

EUS-guided biliary drainage: Is it ready for prime time?

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) currently represents the procedure of choice to achieve biliary drainage (BD) in patients with obstruction of the biliary tree by various etiologies. However, even in experts hands in about 3%–10% of cases, the procedure is not technically feasible due to surgically altered anatomy, gastric outlet obstructions, periampullary diverticula, or complete ductal obstructions.^[1–3] In such cases, percutaneous transhepatic biliary drainage (PTBD) is performed, which is associated with considerable morbidity (in up to 30% of cases), also causing significant discomfort to the patient because of the presence of the percutaneous drain and the need for reinterventions.^[4,5]

In the past decades, endoscopic ultrasound (EUS) has rapidly evolved from a diagnostic procedure into a more therapeutic one. After Giovannini *et al.*^[6] reported, in 2001, the feasibility of EUS-guided BD (EUS-BD), the procedure has emerged as a valid alternative in patients in whom ERCP fails. The EUS-BD technique has evolved over time and is now being reported to be clinically relevant in a significant number of patients.

INDICATIONS AND CONTRAINDICATIONS OF THE PROCEDURE


At present, the accepted indications for EUS-BD drainage include:^[7]

- Failed conventional ERCP performed in referral centers of high expertise
- Altered anatomy by previous surgery making papilla inaccessible
- Failure to access the papilla secondary to malignant involvement or other causes
- Occluding tumor preventing standard biliary cannulation.

Importantly, EUS-BD should be performed by highly trained pancreaticobiliary endoscopists, with mandatory surgical and interventional radiology backup, given the potential for serious adverse events associated with the procedure.^[8]

ACCESS ROUTE

EUS-BD can be performed with a transgastric–transhepatic (intrahepatic [IH]) approach or a transenteric–transcholedochal (extrahepatic [EH]) access

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[Figure 1]. It is still unclear which EUS-BD technique should be used in a given circumstance, and usually, the use of one or the other approaches relies on the expertise and decision of the operator.

The intrahepatic approach

The IH approach is performed with the echoendoscope positioned in the region of the distal esophagus, gastric cardia, or lesser curvature to allow access of the left IH biliary system or in the jejunum in patients with prior gastrectomy.

The extrahepatic approach

In the EH approach, the common bile duct (CBD) is most frequently accessed from the duodenal bulb but

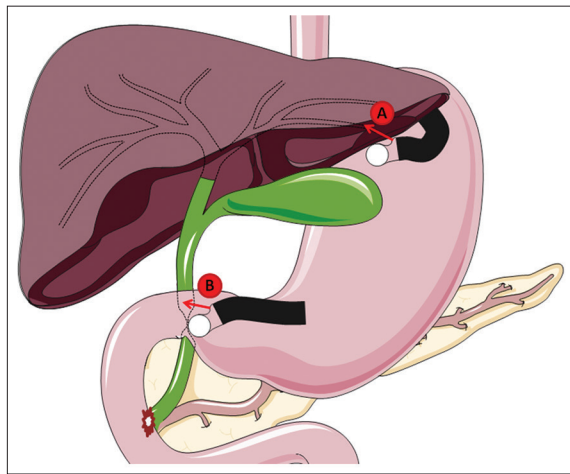


Figure 1. Diagram presenting the access points of the endoscopic ultrasound-guided biliary drainage procedures: (A) Intrahepatic biliary access; (B) extrahepatic bile duct access

sometimes from the distal antrum only or even the pyloric ring.

AVAILABLE CLINICAL EVIDENCE

The large majority of the published studies are retrospective and the outcome of individual procedural approaches grouped together. The results of the published studies with at least fifty patients enrolled are shown in Table 1. The combined technical and clinical success rates in these 16 studies are 92% and 88%, respectively.

Similarly, in a systematic review including 42 studies and 1192 patients, the cumulative technical success rate (TSR) and functional success rate (FSR) for all EUS-guided procedures were 94.5% and 92.5%, respectively.^[25] There is, however, a lack of properly designed studies and many unresolved issues. For example, in the same systematic review, despite a very good TSR (95.8%), the FSR for benign diseases was suboptimal (only 82.3%), which made the authors to conclude that malignant disease probably represents a better indication for EUS-BD.^[25] This low success rate for benign diseases has been also reported in another recent review^[26] and could be related to the difficulty in manipulating the guidewire toward the papilla in normal cases, in which the CBD is not dilated and a rendezvous (RV) procedure is the only option.

The FSRs of studies using plastic stents *versus* studies using metal stents were not statistically different (98.2%

Table 1. Outcome of endoscopic ultrasound-guided biliary drainage evaluated in relevant studies with more than 50 patients

Study	Design	Number of patients	Technical success (%)	Clinical success (%)	Complications (%)
Park <i>et al.</i> , 2011 ^[9]	PS	57	97	89	20
Dhir <i>et al.</i> , 2012 ^[10]	RS	58	98	NR	3
Shah <i>et al.</i> , 2012 ^[11]	RS	66	85	85	9
Vila <i>et al.</i> , 2012 ^[12]	RS	106	69	NR	23
Dhir <i>et al.</i> , 2014 ^[13]	RS	68	96	NR	21
Gupta <i>et al.</i> , 2014 ^[14]	RS	240	87	NR	35
Kawakubo <i>et al.</i> , 2014 ^[15]	RS	64	95	NR	19
Dhir <i>et al.</i> , 2015 ^[16]	RS	104	93	92	9
Poincloux <i>et al.</i> , 2015 ^[17]	RS	101	98	92	12
Cho <i>et al.</i> , 2017 ^[18]	PS	54	100	94	17
Khashab <i>et al.</i> , 2016 ^[19]	RS	121	93	83	17
Khashab <i>et al.</i> , 2016 ^[20]	PS	96	96	90	11
Kumbhari <i>et al.</i> , 2016 ^[21]	RS	87	93	82	NR
Kunda <i>et al.</i> , 2016 ^[22]	RS	57	98	95	7
Nakai <i>et al.</i> , 2017 ^[23]	RS	56	95	NR	21
Tyberg <i>et al.</i> , 2016 ^[24]	PS	52	96	77	10
Total		1387	92	88	18

RS: Retrospective study, PS: Prospective study, NR: Not reported

vs. 94.5%, respectively).^[25] Moreover, in other studies, the transgastric and the transduodenal approaches performed equally in terms of technical success of the procedure, long-term success,^[27] and patient survival.^[19] However, there are authors who report a higher stent dysfunction rate for EUS-hepaticogastrostomy (HGS)^[15] that can be obviated by combining EUS-HGS with antegrade stenting through the papilla.^[28]

In the same systematic review mentioned above, the TSR and FSR for EUS-guided antegrade stenting were 91.3% and 100%, respectively.^[25] For EUS-RV technique, the TSR and FSR were 89.7% and 100%, respectively,^[25] which are slightly lower than that those of the direct transluminal stenting techniques. This is important because when EUS-RV has failed, a transluminal stenting procedure can always be performed in malignant cases. An algorithm for EUS-BD has been proposed, mainly based on the accessibility or not of the papilla [Figure 2].^[29]

Comparing EUS-BD with percutaneous transhepatic BD, no difference in technical success between the two procedures was reported in a recent meta-analysis including 483 patients from nine different studies.^[30] However, the EUS-guided approach was more cost-effective and associated with significantly better clinical success (odds ratio [OR], 0.45), fewer postprocedural adverse events (OR, 0.23), and much lower rates of reintervention (OR, 0.13) than PTBD.

On the other hand, when EUS-BD is directly compared with standard ERCP, there is evidence

from an international multicenter retrospective study involving 208 patients^[16] that EUS-BD can perform as good as ERCP in palliation of distal malignant biliary obstruction. In the EUS study group, among the 104 patients, 68 (65.4%) underwent choledochoduodenostomy (CDS) while the remaining 36 (34.6%) HGS. Similar technical success rates (94.23% vs. 93.26%) and adverse events (8.65% and 8.65%) were found in the two study groups. Importantly, the overall rate of composite success (defined as technical success with >50% reduction in bilirubin concentration within 2 weeks) was superior for the EUS group as compared with the ERCP group (93.93% vs. 79.58%; $P = 0.0001$). This could allow earlier administration of chemotherapy when drainage is performed under EUS, with a possible major clinical impact for the patient.

There is only one study performed in naïve patients who did not undergo previous ERCP, in whom EUS-CDS with direct metallic stent placement was performed using a prototype forward-viewing echoendoscope.^[31] In 17/18 (94%) of the cases, the procedure was technically and clinically successful. In two cases (11%), focal peritonitis occurred but resolved with conservative treatment. During a median follow-up of 187 days, stent occlusion occurred in only two of the patients, with successful stent cleaning in both.

COMPLICATIONS RELATED TO THE ENDOSCOPIC ULTRASOUND-GUIDED BILIARY DRAINAGE PROCEDURE

EUS-BD is an invasive procedure and similarly to PTBD, and ERCP is associated with many potential complications. In the systematic review mentioned above,^[25] the cumulative adverse event rate of EUS-BD was 23.3%. Furthermore, in our review of the studies, with a significant number of patients, the adverse event rate of EUS-BD was 18% [Table 1]. Of note, this figure is higher than the rate of adverse events reported for ERCP (6.8%–7.9% with reported procedure-related fatalities in 0.33% of cases).^[32,33] However, in comparison with PTBD, EUS-BD appears to be safer,^[34] being associated with fewer adverse events (18.2% vs. 39.2%, including reinterventions in 15.7% vs. 80.4%), as resulted from a study involving 73 patients with distal malignant biliary obstruction

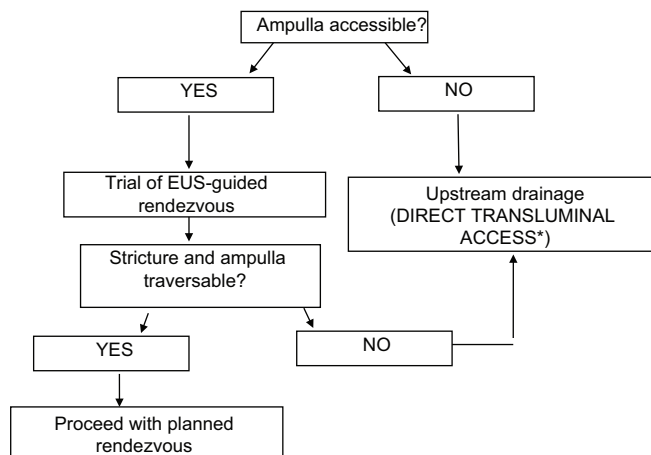


Figure 2. Proposed algorithm for endoscopic ultrasound-guided biliary drainage (adapted from Khashab *et al.*).^[29] *For direct transluminal access either the extrahepatic or intrahepatic approach can be tried; if the first choice unsuccessful, convert to the other approach, if feasible

after failed ERCP, results that were subsequently confirmed in other studies.^[35,36]

Common adverse events that can occur during or after EUS-BD are bleeding, bile leakage, stent migration, cholangitis, and abdominal pain. Most of these adverse events are either self-limited or can be managed conservatively. Comparison between the EUS-CDS and EUS-HGS approaches has failed to disclose significant differences in the rate of procedure-related adverse events.^[19,25] Likewise, EUS-BD in patients with malignant *versus* benign diseases results in similar complication rates.^[14] On the other hand, what seems to be independently associated with their occurrence is the use of plastic stents.^[19] Indeed, in a large systematic review, the rate of adverse events associated with the use of metal stents was 17.5%, significantly lower compared to that of plastic stents (31.0%) ($P = 0.013$).^[25] More recently, a meta-analysis reported a reduced rate of adverse events of EUS-guided RV compared with EUS-guided transmural drainage (11% *vs.* 21%, respectively).^[37]

FUTURE PERSPECTIVES

All the available evidence presented above indicates that EUS-BD is a high technically challenging procedure, which has to be performed by experts trained in pancreaticobiliary endoscopy in a setting with multidisciplinary surgical and radiological support in the event of the occurrence of complications. The efforts to reach a consensus on the better approach to be used in a given clinical scenario and standardization of the EUS-BD procedures are needed.

Another unsettled issue is represented by the minimal requirements for training before being able to perform the procedure. Most experts agree that training in interventional EUS techniques should be coupled with training in ERCP.

Although there are some reports favorably comparing EUS-BD with standard ERCP, the results of the systematic reviews available so far show that it cannot be used at the present time as a substitute for ERCP.^[38] Indeed there is no doubt that there is a huge potential of EUS-BD, but it needs to be coupled with the development of dedicated accessories, along with a better standardization of the techniques and should be compulsory evidence-based to bring the EUS-BD procedure to another level.

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