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EDITORIAL

Does endoscopic ultrasound-guided biliary drainage really have clinical impact?

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Abstract

The well established, gold standard method for treatment of obstructive jaundice involves biliary drainage under endoscopic retrograde cholangiopancreatography (ERCP) performed by pancreatobiliary endoscopists. Recently, interventions using endoscopic ultrasound (EUS) have been developed not only for obtaining cytological and histological diagnosis, but also for biliary drainage as alternative method. EUS-guided biliary drainage (EUS-BD) was first reported by Giovannini *et al*. EUS-BD broadly includes EUS-guided rendezvous technique, EUS-guided choledochoduodenostomy, and EUS-guided hepaticogastrostomy. More recently, EUS-guided antegrade stenting and EUS-guided gallbladder drainage have also been reported. many case reports, series, and retrospective studies on EUS-BD have been reported. However, because prospective studies and comparisons between the different biliary drainage methods have not been reported, the technical success, functional success, adverse events, and stent patency with long-term follow up of EUS-BD are still unclear. Therefore, prospective, randomized controlled studies addressing these issues are needed. Despite this, EUS-BD undoubtedly is clinically useful as an alternative biliary drainage method. EUS-BD has the potential to be a first-line biliary drainage method instead of ERCP if results of clinical trials are favorable and the technique is simplified.

Key words: Endoscopic ultrasound; Endoscopic ultrasound-guided biliary drainage; Endoscopic ultrasound-guided hepaticogastrostomy; Endoscopic ultrasound-guided choledochoduodenostomy; Endoscopic ultrasound-guided antegrade stenting; Endoscopic ultrasound-guided gallbladder drainage

Core tip: To date, many case reports, series, and retrospective studies on EUS-guided biliary drainage (EUS-BD) have been reported. However, because prospective studies and comparisons between the different biliary drainage methods have not been reported, the technical success, functional success, adverse events, and stent patency with long-term follow up of EUS-BD are still unclear. Therefore, prospective, randomized controlled studies addressing these issues are needed. Despite this, EUS-BD undoubtedly is clinically useful. EUS-BD has the potential to be a first-line biliary drainage method instead of endoscopic retrograde cholangiopancreatography if results of clinical trials are favorable and the technique is simplified.

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INTRODUCTION

The well established, gold standard method for treatment of obstructive jaundice involves biliary drainage under endoscopic retrograde cholangiopancreatography (ERCP) performed by pancreatobiliary endoscopists[1-3]. Percutaneous transhepatic cholangiography (PTC) has also been established as an alternative method for biliary drainage[4,5]. However, PTC is associated with several complications, such as cholangitis, bile leakage, and pneumothorax. Moreover, the frequency of major complications, leading to prolonged hospital stay and permanent adverse sequelae, is 4.6%-25%, and that of procedure-related deaths is 0%-5.6%[4,5]. Cosmetic issues due to external drainage also compromise the patient's quality of life. Moreover, a large amount of ascites is a contraindication for PTC. Recently, interventions using endoscopic ultrasound (EUS) have been developed not only for obtaining cytological and histological diagnosis (EUS-guided fine needle aspiration), but also for biliary drainage. EUS-guided biliary drainage (EUS-BD) was first reported by Giovannini *et al*[6]. EUS-BD broadly includes EUS-guided rendezvous technique (EUS-RV)[7,8], EUS-guided choledochoduodenostomy (EUS-CDS)[9,10], and EUS-guided hepaticogastrostomy (EUS-HGS)[11,12]. Recently, EUS-guided antegrade stenting (EUS-AS)[13,14] and EUS-guided gallbladder drainage (EUS-GBD)[15,16] have also been reported.

Technical evaluation of EUS-BD

EUS-RV is mainly indicated for failed ERCP. This technique involves puncture of the intrahepatic or common bile duct using a 19G needle, following which a guidewire is advanced toward the duodenum through the site of stenosis or the ampulla of Vater. However, the technical success rate of this procedure is not very high (70%-100%)[17]. In addition, this technique is not indicated for cases of duodenal obstruction that are caused by tumor invasion, or those with altered anatomy, such as following the Roux-en-Y procedure. To enhance the technical success rate, the puncture needle and the guidewire should be stiff or include some additional technical features.

EUS-CDS is also normally indicated for failed ERCP. Performance of EUS-CDS requires puncture of the extrahepatic bile duct; therefore, this technique is indicated in cases of duodenal obstruction that do not involve the duodenal bulb. The extrahepatic bile duct is punctured by a 19G needle, the guidewire is inserted, and the fistula is dilated using a needle knife, dilator, or balloon dilator. Finally, a fully covered metallic stent is usually placed from the common bile duct to the duodenum. High technical and clinical success rates of this procedure have been reported. The biggest advantage of this method is that it is not associated with acute pancreatitis. EUS-CDS, thus, has the potential to be the biliary drainage method of choice instead of ERCP, although this needs to be confirmed by a randomized controlled trial comparing ERCP and EUS-CDS.

EUS-HGS has the widest indications among the different EUS-BD procedures. It can be performed in patients with altered anatomy, duodenal obstruction, and hepatic hilar obstruction[18]. In this procedure, the intrahepatic bile duct (segment 3) is punctured using a 19G needle, and the guidewire is advanced. Various devices are then used to dilate the fistula. Park *et al*[19] reported the predictors of adverse events with EUS-BD. In their study, post-procedure adverse events developed after EUS-BD in 11 patients (20%). Multivariate analysis demonstrated that use of a needle knife was the single most important risk factor for post-procedure adverse events after EUS-BD (OR = 12.4; P = 0.01). Hence, balloon or dilator catheters may be suitable for dilation of the fistula. In addition, metallic stents should also be used to avoid bile leakage. However, this technique is associated with the risk of fatal adverse events, such as stent migration[20]. If its adverse events can be minimized by various efforts, EUS-HGS may become the EUS-BD technique of choice because of its wide indications.

EUS-AS may also be a promising drainage method. After the intrahepatic bile duct is punctured using a 19G needle, the guidewire is advanced through the site of obstruction. Thereafter, a stent deliverer is inserted and the stent is placed in a trans- or supra-papillary position. In this technique, compared with EUS-HGS, stent migration does not occur, indicating that it seems to be a safe technique. However, re-intervention following stent occlusion, if required, can be challenging. If occlusion of the EUS-AS stent was to occur, we would need to do either of the following: puncture the intrahepatic bile duct and perform EUS-HGS, or place another stent inside the occluded stent. However, the intrahepatic bile duct may not always be dilated enough to allow for puncturing[21]. For this reason, EUS-AS should only be performed in selected patients, such as those with a limited prognosis.

EUS-GBD is probably the most easily performed of all the EUS-BD procedures, because the gallbladder presents a large target for puncture. The gallbladder can be visualized from the antrum or duodenal bulb. After it is punctured using a 19G needle, the guidewire is inserted. Then, the fistula

is dilated using a dilation or balloon catheter, while a pig tail type plastic stent is usually placed (sometimes combined with a metallic stent) to prevent stent migration. This technique is indicated in patients whose cystic duct is intact. If the cystic duct is invaded by tumor, stent dysfunction can occur. Although EUS-CDS or EUS-HGS is usually performed in cases requiring re-intervention, the patient's condition may not be suitable for re-intervention because of tumor progression. In such cases, when performance of EUS-CDS or EUS-HGS is challenging, EUS-GBD may be performed.

To date, there are no reports of randomized controlled studies comparing ERCP with EUS-BD. However, recently, a retrospective study comparing PTC and EUS-BD has been reported[22]. In this paper, of the 73 patients with failed ERCP complicated by distal malignant biliary obstruction who were included, EUS-BD was performed in 22 patients and PTC in 51 patients. Although the technical success rate of PTC was higher than that of EUS-BD, the adverse event rate and total cost were also higher than those of EUS-BD. Interestingly, EUS-BD is associated with a decreased adverse event rate and is significantly less costly due to the need for fewer re-interventions. However, these results should be further evaluated in a prospective clinical trial.

Techniques to minimize adverse events following EUS-BD

According to recent literature reviews of EUS-BD, the adverse event rates of these procedures are still high[17]. Reportedly, several techniques and devices have been introduced to reduce the adverse event rates. In EUS-CDS or EUS-GBD, novel metallic stents have been used to prevent stent migration. Itoi *et al*[23] reported the technique of EUS-GBD using AXIOS stent (Xlumena Inc., Mountain View, CA, United States). This stent is a fully covered, 10 mm diameter, 10 mm long braided stent with bilateral 20 mm diameter anchor flanges. Perez-Miranda *et al*[24] reported using this novel stent for EUS-CDS. This unique stent design may be effective in preventing stent migration. In addition, Teoh *et al*[25] described a simplified method of EUS-GBD using a novel cautery-tipped stent delivery system. However, since use of these novel stents or methods has only been reported as case reports, additional case studies and trials are required for further development of EUS-CDS and EUS-GBD as safe, simple, and effective biliary drainage methods. Likewise, several methods for improving the results of EUS-HGS have also been reported. The clinical impact of EUS-HGS combined with EUS-AS[21] and a novel method of stent placement of EUS-HGS[26] have been previously reported. Recently, Song *et al*[27] performed 10 EUS-HGS cases using a novel hybrid metallic stent that has proximal and distal antimigration flaps at both ends of the covered portion. Paik *et al*[28] described a simplified and modified technique of EUS-HGS, which resulted in a shorter procedural time ($P < 0.001$) and less frequent early adverse events ($P = 0.02$) compared with the conventional technique. Yet, although various techniques have been reviewed[29], the best techniques and devices still need to be determined by a prospective study.

CONCLUSION

In conclusion, to date, many case reports, series, and retrospective studies on EUS-BD have been reported. However, because prospective studies and comparisons between the different biliary drainage methods have not been reported, the technical success, functional success, adverse events, and stent patency with long-term follow up of EUS-BD are still unclear. Therefore, prospective, randomized controlled studies addressing these issues are needed. Despite this, EUS-BD undoubtedly is clinically useful as an alternative biliary drainage method. EUS-BD has the potential to be a first-line biliary drainage method instead of ERCP if results of clinical trials are favorable and the technique is simplified.

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