

# How should we use endoscopic ultrasonography-guided biliary drainage techniques separately?

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Biliary cannulation by endoscopic retrograde cholangiopancreatography (ERCP) is not always successful even when performed by skilled endoscopists. Several underlying reasons include the presence of intradiverticular papillae, a long narrow distal segment of the distal bile duct, altered anatomy, or gastroduodenal obstruction. Traditionally, percutaneous transhepatic biliary drainage (PTBD) or surgical intervention has been performed when ERCP fails. Recently, endoscopic ultrasonography-guided biliary drainage (EUS-BD) has been reported as a useful and safe salvage technique.<sup>[1,2]</sup> EUS-BD broadly includes the EUS-*rendezvous* technique (EUS-RV), EUS-guided choledochoduodenostomy (EUS-CDS), EUS-guided hepaticogastrostomy (EUS-HGS), and EUS-guided antegrade stenting (EUS-AS).

Since EUS-BD was reported for the 1<sup>st</sup> time by Giovannini *et al.*<sup>[3]</sup> in 2001, many retrospective series about EUS-BD have been reported from high-volume centers by skilled endoscopists, revealing high technical success rates of more than 90%. In their multicenter retrospective study of EUS-BD in 246 patients, Gupta *et al.*<sup>[4]</sup> reported the successful biliary drainage rates of 84.3% and 90.4% for EUS-HGS and EUS-CDS, respectively. On the other hand, interestingly, a national survey in Spain wherein most of the institutions

involved were not high-volume centers reported the achievement of technical success in only 67.2% of 106 patients, followed by clinical success in 63.2%. Thus, their data indicates that EUS-BD appears to be an uneasy technique for “Beginners.”

The most serious issue during and after EUS-BD is adverse events. Actually, previous studies have reported early adverse event rates of 10%-30% although the severities of most of these adverse events were mild or moderate.<sup>[5,6]</sup> Moreover, severe adverse events occasionally occur and even a fatal case owing to metal stent migration on the gastric side in the abdominal cavity following EUS-HGS has been reported.<sup>[7]</sup> This kind of adverse event may be never observed in conventional ERCP because of an “intraluminal procedure” but not a “transluminal procedure.” From these viewpoints, EUS-BD thus far has not apparently become a useful alternative to conventional ERCP, although it may be useful for salvage therapy.

Regarding the PTBD status, which is a better alternative method for patients after failed ERCP, PTBD, or EUS-BD? Only one randomized controlled trial (RCT) involving a small number of patients with malignant biliary obstruction has thus far compared PTBD with

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EUS-CDS.<sup>[8]</sup> The data obtained showed no significant differences for both methods (technical and clinical success rates, 100% *vs.* 100%; complication rates, 25% *vs.* 15.3%;  $P > 0.05$ ), and it remains uncertain which method is better.<sup>[8]</sup> Recently, Khashab *et al.*<sup>[9]</sup> have reported a retrospective study comparing PTBD in 51 patients with EUS-BD (EUS-RV followed by EUS-CDS or EUS-HGS) in 22 patients with distal malignant biliary obstruction and failed ERCP. They showed that although the technical success rate was higher in the PTBD group than in the EUS-BD group (100% *vs.* 86.4%, respectively) and the clinical success rates were not significantly different (92.2% *vs.* 86.4%), the adverse event rate was higher in the PTBD group than in the EUS-BD group (index procedure: 39.2% *vs.* 18.2%), as well as the total charges mainly due to the significantly higher rate of re-interventions (80.4% *vs.* 15.7%).

Some advantages of EUS-BD over PTBD are as follows: (1) The external drainage of PTBD may add to the patient's burden owing to the cosmetic problem, skin inflammation or pain, or bile leakage, compromising the quality of life. From this point, the internal drainage of EUS-BD eliminates several issues, (2) EUS-BD using a metal stent, particularly a lumen-apposing metal stent, can also be performed in patients with a large amount of ascites, which is often contraindicated on PTBD, and (3) EUS-BD can be performed in the same position of the patient after failed ERCP. In the case of PTBD, a change in the patient's position is required. Although current EUS-BD data suggest its superiority over PTBD, the most recent data have been reported from high-volume centers by skilled endosonographers. On the other hand, several skilled radiologists who have no skilled endosonographers may maintain the efficacy and safety of PTBD, which has already been widely established. Thus, "Best Practice" should be considered according to the presence of skilled endosonographers or radiologists. Nonetheless, in the near future, EUS-BD will become more and more widely used with the development of dedicated devices and the standardization of techniques than PTBD.

Once a decision to perform EUS-BD has been made, the next step is to determine which biliary approach should be selected (i.e., EUS-CDS, EUS-HGS, EUS-RV, or EUS-AS). At present, there are no optimal answers such as practical guidelines regarding the selection of EUS-BD. Thus far, the selection of the

EUS-BD approach depends on the patient's condition, which may involve the presence of gastric outlet obstruction, the site of biliary obstruction, Roux-en-Y anastomosis or the preference of endoscopists.<sup>[10]</sup> Khashab *et al.*<sup>[11]</sup> compared the outcomes of EUS-RV and EUS-transluminal biliary drainage (EUS-HGS or EUS-CDS) using a standardized approach in 35 patients with malignant biliary obstruction and failed ERCP. They showed that the clinical outcomes and adverse events rates (15.4% *vs.* 10%) were not significantly different between the two groups. EUS-RV has some disadvantages compared with EUS-HGS or EUS-CDS in that EUS-RV requires guidewire manipulation through the biliary obstruction site. As we know, guidewire manipulation is often difficult or impossible even by skilled assistants. Furthermore, the exchange of the echoendoscope with the duodenoscope makes the procedure using a guidewire complicated. Accordingly, transpapillary biliary stenting takes more time to complete by EUS-RV than by EUS-CDS or EUS-HGS (approximately 20 min or more). Thus, we think that EUS-CDS or EUS-HGS may be considered as the first-line approach even in patients with malignant biliary obstruction and an accessible ampulla.

EUS-AS may be an interesting option because of the theoretical physiological bile flow in patients with inaccessible ampulla although there are as yet no reports comparing EUS-AS with other EUS-BD approaches. Iwashita *et al.*<sup>[12]</sup> showed in their review that the overall success and adverse event rates of EUS-AS were 77% and 5%, respectively. The success rate of EUS-AS is inferior to that of EUS-HGS or EUS-CDS owing to the difficulty of guidewire passage and stent delivery system insertion across the strictures. Even if a stent is successfully placed across the stricture, bile leakage from the hepatic puncture site is possible in case of stent dysfunction although there may be less concern about stent inward and outward migrations in the abdominal cavity or stomach, compared with EUS-HGS. Furthermore, re-intervention owing to stent occlusion is not possible, and EUS-HGS or additional EUS-AS is required. Thus, the indication of EUS-AS is limited in selected patients such as those with surgical altered anatomy.<sup>[13]</sup> As one of the options to overcome the disadvantages of EUS-HGS and EUS-AS, combination stenting, namely simultaneous EUS-HGS following EUS-AS may be promising although expensive.

It remains controversial which approach is better if both EUS-CDS and EUS-HGS are available. Artifon *et al.*<sup>[14]</sup> conducted an RCT comparing EUS-CDS with EUS-HGS in 49 patients with unresectable distal malignant biliary obstruction. The outcomes in terms of technical success rate (91% *vs.* 96%), clinical success rate (77% *vs.* 91%), and adverse event rate (12.5% *vs.* 20%) were not significantly different. Although no report has yet revealed a statistically significant difference between the two approaches, in previous reports, the procedure-related adverse event rates of EUS-HGS tended to be higher than those of EUS-CDS.<sup>[12]</sup> Based on our personal experience, there are no obvious eminent advantages and disadvantages between EUS-HGS and EUS-CDS, and that their indications depend on anatomical factors, such as the presence of gastric outlet obstruction, nondilated intrahepatic bile duct, large amount of ascites, and visibility of punctured intrahepatic bile duct and extrahepatic bile duct. Thus, we think that interventional endosonographers should learn both techniques, which are the main EUS-BD techniques.

Finally, we would like to describe the current status and future perspective regarding EUS-BD stents. Several technical tips and devices have been introduced to reduce the adverse event rates of EUS-CDS or EUS-HGS. Regarding drainage devices, biliary covered metal stents (CMSs) have recently become more widely used than plastic stents because of the better drainage made possible by a large bore and the prevention of bile leakage and bile peritonitis. However, there are as yet no commercially available dedicated CMSs for EUS-CDS and EUS-HGS around the world. One of the most serious disadvantages of a braided-type CMS, which is conventionally used on EUS-BD, is its high shortening rate, leading to stent misplacement or migration.<sup>[7]</sup> Furthermore, stent occlusion owing to hyperplasia derived from a traumatic change in the CMS edge is frequently observed. In the case of a nonremarkable dilated intrahepatic bile duct, a large bore CMS appears to be overdilation. Recently, Umeda *et al.*<sup>[15]</sup> have reported the technical feasibility and clinical effectiveness of a newly designed 8 Fr plastic stent dedicated for EUS-HGS. They showed that in 23 cases of EUS-HGS using their new plastic stent, the technical and clinical success rate was 100% with no stent migration and no bile leakage. Based on these results and the size of conventional PTBD tubes (7 Fr or 8 Fr), we believe that an 8 Fr dedicated plastic stent appears to be one of the suitable options

for EUS-HGS treatment, particularly in the case of an unremarkable dilated intrahepatic bile duct or benign diseases such as bile duct stones, benign biliary strictures, and bilioenteric strictures. In terms of EUS-CDS, a novel lumen-apposing biflanged metal stent (8 mm and 10 mm in diameter; AXIOS stent; Xlumena Inc., Mountain View, CA, USA) has recently been developed.<sup>[16,17]</sup> This stent is a dedicated metal stent for EUS-CDS and may contribute to the improvement of its technical success rate.

In conclusion, each of the EUS-BD procedures is useful alternative biliary drainage methods after failed ERCP. However, since these EUS-BD procedures have not yet been standardized, the selection of the approaches for EUS-BD should be based mainly on the patient's condition, patient's anatomy, and specialist's experience with the procedure. Moreover, the procedures should be carried out by skilled endoscopists who can perform each type of EUS-BD at high-volume centers with appropriate backup.

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