Technical tips of endoscopic ultrasound-guided choledochoduodenostomy

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Abstract

Endoscopic ultrasound (EUS) is clinically useful not only as a diagnostic tool during EUS-guided fine needle aspiration, but also during interventional EUS. EUS-guided biliary drainage has been developed and performed by experienced endoscopists. EUS-guided choleodochoduodenostomy (EUS-CDS) is relatively well established as an alternative biliary drainage method for biliary decompression in patients with biliary obstruction. The reported technical success rate of EUS-CDS ranges from 50% to 100%, and the clinical success rate ranges from 92% to 100%. Further, the over-all technical success rate was 93%, and clinical success rate was 98%. Based on the currently available literature, the overall adverse event rate for EUS-CDS is 16%. The data on the cumulative technical and clinical success rate for EUS-CDS is promising. However, EUS-CDS can still lead to several problems, so techniques or devices that are more feasible and safe need to be established. EUS-CDS has the potential to become a first-line biliary drainage procedure, although standardizing the technique in multicenter clinical trials and comparisons with endoscopic biliary drainage by randomized clinical trials is still needed.

Key words: Endoscopic ultrasound; Endoscopic ultrasound-guided choledochoduodenostomy; Endoscopic ultrasound-guided biliary drainage; Percutaneous transhepatic biliary drainage

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Core tip: Endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) is relatively well established as an alternative biliary drainage method. The reported technical success rate of EUS-CDS ranges from 50% to 100%, and the clinical success rate ranges from 92% to 100%. Further, the over-all technical success rate was 93%, and clinical success rate was 98%. Based on the currently available literature, the overall adverse event rate for EUS-CDS is 16%. EUS-CDS may become the first choice of the biliary tract drainage procedure in the local cases such as poor prognosis, the contraindication of percutaneous transhepatic biliary drainage.
INTRODUCTION

Obstructive jaundice is a major adverse effect of pancreatic or biliary carcinoma. This adverse event requires treatment, especially in patients who cannot be treated surgically due to concurrent chemotherapy. Endoscopic biliary stenting (EBS) is a gold standard method of treatment for obstructive jaundice.\(^1,2\) However, this method is associated with several problems, such as post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis. In addition, EBS cannot be performed in patients with selective cannulation failure of the major papilla or an inaccessible papilla due to duodenal invasion. The alternative method under these conditions is percutaneous transhepatic biliary drainage (PTBD).\(^3,4\) However, PTBD can lead to several adverse events, such as cholangitis, bile leakage and pneumothorax. Moreover, the frequency of major complications, such as prolonged hospital stay and permanent adverse sequelae, is 4.6%-25%, and that of procedure-related deaths is 0%-5.6%\(^[5,6]\). Cosmetic issues due to external drainage also compromise the patient’s quality of life.

Endoscopic ultrasound (EUS) is clinically useful not only as a diagnostic tool during EUS-guided fine needle aspiration (FNA), but also during interventional EUS. Among the different types of interventional EUS, endoscopic ultrasound-guided biliary drainage (EUS-BD) has been developed and performed by experienced endoscopists. The technique of EUS-BD depends on the approach route. For transgastric EUS-BD, EUS-guided hepaticogastrostomy (EUS-HGS) is performed, in which the intrahepatic bile duct (usually segment 3; B3) is punctured via the stomach, and stent placement is performed from the intrahepatic bile duct to the stomach.\(^7\) For transduodenal EUS-BD, EUS-guided choledochoduodenostomy (EUS-CDS) is performed, in which the common bile duct (CBD) is punctured, and stent placement is performed from the CBD to the duodenum. For transgastric or transduodenal EUS-BD, EUS-guided gallbladder drainage (EUS-GBD) is performed, in which the gallbladder is punctured and a stent is placed from the gallbladder to the stomach or duodenum.\(^8\) In addition, the EUS-guided rendezvous technique (EUS-RV) is also included as EUS-BD.\(^9\)

While EUS-HGS and EUS-GBD have clinical benefits in certain patients, their use is associated with several adverse events, including stent migration. If stent migration does occur, it is sometimes fatal. Therefore, novel methods or new devices are required to prevent the complications associated with these procedures. EUS-RV is only indicated for patients in whom the ampulla of Vater is accessible by duodenoscopy. This procedure is sometimes difficult and requires a long procedure time.\(^9\)

On the other hand, EUS-CDS is relatively well established as an alternative biliary drainage method with a relatively low rate of adverse events, for biliary decompression in patients with biliary obstruction. However, EUS-CDS can still lead to several problems, so techniques or devices that are more feasible and safe need to be established.

Table 1 shows an overview of previous reports of EUS-CDS\(^[10-45]\). Herein, we present technical tips on the performance of EUS-CDS and review of the literature on EUS-CDS, especially its techniques and adverse events.

INDICATIONS

EUS-CDS is mainly performed for patients with failed EBS excluded prospective clinical trial, as was previously described by Hara et al.\(^[26]\) and Itoi et al.\(^[42]\). This procedure can be performed for obstructions in the middle and lower bile duct.

The primary diseases in patients who underwent EUS-CDS were pancreatic carcinoma (\(n = 98\)), ampullary carcinoma (\(n = 14\)), and cholangiocarcinoma (\(n = 13\)). This indicates that pancreato-biliary carcinoma is the main indication for EUS-CDS. On the other hand, EUS-CDS for benign biliary stricture was only performed in 2 patients, as previously reported. EUS-CDS is contraindicated in patients with surgically altered anatomy, such as a Roux-en-Y anastomosis or duodenal obstruction caused by tumor invasion, through which an endoscope cannot be passed. In such cases, EUS-guided hepaticogastrostomy may be indicated. However, if the duodenal bulb is not involved, EUS-CDS can be performed in combination with duodenal stenting (Figure 1).

The indications for EUS-CDS vs ERCP for benign disease are still not completely known. Therefore, prospective randomized controlled trials comparing EUS-CDS with ERCP are needed to assess the clinical efficacy of the procedure.

Hence, the following are the indications for EUS-CDS: (1) failed EBS; (2) inaccessibility of the ampulla of Vater, such as due to duodenal invasion by the tumor; (3) contraindications for percutaneous transhepatic biliary drainage (PTBD); and (4) middle or lower bile duct obstruction.

DEVICE SELECTION AND TECHNICAL TIPS

Puncture of the common bile duct

To visualize the CBD on EUS, the EUS scope is advanced into the duodenum, turned slightly to the left and angled downwards. The CBD is punctured using a 19-G needle under Doppler visualization, to avoid any intervening vessels. Bile juice is aspirated and a small amount of contrast medium is injected. During this step, it is important to avoid puncturing the duodenal mucosa and cystic duct. As shown in Figure 2, when a double duodenal mucosal line is visualized on EUS, the CBD should not be punctured to avoid puncture and stenting through double duodenal mucosa.

According to previous reports, a 19G or 22G FNA needle or needle knife is used to puncture the CBD. As of now, there are no randomized controlled trials...
| Ref. | $n$ | Disease ($n$) | Indications | Technical success | Clinical success | Puncture device ($n$) | Dilatation device | Stents | Adverse events ($n$) |
|------|-----|--------------|-------------|------------------|------------------|--------------------|----------------|--------|-------------------|
| Giovannini et al$^{[a]}$ | 1 | Pancreatic carcinoma | Faild EBD | 1 (100) | 1 (100) | 5 Fr needle knife, 19 G FNA needle | 6.5 Fr dilator | 10 Fr PS | None |
| Burmester et al$^{[a]}$ | 2 | Pancreatic carcinoma (2) | Faild EBD | 1 (50) | 1 (100) | 19 G fistulome needle knife | None | 8.5 Fr PS | Bile peritonitis (1) |
| Puspok et al$^{[a]}$ | 5 | N/D | Faild EBD | 4 (80) | 4 (100) | Needle knife, 19 G FNA needle | 8 mm balloon | 7-10 Fr PS | None |
| Kahaleh et al$^{[a]}$ | 1 | Pancreatic carcinoma | Faild EBD | 1 (100) | 1 (100) | 19 G FNA needle | N/D | 10 mm MS | Pneumoperitoneum (1) |
| Yamao et al$^{[a]}$ | 5 | Pancreatic carcinoma (3), ampulla carcinoma (2) | Faild EBD | 2 (100) | 2 (100) | Needle knife | 7 Fr, 9 Fr dilator | 7-8.5 Fr PS | Pneumoperitoneum (1) |
| Ang et al$^{[a]}$ | 2 | Pancreatic carcinoma (2) | Faild EBD | 2 (100) | 2 (100) | 19 G FNA needle | 7 Fr dilator | 7 Fr PS | Pneumoperitoneum (1) |
| Fujita et al$^{[a]}$ | 1 | Ampulla carcinoma | Faild EBD | 1 (100) | 1 (100) | 19 G FNA needle | Dilator | 7 Fr PS | None |
| Tarantino et al$^{[a]}$ | 4 | Pancreatic carcinoma (2), cholangiocarcinoma (1), malignant lymphoma (1) | Faild EBD | 4 (100) | 4 (100) | 19 G, 22 G FNA needle, needle knife | 4 mm balloon | PS | None |
| Itoi et al$^{[a]}$ | 4 | Pancreatic carcinoma (2), ampulla carcinoma (2) | Faild EBD | 4 (100) | 4 (100) | Needle knife, 19 G FNA needle | 7 Fr, 9 Fr dilator, balloon | 7 Fr PS (3), NBD (1) | Bleeding (1), peritonitis (1) |
| Brauer et al$^{[a]}$ | 3 | Pancreatic carcinoma (1), gastric carcinoma (1), cholecystolithiasis (1) | Faild EBD | 3 (100) | 3 (100) | 19 G FNA needle, needle knife | N/D | 5 Fr, 10 Fr PS | Cardiac and respiratory failure (1), pneumoperitoneum (1) |
| Horaguchi et al$^{[a]}$ | 8 | Pancreatic carcinoma (5), ampulla carcinoma (1), cholecystolithiasis (1), Lymph note metastasis (1) | Faild EBD | 8 (100) | 8 (100) | 19 G FNA needle | 5 Fr dilator, 4 mm balloon | 7 Fr PS (7), NBD (1) | Peritonitis (1) |
| Hanada et al$^{[a]}$ | 4 | Pancreatic carcinoma (4) | Faild EBD | 4 (100) | 4 (100) | 19 G FNA needle | 6 Fr, 7 Fr dilator | 6 Fr, 7 Fr PS | None |
| Iwamuro et al$^{[a]}$ | 5 | Pancreatic carcinoma (4), ampulla carcinoma (1) | Faild EBD | 5 (100) | 5 (100) | Needle knife | 7 Fr dilator | 7 Fr PS | Abdominal pain, fever (1) |
| Artifon et al$^{[a]}$ | 3 | Pancreatic carcinoma (3), ampulla carcinoma (2) | Faild EBD (2), duodenal invasion (1) | 3 (100) | 3 (100) | 19 G FNA needle, needle knife | Needle knife | 10 mm MS | None |
| Belletrutti et al$^{[a]}$ | 1 | Pancreatic carcinoma | Faild EBD | 1 (100) | 1 (100) | 19 G FNA needle | 6 mm balloon | 10 mm MS | None |
| Hara et al$^{[a]}$ | 18 | Pancreatic carcinoma (15), uterus carcinoma (1), gastric carcinoma (1), gallbladder carcinoma (1) | Faild EBD | 22 (92.9) | 17 (94) | 22G FNA needle, needle knife | 22G FNA needle, needle knife | 6, 7, 9 Fr dilator | 7, 8.5 Fr PS | Bile peritonitis (2), hemobilia (1) |
| Siddiqua et al$^{[a]}$ | 8 | Pancreatic carcinoma (6), cholangiocarcinoma (2) | Faild EBD | 8 (100) | 8 (100) | 19 G FNA needle | Needle knife | 10 mm MS | Stent migration/duodenal perforation (1), abdominal pain (1), pneumoperitoneum (1) |
| Fabbri et al$^{[a]}$ | 12 | Pancreatic carcinoma (7), cholangiocarcinoma (4), ampulla carcinoma (1), gallbladder carcinoma (1) | Faild EBD | 9 (75) | 9 (100) | 19 G FNA needle, needle knife | 4 mm balloon | MS | None |
| Komaki et al$^{[a]}$ | 15 | Unresectable malignant biliary obstruction | Faild EBD | 14 (93) | 14 (100) | 19 G FNA needle, needle knife | Dilator | 7 Fr PS | None |
| Prachayakul et al$^{[a]}$ | 1 | Pancreatic carcinoma | Faild EBD | 1 (100) | 1 (100) | N/D | Dilator | PS | None |
| Ramirez-Luna et al$^{[a]}$ | 9 | Pancreatic carcinoma (4), cholangiocarcinoma (2), metastases (1), ampulla carcinoma (1), neuroendocrine (1) | Faild EBD | 8 (89) | 8 (100) | 19 G FNA needle | Needle knife, 6, 7, 10 Fr dilator | 7, 8, 10 Fr PS | Biloma (1) |
| Park do et al$^{[a]}$ | 26 | Pancreatic carcinoma | Faild EBD | 24 (92) | 22 (92.9) | 19 G FNA needle | 4 Fr ERCP cannula, 6, 7 Fr dilator, needle knife | PS, MS | Bile peritonitis (2), unknown (3) |
Comparing the outcomes of various FNA needles in EUS-CDS. Recently, a novel FNA needle (Sono Tip Pro Control 19G needle, Medi-Globe GmbH, Rosenheim, Germany) (Figure 3) has become available. The cut surface of this FNA needle is 5 mm long, and is believed to be extremely sharp. Therefore, we think this needle is appropriate for use in interventional EUS.

**Guidewire insertion into the bile duct**

After the contrast is injected into the CBD, the guidewire is placed deep in the intrahepatic bile duct. On EUS imaging, when the CBD is aligned parallel to the FNA needle, the guidewire can be easily advanced toward the hepatic hilum.

To enable passage of a 0.035 inch stiff guidewire into the needle, a 19-gauge needle should be selected. A 0.025 inch guidewire with a highly flexible tip, sufficient stiffness, and easily seeking ability (VisiGlide; Olympus Medical Systems, Tokyo, Japan) is preferable. To avoid wire sharing, a novel guidewire which top formation is coil (Cyst-wire, Medi-Globe) (Figure 4) is also useful.

**EBD: Endoscopic biliary drainage; FNA: Fine needle aspiration; EBS: Endoscopic biliary stenting; ERCP: Endoscopic retrograde cholangiopancreatography; NBD: Negative binomial distribution; NA: Not applicable; PS: Plastic stent; MS: Metal stent; N/D: Not determined.**
devices, it is important to be able to view the devices under both EUS and fluoroscopic guidance, to ensure that they fit the axis.

**Devices used to dilate the fistula**

Various devices have been previously described for dilatation of the fistula after puncturing the CBD. The most common devices for transmural tract dilation are the dilator (6 to 10 Fr; Soehendra biliary dilation catheters, Cook Medical), balloon catheter (4-8 mm; MaxForce or Hurricane RX; Boston Scientific), or needle knife (Microtome, Boston Scientific). Park reported that the overall adverse event rate of EUS-BD, including EUS-CDS and EUS-HGS, was 27% (15/55). They also described the use of a needle...
metal stents (SEMS) should be selected. However, therefore, partially or fully covered self-expandable stents have a longer patency than plastic stents. Second, benefits. First, because of their large diameter, metallic stents are expected to offer several clinical advantages associated with a low rate of adverse events and long success rate compared with ERCP. Therefore, if EUS-CDS is preferable in order to avoid stent migration.

Stent migration is also usually a challenging complication of EUS-BD. With the use of the standard metallic stent, some authors described that a double pigtail plastic stent can be placed inside the metal stent, with the pigtail functioning as an anchor. Among standard metallic stents, metallic stents with a wide flange should be selected, and stent shortening to a length of 60 mm may be preferable in order to avoid stent migration.

Recently, a novel SEMS has been developed. The NAGI-Stent (Taewoong-Medical Co., Seoul, South Korea) is delivered through a 10.5 Fr catheter, and consists of a fully covered 20 mm long and 16 mm diameter stent with bilateral anchor flanges. The AXIOS stent (Xlumena Inc., Mountain View, CA, United States) is a fully covered, 10 mm diameter, 10 mm long, braided stent with bilateral 20 mm diameter anchor flanges. These novel SEMSs are used for EUS-guided pseudocyst drainage and EUS-guided cholecytostomy. This SEMS seems to be useful for EUS-CDS as well, although clinical trials are needed to confirm its utility.

According to previous reports, the mean stent patency in EUS-CDS was similar to PTBD (198 d vs 184 d, P = 0.86). Although there were no reports of comparison between EUS-CDS and EBS, stent patency of EBS (covered metallic stent; 585 d, uncovered metallic stent; 314 d) may be longer than EUS-CDS according to previously described report. Randomized clinical trials are needed with standardizing kinds of biliary stents.

SUCCESS RATE

The reported technical success rate of EUS-CDS ranges from 50% to 100%, and the clinical success rate ranges from 92% to 100%. Further, the over-all technical success rate was 93% (199/213), and clinical success rate was 98% (183/187). This is a relatively high success rate compared with ERCP. Therefore, if EUS-CDS is associated with a low rate of adverse events and long stent patency, it has the potential to be the bile drainage method of choice instead of EBS. A prospective randomized clinical trial is needed to compare endoscopic biliary drainage and EUS-CDS.

ADVERSE EVENTS

Based on the currently available literature, the overall adverse event rate for EUS-CDS is 16% (34/213). EUS-CDS has the potential to cause several adverse events compared with those using a needle knife. Studies comparing these devices are, therefore, warranted.

Stent selection

Both plastic and metallic stents have been used during EUS-CDS. Previously, plastic stents with diameters ranging from 5 to 10 Fr were used. Generally, because of the diameter of the working channel of the EUS is 3.7 mm, a 7 or 8.5 Fr plastic stent is used. However, as shown in Figure 6, bile leak can occur with plastic stent placement. This patient had abdominal pain and fever for up to 3 d after EUS-CDS, and computed tomography and duodenoscopy showed bile leakage. If a large fistula is created during stent placement, bile leakage from the gap between the stent and the fistula is likely to occur because of the fine gauge of the plastic stent.

On the other hand, although no comparative studies exist, metallic stents are expected to offer several clinical benefits. First, because of their large diameter, metallic stents have a longer patency than plastic stents. Second, due to the close proximity between the metallic stent and the duodenal wall and bile duct, bile leak is less likely to occur. Use of an uncovered metallic stent, however, can easily cause bile leakage, which is sometimes fatal. Therefore, partially or fully covered self-expandable metal stents (SEMS) should be selected. However, although these SEMS have the advantage of preventing bile leakage, they also have the disadvantage of causing occlusion of the side branch of the bile duct. This suggests that if the distance between the site of the puncture and the hepatic hilar portion is short, a partially covered SEMS should be selected to prevent occlusion of the intrahepatic bile duct. Unfortunately, when a partially covered SEMS is used, bile leak can occur from the uncovered part, particularly between the bile duct and the gastrointestinal tract.

Figure 5  Cysto-Gastro-Set (Endoflex, GmbH, Voerde, Germany). This devise is always coaxial with the guidewire.
events, including: (1) infection (peritonitis, cholangitis, cholecystitis); (2) pneumoperitoneum; (3) bile leakage, biloma; (4) bleeding; (5) abdominal pain; (6) perforation; and (7) stent migration.

Based on previous reports, the most frequent adverse events were pneumoperitoneum (28%, 9/34). In most EUS-CDS cases, if adverse events do occur, they can be treated conservatively. However, two deaths related to EUS-CDS, due to cardiogenic shock and bile leakage, were also reported by Maluf-Filho et al [41]. In both these patients, the bile leak occurred because of use of an uncovered SEMS. However, even if a fully covered SEMS is selected, the risk of bile peritonitis still remains. This adverse event may occur because of bile or air leak during dilation of the fistula while inserting the stent delivery system. Therefore, to avoid these adverse events, more developed devices that would enable one-step stent placement (without dilation of the fistula) are strongly needed. To avoid bleeding, use of color Doppler ultrasound to detect vascular structures can decrease the risk of bleeding.

CONCLUSION

SEM stents should be selected during EUS-CDS to avoid several adverse events, although the possibility of stent migration still remains. The data on the cumulative technical and clinical success rate for EUS-CDS is promising. EUS-CDS may become the first choice of the biliary tract drainage procedure in the local cases such as poor prognosis, the contraindication of PTBD.

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