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Choose the best alternative wisely for biliary interventions after failed ERCP!

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Endoscopic retrograde cholangiopancreatography (ERCP)-guided biliary access and subsequent interventions fail in 5% to 10% of patients mainly due to altered anatomy, duodenal obstruction, or difficult cannulation of the major papilla. Until recently, percutaneous transhepatic biliary drainage (PTBD) was considered the standard rescue approach for these cases. The technique is effective but can be challenging and may cause various complications. Guidelines recommend a procedural threshold for biliary cannulation of dilated ducts in 95% and major complications in 10% of cases [1]. However, drainage-related adverse events (AEs) can occur in up to 40% of patients [2]. Endoscopic ultrasound-guided biliary drainage (EUS-BD) is now proposed as a less invasive alternative. A recent meta-analysis showed rates of 90% and 17% for technical success and AEs, respectively [3]. According to recent European Society of Gastrointestinal Endoscopy guidelines, EUS-BD is recommended over PTBD in distal malignant biliary obstruction when local expertise is available [4]. Current evidence supports EUS-guided choledochoduodenostomy (EUS-CDS) over EUS-guided hepaticogastrostomy (EUS-HGS) due to its lower rate of AEs. For malignant hilar biliary obstruction, multidisciplinary consultation is recommended to determine the most effective biliary drainage strategy [4].

In this issue of endoscopy, Koutlas et al. report on a propensity score matched analysis of a retrospective comparison between EUS-HGS and PTBD after failed ERCP [5]. In a 1:2 ratio, 32 patients undergoing EUS-HG were matched with 64 PTBD cases with no significant differences in patient characteristics. Indications widely ranged from various benign biliary diseases and malignancies in 40% and 60% of cases, respectively. Two-thirds of the latter caused distal biliary obstruction. The primary outcome was clinical success. For malignant indications, it was defined as a decrease of the serum bilirubin level by at least 50% within 2 weeks after the procedure. For benign diseases, it was determined by interventional resolution of the biliary disorder. The results of the analysis showed high technical success rates of 91% for EUS-HGS and 98% for PTBD. The reported clinical success of 100% for EUS-HGS was surprisingly related to patients in which a technical approach was successful. It was only 88% on an intention-to-treat (ITT) analysis (28 of 32 cases). The corresponding rate for PTBD was 73% (47 of 64). The study does not provide a statistical comparison for the ITT analysis but only for the per protocol-related data for which the difference was significant. Further significant advantages of EUS-HGS were shorter procedure duration, shorter hospitalization, and lower reintervention rates (53% vs 89%, $P < 0.0001$) compared with PTBD. AEs were much more frequently registered in the PTBD group (48 versus 4, $P < 0.0001$). Severe AEs occurred only due to percutaneous procedures at a rate of 8%. Most of the significant advantages of EUS-HGS over PTBD were also reported for the subgroups of benign and malignant biliary diseases. The authors emphasize the advantages of HGS over

other EUS-BD techniques, in particular, in patients with gastric outlet obstruction where EUS-CDS is difficult to perform. In addition, the HG metal stent is far from obstructing sites which avoids stent dysfunction due to tumor ingrowth.

The study suggests that EUS-HGS is superior to PTBD for the majority of ERCP failures for biliary drainage. Can they be generalized for everyday clinical practice? A comparison of EUS-BD with PTBD should consider indications, technical procedure details, and expertise of interventionalists. A recent systematic review and meta-analysis compared EUS-BD with PTBD for failed ERCP cases [6]. Three randomized controlled trials (RCTs) and six observational retrospective studies were included. All except one study enrolled only patients with malignant biliary diseases. All currently available techniques for EUS-BD (antegrade stent placement, hepaticogastrostomy, rendezvous procedure, or choledochoduodenostomy) were used. Overall results of this analysis demonstrated significantly better clinical success, lower rates of AEs, and fewer reinterventions for EUS-BD. A comparison between the different EUS and percutaneous transhepatic cholangial drainage (PTCD) techniques could not be provided due to the limited number of cases. Another meta-analysis included six RCTs and four retrospective studies for comparison of EUS-BD versus PTCD in a total of 1131 patients with failed ERCP for drainage of distal malignant biliary obstruction [7]. Results indicate that EUS-BD is equally effective but safer in terms of acute and total AEs compared with PTBD. For this indication, a recent multicenter RCT even showed that EUS-CDS of first intent is noninferior to ERCP [8].

In contrast to distal biliary obstruction, the current analysis was not well matched for drainage of proximal stenoses. Only one of 19 patients was treated by EUS-HG whereas 18 underwent PTCD. This imbalance is probably due to limited indications for EUS-HGS. The majority of patients with Bismuth type III and IV strictures can be only partially drained because of a difficult access to obstructed right-sided segments. Therefore, it is mainly used as a salvage or complementary technique in addition to ERCP- or PTC-guided stent placements. In contrast, PTCD allows drainage of each obstructed segment in both liver lobes. The number of drains and subsequent stents can be adjusted for achieving decompression of more than 50% of the liver volume that is needed for clinical success. These interventions are challenging and may cause severe AE. They cannot fairly be compared with EUS-HG in the current study because EUS-HGS was used almost exclusively (95%) for distal biliary obstruction [5].

Benign biliary disorders in 38 patients were mainly related to choledocholithiasis (n = 15) and biliary strictures (n = 23) [5]. EUS-HGS and PTBD were equally effective but the latter was inferior in terms of AEs, procedure duration, number of reinterventions, and hospitalization. On an ITT analysis, clinical success was achieved by EUS-HGS in eight of 10 patients (80%) and by PTBD in 26 of 28 cases (93%). Unfortunately, technical details for treatment of bile duct stones and benign stenoses were not reported. Advanced techniques allow cholangioscopically-guided lithotripsy through an established HGS or a PTCD tract. Benign stenoses can be treated with multiple stents inserted through the HGS route. In contrast, percutaneous interventions are difficult for exchange and removal of plastic stents. However, large-bore tubes achieve the same effect of keeping strictures open and providing internal biliary drainage. They can be equipped with a flat stop cock for positioning at the skin level. They are well tolerated by patients and can be easily exchanged. Another option is PTCD-guided placement of retrievable PTFE-covered stents [9].

Koutlas et al. applied advanced techniques for EUS-HGS by using fully-covered self-expandable biliary stents. They inserted double pigtail plastic stents through the HGS metal stents to minimize the risk of dislocation and to establish antegrade and retrograde drainage [5]. In contrast, PTCD was performed with conventional techniques, e. g. serial tract dilatation up to 12F and temporary external drainage. It technically succeeded in all cases but required a very long procedure time (median of 166 minutes). A clinical success was surprisingly not achieved in one-fourth of the patients. The catheters were routinely exchanged. In addition to these scheduled reinterventions, catheters had to be replaced in 29 cases due to dislodgement or obstruction. These complications caused 60% of all PTCD-related AEs and explain the inferiority to EUS-HGS in terms of the number of reinterventions and duration of hospitalization.

Nowadays advanced PTCD techniques allow placement of self-expanding metal stents for malignant biliary obstruction through an 8- to 10F tract or cholangioscopically-guided lithotripsy through a 12F sheath in the first or second session. All other interventions that can be performed through a HG tract can be also done through a mature cutaneobiliary fistula or a sheath. PTCD safety catheters can be locked because internal drainage can be usually initially established. They can be removed a few days after biliary metal stenting or definitive treatment of benign diseases. A recent multicenter, prospective, single-arm, observational study on PTCD after failed endoscopic procedures in 117 patients with malignant and benign biliary disease reported a clinical success rate of 96% after a single procedure and a mean total beam-on time of 9.5 minutes [10]. Complications rate recorded up to 30 days follow-up was 10.8%, all of minor grades. Drainage displacement occurred in only 5% of the patients up to 1 week after positioning.

The unfavorable results for PTCD in the current study seem to be related to limitations in performance and use of advanced techniques. The authors do not refer to the expertise of the interventionalists. In contrast, they emphasize that all EUS-guided procedures were performed by a single experienced therapeutic endoscopist in a high-volume center [5].

Conclusions

In conclusion, EUS-BD (CDS or HGS) performed by skilled endoscopists should be preferred over PTCD in cases with distal malignant biliary obstruction after failure of ERCP. On the other hand, selection of drainage procedures for malignant hilar stenoses should be based on magnetic resonance cholangiopancreatography findings in a multidisciplinary setting. PTCD will be frequently needed but can be combined with EUS-HGS. Non-ERCP-guided treatment of benign biliary diseases can be challenging but there are new interventional options for an

EUS-guided access as well as for advanced percutaneous techniques. A team approach is recommended with consideration for local expertise and logistics. If optimal care cannot be provided, patients should be referred to a high-volume center for hepatopancreatobiliary diseases. These institutions should collaborate to initiate multicenter RCTs to compare competing or complementary techniques for biliary interventions in well-defined groups of patients.

Conflict of Interest

The authors declare that they have no conflict of interest.

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