—Original Article—

The underutilization of EUS-guided biliary drainage: Perception of endoscopists in the East and West

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ABSTRACT

Background and Objectives: EUS-guided biliary drainage (EUS-BD) is increasingly utilized to manage unresectable malignant biliary obstruction after a failed ERCP. However, there is no data on how endoscopists perceive EUS-BD. The aim of this study was to investigate the perception of endoscopists on EUS-BD. **Patients and Methods:** A survey questionnaire of six topics with 22 survey statements was developed. A total of 17 pancreatobiliary endoscopists (10 from East and 7 from West) were invited to survey. The participants were asked to answer the multiple choice questionnaire and give comments. The opinions of the participants for individual survey statements were assessed using 5-point Likert scale. **Results:** All participants completed the survey. The endoscopists had a trend to perceive EUS-BD as a procedure indicated after a failed ERCP. Various EUS-BD methods were regarded as having different efficacy and safety. The superiority of EUS-BD over percutaneous transhepatic BD (PTBD) with regard to efficacy, procedure-related adverse events, and unscheduled re-intervention was not in agreement. **Conclusions:** EUS-BD was not yet perceived as the initial procedure to relieve the unresectable malignant biliary obstruction. Various EUS-BD methods were regarded as having different efficacy and safety. The superiority of EUS-BD over PTBD was not in agreement. Refining the procedure, developing dedicated devices, and gaining expertise in the procedure are necessary to popularize EUS-BD.

Key words: Biliary drainage, endoscopic ultrasound, perception

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INTRODUCTION

ERCP with biliary drainage (BD) is the standard management of unresectable malignant biliary obstruction.[1-3] However, the failure rate of ERCP ranges from 5% to 7%.[4] Traditionally, percutaneous transhepatic BD (PTBD) has been the standard procedure to relieve malignant biliary obstruction after failed ERCP.[5]

Since the first introduction of EUS-guided choledochoduodenostomy (EUS-CDS) in 2001,[6] various EUS-guided BD (EUS-BD) methods have been developed. Recent meta-analyses demonstrated a high technical success rate of EUS-BD and clinical superiority over PTBD.[7,8] However, some argue that EUS-BD is not frequently utilized,[9] and the reasons for this are unclear. To the best of our knowledge, there is no study on how endoscopists perceive EUS-BD.

The aim of this study was to investigate the perception of endoscopists on EUS-BD. We developed survey statements which encompassed various topics regarding EUS-BD.

PATIENTS AND METHODS

Survey development

The survey statements were developed through a series of discussions. The Korean co-authors made the first draft statements with a review of literature. Initial draft included the topics of "Definition," "Indication," "Techniques" and "Outcomes." On March of 2016, a meeting to develop the survey statements was held in Seoul, Korea. Eventually, the survey included six topics: (1) Definition, (2) Indication, (3) Resource Requirement and Training, (4) Techniques, (5) Outcomes of EUS-BD in Expert Hands, and (6) Areas of Further Research with 22 survey statements. The opinions of the participants for individual survey statements were assessed using 5-point Likert scale [Table 1]. The topics and statements are listed in Table 2.

Survey questionnaire and study participants

Two authors (WJY and DHP) were involved in the selection of the participants. Gastrointestinal endoscopists who participated in at least 1 study on EUS-BD were screened. We excluded endoscopists with extensive publication on EUS-BD, as this person might be biased in favor of EUS-BD. A total of 17 pancreatobiliary endoscopists (6 from Korea, 4 from Japan, 3 from Spain, and 4 from the United States) with various experiences in EUS-BD were selected as participants. These endoscopists had at least five cases of EUS-BD procedures in their endoscopic career and one publication (full-length article or abstract form) regarding EUS-BD. The questionnaire was sent to the participants through E-mail. In addition to answering the multiple choice questionnaire, the participants were asked to freely give any comments that they had for individual survey statements. This study (IRB No. 2017-1331) was considered nonhuman subjects research by the Asan Medical Center Institutional Review Board and was exempt from review.

Table 1. Scores on opinion

Opinion	Score
Definitely yes	5
Probably yes	4
No specific recommendation	3
Probably no	2
Definitely no	1

Statistical analysis

The score of each survey statement is presented as mean ± standard deviation. The analysis of variance (ANOVA) was performed to check if there was any significant difference among the mean score of survey statements. Pairwise comparison using the Tukey's method was done to see which statements had significantly different mean scores. A two-sided $P < 0.05$ was considered statistically significant. Statistical analyses were performed using STATA 12.1 (StataCorp LP, College Station, Texas, USA).

RESULTS

Survey topic scores

All 17 invited endoscopists completed the survey (100% response rate). The overall mean scores of the survey topics ranged between 3.5 points and 4.7 points. The topic of "Outcomes of EUS-BD in Expert Hands" had the lowest overall mean score. ANOVA of the overall topic mean scores showed that there was a significant difference in these scores ($P < 0.001$). Pairwise comparison using Tukey's method showed that the overall mean score of the topic of "Outcomes of EUS-BD in Expert Hands" was lower than that of other topics.

Individual survey statement scores

The mean scores of the survey statements ranged between 3.1 points and 4.9 points. The mean scores were higher than 4 points for all the statements in the topics of "Definition," "Resource Requirement and Training," "Techniques," and "Areas of Further Research." For the topic of "Indication," the mean scores were higher than 4 points except for statement 2.3, the mean score of which was 3.9 points. Of interest, the mean scores of all statements in the topic of "Outcomes of EUS-BD in Expert Hands" were <4 points, reflecting the conservative view toward the EUS-BD. ANOVA of the survey statement scores indicated that there was a significant difference in the mean scores ($P < 0.001$). Pairwise comparison of the means using Tukey's method indicated that the mean scores of the survey statements 2.3, 5.1, 5.2, 5.3, and 5.4 were significantly lower than that of at least 1 survey statement with a mean score higher than 4 points [Table 2].

For topic 2, the mean scores were higher than 4 points except for statement 2.3 (mean score 3.9 points). In response to this statement, the participants commented that EUS-BD is indicated only when ERCP is not possible and not as the primary procedure.

The mean scores of all the statements in the topic 5 were <4 points, likely reflecting the overall conservative view of the group toward the EUS-BD. Most participants were concerned about the paucity of evidence. Various EUS-BD methods were perceived as having different efficacy and safety. For survey statement 5.1, the participants were in favor of EUS-CDS over EUS-guided hepaticogastrostomy (EUS-HGS) regarding stent patency, safety, and learning curve. The result of survey statement 5.2 indicated disagreement on safety issues between EUS-guided transmural stenting and EUS-guided rendezvous. The participants who gave personal comments on this topic stated that although EUS-guided rendezvous may be less effective, it may be safer than EUS-guided transmural stenting. Survey statements 5.3 and 5.4 sought to compare the perception of endoscopists on EUS-guided transmural stenting with that of PTBD. The superiority of EUS-BD over PTBD was not in agreement. Some participants commented that PTBD is more widespread than EUS-BD and that there is a lack of evidence to directly compare the procedures.

DISCUSSION

The purpose of this study was to investigate the perception of endoscopists on EUS-BD. Most participants (1) considered EUS-BD to be a procedure indicated after failure of ERCP, (2) did not agree that various EUS-BD methods had similar efficacy and safety, and (3) did not agree that EUS-BD is comparable or superior to PTBD.

Selective biliary cannulation in patients with native upper GI anatomy is successful in more than 90% of procedures by expert endoscopists. However, bile duct access cannot be achieved due to various reasons such as failed biliary cannulation, gastric outlet obstruction, altered anatomy, and periampullary diverticulum.[10] In such situations, PTBD has been widely utilized.

First introduced by Giovannini *et al.* in 2001,[6] EUS-BD has been increasingly utilized when ERCP fails. A recent meta-analysis demonstrated technical success rate of 90% and postprocedure adverse event rate of 17%. In this analysis, distal CBD stricture and transpapillary drainage were associated with higher technical success rate; intrahepatic access was associated with higher adverse event rate.[7] Another meta-analysis reported cumulative technical success rate, functional success rate, and adverse-event rate of 94.71%, 91.66%, and 23.32%, respectively. Transduodenal and transgastric approach did not show statistically significant differences with regard to these parameters.[11] A meta-analysis comparing EUS-BD and PTBD after ERCP failure showed that EUS-BD was associated with better clinical success and lower rate of reintervention compared to PTBD.[8] A survey on patient preference between EUS-BD and PTBD after a failed ERCP showed that about 80% of the patients preferred EUS-BD to PTBD; they were willing to undergo EUS-BD if EUS-BD expertise was available and adverse event rate was lower than that of PTBD.[12]

However, although EUS-BD is gaining popularity, there has been argument that EUS-BD is not so frequently utilized even in centers with high-volume of EUS intervention. In a report in a letter format, Tonozuka *et al.*[9] reported that of 634 endoscopic BD cases performed in a year, only 21 (3.3%) EUS-BD-related procedures (19 EUS-BD and 2 rendezvous) were conducted to achieve BD. In this report, 7 PTBD-related procedures (3 PTBD and 4 rendezvous) were done.

Table 2. Survey topics, statements and scores

	Score (mean±SD)
1. Definition	
1.1. We suggest that the term "endosonographic cholangiopancreatography" is the most appropriate term to define the diagnostic and therapeutic biliary and pancreatic ductal access using EUS.	4.1±0.8
1.2. EUS-BD is defined as therapeutic procedure to decompress the obstructed bile duct under EUS guidance.	4.9±0.3
1.3. EUS-BD is comprised of EUS-guided antegrade stenting, EUS-guided rendezvous, and EUS-guided transmural stenting. EUS-guided transmural stenting can be completed by EUS-CDS or EUS-HGS.	4.3±1.0
2. Indication	
2.1. EUS-BD is a viable alternative to endoscopic transpapillary drainage after failed ERCP or in patients at high risk of cannulation failure (*e.g.*, surgically altered anatomy, ampullary pathology, malignant duodenal stenosis, or enteral stent covering the papilla).	4.9±0.3
2.2. EUS-BD may be contraindicated in patients who have intolerance to endoscopy, or have uncorrected coagulopathy.	4.7±0.5
2.3. EUS-guided transmural stenting is commonly indicated for the palliation of unresectable malignant distal biliary obstruction (*i.e.*, >2 cm from the hilum).	3.9±1.2
2.4. EUS-BD, specifically EUS-HGS, can be performed in patients with malignant hilar biliary obstruction when ERCP fails. However, limited biliary decompression through left intrahepatic duct may occur in these circumstances.	4.2±0.6
2.5. EUS-HGS is a viable rescue option when internal biliary stenting through PTBD fails.	4.4±0.8
3. Resource Requirement and Training	
3.1. EUS-BD should be reserved for endoscopy teams that are highly competent at both EUS and ERCP, and carried out at centers with adequate surgery and radiology backup, preferably under IRB-approved study protocols.	4.4±0.8
3.2. Supervised training of EUS-BD is recommended.	4.8±0.4
4. Techniques	
4.1. The choice of EUS-BD is made according to patient anatomy including duodenal obstruction and surgically altered anatomy.	4.8±0.4
4.2. Dilation of the bilioenteric tract can be achieved by using a balloon, bougie, cystotome, or dedicated device for one-step EUS-BD.	4.8±0.4
4.3. Metal stents may be more appropriate for the EUS-guided transmural stenting than plastic stents as to minimize the risk of adverse event including bile leak.	4.3±0.8
4.4. Identification of the optimal biliary access point, guidewire manipulation, fistula dilation, and stent placement are prerequisites for successful EUS-guided transmural stenting.	4.9±0.2
5. Outcomes of EUS-BD in Expert Hands	
5.1. EUS-CDS and EUS-HGS techniques provide similar efficacy and safety and both are valid options for relieving malignant biliary obstruction after failed ERCP, in experienced hands.	3.6±1.1
5.2. EUS-guided transmural stenting is comparable to EUS-guided rendezvous with conversion to ERCP with regard to efficacy and safety.	3.1±1.2
5.3. EUS-guided transmural stenting and PTBD have similar levels of efficacy in patients with unresectable malignant distal biliary obstruction and inaccessible papilla in terms of technical and clinical success.	3.7±0.8
5.4. EUS-guided transmural stenting may be superior to PTBD with regard to procedure-related adverse events and unscheduled re-intervention.	3.6±0.7
6. Areas of Further Research	
6.1. Further research is needed to define the optimal biliary access point in EUS-HGS with transmural, antegrade, and rendezvous approach.	4.5±0.5
6.2. A prospective comparison of ERCP and primary EUS-BD is needed for treatment of patients with distal malignant biliary obstruction.	4.4±0.9
6.3. In patients with bilioenteric anastomosis and intrahepatic stones, further research on safety and efficacy of EUS-BD with antegrade approach and dedicated device may be required.	4.5±0.5
6.4. In patients with isolated right intrahepatic duct obstruction, further research on safety and efficacy of EUS-guided hepaticoduodenostomy may be required.	4.5±0.6

P<0.001 for analysis of variance of survey scores. EUS-BD: EUS-guided biliary drainage, EUS-CDS: EUS-guided choledochoduodenostomy, EUS-HGS: EUS-guided hepaticogastrostomy, SD: Standard deviation, PTBD: Percutaneous transhepatic biliary drainage

In our study, the participants were in favor of ERCP as the initial choice for palliation of malignant distal biliary obstruction. As there is no head-to-head direct comparison of ERCP and EUS-BD, this result may be taken as a matter of course. A prospective comparison of ERCP and EUS-BD for palliation of malignant biliary obstruction is being conducted, and it would be interesting to see the results.

The participants gave low scores for the survey statements on the topic of "Outcomes of EUS-BD in Expert Hands." It seems that most participants regard EUS-guided rendezvous as a safer procedure compared to EUS-guided transmural stenting. EUS-CDS was perceived to be safer than EUS-HGS. Despite the available data, the participants were conservative with regard to comparing EUS-BD and PTBD. Since most

of the studies on EUS-BD have been conducted by a single experienced endoscopist, the high success rate and low adverse event rate may not be generalized.[13]

Although there is growing evidence of the clinical usefulness of EUS-BD, there are hurdles for endoscopists to comfortably perform EUS-BD in clinical practice. One of the limitations to wide-spread use of EUS-BD is that it is still regarded as a complex procedure.[14] It involves puncture, guidewire manipulation, fistula dilation, and stent deployment. In the study by Oh *et al.*,[15] the number of procedures required to stabilize the procedure time and adverse events of EUS-HGS was 33. Lack of devices dedicated to EUS-BD added to the difficulty in widespread utilization of EUS-BD. A recent study comparing EUS-BD and ERCP for primary palliation of malignant biliary obstruction indicated that the use of a dedicated one-step device for tract dilation and stent introduction resulted in the decrease of the risk of bile leak and delayed luminal injury from electrocautery. It also resulted in shortened procedure time.[16] As EUS-BD is usually done after a failed ERCP, it would take a long time to gain expertise. Another hurdle is the possibility of serious complications. In the Spanish national survey, of 125 patients who underwent EUS-guided cholangiopancreatography, complication occurred in 29 patients (23.2%). The complications were bilomas (n = 7), hemorrhages (n = 6), perforations (n = 4), acute pancreatitis (n = 5), cholangitis (n = 3), liver hematomas (n = 2), abscess (n = 1), and pancreatic pseudocyst (n = 1). Five patients (4%) died as direct consequences of the complications.[17]

There were limitations to this study. First, the number of survey participants was too small to adequately represent the perception of EUS-BD among the endoscopists of the East and West. A larger group of survey participants, preferably with diverse spectrum of experiences in EUS-BD, may have provided a better information on the real-world perception of the procedure. Second, the regions where the participants practiced were limited. The regional differences in experience and resources may affect the results of the survey. However, we believe that this study is the first to address the real-world perception of EUS-BD in East and West. In addition, recently published consensus guidelines on the optimal management in interventional EUS procedures share similarities with our results on indications, resource requirement and training, and techniques.[18]

CONCLUSIONS

A substantial number of endoscopists in East and West surveyed did not believe the impact of EUS-BD in the management of biliary obstruction after failed ERCP. This limited awareness may represent a barrier to successful utilization of EUS-BD. Refining the procedure and developing dedicated devices with procedural expertise is necessary to make EUS-BD as a routine clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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