodgment or occlusion by food.

In patients with previous PT-GBD, internalization of gallbladder drainage was achieved by artificial distension of the gallbladder with infusion of saline or contrast via the percutaneous cholecystostomy drainage tube. If the gallbladder was contracted or large stones occupied the space, contrast or saline was injected through a 19G or 22G EUS needle before insertion of the LAMS.

In patients with concomitant choledocholithiasis or cholangitis, endoscopic retrograde cholangiopancreatography was performed at the same session.

### Definitions

AC was diagnosed according to the Tokyo guidelines criteria based on a combination of clinical symptoms (fever, right upper quadrant pain, positive Murphy's sign), laboratory data (high serum C-reactive protein, leukocytosis), and imaging findings (US, EUS, or computed tomography [CT]) [1]. Patients who were at very high risk for cholecystectomy and underwent EUS-GBD as a definitive treatment were included in this study. Patients were deemed very high risk for cholecystectomy if they satisfied at least one of the following criteria: age > 80 years, American Society of Anesthesiologists (ASA) grade ≥ 3, age-adjusted Charlson comorbidity index > 5, Karnofsky score < 50, and/or Rockwood score 7 to 9. All patients were evaluated by the surgeon to confirm their high surgical risk and exclude cholecystectomy.

AEs were defined as any procedure-related event appearing during or after the procedure. Early AEs occurred within 7 days after the procedure, and late AEs occurred 7 days after the procedure. They were graded for severity according to the American Society for Gastrointestinal Endoscopy severity grading system [6].

Biliary events (BEs) were defined as the occurrence of biliary colic, cholangitis, choledocholithiasis, or acute biliary pancreatitis during follow-up. LAMS-related AEs (LAMS-RAEs) were defined as internal or external migration of the stent, delayed bleeding, buried stent syndrome, gastric emptying obstruction, or stent obstruction with recurrence of AC.

For data compilation, yearly observation of imaging test and medical history were verified. Data regarding baseline demographics and diagnosis, endoscopic procedure, AE, migration, stent retrieval, and mortality were retrieved from the prospective LAMS registry. In addition, all-cause emergency room visits and hospital admissions were retrieved from electronic medical records, as well as all notes and reports made by physicians about outpatient visits. Reports of imaging studies and all other procedures performed were also reviewed. All post-EUS-GBD imaging tests available for each patient from every AE or for any other reason were reviewed to assess the presence or absence of the stent. Discharge reports after every hospital admission were also included.

After discharge from the hospital, no revisions were scheduled unless an AE or suspected LAMS dysfunction occurred. In this case, a gastroscopy was performed. A regular endoscope was inserted through the LAMS into the gallbladder to check for the presence of gallstones, food, or detritus. In case of internal migration or buried stent, the LAMS was removed and replaced with a 7F double-pigtail plastic stent or a full covered self-expanded metal stent.

## Outcome measurements

Outcome measurements included technical success, clinical success, intraprocedural AEs, recurrent biliary events, LAMS-RAEs, recurrent cholecystitis, reinterventions, readmissions or any medical assistance up to 3 years after the procedure, or death. Technical success was defined as the ability to access and drain the gallbladder by placement of a stent. Clinical success was defined as improvement in clinical symptoms and laboratory tests.

## Statistical analysis

Statistical analyses were performed using SPSS V.29.0 statistical software (SPSS, Chicago, Illinois, United States). Descriptive statistics are reported as frequencies (proportions) and means (95% confidence interval [CI]) or medians (interquartile range) as appropriate. Comparisons between patients were made by $\chi^2$ test or Fisher's exact test for categorical data, and Mann-Whitney U test and t-test for continuous data, where appropriate.

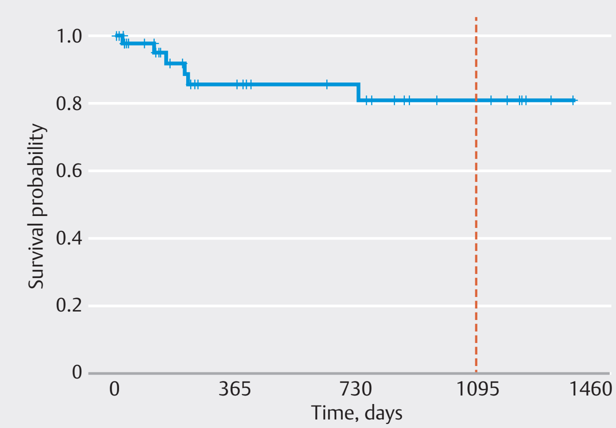
Dysfunction-free survival was analyzed by Kaplan–Meier statistics. Patients were censored at dysfunction, death, and last telephone follow-up – whichever came first. Predictors of dysfunction were analyzed through Cox proportional hazards regression and results expressed as hazard ratios (HRs) and 95% CIs.

# Results

Between September 2016 and April 2022, 68 patients were assessed for EUS-GBD, among whom 62 patients (91.7%) were drained successfully. Twelve patients with another indication were excluded, and the 50 patients with gallbladder drainage using Hot Axios stent for AC were analyzed.

The reasons for technical failure were scleroatrophic gallbladder in one case, gallbladder perforate in two cases, colon interposition in one case, and gallbladder further than 1.5 cm from the gastrointestinal tract in two cases. Clinical success was achieved in 49 of 50 patients (98%). No intraprocedural AEs were observed, and there was only one early AE (< 7 days) due to gastric emptying obstruction, whereas the remaining AEs were delayed. Patient characteristics and details of the procedure are shown in Table 1 and Table 2, respectively.

The median follow-up for all patients was 25.0 months (IQR: 1.8–38.5; range 0–57 months). The median follow-up of patients alive at the end of the study was 41 months (IQR: 38–44.5; range 36–50 months), whereas the follow-up of patients who died during the study was 7.7 months (IQR: 1.1–29.2; range 0–57 months). Six patients (12%) died during the first 30 days, 20 patients (40%) at 1 year, 25 patients (50%) at 2 years, and 35 patients (70%) at 3 years. The patient who presented with clinical failure died 4 days after the procedure due to refractory sepsis. Table 3 shows all causes of death during the follow-up.




▶ **Fig. 1** Kaplan–Meier curve of biliary event-free survival following endoscopic ultrasound-gallbladder drainage.

## Adverse events

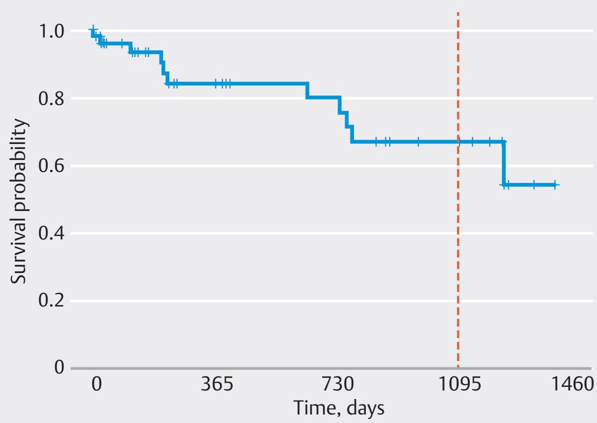
The cumulative number of patients who developed AEs in the follow-up were: two (4%) at 30 days, nine (18%) at 1 year, 10 (20%) at 2 years and 13 (26%) at 3 years. Thirteen patients presented with 23 AEs, only three of which were severe. Table 4 shows the AEs and their resolution in each patient and Table 5 shows details of AEs in each category. No association was observed between the different variables analyzed for the occurrence of complications: cirrhosis, anticoagulation, antiplatelets, Charlson index, ASA, severity of cholecystitis, previous cholecystitis, previous percutaneous cholecystostomy, conversion of percutaneous cholecystostomy, type of sedation, size of stones, size of coaxial pigtail or ERCP in same session. Biliary events (BEs) and LAMS-related AEs (LAMS-RAEs) are summarized below.

### Biliary events

We found 9 BEs in six patients (11.1%), with a median occurrence of 186 days (IQR: 96–360; range: 24–743 days): six cholangitis, one choledocholithiasis, one biliary colic, one hepatic abscess. The severity of the BEs was mild in two patients (22.2%), moderate in four patients (44.2%), and severe in three patients (33.3%), and resolution was endoscopic in seven cases (78%), conservative in one case (11%), and via interventional radiology in one case (11%) requiring drainage of liver abscesses associated with cholangitis. Most of the BEs occurred in the first year (▶ **Fig. 1**).

### LAMS-RAEs

We found 14 LAMS-RAEs in 11 patients (22%), with a median occurrence of 674 days (IQR: 116–777 range: 5–1229 days): three stent occlusions with recurrence of AC, two buried stents, two gastric outlet obstructions, and seven migrations. Treatment of these events was endoscopic in seven cases (50%), with stent cleaning in the two cases of stent occlusion, stent re-




▶ **Fig. 2** Kaplan–Meier curve of LAMS-RAE-free survival following endoscopic ultrasound-gallbladder drainage.

moval in the two cases of buried stents and intravesicular migration, and stent repositioning with pigtail in the patient with two episodes of gastric outlet obstruction. In the remaining seven cases, management was conservative (50%). Only five LAMS-RAEs (37.5%) were symptomatic, with all migrations being asymptomatic, as well as the two cases of buried stents. LAMS were removed in four patients due to AEs.

Three recurrences of AC were observed in two patients (4%) due to obstruction of the stent. In one patient, the first episode was managed endoscopically by conservative management and cleaning the stent. In the second patient, who presented with obstruction of the LAMS by large stones, cholecystoscopy and electrohydraulic lithotripsy were performed.

LAMS-RAEs increased over time (▶ **Fig. 2**), but symptomatic complications developed only in the first year, and the increase in LAMS-RAEs after the first year occurred at the expense of exclusively asymptomatic events.

Although no significant association was observed for the appearance of LAMS-RAEs related to the location of the stent in the gastric or duodenal position ($P = 0.3$), we observed that symptomatic LAMS-RAEs occurred in 66.7% of patients with gastric location of the stent compared to 12.5% of symptomatic LAMS-RAEs with a duodenal location ($P = 0.03$).

### Migration

Thirty-eight of the 50 patients had imaging tests during follow-up (Rx abdomen, ultrasound, CT or gastroscopy). Twelve patients did not have any imaging test at follow-up after LAMS deployment. In six patients, the first imaging test showed the absence of a LAMS. In the remaining 32 patients, the presence of the LAMS was confirmed by imaging or gastroscopy.

Twelve months after LAMS deployment, we found that 19 of 30 patients who remained alive (63.3%) had a subsequent imaging test confirming the presence of the stent at that time. Migration of the Axios stent was evident in seven patients (14%) after a median of 777 days (630–1077; range: 25–1229): intravesicular in one case, expulsion into the duodenum with extraction of the stent during ERCP in one case, and by spontaneous expulsion of the stent and casual finding in an imaging test performed for another reason in five cases. The follow-up after migration of the LAMS was a median 304 days (137–488; range: 11–1722), with no subsequent recurrence of cholecystitis in any of these patients.

### Delayed bleeding, antiplatelet therapy, and anticoagulation

Eighteen patients (36%) were on anti-aggregant therapy (16 aspirin, 2 clopidogrel, 1 double anti-aggregation), and 12 patients (24%) were on anticoagulation therapy: five acenocumarol, seven direct oral anticoagulants (DOACs). Aspirin was not discontinued for the procedure in any case. In one case, clopidogrel was replaced by aspirin; in the other cases, clopidogrel or double antiplatelet was not discontinued. In patients with anticoagulant treatment, the effect of acenocumarol was reversed for the procedure and the DOACs suspended between 24 to 72 hours according to current guideline recommendations. No episode of early or delayed gastrointestinal bleeding was recorded during the entire follow-up.

## Discussion

Data from our cohort with 3-year follow-up show that treatment of AC with placement of LAMS by EUS-GBD without scheduled removal thereafter is safe, with a low rate of symptomatic AEs. Moreover, there was no significant progressive increase in the AE rate associated with EUS-GBD. Most of the BEs occurred in the first year, whereas LAMS-RAEs increased over time. However, the only symptomatic LAMS-RAEs occurred during the first year, and the increase after the first year occurred at the expense of exclusively asymptomatic events. Therefore, this finding should not motivate revision or removal of the LAMS. These data seem relevant because, even in a fragile population with a high life expectancy, it is not unlikely that we will find patients with follow-up much longer than 1 year. On the other hand, most AEs are resolved by endoscopy or conservative treatment. To date, this study has the longest reported follow-up on EUS-GBD with LAMS in patients with AC. Previous long-term reports with 1 year follow-up do not allow the evaluation of all concerning questions about indwelling LAMS in fragile, but not terminal, patients.

The treatment of AC depends mainly on the severity of the cholecystitis, the patient's general condition, and comorbidity. Laparoscopic cholecystectomy is considered the treatment of choice. In patients in whom surgery is ruled out and who do not respond to antibiotic treatment, PT-GBD, EUS-GBD, or endoscopic transpapillary gallbladder drainage (ETGBD) is indicated [1]. Recently, EUS-GBD has replaced PT-GBD in the treatment of high-surgical-risk patients with AC due to better outcomes [3,4]. A recent multicenter prospective randomized study comparing EUS-GBD and PT-GBD observed a significant decrease in AEs at 1 year (25.6% vs. 77.5%, $P < 0.001$), lower 30-day reintervention rate (2.6% vs. 30%, $P = 0.001$), and recurrence of cholecystitis (2.6% vs. 20%, $P = 0.029$), as well as lower readmission rate, post-procedural pain, and analgesia requirements in the EUS-GBD group [4]. Recent meta-analyses corroborate these data for EUS-GBD versus percutaneous drainage [7, 8]. Similarly, EUS-GBD has shown better results compared to ETGBD, with a higher technical and clinical success rate, as well as a lower rate of AC recurrence with no differences in AEs [9, 10]. Our results with 91.7% technical success and 98% clinical success corroborate the data published previously [11, 12].

However, there is no established recommendation for subsequent management of patients once EUS-GBD has been performed. Some authors have suggested a proactive strategy of direct peroral cholecystoscopy and complete stone clearance, allowing removal of the LAMS with or without double-pigtail replacement [4, 11]. This strategy may prevent AEs associated with indwelling LAMS, such as delayed bleeding, buried stent, ingrowth or overgrowth, migration, and other complications. However, many patients ultimately do not undergo revision because they are fragile. In the DRAC1 study, only 67.5% of patients underwent revision because the rest of the patients were too fragile and rejected this option. In addition, in 88.9% of the patients who underwent revision, spontaneous passage of lithiasis was observed without a need for additional endoscopic measures [4]. In the study by Irani SS et al., LAMS were removed in only 63.3% of the patients, due to fragility or comorbidity in 26.7% of the patients [12]. Furthermore, complete gallbladder cleansing can be challenging. In a study reported by Chan et al., a mean of 1.25 sessions of cholecystoscopy were needed for a complete stone clearance rate of 88% [13]. In this study, 56% of the patients had spontaneous stone passage on cholecystoscopy after EUS.

For this reason, we chose a strategy of indwelling EUS-GBD and placement of a coaxial double-pigtail stent to avoid obstruction of the stent by food or lithiasis, with endoscopic revision only in cases with or suspected of AEs. With this strategy, we observed a total AE rate of 18% after the first year, lower than that reported in the DRAC1, which had a total complication rate of 25% [4]. Furthermore, the recurrence rate for cholecystitis of 4% in our series is similar to the recurrence rates for cholecystitis observed in studies with shorter follow-up periods, which range from 2.6% to 7% [4, 12, 14, 15]. Thus, a strategy of indwelling LAMS seems comparable in the short term to a strategy of proactive cholecystoscopy and complete stone clearance, which would obviate the need for systematic endoscopic revision in patients at high surgical risk who undergo EUS-GBD. Clearly, these data are superior to a conservative strategy, as shown in a 2-year follow-up study of 197 patients with AC who did not undergo surgery but had a 38.5% BE rate and 27% recurrence rate for cholecystitis [16].

There are few long-term data on EUS-GBD, with published follow-up periods of only 1 year [4, 12]. The only study published to date with a follow-up of more than 1 year is the study by Yuste et al. [5] in which 22 patients were included with a median follow-up of 24.4 months (IQR: 18.2–42.4), but patients who had not completed a follow-up of at least 12 months were excluded, which could imply bias as the first year is the period of time when most BEs occur in our series. Nevertheless, using a protocol similar to ours without systematic endoscopic review, the authors concluded that indwelling LAMS is a definitive treatment in non-surgical patients.

Although we found no significant differences between the duodenal or gastric route in the occurrence of LAMS-RAEs, we did observe an increase in symptomatic LAMS-RAEs associated with gastric placement of the LAMS (66.7% vs. 12.5%, $P = 0.03$), so this group of patients could potentially benefit from a strategy of revision, eventual cleaning of the gallbladder, and removal or replacement of the LAMS with a pigtail. Similarly, 46.2% of the patients who presented with AEs developed a second episode that was symptomatic in 83.3%, so we consider that, once a patient presents an AE, it would be advisable to perform endoscopic revision with LAMS removal to avoid successive AEs.

One of the concerns about leaving a LAMS permanently is the possibility of delayed bleeding, which occurs in pancreatic collections drained with LAMS when the stent is maintained for a long time [17]. In our series, we found no cases of gastrointestinal bleeding, despite the fact that 36% of the patients were on antiplatelet therapy and 24% of patients were receiving anticoagulation therapy. This reflects the safety of EUS-GBD even in anticoagulated/anti-aggregation patients and rules out the need to remove the gallbladder stent due to the risk of bleeding associated with LAMS.

Regarding migration, we found a rate of 14% in our series, higher than in other published series [4, 5]. However, this is justified by most migrations occurring late in our series with a median time to migration of 777 days. However, none of the patients had recurrence of cholecystitis. One possible explanation is that migration occurs when the gallbladder has been spontaneously cleared due to collapse of the gallbladder, which is why new episodes of AC would not occur.

Our study has some limitations, such as the fact that it is a retrospective review of a prospectively maintained database, so that events that have not motivated the medical consultation could go unnoticed, although information about the relevant events that would motivate the medical visit would be collected. Furthermore, it is the experience of a single center, so the high technical success rates could be affected in centers with less experienced endoscopists.

# Conclusions

In conclusion, the current study provides definitive data that confirm that EUS-GBD with indwelling LAMS in high-surgical-risk patients is an effective and safe technique in the long term. Based on our results, most patients do not require endoscopic revision and removal of the stent, and this strategy is reserved for those who present with a first complication or in cases in which drainage is performed through the stomach. However, comparative studies with a strategy of an indwelling stent or removal of the LAMS would be required to confirm these findings.


## Conflict of Interest

Belén Martínez-Moreno and José Ramón Aparicio are Boston Scientific consultants. The rest of the authors have nothing to declare.

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