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EDITORIAL

Endoscopic ultrasound-guided biliary drainage

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Abstract

Endoscopic ultrasound (EUS)-guided biliary drainage has emerged as a minimally invasive alternative to percutaneous and surgical interventions for patients with biliary obstruction who had failed endoscopic retrograde cholangiopancreatography (ERCP). EUS-guided biliary drainage has become feasible due to the development of large channel curvilinear therapeutic echo-endoscopes and the use of real-time ultrasound and fluoroscopy imaging in addition to standard ERCP devices and techniques. EUS-guided biliary drainage is an attractive option because of its minimally invasive, single step procedure which provides internal biliary decompression. Multiple investigators have reported high success and low complication rates. Unfortunately, high quality prospective data are still lacking. We provide detailed review of the use of EUS for biliary drainage from the perspective of practicing endoscopists with specific focus on the technical aspects of the procedure.

Key words: Bile duct; Biliary obstruction; Biliary drainage; Endoscopic ultrasound; Endoscopic ultrasound-guided biliary drainage

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) has become the procedure of choice for the management of biliary obstruction[1]. If ERCP fails to achieve biliary drainage, more invasive options are usually considered. These include percutaneous transhepatic biliary drainage (PTC) and surgical intervention but they have been associated with a higher risk of complications and prolonged hospital stay[2]. Recently, endoscopic ultrasound (EUS)-guided biliary drainage has been introduced as an alternative for patients who had failed ERCP. EUS was developed in the early 1980s to overcome the limitations of abdominal ultrasonography and computed tomography for pancreatic imaging[3]. Since its introduction, EUS has become a very valuable imaging tool to visualize the gastrointestinal luminal wall and its adjacent structures. The proximity of the EUS probe to the area of interest not only provides high resolution images but also allows for real time EUS-guided fine needle aspiration (FNA) tissue sampling. The high quality imaging combined with FNA capability has made EUS an indispensable diagnostic modality. EUS has also been utilized as a therapeutic tool but until recently its role has been confined mostly to injection of various substances[4,5]. The availability of larger channel echo-endoscopes has allowed the broadening of the therapeutic applications of EUS by combining the advantages of real-time ultrasound and fluoroscopy imaging with the use of ERCP based devices and techniques. As a result of these developments and combination of technologies, EUS-guided biliary drainage has become possible.

EUS-guided diagnostic cholangiography was first reported by Wiersema *et al*[6] in 1996 and the first EUS-guided biliary drainage was reported in 2001 by Giovannini *et al*[7] by creating a choledochoduodenal fistula using a needle knife followed by transduodenal stenting in a patient with pancreatic cancer. These initial reports were followed by the description of technique modifications and expanding indications including EUS-guided hepaticogastrostomy with stent placement[8], transduodenal EUS-rendezvous biliary access[9,10] and EUS-guided biliary therapy of choledocholithiasis with the creation of a neopapilla[11]. Since then a number of series have reported variations on these techniques[12-31] including the recent description of a placement of a fully covered metal stent as a route for interventional endoscopic procedures in the bile duct[32]. A published large case series (≥ 10 cases) on EUS-guided biliary drainage is shown in Table 1.

The purpose of this manuscript is to provide a detailed review of the use of EUS for biliary drainage from the perspective of practicing endoscopists with specific focus on the technical aspects of the procedure. We performed a Medline search using the key words EUS, biliary drainage, biliary obstruction, therapeutic EUS and interventional EUS. In addition we manually reviewed the references of the identified review papers.

INDICATIONS FOR EUS-GUIDED BILIARY DRAINAGE

ERCP guided stent placement has become the procedure of choice for biliary decompression but it can be occasionally associated with difficulty gaining access to the obstructed biliary tract. In a recent prospective study, first attempt ERCP failed in 25% of patients with obstructive jaundice due to pancreatic cancer[33]. The two main reasons for failed ERCP are failure to cannulate the bile duct or inability to reach the papilla due to duodenal stenosis or post surgical changes. For patients with accessible papillae, most endoscopists will consider a second attempt at ERCP to gain access to the bile duct. Traditionally, patients who had ultimately failed ERCP have been offered PTC or surgical biliary decompression but these approaches are associated with a higher rate of complications and prolonged hospital stay[2]. Lately, EUS-guided biliary drainage emerged as a less invasive alternative for biliary drainage. EUS-guided decompression is not only minimally invasive but it is a single step procedure that provides more physiological internal bile drainage with improved patient comfort and decreased risk for fluid and electrolyte disturbances. Furthermore, EUS-guided biliary drainage using transgastric puncture of the intrahepatic duct or the common bile duct is feasible in patients with inaccessible papillae due to duodenal obstruction, surgically altered anatomy or hilar block due to cholangiocarcinoma or gallbladder cancer[11]. Finally, EUS-guided biliary drainage may be safer than PTC since the bile duct is accessed under real-time EUS guidance using Doppler to avoid blood vessels in the needle path[34-36]. The patient preparation for EUS-guided biliary drainage is not different from the standard preparation for ERCP as the patient's position is prone on the fluoroscopy table. All patients should receive periprocedural antibiotics. General anesthesia can be considered but the majority of cases can be done with monitored sedation. Contraindications include coagulopathy and severe hemodynamic instability.

INSTRUMENTATION

Both EUS and fluoroscopy equipment should be available in the procedure room. The use of a therapeutic channel (3.7 mm on the Olympus and 3.8 mm on the Pentax linear echo-endoscopes) is recommended. It is possible to use the diagnostic channel (2.8 mm) linear echo-endoscope to perform the puncture and wire insertion into the bile duct and then exchange the scope over the wire with the therapeutic channel ERCP scope but this maneuver is more complex and the bile duct access can be easily lost during the scope exchange.

Both 22 and 19 gauge EUS needles can be used for the initial puncture of the bile duct. In general, the use of a 19 gauge needle will allow the passage of 0.035 inch wire but the stiffness of the 19 gauge needle may provide a challenge to advance the needle tip to the desired target (i.e., bile duct). The 22 gauge needle provides better flexibility but allows passage of only 0.018 inch guidewire. The new blunt-tip Access Needle (Cook Endoscopy, Winston-Salem, NC, United States) is now available for initial puncture. This needle allows smooth guidewire manipulation and prevents guidewire damage as seen with the standard sharp tip needles. The EUS needle can be preloaded with the guidewire and pre-flushed with contrast using a three way IV adaptor so that contrast can be injected without removing the guidewire during its manipulation. Besides the standard ERCP devices, an over-the-wire needle-knife sphincterotome or Cystotome (Cook Endoscopy, Winston-Salem, NC, United States) should be available along with choices of plastic (straight or pigtail) and self-expandable metallic stents (uncovered, partially covered or fully covered) of varying calibers and lengths[35,37,38]. A list of the typical devices that are needed to perform EUS-guided biliary drainage is presented in Table 2.

TECHNIQUES

The reported success rate of EUS-guided biliary drainage ranges from 73% to 97%[14,19,22,30,31,39,40]. EUS-guided biliary drainage should be as effective as transpapillary biliary drainage once the stent is successfully placed. Simultaneous tissue diagnosis and staging can be provided in the same setting. Several approaches to access the biliary tree

Table 1 Published large case series on endoscopic ultrasound-guided biliary drainage

Authors	Yr	Number of cases	Technical success (%)	Complication (number of cases)
Kahaleh *et al*[14]	2006	23	91	Bile leak (1), pneumoperitoneum (2), bleeding (1)
Bories *et al*[31]	2007	11	91	Biloma (1), cholangitis (1), stent occlusion (1)
Will *et al*[22]	2007	12	90	Pain (1), cholangitis (1)
Shami *et al*[34]	2007	23	91	Bile leak (1), pneumoperitoneum (2)
Park *et al*[38]	2009	14	100	Stent migration (1)
Maranki *et al*[27]	2009	49	84	Biliary peritonitis (1), pain (1), pneumoperitoneum (4), aspiration pneumonia (1), bleeding (1)
Kim *et al*[19]	2010	15	100	None

Table 2 Devices for endoscopic ultrasound-guided biliary drainage (in addition to standard endoscopic retrograde cholangiopancreatography devices)

Therapeutic EUS scope
19 and 22 gauge standard EUS-FNA needles
19 gauge access EUS needle (Cook Endoscopy)
Standard length guide wires (450 cm)
0.035 inch
0.018 inch
Over-the-wire needle-knife sphincterotome
Cystotome (Cook Endoscopy)
Biliary dilation balloons
Three way IV adaptor with needleless cap
Stents
Plastic stent
Pigtail biliary stent
Straight biliary stent
Self expandable metal stents (uncovered, partially covered and fully covered)

EUS: Endoscopic ultrasound; FNA: Fine needle aspiration.

and provide biliary drainage have been described either *via* the duodenum or the stomach into the common bile duct or hepatic duct, respectively. EUS-guided biliary drainage can be divided into three principal methods[41]. (1) EUS-ERCP rendezvous technique. With this technique the EUS is used solely to puncture the obstructed duct and pass a guidewire antegrade through the papilla for subsequent rendezvous by ERCP[30]; (2) Stent placement *via* the EUS endoscope across the site of biliary obstruction in antegrade fashion in which EUS is used to create a temporary fistula *via* a transgastric or transduodenal access to allow stent placement; and (3) Transluminal drainage in which EUS is used to create a permanent fistula and subsequent stent placement is performed across that fistula between bile duct and bowel wall. In this approach the site of biliary obstruction is not traversed by a stent but rather an alternative tract for bile drainage is created by creation of a bilioenteric fistula.

EUS access to the biliary tree is first gained under real time guidance using the EUS needle. Contrast is then injected *via* the needle under fluoroscopic visualization to obtain a cholangiogram followed by insertion of a guidewire into the biliary tree. The use of 0.035 inch guidewire (requires 19-gauge needle for initial access) is preferred because it may facilitate traversing of strictures and stent placement. The created fistula can then be enlarged with an ERCP cannula, tapered biliary dilators, needle-knife, cystotome, or biliary balloon dilator and in some cases may require the use of several devices[34]. Once the fistula tract is enlarged, the type of stent placement is decided based on the obstruction site (whether the stricture is accessed in antegrade or retrograde fashion and whether the stricture has been traversed with the guidewire). When the site of obstruction cannot be traversed, then transluminal stenting may be performed with the end of the stent lying within the biliary tree proximal to the obstruction and the other end of the stent lying in the stomach or duodenum. Stent placement can also be done through an existing duodenal metal stent in combined biliary and duodenal obstruction situations[42]. Combined duodenal stent placement and EUS-guided biliary drainage can be used for malignant duodenal obstruction with biliary stricture[43].

Bile duct access

Bile duct access depends on the level of obstruction and whether the ampulla is endoscopically accessible.

Transhepatic approach (hepaticogastrostomy): The echo-endoscope is positioned within the proximal stomach (cardia or proximal body) and oriented along the lesser curvature of the stomach or more posterior position to visualize the dilated left intrahepatic bile ducts. Color Doppler is used to rule out overlying vasculature before inserting the needle into the identified dilated intrahepatic bile duct branch. Bile is aspirated and contrast is instilled to confirm placement. Several options exist based on the level of obstruction, success of traversing the obstruction with guidewire and availability of endoscopic assess to the papilla. (1) A guidewire is advanced in an antegrade fashion through the EUS needle and manipulated across the biliary obstruction and into the duodenum under fluoroscopic and endosonographic guidance. Several loops of wire should be created to reduce the risk of wire dislodgement. If access to the second portion of the duodenum is feasible the procedure can be completed with the rendezvous technique with standard ERCP scope; (2) If the stricture is traversed with the guidewire and the duodenum is not accessible, a stent can be inserted across the biliary stenosis in antegrade fashion. To allow passage of the stent, the fistula tract should be enlarged as previously described; and (3) If the guidewire cannot be advanced across the obstruction, a transluminal drainage approach can be utilized by deploying a stent that bridges the fistulous tract (the distal end of the stent is in the dilated intrahepatic duct within the left lobe and the proximal end of the stent is in the cardia of the stomach).

Extrahepatic approach (transcholedochal or choledochoduodenostomy): The echo-endoscope is placed in the distal antrum or duodenum, permitting imaging of the common bile duct. Color Doppler is used to rule out overlying vasculature. Bile duct puncture is carried out with an EUS needle under endosonographic control. The bile duct typically is entered in its midportion (superior to the intrapancreatic portion and inferior to the hilum) then several options are available depending on the site of obstruction: (1) for distal (intrapancreatic portion) main bile duct obstruction, a stent can be deployed bridging the created fistulous tract and therefore creating choledochoduodenostomy proximal to the obstruction; (2) alternatively, an attempt to manipulate the wire and traverse the stricture in antegrade fashion can be made and then the procedure can be completed with the duodenoscope by rendezvous technique; and (3) if the obstruction is proximal to the entry point in the bile duct (e.g., hilum), the stricture should be traversed in retrograde fashion and then stented.

Stent placement

Enlargement of the fistulous tract is usually necessary before stent placement. Stent insertion may be performed in an antegrade fashion *via* the echo-endoscope or as a rendezvous procedure with ERCP depending on the transpapillary accessibility and the ease of stent deployment. Rendezvous drainage requires endoscopic access to the region of the papilla, while direct transluminal stent placement entirely by EUS does not.

Antegrade: The stent is placed using the echo-endoscope in an antegrade fashion. Stent placement can be transluminal (transgastric or transduodenal). An attempt should be made to traverse the stricture followed by stent placement with the stent bridging the stricture. Stent placement creating bilioenteric anastomosis is an option if trans-stricture stenting is unsuccessful. If feasible, placement of the stent across the site of obstruction is the preferred approach.

Rendezvous (retrograde): This technique is for ERCP access *via* the native papilla or surgical anastomosis by EUS-guided placement of a guidewire and subsequent access by ERCP. EUS-guided rendezvous was first reported for pancreatic duct access in 2001 and for both biliary and pancreatic ductal drainage in 2004[9]. The bile duct is accessed proximal (superior) to the obstruction (transgastric or transduodenal). The wire is used to transverse the stricture in antegrade fashion and then curled in the duodenum. The echo-endoscope is removed carefully while leaving the wire in place. A duodenoscope is advanced to the duodenum and the wire exiting the papilla is grasped with a snare and withdrawn through the accessory channel. The procedure is then completed with standard ERCP techniques.

It is believed that placement of a longer stent may diminish the risk of bile leak. In our institution, we favor the use of a fully covered metal stent but there are no studies evaluating the performance among different stents.

Exchanging the occluded stent

An occluded stent can be removed by using snare or a Dormia basket through the duodenoscope. The fistulous tract can then be recannulated, followed by new stent placement[44]. If the stent has not been *in situ* for 2-3 wk and there are concerns for the maturity of the fistula, the guidewire should be inserted into the bile duct through or alongside the occluded stent by ERCP catheter before removing the stent[44]. If a metal stent was used at the initial procedure, a plastic stent can be inserted *via* the occluded metal stent. EUS-guided stent placement can be an option for biliary diversion for an occluded biliary metal stent after a failed reinterventional ERCP[45].

Technical tips: The extrahepatic bile duct is very close to the portal vein in the first and second portion of the duodenum and the intrahepatic bile duct is close to the intrahepatic portal vein. Therefore, the puncture should be done very carefully especially in patients with mild dilatation of the hepatic bile duct. Angling the needle combined with gradual retraction and re-advancement can help the guidewire advance and traverse the obstruction[46]. The use of the EchoTip Ultra Access Needle (Cook Endoscopy, Winston-Salem, NC, United States) may significantly facilitate wire manipulation once bile duct access is achieved. The Access Needle has a sharp beveled stylet that protrudes beyond the blunt needle tip to facilitate easy puncture. Once the tip of the needle reaches the bile duct, the stylet is then removed. The blunt needle tip allows for smooth wire manipulation including advancement and withdrawal and prevents "pilling" of the hydrophilic wire coating as it frequently happens with standard sharp tip EUS needle. In addition, fluoroscopic techniques allowing imaging at different angles may facilitate wire passage. Care should be taken to limit the volume of the contrast injection to help maintain the visualization of the targeted area.

RESULTS OF EUS-GUIDED BILIARY DRAINAGE

The reported success rate of EUS-guided biliary drainage ranges from 73% to 97%[14,19,22,30,31,39,40]. EUS-guided biliary drainage should be as effective as transpapillary biliary drainage once the stent is successfully placed. Simultaneous tissue diagnosis and staging can be provided in the same setting. EUS-guided biliary drainage appears to carry significant advantages over PTC and surgical biliary decompression and can be considered as a first step in patients who had failed ERCP[34-36]. It should be emphasized that the perceived advantages of EUS-guided biliary drainage over PTC or surgery have not been evaluated in prospective randomized studies and therefore the final choice of therapeutic modality should be based on local expertise and patient preferences.

COMPLICATIONS

The reported complication rates vary from 4% to 21%[14,38,40,47]. Internal drainage eliminates skin infection and maintenance issues of external drainage. Pancreatitis is a complication associated with prior failed ERCP and not attributed to EUS biliary drainage because of the lack of influence on the pancreatic duct[19].

The most common complications are biliary leakage and pneumoperitoneum (perforation into the peritoneal cavity or retroperitoneum, depending on the path of the access)[7,13,14,21,26,27]. The pneumoperitoneum is an early complication and usually self-limited[38]. Biliary leakage may occur predominantly with extrahepatic duct puncture, transluminal drainage, and larger hole[14,20,26,27]. Confirmation of the absence of bile leakage can be done using contrast medium on fluoroscopy. Focal bile peritonitis tends not to occur if the stent is promptly placed after dilation of the fistula[13,25]. Other common complications include abdominal pain and cholangitis[31]. Other reported complications include bacteremia, bleeding, biloma, ileus, aspiration pneumonia, cholecystitis, duodenal perforation and cardiopulmonary failure[11,14,19,31]. The use of color Doppler ultrasound to detect vascular structures can decrease the risk of bleeding[13,25]. No mortality has been reported to date. When comparing drainage using a stent across a fistula *vs* the rendezvous technique, the rendezvous drainage is less likely to lead to perforation, leakage, bleeding, or peritonitis which is attributed to the more physiological approach[41].

Late complications are stent migration and occlusion[31,35]. To date, there have been no long term follow-up reports on stent patency in a large number of patients. A case series of five cases reported by Yamao *et al*[48] using 7-8.5-Fr plastic stents *via* EUS-guided choledochoduodenostomy had an average stent patency of 211.8 d. The relatively long patency time of stent is believed to be due to the stent placement being far from the obstructing tumor[44].

LIMITATIONS

Advanced or complex strictures may not be traversed by EUS-guided approach and hence the percutaneous or surgical approach should remain an option.

The plastic stents' size is limited by the working channel of the linear echo-endoscope. Furthermore, the therapeutic EUS scopes channel is smaller than the therapeutic ERCP scope channel (4.2 mm *vs* 3.8 mm). Although a 10-Fr plastic stent can be deployed *via* the therapeutic EUS scope, it can be technically challenging due to significant friction in the relatively narrow channel. Finally, simultaneous passage of two wires into the bile duct as a safety measure to preserve access follow by 10-Fr stent placement over one of the guidewires is impossible with the current EUS therapeutic channel size.

These EUS drainage techniques have exciting potential but are performed mostly in tertiary referral centers by expert therapeutic endoscopists. Only endoscopists who are skilled at both ERCP and EUS should perform this procedure to avoid potential serious complications. Additionally, trained hepato-biliary surgeons and interventional radiologists should be available in the event of failure or complication.

At present, there are no dedicated devices for EUS-guided biliary drainage. The standard EUS and ERCP devices are being used for this purpose.

Although many case series have been reported, firm conclusions are limited due to great variations among studies in the endoscopic approaches applied, procedural goals, technical and clinical endpoints, definitions of success and duration and extent of follow-up. Furthermore, we lack data from well designed prospective randomized controlled studies comparing different therapeutic approaches.

We do not have a firm understanding on the exact rate of EUS guided biliary drainage complications as it is well recognized that underreporting can occur in retrospective case series.

CONCLUSION

EUS-guided biliary drainage has provided a new and promising route for biliary decompression. It has been reported to be feasible, highly successful and safe. It provides significant advantages over PTC and surgical biliary drainage and has become the procedure of choice in patients with obstructive jaundice who had failed ERCP in many institutions. The procedure is technically complex and confined to major referral centers. Despite the perceived advantages of EUS-guided drainage over PTC or surgery, well-designed, prospective, comparative studies are lacking. Therefore the choice of therapeutic modality in patients with biliary obstruction who had failed ERCP should be based on local expertise and patient preference.

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