# EUS-guided biliary drainage: A realistic perspective

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ERCP is the primary therapeutic endoscopic intervention for the management of biliary obstruction and has been for decades, essentially replacing surgical approaches for the management of bile duct obstruction.<sup>[1]</sup> Biliary cannulation – the gateway maneuver essential for a successful ERCP – is successful over 95% of the time in the hands of experienced, high volume endoscopists who perform ERCP in patients with native anatomy.<sup>[2]</sup> For the vast majority of patients, ERCP is successfully performed using standard approach, tools, and techniques, without any need for additional intervention.

Percutaneous interventional radiology-based approaches have been and remain the most common second-line approaches for achieving biliary access, drainage, and therapy in the event of failure of ERCP. Percutaneous approaches are all catheter-based, and these biliary drainage tubes are both unpopular with, and unpleasant for, patients. Patient and provider preferences for a less invasive second-line approach for biliary access, coupled with expansion of therapeutic EUS and EUS-guided interventions, have led to the development of EUS-guided biliary drainage (EUS-BD) approaches.

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EUS-BD is a logical extension of the concept of accessing the bile duct using an EUS needle, through which a wire and, using a newly made tract drainage catheter or stent may be placed for drainage. EUS-BD was first described in 2001 for the treatment of obstructive jaundice in a patient with a pancreatic head mass.<sup>[3]</sup> EUS-BD comprises three main approaches: transluminal, rendezvous, and antegrade. Transluminal drainage involves the creation of a new biloenteric fistula between the biliary tree and the duodenal or gastric lumen. The rendezvous approach involves EUS-guided introduction of a guidewire through an access needle positioned in the biliary tree. This guidewire is then advanced across the ampulla. Biliary cannulation is then achieved over or next to this guidewire. The antegrade approach involves achieving transluminal drainage through the proximal biliary tree and is often used in patients with surgically altered anatomy. Antegrade wire access is often obtained through a dilated hepatic duct (e.g. dilated left hepatic duct with the tip of the echoendoscope positioned along the lesser curvature of the stomach) for biliary endotherapy and possible antegrade stent placement through an echoendoscope. In addition to the three approaches detailed above, EUS-BD may also be classified by the biliary access point for each approach: the intrahepatic

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approach (including hepatogastric anastomosis and antegrade stent placement) or the *extrahepatic* approach (including choledochoduodenostomy and rendezvous).

EUS-BD approaches have a broad range of reported success and adverse event rates. For these approaches, the associated adverse events include cholangitis, stent migration, and occlusion. There is a likely some degree of publication bias, with better outcomes being more likely to be reported. However, the development of bile leaks and peritonitis tend to be the most concerning associated adverse events. With the rendezvous technique, reported success rates have ranged from 35% to 100%, and the range of procedure-associated adverse events is as high as 25%.[4-10] Antegrade EUS-BD has been shown to have a success rate of 95% in patients with surgically altered anatomy, with an adverse event rate of approximately 20%.[11] Biliary sphincterotomy is not performed with antegrade EUS-BD, and this has been proposed as an explanation for higher rates of post-ERCP pancreatitis with this approach. Transluminal EUS-BD with creation of a hepatogastric or choledochoduodenal drainage tract using a covered lumen apposing metal stents (LAMSs) similarly has a broad range of success rates, ranging from 50% to 100% and adverse event rates typically in the 10%-20% range.[3,12,13]

Each of these EUS-BD approaches is complex, with key "make or break" points in the procedure and a slim margin for error in their execution. These interventions are ideally performed in high volume settings by technically savvy endoscopists working with highly trained and experienced endoscopy technicians. This tertiary care setting, however, does not reflect the lower volume community practices, in which the majority of ERCPs are performed in the United States.<sup>[14]</sup> These lower volume ERCP settings may be expected to have cannulation failure rates and a need for EUS-BD that is higher than in the tertiary care setting where EUS-BD is best performed. Another factor which has limited "real world" use of EUS-BD is the lack of dedicated tools for EUS-BD.

Algorithms have been proposed for EUS-BD, with approach selection based on the presence of a dilated intrahepatic biliary tree.<sup>[13]</sup> However, the implementation of an algorithm presupposes endoscopist familiarity with, and competence in, performing EUS-BD, which few advanced endoscopists truly possess. Even at high volume centers, ERCP failure is sufficiently uncommon that <20 EUS-BD procedures might be necessary annually and probably far fewer than that. When divided among endoscopists practicing in this high-volume setting, each endoscopist may perform five or fewer EUS-BD procedures annually. Analogous to surgical interventions, complex procedures such as EUS-BD are subject to a volume-outcomes relationship, whereby increased annual volume predicts technical and clinical success and adverse event rates of the intervention.

At centers where therapeutic EUS is routinely performed, other EUS interventions may cross-train an endoscopist in the performance of EUS-BD, but at centers where EUS interventions are rare, this may represent a barrier to widespread adoption of EUS-BD. To underscore this point, in 2011, a consortium involving forty experts internationally recommended that EUS-BD should be performed by endoscopists trained in both EUS and ERCP, with at least 4–5 years of experience (at least 200–300 ERCPs and EUS procedures annually) with at least a 95% success rate for ERCP and in the setting of surgical and interventional radiology backup.<sup>[15]</sup> These recommendations are not enforced but are worthy of consideration.

Another notable factor limiting-training in and utilization of EUS-BD is the near-complete lack of devices specifically designed and approved for use in this setting in the United States. With perhaps no exceptions, devices for EUS-BD are used in an off-label manner, which limits the potential for device manufacturer or society-based courses to train endoscopists in EUS-BD. Most EUS-BD accessories are designed for ERCP and as such, do not properly fit an echoendoscope in terms of length, operating handle position, or the ability to connect to the Luer lock on the endoscope control handle. When LAMSs were approved for on-label uses such as the endoscopic drainage and debridement of pancreatic pseudocysts and walled-off pancreatic necrosis, the number of these procedures exploded. We suspect something similar will happen when dedicated EUS-BD devices are made available.

The complexity of cannulation during ERCP and the range of therapeutic interventions performed during ERCP have escalated over time.<sup>[16]</sup> As bariatric surgery rates rise and endoscopists increasingly encounter patients with surgically altered anatomy

who require ERCP, the potential for failed cannulation during complex ERCPs may be reasonably expected to rise.<sup>[16,17]</sup> In the past decade, interventional EUS has matured as a therapeutic approach for the management of pancreatic fluid/necrotic collections, with the development of dedicated "on-label" devices that have enabled training platforms to enhance endoscopists familiarity and expertise in managing these fluid/necrotic collections.<sup>[18]</sup> EUS-BD has great potential for success as a second-line biliary access approach following failed ERCP, but until we have "on-label" accessories for EUS-BD, and the approach is taught more widely and rigorously studied in real world scenarios, it is unlikely to achieve widespread adoption.

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## Conflicts of interest

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