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REVIEW

Endoscopic ultrasound-guided biliary drainage as an alternative to percutaneous drainage and surgical bypass

Varayu Prachayakul, Pitulak Aswakul

Varayu Prachayakul, Siriraj GI Endoscopy Center, Division of Gastroenterology, Department of Internal Medicine, Siriraj Hospital, Faculty of Medicine, Mahidol University, Bangkok 10700, Thailand
Pitulak Aswakul, Liver and Digestive Institute, Samitivej Sukhumvit Hospital, Bangkok 10120, Thailand
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Correspondence to: Varayu Prachayakul, MD, Siriraj GI Endoscopy Center, Division of Gastroenterology Department of Internal Medicine, Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand. kaiyjr@gmail.com
Telephone: +66-818-654646
Fax: +66-241-15013
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Abstract

Endoscopic retrograde cholangiopancreatography had been a treatment modality of choice for both benign and malignant biliary tract obstruction for more than half century, with a very high clinical success rate and low complications. But in certain circumstances, such as advanced and locally advanced pancreatobiliary malignancies (pancreatic cancer, cholangiocarcinoma, ampullary tumor) and tight benign strictures, endoscopic retrograde cholangiopancreatography (ERCP) fails. Up to this point, the only alternative interventions for these conditions were percutaneous transhepatic biliary drainage or surgery. Endoscopic ultrasound guided interventions was introduced for a couple decades with the better visualization and achievement of the pancreatobiliary tract. And it's still in the process of ongoing development. The inventions of new techniques and accessories lead to more feasibility of high-ended procedures. Endoscopic ultrasound guided biliary drainage was a novel treatment modality for the patient who failed ERCP with the less invasive technique comparing to surgical bypass. The technical and clinical success was high with acceptable complications. Regarded the ability to drain the biliary tract internally without an exploratory laparotomy, this treatment modality became a very interesting procedures for many endosonographers, worldwide, in a short period. We have reviewed the literature and suggest that endoscopic ultrasound-guided biliary drainage is also an option, and one with a high probability of success, for biliary drainage in the patients who failed conventional endoscopic drainage.

Key words: Endoscopic ultrasound; Endoscopic ultrasound; Biliary drainage; Choledochoduodenostomy; Hepaticogastrostomy; Technique

Core tip: Failure of endoscopic retrograde cholangiopancreatography occurs in 5%-10% of the cases from many etiologies. However, there are few alternative options for biliary drainage up to the present time. Percutaneous biliary drainage and surgical bypass have their own drawbacks. Endoscopic ultrasound guided biliary drainage (EUS-BD) is a new platform with a very high technical and clinical success rate with

an acceptable complications. This review focused on the techniques, instruments including tips and tricks of this treatment modality. EUS-BD would become another alternative options for biliary drainage for both benign and malignant conditions in the future.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was first introduced by Demling and Classen[1] in 1970 and is now the treatment of choice for pancreatobiliary diseases. It was originally used as a diagnostic tool, but since the development of magnetic resonance imaging (MRI) and computed tomography (CT), which provide superior soft tissue details of the pancreatobiliary tract, ERCP has been used exclusively for therapeutic purposes. Pancreaticobiliary obstructions are the most common cause of pancreatobiliary disease. Because of the development of ever better endoscopy instruments and technologies, the overall success rate of ERCP is now 90% to 95% with a complication rate of 5% to 7%[2-16]. Selective bile duct cannulation, if performed by experienced endoscopists, is an effective treatment for over 90% of cases of pancreatobiliary disease without anatomical obstructions. It is not effective in only 3% to 5% of cases, usually due to gastroduodenal obstruction, failed cannulation, distorted ampullae, altered anatomy, a periampullary diverticulum, or previous enteral stents. In cases of failed ERCP, patients are usually referred for either percutaneous transhepatic biliary drainage (PTBD) or surgical bypass. Both these procedures have high rates of undesirable complications. Endoscopic ultrasound-guided biliary drainage (EUS-BD) is a new technique that was developed within the last decade. It is an attractive alternative to PTBD or surgery when ERCP fails, but there is no strong evidence-based data on which procedure is best in this setting. We have reviewed the literature and summarize the advantages and disadvantages of PTBD, surgical bypass, and EUS-BD, including which technique is best for different clinical situations and how to maximize procedural success and reduce complications for each method.

Percutaneous transhepatic biliary drainage

Percutaneous transhepatic biliary drainage (PTBD) is a treatment option for patients for whom ERCP was not successful. The first report on PTBD was in 1961 by Catalano *et al*[17], and it was the treatment of choice for biliary drainage for more than two decades. The technical success rate for PTBD ranges from 75% to 100% and the clinical success rate ranges from 65% to 92%. The complication rate ranges from 9% to 31%[18-21]. Ho *et al*[22] published a review article on why PTBD should be considered first-line treatment for biliary drainage. Data showed that PTBD was superior than endoscopic biliary drainage in malignant hilar biliary obstruction with a technical success rate of 89% *vs* 41%, respectively ($P < 0.001$) and complication rates of 52% and 18%, respectively ($P = 0.04$). The data on the best type of drainage for distal CBD obstruction was inconclusive. PTBD is successful even in patients who have poor performance status. It also takes less procedural time and has few complications. The drawbacks are that it cannot be used in the presence of moderate to marked ascites and the fact that bile drainage is external, which impairs the patient's quality of life and involves difficulty in taking care of the catheter.

Surgical bypass

Surgical bypass is another treatment option after failed ERCP or unresectable hilar cholangiocarcinoma. Glazer *et al*[23] published a meta-analysis of randomized controlled trials of immediate stent placement *vs* surgical bypass in the palliative management of malignant biliary obstruction and found that there was significantly less recurrent biliary obstruction after surgical bypass than after stent placement (RR 0.14, 95%CI: 0.03-0.63, $P < 0.01$). The technical success rates (RR 0.99, 95%CI: 0.93-1.05; $P = 0.67$) and complication rates (RR 1.54, 95%CI: 0.87-2.71; $P = 0.14$) were not significantly different. Despite the more invasive approach, surgery produced better drainage; the drainage was internal, which had less effect on the patient's quality of life; and the interval to recurrent biliary occlusion was longer. Unfortunately, this technique is only suitable for patients who are good surgical candidates, which limits its use in cases of advanced malignant biliary obstruction.

EUS-BD

EUS-BD has been increasingly used as a minimally invasive alternative to surgery or radiologic intervention for biliary drainage after failed ERCP. EUS-BD can be performed *via* the papillary or gastrointestinal lumen. In the transpapillary route, rendezvous retrograde or antegrade stenting is used. For gastrointestinal luminal access, choledochoduodenostomy or hepaticogastrostomy is used, depending on the desired site of access. Artifon *et al*[24] conducted a randomized trial of EUS-guided choledochoduodenostomy or percutaneous drainage for unresectable distal biliary obstruction after failed ERCP. Technical success and clinical success were 100% in both groups. The complication rate for PTBD was 15.3% and the complication rate for EUD-BD was 25% ($P = 0.2$), and the cost of the procedures was similar (7570 USD and 5573 USD respectively, $P = 0.39$). Khashab *et al*[25] also conducted a trial of PTBD ($n = 51$) and EUS-BD ($n = 22$) after failed ERCP. Their technical success rate was higher in the PTBD group than the EUS-BD

Table 1 Advanvtage and disadvantage of puncturing sites

Route of access	
Extrahepatic route	Intrahepatic route
Easy approach (especially for large-caliber CBD)	The duct to be punctured is far from the scope
The puncture site is close to the scope	Easier scope positioning to achieve desired direction from the punctured duct
More difficult scope positioning to achieve desired direction from the punctured duct (rendezvous)	Easy scope handling
Easy guidewire negotiation and neo-tract creation (EUS-BD)	Difficult guidewire negotiation and neo-tract creation
Difficult scope handling	Higher risk of bleeding
	Higher risk of bile leakage

CBD: Common bile duct; EUS-BD: Endoscopic ultrasound guided biliary drainage.

group (100% *vs* 86.4%, $P = 0.007$), and their clinical success rates were 92.2% *vs* 86.4%, $P = 0.40$. PTBD was associated with higher adverse events (index procedure: 39.2% *vs* 15.7%), but stent patency and survival rate were equivalent in both groups. PTBD cost more than twice as much to perform as EUS-BD ($P = 0.004$), mainly because the re-intervention rate was higher (80.4% *vs* 15.7%, $P < 0.001$). Multicenter studies and other cases reports and case series[26-41] have confirmed the safety and efficacy of EUS-BD alone. In the authors' opinions, there was no one best approach among these three platforms for patients who failed ERCP. We recommend surgical bypass for patients with both duodenal and biliary obstructions who are good surgical candidates, but EUS-BD might be better than PTBD in patients with a large volume of ascites or patients who refuse external drainage. First-line treatment options depend on each institution's facilities, the clinician's expertise, and the patient's preferences after receiving enough information to accurately evaluate each procedure's strengths, weaknesses, and impact on quality of life.

EUS-guided biliary drainage

The use of endoscopic ultrasound-guided cholangiography was initially described by Wiersema *et al*[42] in 1996. The first EUS-guided biliary drainage was reported by Giovannini *et al*[43] in 2001. In 2004, Mallory *et al*[44] reported the first case of EUS-guided ERCP using the rendezvous technique.

Endoscopic ultrasound-guided biliary drainage can be classified into two major groups: the transpapillary approach (rendezvous retrograde and antegrade stent insertion) and the transmural approach (choledochoduodenostomy and hepaticogastrostomy)[45-48].

When to use the transpapillary rendezvous route

EUS-guided biliary drainage should be reserved for patients for whom ERCP was not successful. Some experts recommend the transpapillary (rendezvous) approach before the transmural approach[49-51]. Rendezvous technique is impossible if the ampulla is not accessible; but, even in patients with accessible ampullae, the rendezvous procedure can be difficult because it is necessary to change from the echoscope to the duodenoscope and the railroad technique during guide wire grasping is not always easy. In the authors' opinion, the advantage of the procedure is that it's not necessary to create a bilo-entereic tract, which can sometimes produce leakage and bleeding. In patients with surgically altered anatomy in which the anastomotic opening could not initially be seen and the access to the opening was not too difficult. When the position of the echoscope is good enough and dilatation and the guidewire can be passed down to the duodenum easily, rendezvous is a good option. If access is through the intrahepatic ducts (left lobe segments Ⅱ or Ⅲ) or extra-hepatic duct [common bile duct, (CBD)] the route depends on the location of the obstruction and the expertise of the endoscopist. If the site of obstruction is located above the proximal to mid-CBD, the intra-hepatic route is best. For distal obstruction with large CBD caliber, the extrahepatic route is the ideal choice.

Each route has advantages and disadvantages. It is easier to make the puncture using the extra-hepatic route, but the echoscope is in an upward curving position that makes it more difficult to control and easier to slip out. The puncture and guidewire placement are more difficult in the transmural route, but handling the scope is easier.

When to use the transmural route

The transmural route of EUS-guided biliary drainage can be achieved through an EUS-guided choledochoduodenostomy or an EUS-guided hepaticogastrostomy. The site of puncture depends on the location of the obstruction. If the obstruction site is distally located, choledochoduodenostomy is procedure of choice, while hilar obstructions are best served by a hepaticogastrostomy. It is easier to perform the puncture and handle the scope in segment Ⅱ of the left lobe of the liver[52,53] and the endoscopist who performed the procedure has to confirm that the puncture site is not in the esophagus in order to avoid higher risk of mediastinitis. Even though some experts use the right lobe[54], it is not yet standard of practice.

Tips for EUS-guided biliary drainage

Where to puncture: We summarized the advantages and disadvantages of extrahepatic and intrahepatic duct puncture in Table 1.

Table 2 Compare the two neo-tract creation methods

Neo-tract creation methods	
Cauterization	Non-cauterization
Easy neo-tract creation with no need for forceful manipulation	More difficult and forceful manipulation, especially when the intervening tissue is thick or the direction is inappropriate
More tissue injury from thermal burn	Less injury, smaller diameter of the neo-tract
The procedure takes less time	Lower risk of bile leakage or bleeding
More complications, especially bile leakage or perforation	

Table 3 Compare the two neo-tract dilation methods

Dilatation methods	
Balloon dilation	Graded dilation
Radial force leads to bigger neo-tract diameter (easier but greater risk for bile leakage, bleeding and perforation)	Axial force creates a smaller neo-tract. More difficult, but less leakage and less bleeding)
Easier stent insertion	Stent insertion can be more difficult
Only a single dilation session is needed and there are fewer guidewire exchanges	More sessions of dilation are needed and there are more frequent guidewire exchanges

How to create the bilo-enteric tract

There are two major ways to create a bilo-enteric tract: cauterization with a needle knife or small caliber cystotome especially 6 Fr in diameter[55-66] and non-cauterization with a tapered-tip catheter[67] or Soehendra stent retriever[68]. Neo-tract creation is followed by neo-tract dilation. The advantages and disadvantages of these two approaches are summarized in Table 2.

Neo-tract dilation can also be performed two ways: balloon dilation or graded dilation. Both methods are evaluated in Table 3.

There is no best approach. The technique of choice depends on the individual endoscopist's expertise. If balloon dilation must be used, the authors recommend the small size (4 mm diameter) balloon dilator.

What is the best stent?

In the early years of EUS-guided biliary drainage, the most commonly used stent was plastic; but many experts used fully covered, self-expandable metal stents (FCSEMS) instead of plastic stents and reported good outcomes[69-71]. Many types of metallic stents were developed for this purpose. Even though metal stents create a wider lumen with better drainage ability, they are more expensive and there is a risk of migration. Recently, Galasso *et al*[72] developed a stent suitable for EUS-guided hepaticogastrostomy called the Gio-Bor stent. It is a half-covered SEMS stent (Figure 1). The authors recommend an FCSEMS or partial CSEMS stent 40 to 60 mm in length for EUS-CD and 80 to 100 mm in length for EUS-HG. The small introducer (7 Fr) FCSEMS and partial CSEMS are shorter procedures and need fewer guidewire exchanges. However, there was a multicenter Japanese study[38] demonstrate that higher bile leakage was associated with plastic stent placement, therefore there was a trend towards to preference of using covered SEMS to prevent this complication.

What are the commonly encountered problems?

How to locate the puncture site: The site of puncture should be evaluated both endosonographically and fluoroscopically. Endosonographic tracing of the left intrahepatic bile duct was important in guiding the tip of needle and helping the endoscopist select the segment most suitable for puncture and easy guidewire negotiation. The fluoroscopic view can also help the endoscopist assess the best angle for bile duct puncture and easy neo-tract creation. Interestingly, if the scope's tip is perpendicular to the gastroduodenal wall, it will make the dilation process more difficult, so we recommend a slightly tangential angle. If the tip of the scope is too angulated, it will make the puncture more difficult. The distance between the punctured duct and the probe should be no more than 1-2 cm. Before starting the puncture, check Doppler color flow to avoid the intervening vessel.

DIFFICULT GUIDEWIRE NEGOTIATION

Using a 0.025 stiff guidewire (VisiGlide) or a 0.035 hydrophilic tip guidewire will make guidewire negotiation easier. The direction of the needle tip will directly affect guidewire manipulation. If the direction of the needle is opposite to the desired guidewire direction, manipulation will be really difficult. Moving the guidewire back and forth just a little bit (jiggling maneuver) will help change the guidewire direction. Using guidewires designed for manual twisting maneuvers or that have accessories, such as Terumo or ViziGlide guidewires, will make guidewire manipulation easier.

Guidewire shearing or knotting

Most endoscopists who perform EUS-guided biliary drainage have experience with guidewire shearing or knotting during the procedure. Saxena *et al*[73] and

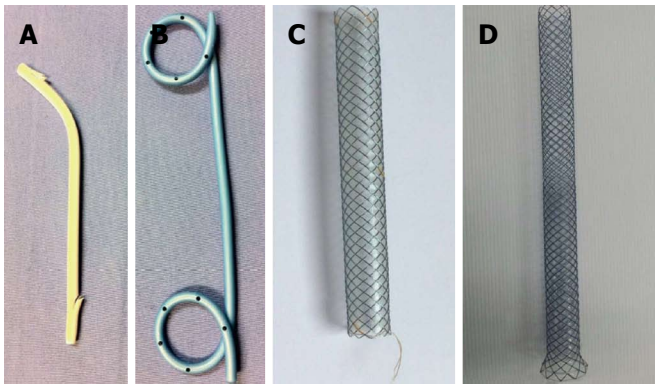

Figure 1 The different types of stents used in Endoscopic ultrasound guided biliary drainage. A: Plastic stent; B: Double-pigtail plastic stent; C: Fully covered, self-expandable metal stent; D: The Gio-Bor stent.

Figure 2 The Soehendra stent retriever was used in neo-tract creation.

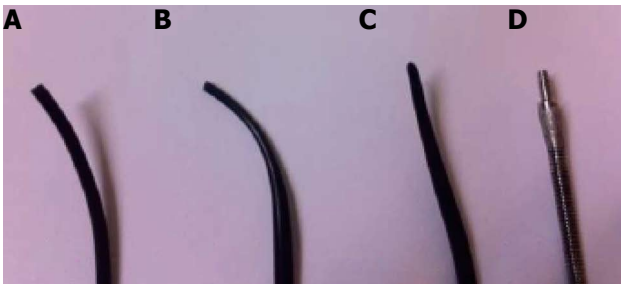

Figure 3 Different types of catheter tips. A: Soehendra stent dilator; B: Tapered tip catheter; C: Sharp tip catheter (self-made); D: Soehendra stent retriever.

Khashub *et al*[74] recommend flushing the channel with water and using a special type of needle, such as an access needle, which is designed to resolve these problems. However, in the authors' experience, this specially designed needle was not sharp enough in some situations and did not prevent guidewire shearing. We found that the way to prevent shearing and knotting was to push, not pull, the guidewire back, even if the desired duct was not yet punctured, and to exchange the needle for the small-sized dilator or tapered-tip catheter after the guidewire was looped and continue the guidewire negotiation later on. We have had no problem with shearing or knotting if we followed these guidelines.

How to deal with thickened soft tissue between the puncture site and bile duct

The distance between the puncture site and the desired duct is a very important factor in neo-tract creation. If the distance is longer, it is more difficult to penetrate through the tissue and pierce the bile duct. Another factor is the stiffness of the tissue between the puncture site and the bile duct. If the patient has liver fibrosis, the tissue is stiffer and this can make creation of a neo-tract more difficult. If difficulty is encountered, we recommended that the endoscopist should, firstly, re-check the position of the scope tip to make sure it is not perpendicular to the gastric wall. If graded dilation is being performed, change the dilating catheter to a smaller size or a catheter with a tapered tip, use a tapered-tip cannulation catheter, or re-shape the tip of the catheter by cutting it to a needle shape. Dilating with a Soehendra stent retriever, which has a drilling effect, might also be useful (Figure 2). If all of the above methods fail, cauterization may be necessary. Different types of catheter tips are shown in Figure 3.

Complications can occur if the needle knife is used with the Odd ratio of 12.4[75]. To minimize possible tissue damage during neo-tract creation, only open the knife half of its full length and cauterize until it enters the duct. In process of dilation, the dilator should be inserted after the knife is used. For cystotome usage, it very important to push the cystotome catheter against the mural and bile duct wall firmly, before starting the cauterization (this technique would help to enter the bile duct easily).

HOW TO MINIMIZE THE COMPLICATIONS DURING NEO-TRACT DILATION

Generally, the least chance of bile leakage and bleeding if the diameter of neotract is as small as possible. Therefore, the authors recommend not to dilate the neo-tract larger than the size of stent introducer (always not more than 8.5 Fr). For graded dilation technique, 8.5 Fr size is suitable for Soehendra dilator and only 7 Fr size is suitable for Soehendra stent retriever whereas smaller balloon especially not more than 4 mm in diameter is suitable for balloon dilation.

FUTURE RESEARCH AND DEVELOPMENT

The development of single step device which might be more suitable to each specific procedure would be helpful the help endoscopist to overcome the cubersome techniques such as multiple guidewire exchanges and would make the procedure time shorter; Smaller introducer (7 Fr) of smaller sized covered SEMSs (6 or 8 mm in diameter) would be benefit for less complications and shorter procedure time; Randomized control trial that EUS-BD as the treatment of choice in some particular conditions such as surgical altered anatomy would be interesting; The possibility of using EUS-BD as the preferable options than transpapillary drainage should be widely discussed and prospective study should be conducted.

CONCLUSION

EUS-guided biliary drainage is safe and effective when performed by an experienced endoscopist, and is an alternative to PTBD and surgical bypass after failed ERCP. Unfortunately, it use is still limited to tertiary care hospitals with advanced-complex endoscopy units. Clinicians will need to choose a treatment method based on each patient's status, preferences, and the facilities of the hospitals in their area.

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