EUS-guided gallbladder drainage in acute cholecystitis: long-term problems with surgical approach

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Professional societies have endorsed endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) as an alternative to percutaneous cholecystostomy in high-risk surgical patients with acute cholecystitis. In a retrospective case series, we encountered 3 of 25 patients who improved clinically after EUS-GBD and subsequently had their surgical risk status reversed when cholecystectomy was indicated due to persistent symptoms. However, the presence of a lumen-apposing metal stent (LAMS) precluded a minimal invasive surgical approach and necessitated conversion to open or subtotal cholecystectomy. Therefore, EUS-GBD should be reserved for a selective cohort of never-surgery patients and not for all patients broadly stratified as high-risk surgical candidates.

IN MORE DETAIL
Randomised trials and meta-analysis comparing EUS-GBD using LAMS versus percutaneous cholecystostomy in high-risk surgical patients with acute cholecystitis have favoured EUS-GBD as it is associated with lower rates of adverse events, reinterventions and readmissions.1 2 Recently, the European Society of Gastrointestinal Endoscopy guidelines, American Gastroenterological Association practice update and Tokyo Guidelines have endorsed EUS-GBD as an alternative to percutaneous cholecystostomy in high-risk surgical patients.3–5 More recently, the US Food and Drug Administration approved the use of LAMS for gallbladder drainage in high-risk patients unfit for cholecystectomy. Given the lack of long-term follow-up data, we examined the clinical outcomes of EUS-GBD at our institution.

This was a retrospective study of patients who underwent EUS-GBD between July 2021 and June 2023 at Orlando Health in Orlando, Florida. Patients with acute cholecystitis deemed high-risk for surgery and whose gallbladder were located adjacent to the gastric or duodenal lumen were included. Excluded were patients whose gallbladder was inaccessible for EUS-GBD or had irreversible coagulopathy. EUS referrals were made by internists in consultation with acute care or general surgeons. All procedures were performed with a linear array echoendoscope under monitored anaesthesia care using propofol administered by anaesthesiologists. The LAMS (Hot AXIOS, Boston Scientific) used in this study had a single-step cautery-tipped delivery system with dimensions of 15 mm (diameter) by 10 mm (length). Anchoring plastic stents were not placed in any patient. The site through which the stent was deployed was either the stomach or duodenum depending on proximity to the gallbladder. All patients were discharged from hospital after resolution of presenting symptoms. Outpatient and inpatient medical records were reviewed to obtain clinical follow-up. The primary outcome measure was symptom recurrence necessitating subsequent reintervention. Secondary outcome was adverse events.

Twenty-five patients (12 females, median age 74 years (IQR, 57–82)) underwent EUS-GBD over a 24-month period. All patients presented with sepsis or acute cholecystitis and underlying aetiology were gallstones (72%) or inoperable pancreatic-biliary malignancy causing cystic duct obstruction (28%). Reasons for poor surgical candidacy were terminal malignancy (n=8), coronary artery disease (n=7), advanced cirrhosis (n=1), irreversible neurological disease (n=4) and advanced age (>85 years; n=5). LAMS was placed via the stomach in 14 patients (56%) and duodenum in 11 (44%). While 24 of 25 (96%) patients had resolution of sepsis/cholecystitis within 48 hours, an adverse event of bile leak was observed in one (4%) who had pancreatic cancer and opted for hospice care. The median length of hospital stay after LAMS placement was 3 days (IQR, 2–6).

At median follow-up of 277 days (IQR, 170–393), 17 patients were alive and 8 were deceased due to progression of malignancy (n=4), neurological deterioration (n=2) and sepsis from COVID-19 (n=1) or spontaneous bacterial peritonitis (n=1). Of 17 patients who were alive, 9 were asymptomatic (52.9%) and 8 (47.1%) reported persistent biliary-type pain that warranted reintervention in 3 (12%). Attempted minimally invasive (robotic/laparoscopic) cholecystectomy by general surgeons was unsuccessful in all three patients, who had undergone transgastric EUS-GBD, due to presence of perihepatic adhesions and/or cholecystogastric fistula attributed to indwelling LAMS that necessitated conversion to open or subtotal cholecystectomy (Figure 1) (median surgery duration, 135 min (range, 120–183)). At 3-month follow-up, all three patients were clinically well without persistent symptoms.

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Cholecystectomy is a commonly performed surgical procedure with the vast majority being undertaken laparoscopically. For patients who are not surgical candidates, percutaneous cholecystostomy is the preferred non-operative method for gallbladder decompression. The Tokyo Guidelines recommend percutaneous cholecystostomy for patients with...
severe acute cholecystitis who are graded ≥3 by the American Society of Anesthesiologists, graded ≥4 by the Charlson comorbidity index, jaundiced or have neurological or respiratory dysfunction. Although optimal timing for reassessment of patients with percutaneous drainage catheter for definitive treatment is debatable, a general consensus is 4–6 weeks.

EUS-GBD is proposed as a novel treatment option in lieu of percutaneous cholecystostomy for high-risk surgical patients. In the present study, the surgical risk status of 3 of 25 patients (12%) was reversed after EUS-GBD. All three patients at initial presentation were septic and had cardiac comorbidities that placed them at high-risk for undergoing surgery. However, after resolution of sepsis, the surgical risk stratification was lowered. When subjected to minimally invasive cholecystectomy, the procedures were technically unsuccessful due to the presence of an indwelling transgastric LAMS.

In a Medicare claims analysis, an increase of 567% was observed in patients undergoing percutaneous cholecystostomy as compared with only 3% for laparoscopic cholecystectomy. This trend is likely because by providing temporary decompression, percutaneous cholecystostomy acts as a bridge to surgery. While EUS-GBD in lieu of percutaneous cholecystostomy may not impede performance of open cholecystectomy in majority of patients, it could however negatively impact minimally invasive technical approaches. Therefore, EUS-GBD should not be offered as a routine alternative to percutaneous cholecystostomy in all high-risk surgical patients, particularly when the underlying comorbidity is potentially reversible. Preferably, the procedure should be relegated to a subset of patients who are never-surgery candidates, such as those with primary pulmonary hypertension, advanced cirrhosis, inoperable malignancy or irreversible severe neurological dysfunction.

Another important take-home message from the present study is that more than 50% of patients had persistent biliary-type pain after EUS-GBD. While the acute illness (cholecystitis) may have resolved, the presence of LAMS may not relieve pain originating from a chronically diseased gallbladder. Also, long-term high-quality data on indwelling LAMS are lacking. In patients with prolonged life expectancy or in those with recurrent cholecystitis (reported at 6%), treatment options may include exchange of LAMS for double pigtail plastic stents or endoscopic lithotripsy with retrieval of gallstones via the LAMS. Should cholecystectomy be undertaken, some authors recommend removal of LAMS prior to surgery with endoscopic closure of the fistula tract. While EUS-GBD can be undertaken by adopting either a transgastric or transduodenal route, the transgastric approach provides the advantage of easier closure of the fistula endoscopically after LAMS removal or intraoperatively where surgical mobilisation and repair are relatively easier to perform. In one recent retrospective study comparing outcomes among patients undergoing cholecystectomy after EUS-GBD or percutaneous cholecystostomy, 35% of the EUS-GBD cohort required open or conversion to open cholecystectomy; in two patients the surgery was aborted due to presence of significant inflammation. In our opinion, should surgery be contemplated in this patient cohort, it is best performed by expert surgeons for optimal outcomes.

In light of our preliminary experience in Orlando, we propose a practical algorithm to guide endoscopic management of acute cholecystitis (figure 2). While laparoscopic cholecystectomy should be the treatment of choice in low to moderate risk patients, those deemed inoperable at presentation should be stratified to high-risk or never-surgery status. High-risk patients

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**Figure 1** Subtotal cholecystectomy specimen showing gallbladder with indwelling lumen-apposing metal stent and food particles after failed robotic approach.

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**Figure 2** Proposal from Orlando for multidisciplinary approach to management of acute cholecystitis in the era of EUS-guided lumen-apposing metal stent for gallbladder drainage. EUS, endoscopic ultrasound; GBD, gallbladder drainage.
will include those with potentially reversible comorbidities or in whom the risk status cannot be ascertained accurately due to the severity of clinical presentation. These patients should preferably be treated by percutaneous cholecystostomy or transpapillary cystic duct stenting at endoscopic retrograde cholangiopancreatography as a bridge to therapy and the surgical risk status reassessed at 4–6 weeks. While all operable patients should undergo minimally invasive cholecystectomy, the gallbladder and cystic duct patency should be assessed in the percutaneous cholecystostomy cohort by contrast injection via the percutaneous drain. The drainage catheter may be removed in patients with a patent cystic duct and acalculous gallbladder. In those with cystic duct obstruction or gallstones, lithotripsy or other manoeuvres may be undertaken via endoscopic or percutaneous approaches followed by removal of the percutaneous catheter. Should such approaches fail, or in the absence of requisite technical expertise, as an alternative method, EUS-GBD may be undertaken using LAMS. In the high-risk cohort treated by transpapillary stenting who cannot undergo surgery, the stent can be removed in asymptomatic patients; in others, particularly with residual gallstones, the transpapillary stent may need to be exchanged periodically or patients may undergo EUS-GBD as definitive palliative measure. For patients deemed to be never-surgery candidates, given the need for fewer reinterventions and better quality of life, EUS-guided GBD using LAMS should be the preferred first-line treatment option and considered destination therapy. Percutaneous cholecystostomy or transpapillary cystic duct stenting can be undertaken as second line measures when EUS expertise is unavailable or technically not possible.

In summary, EUS-GBD is a highly effective technique for relief of acute cholecystitis in patients who are never-surgery candidates. Accurate preprocedural risk stratification is important as performance of EUS-GBD can potentially preclude subsequent attempts at minimally invasive cholecystectomy. Therefore, multidisciplinary consensus is essential to guide clinical management. Finally, long-term data are needed in patients with indwelling LAMS to further optimise endoscopic management of acute cholecystitis.

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