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# EUS-Guided Choledochoduodenostomy: Current Role and Status



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## INTRODUCTION

There are a variety of conditions which may lead to biliary obstruction, usually as a result of malignancy. Endoscopic retrograde cholangiopancreatography (ERCP) is usually highly successful in relieving biliary obstruction via stent placement in these patients, but can fail if the ampulla is not reachable due to gastric outlet obstruction (GOO).<sup>1,2,3,4</sup> The 2<sup>nd</sup> portion of the duodenum/papilla can become infiltrated by invasive malignancy, which can also hamper efforts at deep biliary cannulation.<sup>1-2,4</sup> Up to 80% of biliary obstruction cases are due to pancreatic cancer, followed by duodenal cancer, cholangiocarcinoma, metastatic disease, and ampullary cancer.<sup>4,5,6,7,8,9,10,11</sup> To a lesser degree, biliary obstruction can also occur with benign conditions such as choledochal cysts, chronic pancreatitis, and post-cholecystectomy biliary strictures.<sup>12</sup>

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Percutaneous biliary drainage (PTBD) and surgery are the traditional methods for biliary drainage when ERCP is not possible or has failed.<sup>13</sup> However, surgical biliary bypass is associated with high morbidity and costs when compared to endoscopic therapy.<sup>2,13</sup> While PTBD is effective, it is associated with significant adverse events including fistulas, bleeding, and abscess formation.<sup>2</sup> Moreover, external drains frequently require exchanges and can significantly impact a patient's quality of life.<sup>13</sup> As a result, EUS-guided choledochoduodenostomy has emerged as another option to manage biliary obstruction in these cases.

## Development of EUS-Guided Choledochoduodenostomy (EUS-CDS)

Giovanni et al. first reported EUS-CDS in 2001.<sup>14</sup> EUS-CDS is thought to be an easier procedure for draining biliopancreatic tumors.<sup>7</sup> Moreover, the rate of tumor ingrowth may be lower as the biliary stricture is not traversed and a fistula is formed away from the tumor.<sup>5,15</sup> While earlier studies suggested EUS guided biliary drainage (EUS-BD) offered greater stent patency than endoscopic transpapillary stenting (ETS), more recent studies

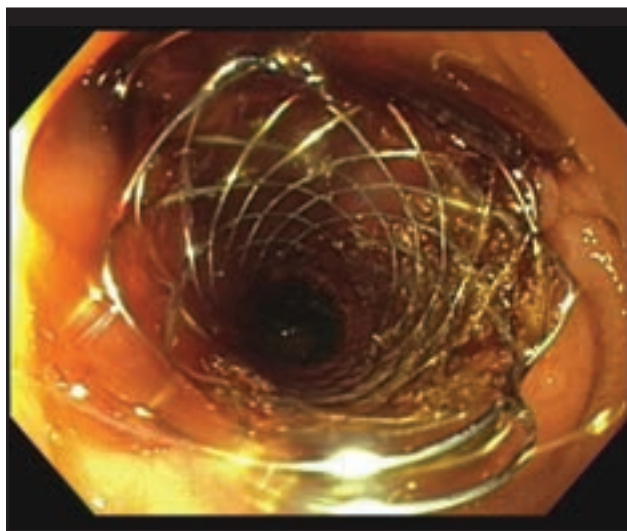
demonstrate similar clinical efficacy, with shorter procedure time and decreased incidence of post-procedural pancreatitis in EUS-CDS.<sup>15,16</sup>

There are two primary approaches to EUS-BD: hepatogastrostomy (EUS-HGS) and EUS-CDS.<sup>11</sup> EUS-HGS targets the intrahepatic bile ducts from the stomach, but as there is a thick wall to penetrate, stent deployment can be technically difficult.<sup>17</sup> Movement of the liver during breathing may lead to inward stent migration and additional risks include bile leak, biloma, and gastric perforation.<sup>17,18</sup> Furthermore, procedural time with EUS-HGS is usually longer as there are more manipulations with the guidewire.<sup>18</sup> In EUS-CDS, the extrahepatic biliary ducts are accessed in a transmural manner via the duodenal bulb. The thinner duodenal wall facilitates puncture and abuts the bile duct with minimal respiratory influence.<sup>17</sup> It is important to note that stent deployment in the duodenal bulb can be technically challenging because of a relatively unstable endoscope position and small space between the echoendoscope tip and duodenal wall.<sup>6</sup>

EUS-CDS was initially performed with plastic stents and while inexpensive, it was prone to bile leaks.<sup>5,6</sup> Due to small luminal diameter, there was also an increased risk of early stent occlusion.<sup>6,15,19</sup> Since patency decreased after 3 months, the stents were designed to be easily removed and exchanged as needed.<sup>19</sup>

The next innovation in EUS-CDS development was the use of covered metal stents. Because of expandability, fully covered or partially covered self-expanding metal stents (SEMS) can potentially seal the gap between fistula and stent better than plastic stents, thus minimizing bile leakage.<sup>13,20</sup> (Figure 1) When compared with plastic stents, SEMS offered larger diameters (8-10mm vs. 7-10Fr), which increased the duration of stent patency.<sup>20</sup> However, an issue that has been noted is the rate of stent migration, since tubular SEMS have no antimigration system.<sup>6,20</sup> Furthermore, while SEMS possesses an adequate diameter for effective biliary drainage, the ends of the stent may lead to tissue injury and bleeding in the duodenum and/or the biliary tree.<sup>6</sup>

The advent of the lumen apposing metal stent (LAMS) enabled creation of anastomoses to drain entities such as pancreatic fluid collections and the gallbladder.<sup>21</sup> Prior biliary drainage techniques were

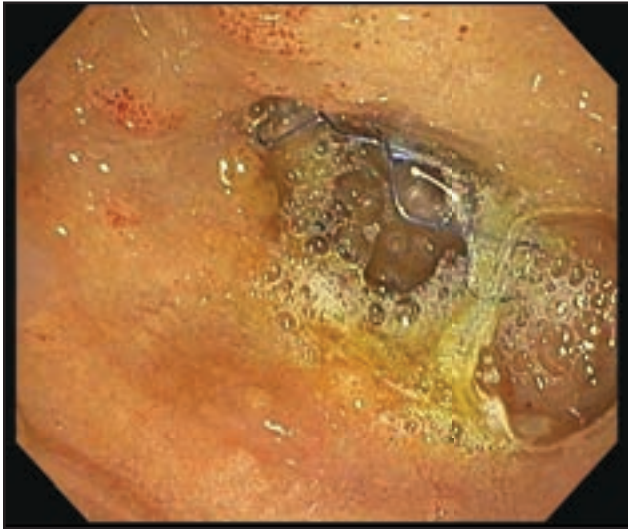


**Figure 1. Fully Covered Self-Expanding Metal Stent after deployment across the duodenal bulb into the distal common bile duct in a patient with pancreatic cancer.**

performed without dedicated accessories, so the emergence of LAMS was soon applied to drainage of biliary obstruction.<sup>1</sup> The 6mm x 8mm LAMS, 8mm x 8mm LAMS, and the 10mm x 10mm LAMS are used most frequently for biliary drainage (in an off-label manner). The choice of stent size is largely determined by operator preference, taking into account the size of the bile duct and the luminal access point.<sup>1,8,13</sup> As the LAMS diameter ranges from 6mm to potentially 10mm, this provided better drainage compared to PTBD catheters and the flanges prevent migration.<sup>10</sup> LAMS greatly simplified the technique for EUS-CDS, but in this form, several steps are still required to properly place the stent.<sup>6</sup>

### **EC-LAMS: The Current Approach for EUS-Guided Choledochoduodenostomy**

While there is high clinical success for EUS-CDS, there is also a relatively high rate of associated adverse events and a small but definite mortality risk (0.4%) which may reflect the learning curve.<sup>22</sup> This has led to the development of dedicated accessories for EUS-CDS.<sup>22</sup> Electrocautery Enhanced LAMS (EC-LAMS) span two gastrointestinal lumens using an electrocautery enhanced cutting tip, so tract dilation is not required, nor is even the use of a guidewire as the stent placement can be performed via the freehand technique.<sup>23</sup> EC-LAMS eliminates



**Figure 2. Duodenal bulb in a patient with biliary obstruction and pancreatic cancer. Prior duodenal stent in place. The 2<sup>nd</sup> duodenum is not endoscopically accessible.**



**Figure 3. EUS image of dilated common bile duct.**

device exchanges and has markedly increased efficiency of EUS-CDS.<sup>8</sup>

Under endosonographic guidance, a needle (frequently 19-gauge) is used to puncture the extrahepatic bile duct via the duodenal bulb.<sup>24</sup> Bile is aspirated, and contrast is injected to create a cholangiogram and confirm the location under fluoroscopy. Either a 0.025" or 0.035" guidewire is then passed into the bile duct. The needle is removed, and the EC-LAMS system is passed over the guidewire and once at the duodenal wall, current is used to advance the system into the bile duct through the duodenal wall and the bile duct wall. The distal flange is deployed under endosonographic and/or fluoroscopic guidance and the proximal flange is deployed under endoscopic guidance. A second stent can be placed on the non-perpendicular axis of the LAMS into the bile duct to prevent the wall from collapsing into the inner flange after biliary decompression, if desired.<sup>23</sup> Wire placement was recommended before the ability to recapture the LAMS, to prevent misdeployment.<sup>13</sup> However, in experienced hands, wire access is not always necessary, and the entire procedure can be performed via a freehand technique to save time and increase efficiency.<sup>4</sup> (Figures 2-7)

Compared to multi-stage process, EC-LAMS decreases adverse events, procedural time, and

fluoroscopy exposure.<sup>13</sup> It is worth noting that post-ERCP pancreatitis can affect eligibility for curative surgery for advanced pancreatic disease, but EUS-guided procedures avoid manipulation of the papilla entirely and, by and large, do not cause post-procedure pancreatitis. Thus, some sources suggest that EUS-CDS should be evaluated as a primary procedure for stenting biliary obstruction, disease staging, and tissue sampling, although at most centers ERCP remains first-line therapy.<sup>4</sup>

### Risks and Adverse Events

Despite the benefits of EUS-CDS, there are immediate and delayed adverse events which are important to acknowledge.

With regard to LAMS, there is the possibility of misdeployment, dislodgement, as well as duodenal perforation, and bleeding.<sup>1,22</sup> Reintervention is most commonly required for stent obstruction secondary to disease progression, food impaction, sump syndrome (accumulation of debris in the common bile duct (CBD) distal to the anastomosis in a side-to-side choledochoduodenostomy), stent migration, LAMS dysfunction, and cholangitis.<sup>1,6,13,22</sup> It is thought that smaller stent diameter (6mm/8mm) may be more prone to clogging than a larger bore stent (10mm).<sup>6</sup> Moreover, the distal flange can kink in the bile duct after decompression, resulting



**Figure 4. Electro-cautery enhanced LAMS used to create a choledochoduodenostomy.**



**Figure 5. Dye is injected to create a cholangiogram and a guidewire is inserted for stability.**

in stent occlusion and cholangitis.<sup>6</sup> Thus, many sources recommend LAMS placement may be best in patients with a dilated CBD i.e. > 10-15mm to allow for safer opening of the distal flange.<sup>10,13</sup>

In regard to fully covered self-expanding metal stents (FC-SEMS), early adverse events include cholangitis, cholecystitis, liver abscess, and peritonitis.<sup>15,22,24,25</sup> Migration is a frequent reason for reintervention, seen in approximately 20% of cases, followed by food impaction, tumor ingrowth, stent dysfunction, and to lesser degree, infections.<sup>22,24,25</sup>

Early adverse events following plastic stent placement include bile peritonitis, hemobilia, and pneumoperitoneum.<sup>26</sup> Delayed adverse events include stent occlusion and migration.<sup>5,26</sup> Da Silva et al. reported a particularly severe case of two double pigtail stents migrating from the duodenal bulb into the abdominal cavity, requiring surgical management. This led to concerns regarding the challenging nature of plastic stent positioning and placement.<sup>11</sup>

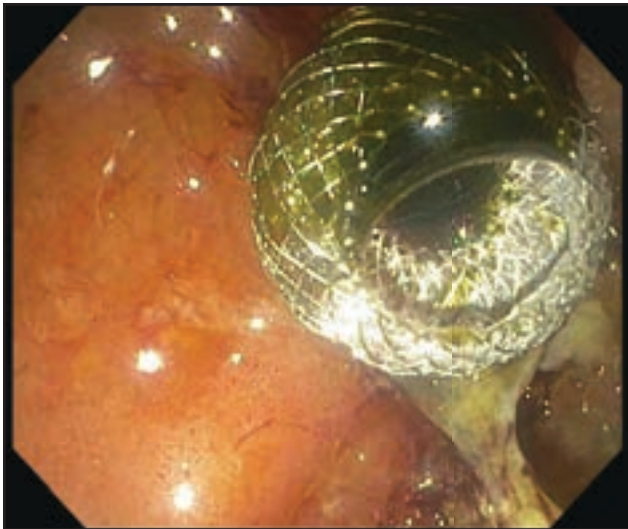
Vanella et al. advocated for dividing LAMS dysfunction into categories to standardize research, evaluate pathogenesis of the dysfunction, and develop rescue strategies.<sup>3</sup> Type 1 dysfunction is sump syndrome, managed with transpapillary stent placement. Type 2 dysfunction is stone impaction (type 2a) or food impaction (type 2b), both of which are treated with balloon extraction. Type 3

dysfunction is LAMS invasion on the biliary side (3a) or duodenal side (3b), treated by placing double pigtail stents or SEMS through the LAMS. Type 4 dysfunction is LAMS migration, which can be managed by replacing the LAMS through the same fistula, creating a new EUS-CDS, or other methods of EUS-BD. Type 5 dysfunction exists when the malignant biliary obstruction occurs concurrently with a GOO, compromising EUS-CDS patency. The ideal situation would be to resolve the GOO via EUS-guided gastroenterostomy. However, if this does not work, percutaneous transpapillary stenting or EUS-HGS are additional options.<sup>3</sup>

### Comparison Studies

Biliary drainage procedures have evolved over time and several studies have evaluated these different techniques. In a retrospective cohort study, Sawas et al. evaluated EUS-CDS (via LAMS and SEMS) vs. PTBD in 86 patients. There was similar technical success (100% in EUS-CDS vs. 96.6% PTBD), but EUS-CDS carried greater clinical success (84.6% vs. 62.1% in PTBD) and had lower adverse event rate (14.3% vs. 29.3% in PTBD). There was no significant difference in survival between the 2 groups and the re-intervention rate was significantly lower with EUS-CDS vs. PTBD (10.7% vs. 77.6%,  $p < 0.001$ ).<sup>10</sup>

Furthermore, in a retrospective cohort analysis by Kawakabu et al. comparing optimal drainage



**Figure 6. Endoscopic image of LAMS after deployment.**



**Figure 7. Final fluoroscopic image of LAMS choledochoduodenostomy after creation with internal biliary drainage.**

technique, 26 patients underwent EUS-CDS and 56 patients underwent ETS with covered metal stents. Clinical success was similar between the two groups (96.2% in EUS-CDS vs. 98.2% in ETS,  $p=0.54$ ), however adverse events occurred in 26.9% of those with EUS-CDS compared to 35.7% of those with ETS. While these figures appear high, the study involved a small sample size and most adverse events were milder cases of pancreatitis, abdominal pain, and fevers. This study suggests that when managing distal malignant biliary obstruction (MDBO) caused by non-pancreatic cancer, there is similar success and efficacy between EUS-CDS and ETS, but the former reduces risk of pancreatitis.<sup>15</sup> Notably, this study was conducted among centers with extensive experience in interventional EUS. As EUS-CDS may not be feasible if the required expertise is not available, ERCP is the most commonly used technique, given the widespread availability and good clinical success rate.

De Benito Sanz and colleagues conducted a retrospective study of 57 patients comparing LAMS to SEMS among patients undergoing EUS-CDS. There was 95% technical success in each cohort and similar clinical success (LAMS 94.7% vs. SEMS 100%,  $p=NS$ ). There was a 5.4% mild adverse event rate for the LAMS cohort compared to a 10% mild adverse event rate with SEMS and a 5.4% serious adverse event rate requiring surgical

management for bile leak in the LAMS cohort versus 5% serious adverse event rate requiring surgery in those with SEMS ( $p=0.71$ ). Overall, there were equivalent results among the two stent types, however SEMS were more affordable and didn't require as dilated a CBD, while EC-LAMS allowed a simpler insertion process. The authors concluded that choice of therapy depended on center expertise, cost of treatment, and safety concerns.<sup>22</sup>

There was further refinement of the LAMS technique as demonstrated by the multicenter retrospective analysis by El Chafic et al., where EUS-CDS was successfully completed with EC-LAMS in 64/67 patients with technical success 95.5%. A plastic/metal stent was placed through the lumen of the LAMS in 78.1% of patients to maintain a non-perpendicular LAMS orientation into the bile duct and prevent the bile duct wall from collapsing into the inner flange after decompression. Biliary re-intervention for obstruction was required in 7 patients. The authors determined that EC-LAMS could be performed with high clinical and technical success and inserting an axis-orienting plastic stents through the lumen of the LAMS may reduce the need for biliary re-interventions.<sup>23</sup>

Fugazza et al. conducted a multicenter retrospective analysis of EUS-CDS using LAMS in patients with MDBO after failed ERCP. Centers with low and high experience in placing LAMS

for EUS-CDS were evaluated. The single stage technique was used in 89.7% of low-experience centers, compared with 98% of high-experience centers. Similarly, guidewire was utilized in 10.3% of low-experience centers, versus 2% of high-experience centers ( $p=0.004$ ). There was similar technical success among the cohorts, which was associated with shorter procedures and larger CBD size. The authors concluded that the study findings provided evidence for reproducibility of EUS-CDS for challenging cases of MDBO among a wide variety of centers.<sup>9</sup>

A retrospective study by Wei et al. examined EUS-CDS for MDBO using EC-LAMS and several metrics were evaluated. Technical success with 6mm EC-LAMS was similar to that of 8-10mm EC-LAMS, but higher adverse event rates (OR 3.71,  $p=0.008$ ) and reintervention rates (OR 6.17,  $p=0.019$ ) were seen in the 6mm LAMS cohort due to stent occlusion and cholangitis. Due to orientation of EC-LAMS in the duodenal bulb, the luminal opening can become occluded with debris. A larger diameter EC-LAMS may circumvent this, but placement can be challenging due to the flange size. An additional observation from this study was that indwelling EC-LAMS did not hinder surgery in patients that subsequently underwent pancreaticoduodenectomy.<sup>4</sup>

## CONCLUSION

Both benign and malignant conditions can lead to biliary obstruction, but when ERCP fails, a few good options are available. Surgical management is associated with significant cost and morbidity and while percutaneous approaches with external drains are highly effective, these may lead to fistulas and negatively affect quality of life. EUS-CDS provides an alternative means of biliary decompression with decreased mortality and incidence of pancreatitis. LAMS increased efficiency of the procedure and ongoing refinement of the technique will address other adverse events which are encountered (i.e., stent occlusion and cholangitis). While factors such as cost of treatment and technical expertise may influence the adoption of this practice, for patients with MDBO and failed ERCP or those in whom ERCP is not technically possible, the results thus far have been promising and the procedure is entering more widespread practice. ■

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