EUS-Gallbladder Drainage: Is it Time to Replace Percutaneous Drainage?

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Abstract

Background: Acute cholecystitis in patients who are not suitable for surgery can now benefit from EUS-GBD to overcome the limitations of percutaneous transhepatic gallbladder drainage (PT-GBD) associated with poor quality of life and increased morbidity.

Methods: The technique use is very similar to EUS guided drainage of pancreatic fluid collection and involve EUS guided access of the gallbladder with creation of a gastric or duodenal fistula followed by placement of a stent

Results: There were many documented cases in the literature. The overall reported technical success rate is 87/90 (96.6%). All patients with technical success were clinically successful. A total of 11/90 (12.2%) patients had complications including pneumoperitoneum, bile peritonitis and stent migration.

Conclusions: EUS-GBD provide gallbladder drainage in situations where percutaneous or transpapillary drainage is not feasible or technically challenging, it also offer the patients a better option with improved quality of life and decreased global morbidity by avoiding percutaneous access.

Introduction:

Surgical cholecystectomy has been the mainstay of treatment for acute cholecystitis. For patients with advanced age, comorbidities, use of anti-platelet medications, and/or the presence of advanced malignancy, gallbladder drainage has been recommended instead of surgery. Techniques for non-surgical gallbladder drainage include percutaneous transhepatic gallbladder aspiration or drainage (PT-GBD) and transpapillary endoscopic gallbladder stenting. Endoscopic transpapillary drainage can be technically difficult in some cases with biliary or pancreatic malignancy due to cystic duct obstruction or previously placed metal stents. The need for alternative methods of gallbladder drainage during the evolution of EUS guided drainage techniques for extra-luminal collections such as pseudocysts has lead to development of EUS guided gallbladder drainage (EUS-GBD) techniques.
Materials and methods:

1. Echoendoscopes

Conventional curved linear array oblique viewing therapeutic echoendoscopes are typically used (GF-UCT 180, Olympus America, Melville, NY). The working channel of this scope is 3.7 mm, allowing placement of 10 mm fully covered metal stents and 10 F double pigtail stents. Itoi and colleagues have also reported the use of a prototype forward view curved linear array echoendoscope, which may enable the endoscopist to overcome this issue by exerting force directly with the scope towards the target.

2. Patient selection and preparation

Contrast enhanced abdominal CT or magnetic resonance imaging should be reviewed as a roadmap prior to endoscopic intervention. All patients should receive general anesthesia and antibiotics.

EUS guided gallbladder drainage technique (Table 1)

1. Endoluminal puncture site

Endoscopic ultrasound is used to identify the site of initial puncture at a location where the gallbladder lies closest to the bowel lumen, avoids blood vessels and a stable position of the endoscope tip can be easily maintained. The gastric antral wall has been the preferred site for the initial puncture to access in few large case series, while some authors report the use of a transduodenal approach with similar success rates. Lee and colleagues reported use of the transgastric approach to access the body of the gallbladder and the transduodenal approach for the gallbladder neck. In early reports of EUS-GBD, Lee et al. and Baron et al. commented that directing the puncture needle to the gallbladder neck can be advantageous since it is less mobile and is less likely to move away from the duodenal wall.

2. Puncture needle

Most reports have consistently used a 19 gauge fine needle aspiration (FNA) needle to obtain access (Figure 1). Subtil et al. have described use of a one step device (Giovannini Needle Wire Oasis, Cook Ireland Ltd, Limerick, Ireland), which allows puncture, dilation, electrocautery, and placement of the stent in one device. This system is advantageous because it reduces the time that passes from the initial needle puncture until stent deployment, which reduces the risk of loss of guidewire access and potential complications. However, this system is only available for 8.5 and 10 F straight stents.

3. Tract dilator

After gaining access with a 0.035 inch guidewire, which is coiled into the gallbladder, the fistula tract is dilated using either a mechanical or electrocautery device (Figure 2). A biliary dilation catheter (Soehendra, Cook Medical) has been used as the initial dilating device in many reports. A triple lumen cystoenterostome (6F or 10F Cysto-Gastro Set, Endo-flex, Voerde, Germany or Cystotome, Cook Endoscopy) is another preferred dilation device, which can assist in dilation using diathermy and/or a needle knife. A cystoenterostome has
<table>
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<tr>
<th>Author/Year/location</th>
<th>Number of cases</th>
<th>Indications</th>
<th>Initial puncture site</th>
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<th>Endoprosthesis for drainage</th>
<th>Mean procedure time (min)</th>
<th>Technical success rate</th>
<th>Clinical success rate</th>
<th>Length of follow up</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>Jang et al. [9] 2012 Korea</td>
<td>30</td>
<td>Acute cholecystitis unsuitable for emergency cholecystectomy</td>
<td>Stomach or duodenal wall (numbers not specified)</td>
<td>6F dilator catheter (43.3%) Triple lumen needle knife (56.7%)</td>
<td>5 F nasobiliary drainage tube</td>
<td>23 ± 7</td>
<td>97%</td>
<td>100%</td>
<td>221 days (6 days for patients who underwent cholecystectomy)</td>
<td>Loss of guide wire access</td>
<td>Pneumoperitoneum (2/30) Self limiting</td>
</tr>
<tr>
<td>Itoi et al. [8] 2012 Japan</td>
<td>5</td>
<td>Acute cholecystitis in non-surgical candidates (3 pancreatic cancers, 1 cholangiocarcinoma 1 gallstone disease)</td>
<td>1 stomach 4 duodenum</td>
<td>4 mm hurricane dilating balloon (N=4) 10F cystotome (N=1)</td>
<td>Lumen opposing stent (AXIOS, Xlumena Inc, Mountain View, Calif) 10 mm diameter (length 6 mm in 4 cases and 10 mm in one case)</td>
<td>23.4</td>
<td>100%</td>
<td>100%</td>
<td>9 months</td>
<td>None</td>
<td>Mild self limited oozing along fistula tract</td>
</tr>
<tr>
<td>Serna-Higuera et al. [10] 2012 Spain</td>
<td>13</td>
<td>Acute cholecystitis in non surgical candidates for emergent cholecystectomy</td>
<td>12/13 transgastric 1/13 transduodenal</td>
<td>8.5F Cystotome followed by 4 mm hurricane biliary balloon dilator</td>
<td>Lumen opposing stent (AXIOS, Xlumena Inc, Mountain View, Calif)</td>
<td>Not reported</td>
<td>84.6%</td>
<td>100%</td>
<td>100.81 days</td>
<td>Thickened gallbladder wall Uncontrolled stent release</td>
<td>Hematochezia (1/11) Right hypochondrium pain (1/11) Both self limiting</td>
</tr>
<tr>
<td>Jang et al. [11] 2011 Korea</td>
<td>15</td>
<td>Acute Cholecystitis unsuitable for cholecystectomy after failed ERCP with transpapillary cystic approach</td>
<td>10/15 transgastric 5/15 transduodenal</td>
<td>6 or 7 F Soehendra biliary dilation catheter -Triple lumen needle microtome</td>
<td>Partially covered SEMS 10 mm diameter and 4.7 mm length (Modified* BONA-AL Stent, Standard Sci Tech Inc, Seoul, Korea)</td>
<td>Not reported</td>
<td>100%</td>
<td>100%</td>
<td>145 days</td>
<td>None</td>
<td>Pneumoperitoneum (2/15) Self limiting</td>
</tr>
<tr>
<td>Song et al. [12] 2010 Korea</td>
<td>8</td>
<td>Acute Cholecystitis poor surgical candidates after failed transpapillary cystic approach (4 cholangiocarcinoma, 2 liver cirrhosis, 1 on anticoagulation, 1 malignant cystic duct obstruction)</td>
<td>7/8 transduodenal 1/8 transgastric</td>
<td>6 or 7 F tapered tip biliary dilation catheter -7F Triple lumen needle microtome</td>
<td>7F double pigtail plastic stent</td>
<td>28 (range 17-32)</td>
<td>100%</td>
<td>100%</td>
<td>186 days</td>
<td>Clogging of stent (no clinical consequence)</td>
<td>1 pneumoperitoneum (self limiting) 1 bile peritonitis 1 distal stent migration</td>
</tr>
<tr>
<td>Subtil et al. [4] 2010</td>
<td>4</td>
<td>Acute cholecystitis with Transgastric pr</td>
<td>10F cystotome</td>
<td>8.5F stent modified</td>
<td>Not</td>
<td>100%</td>
<td>100%</td>
<td>Not reported</td>
<td>Stent</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Author/Year/Location</td>
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<td>[13] Spain 2010</td>
<td>1</td>
<td>Acute cholecystitis in patient with malignant biliary obstruction treated with covered SEMS</td>
<td>Transgastric</td>
<td>Needle knife papilotome</td>
<td>6F or 10F Cysto-Gastro Set (Endo-flex, Voerde, Germany) Cystotome (Cook endoscopy)</td>
<td>Not reported</td>
<td>100%</td>
<td>100%</td>
<td>6 months</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lee et al.[17] Korea</td>
<td>9</td>
<td>Acute Cholecystitis (Gallstone induced) in elderly or high risk due to co morbidities or on anticoagulation not suitable emergent cholecystectomy</td>
<td>Transgastric</td>
<td>4 F or 7F bougie (Soehendra biliary dilataion catheter)</td>
<td>6F nasobiliary drainage tube</td>
<td>20 (range 10-35)</td>
<td>100%</td>
<td>100%</td>
<td>3-12 months</td>
<td>None</td>
<td>Pneumoperitoneum (19) self limiting</td>
</tr>
<tr>
<td>Baron et al.[18] 2007 USA</td>
<td>1</td>
<td>Acute Cholecystitis in patient with cholangiocarcinoma with bilateral metal biliary stents</td>
<td>Transduodenal</td>
<td>4 mm balloon</td>
<td>7F X 4cm double pigtail biliary stent</td>
<td>Not reported</td>
<td>100%</td>
<td>100%</td>
<td>11 weeks</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Abbreviations: SEMS: Self-Expandable Metal Stents; Modified BONA-AL - modified by enlarging the flares (22 mm external diameter) and the ends of the stent had a 90° angulation to prevent migration after placement.
the advantage of performing dilation without lifting the ultrasound probe from the gut wall while diathermy causes melting of tissue and inflammatory reaction which can aid in keeping the tissue layers together. Some authors have described the use of 4 mm hurricane biliary balloon dilator either alone or in tandem with the methods mentioned above to achieve adequate dilation.\textsuperscript{8,10}

4. Endoprosthesis

After tract dilation, the stent delivery system or stent followed by the pushing catheter is advanced over the wire and into the cyst. The tip of echoendoscope is then carefully lifted from the luminal wall maintaining the direction to allow visualization of the stent deployment. The distal end of stent is deployed under fluoroscopic guidance, then the proximal end is then deployed endoscopically. The stent length is determined by the combined thickness of the interposed tissue as measured by EUS (Figure 3).

Plastic biliary stents (PBS) were used in most early studies describing EUS-GBD. A variety of PBS such as double pigtail, single pigtail and straight have been used with similar success rates (Table 2).\textsuperscript{12-17} The insertion of a plastic stent usually requires a tract diameter slightly larger than the stent to be placed, which could lead to a gap and potential leakage.\textsuperscript{11} Self expanding metal stents (SEMS) were used for EUS-GBD in one case series of fifteen patients in an attempt to circumvent the limitations of PBS by sealing the gap between the stent and the fistula as the stent expands.\textsuperscript{11} SEMS can also be repositioned if desired, avoiding the need for a second puncture. Jang and colleagues described the use of 10 mm diameter covered metal stents (BONA-AL Standard Sci Tech Inc, Seoul, Korea), which are modified with flared ends up to 22 mm to prevent migration.\textsuperscript{11} The larger diameter of the stent lumen also decreases risk of stent occlusion. Lumen-apposing stents (AXIOS, Xlumena Inc, Mountain View, California) are the newest development in the arena of EUS-GBD. The AXIOS stents have a 10 mm diameter with bilateral anchor flanges, which provide lumen to lumen apposition and prevent leakage.\textsuperscript{8} It is also possible to access the gallbladder lumen through the stent with a slim endoscope to perform biopsies, remove stones or for debridement.\textsuperscript{8,10}

Literature Review (Table 1)

Indications for the procedures included patients with acute cholecystitis that were not suitable for surgical cholecystectomy due to malignancy or other comorbidities and/or after failed endoscopic transpapillary gallbladder stenting. The initial needle puncture was made in a transgastric fashion in 41/60 patients (68.3%) and transduodenally in 19/60 patients (31.6%). One study including 30 patients did not specify whether the puncture was performed transgastrically or transduodenally. Nasocystic drainage tubes were used in 41/90 (45.6%) patients, plastic stents were used in 16/90 (17.8%) of patients, and covered metal stents were used in 33/90 (36.7%) patients.

The overall reported technical success rate is 87/90 (96.6%). Technical failures were attributed to loss of guidewire access (n = 1), uncontrolled stent release (n = 1) and cobblestone gallbladder limiting advancement of guidewire (n = 1). Clinical success defined as improvement in clinical and laboratory parameters was achieved in 100% patients when EUS-GBD was technically successful.

A total of 11/90 (12.2%) patients had complications. Pneumoperitoneum (n = 6) was the most commonly reported complication and was self limited in all cases.\textsuperscript{9,11,12,17} Bile peritonitis (n = 1) and stent migration (n = 1)
were reported with placement of PBS.\textsuperscript{12} Bile peritonitis was managed conservatively. Distal stent migration was seen as a late complication at 3 weeks post-procedure and was without clinical consequence.\textsuperscript{12} AXIOS stents have been associated with self-limited hematochezia (n = 1), right hypochondrium pain (n = 1) and oozing at fistula site (n = 1).\textsuperscript{8,10} Other procedure related events reported include: transient dislodgement of cystoenter-ostome requiring a second puncture with a resultant small bile leak, and clogging, migration or spontaneous expulsion of stent without clinical consequences.\textsuperscript{9,10,12,13,16}

\textbf{Discussion}

Percutaneous techniques have been used for gallbladder drainage for years with good technical and clinical success rates. Risks involved with PT-GBD include liver injury secondary to puncture causing hemorrhage, pneumothorax, bile leak, dislodged tube, and skin site infections, which compromise quality of life and increase length of hospital stay.\textsuperscript{2} PT-GBD has a complication rate ranging up to 12%\textsuperscript{19} and issues such as catheter related pain, management of bile bag and cosmetic problems affect quality of life.\textsuperscript{20} Most patients treated with percutaneous techniques eventually will need a cholecystectomy or acute cholecystitis can recur.\textsuperscript{21} To overcome these limitations, there has been a need for find alternative techniques to manage patients with acute cholecystitis who are poor surgical candidates.

ET-GBD can be technically challenging in the setting of acute cholecystitis and has a risk of post-ERCP pancreatitis.\textsuperscript{22,23} It may not be feasible in patients with an inaccessible papilla or biliary obstruction due to malignancy. EUS-GBD can be a valuable alternative in selected patients not candidates of PT-GBD or ET-GBD. EUS-GBD is carried out through gastric or duodenal wall, avoiding puncture of liver, which is more vascular and is safer in patients with coagulopathy or using anti-platelet agents.\textsuperscript{7-17} It can also be performed safely in patients with perihepatic ascites where PT-GBD is not feasible.

The technique of EUS guided drainage has evolved over past decade with drainage of extraluminal collections such as pancreatic pseudocysts, necrosis and abscesses.\textsuperscript{24,25} We have previously reported drainage of bilomas and gallbladder fossa fluid collections with success.\textsuperscript{6,26} Baron and colleagues first reported successful EUS guided transduodenal gallbladder drainage using double pigtail PBS in a patient with cholangiocarcinoma and bilateral metal biliary stents.\textsuperscript{18} Limited opposition of PBS with the tract wall lead to bile leak and stent migration,\textsuperscript{12,13} although it has been postulated that thickened gallbladder wall and or surrounding adhesions can decrease the risk of bile leak.\textsuperscript{17,18} Most authors have used 7 F or 8.5 F diameter PBS which could clog due to thick drainage.\textsuperscript{12} SEMS avoid these potential limitations of PBS by causing apposition at the tract wall to decrease chances of leakage and a have wider internal diameter that reduces the risk of clogging. Jang and colleagues described use of partially covered SEMS modified by adding flaring and angulations at the distal ends to prevent stent migration.\textsuperscript{11} The ends of SEMS have the potential to cause injury and bleeding by abutting with the gallbladder or bowel lumen, although this has not been reported.\textsuperscript{27} The lumen opposing AXIOS stent is another modification of SEMS by means of a “saddle” shape with distal anchor flanges to ensure both lumen apposition and drainage. Two recent case series involving 18 patients have shown reasonable success rates.\textsuperscript{8,10} Deployment of AXIOS stents can be technically challenging, particularly in patients with a thickened gallbladder wall leading to low technical success rates in the initial pilot study.\textsuperscript{10} The stents have shown to provide an additional advantage of allowing access to the gallbladder lumen with slim (<10 mm) endoscope to perform biopsies, stone removal
or debridement.\textsuperscript{8,10}

Early experience with EUS-GBD procedures has shown minimal adverse events. Pneumoperitoneum, the most common adverse event, was reported only in case series using a biliary dilation catheter for tract dilation. Due to lack of detailed information on individual cases, pneumoperitoneum cannot be clearly be attributed to biliary dilation catheters, but it has been postulated that the sheer force by the dilators has potential to detach and push away the gallbladder wall possibly leading to pneumoperitoneum. SEMS or AXIOS stents are promising since complications associated with PBS such as bile leak and stent migration have not been reported. EUS-GBD with placement of SEMS or AXIOS stent is a reasonable palliative option in patients with malignancy affecting biliary system and avoids recurrence of cholecystitis due to stent blockage or removal as seen with other techniques which use smaller diameter drains. EUS-GBD with AXIOS can also aid in treatment of large stones by performing cholecystoscopy.\textsuperscript{10}

In summary, EUS-GBD is an evolving alternative to PT-GBD or ET-GBD in selected patients as a bridge to surgery or for palliation. The potential to perform therapeutic maneuvers will expand its applications in future. With continued development of EUS drainage accessories and experience with the drainage techniques, EUS-GBD is likely to have better technical success rates with minimal adverse events. With the widespread adoption of EUS-GBD, the indications are likely to expand. It can potentially be an access point for therapies directed towards biliary tree or liver such as photodynamic therapy, radiofrequency ablation through a transcystic approach in patients with inaccessible ampulla due to malignancy or altered anatomy after bariatric surgery.

References