### ORIGINAL ARTICLE: Clinical Endoscopy

# Biliary drainage: role of EUS guidance

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**Background and Aims:** EUS-guided biliary drainage is a technique being increasingly used when ERCP fails, and it has been the focus of multiple studies and investment in recent years. However, the proportion of cases for which it is really indicated has not been established. The aim of this study is to determine how often EUS-guided biliary drainage is needed in a tertiary-care level therapeutic endoscopy unit.

**Methods:** This is a prospective cohort study at a single tertiary-care center with a high volume of therapeutic endoscopy. A thousand consecutive ERCPs performed from November 1, 2013 to September 12, 2014 were screened, and those with previous biliary intervention were excluded (n = 476). EUS-guided biliary drainage was performed in suitable patients with failed ERCP and malignant biliary obstruction. The main outcome measures were the rates of ERCP failure and EUS-guided biliary drainage.

**Results:** A total of 524 native papilla ERCPs were performed (41.2% male; median age 60 years, range 6-97 years; 9.4% outside failed ERCP; 1.9% surgically altered anatomy). The ampulla was reached in 518 (98.9%) and not reached in 6 (1.1%) because of surgically altered anatomy (n=2), malignant duodenal stenosis (n=3), or both (n=1). The overall ERCP failure rate was 1.7% (9/524). Cannulation was successful in 99.4% (515/518) and unsuccessful in 0.6% (3/518) of cases in which the ampulla was reached. EUS-guided biliary drainage was indicated in 0.6% (3/524) of all referred native papilla ERCPs, or 33% (3/9) of those patients with failed ERCP; EUS-biliary drainage was successful in all cases.

**Conclusions:** In a tertiary-care center, use of advanced ERCP techniques results in a high technical success rate. EUS-guided biliary drainage was required in only 0.6% of native papilla ERCPs, and although a number of excellent indications exist, it should not replace good ERCP technique. (Gastrointest Endosc 2016;83:160-5.)

ERCP is the preferred method to access the bile duct, and it is performed with both diagnostic and interventional intent. Biliary cannulation is an essential procedural step, which fails in 4% to 16% of ERCPs. 1-4 Cannulation failure may be a result of patient and disease factors, such as altered papillary structure (eg, ampullary adenoma or cancer, duodenal diverticulum) or inability to reach the papilla (eg, duodenal stricture or gastric outlet obstruction, post-surgical anatomy). Biliary access and drainage after failed ERCP has historically been treated by using two main approaches: percutaneous transhepatic biliary

drainage (PTBD) or surgery. Although both techniques are associated with considerable morbidity, patients undergoing PTBD frequently require multiple repeat interventions, and surgical drainage carries a significant risk for mortality. <sup>5-9</sup>

EUS-guided biliary drainage (EUS-BD) has emerged over the last decade as an effective alternative, having significant potential for providing the least invasive and lowest risk method for biliary access. In 2008, an EUS working group convened to establish research priorities in an effort to accelerate the growth and development of

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; EUS-BD, EUS-guided biliary drainage; PTBD, percutaneous transbepatic biliary drainage.

DISCLOSURE: All authors disclosed no financial relationships relevant to this article.

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http://dx.doi.org/10.1016/j.gie.2015.06.019

Received January 28, 2015. Accepted June 11, 2015.

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interventional EUS. Hepaticogastrostomy and choledochoduodenostomy were assigned a high level of priority, with recommendations for procedural technique standardization, larger prospective clinical studies, and development of EUS-specific devices. <sup>10-12</sup> These recommendations later were supported by the American Society for Gastrointestinal Endoscopy (ASGE). <sup>13</sup> Since 2008, multiple studies on EUS-BD by experienced endoscopists and involving more than 15 patients per study have been reported, with technical and functional success rates between 73% and 98% and 75% and 100%, respectively, and adverse event rates between 3% and 23%. <sup>14-31</sup>

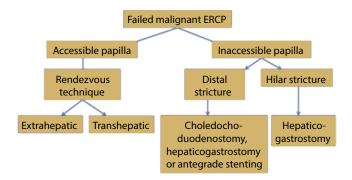
EUS-BD is becoming an established technique for biliary access after failed ERCP in specialized centers and, like all new interventions, requires ongoing evaluation to establish its role in clinical practice. The aim of this study was to establish how often EUS-BD is really needed in tertiary-care level therapeutic endoscopy unit and to assess whether the degree of excitement, hype, and investment in EUS-BD is warranted, given the predicted need for biliary drainage after failed ERCP.

#### **PATIENTS AND METHODS**

A prospective cohort study was conducted at a single tertiary-care center with a high volume of therapeutic endoscopy (>1100 ERCPs and >2600 EUSs annually). Hospital ethics approval was obtained. A thousand consecutive ERCPs performed for primary biliary indications from November 1, 2013 to September 22, 2014 were screened. Patients with native papillae were included, and those who had previous biliary intervention were excluded. All patients referred from outside centers for failed ERCP had repeat attempts at ERCP before consideration for EUS-BD. Procedures were performed by 4 endoscopists with a median of 11 years of ERCP experience (range 28 years).

ERCPs were performed with patients under general anesthesia with Olympus TJF-Q180V duodenoscopes (Olympus, Tokyo, Japan) by using carbon dioxide insufflation. ERCP complexity was graded by using the ASGE complexity score.<sup>32</sup> Choice and sequence of biliary devices, cannulation method, and postprocedural management was at the endoscopist's discretion. As per departmental protocol, all patients with failed ERCP were assessed for EUS-BD (Fig. 1) and referred for PTBD or surgery if unsuitable for PTBD. EUS-BD was performed either directly after a failed ERCP or at a second scheduled procedure.

EUS was performed by using a curvilinear array echoen-doscope (GF-UCT180; Olympus). The rendezvous technique was preferentially used if the papilla was accessible, with preference given to the extrahepatic approach unless the obstruction was proximal or the patient had altered GI anatomy. Extrahepatic biliary stenting (choledochoduodenostomy or hepaticogastrostomy) was



**Figure 1.** EUS-guided biliary drainage algorithm after failed ERCP for malignant obstruction.

performed if the papilla could not be reached, with the former reserved for malignant distal strictures and the latter approach for proximal (hilar) biliary strictures. EUS-BD was not attempted in cases with high procedural risk, when the risk of proceeding to EUS-BD was thought to outweigh the potential benefit, when the clinical benefit of drainage was limited, and for benign disease, if the ampulla was inaccessible.

Biliary access was gained by using a 19-gauge needle (Expect, Boston Scientific Corporation, Natick, Mass) and a 450-cm by 0.025-inch straight tip wire (VisiGlide, Olympus America Inc, Center Valley, Pa). If the choledochoduodenostomy tract required dilation before stent insertion, a 4.5F taper tip catheter (ProForma Cannula; ConMed Corporation, Utica, NY) was used; a needleknife sphincterotome over the wire was used if mechanical tract dilation was not successful. Additional dilation of the stomach wall with a 6- to 8-mm ERCP balloon dilator was performed for hepaticogastrostomies. Stent placement was performed by using a fully covered metal biliary stent (Wallflex, Boston Scientific, Natick, Mass). Demographic and procedural data were collected, including cannulation technique, procedural outcomes, and postprocedural management.

#### Outcome measures

This study assessed the rate of successful and failed biliary cannulation and additional interventions required after failed cannulation.

## **Definitions**

Standard cannulation technique was defined as biliary cannulation by using a sphincterotome or cannula, with or without device exchange or wire tip or contrast material guidance. Advanced cannulation techniques included cannulation beside a pancreatic wire or stent, needle-knife access papillotomy over a pancreatic stent or performed freehand, cannulation through a duodenal stent, and back-loading of the duodenoscope over a duodenal wire to pass a luminal stricture. Successful biliary cannulation was defined as deep biliary access allowing performance of the required ERCP maneuvers.

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