Selection methods for endoscopic ultrasound-guided biliary drainage cases that are appropriate for beginners

MITSURU SUGIMOTO[1], TADAYUKI TAKAGI[1], REI SUZUKI[1], HIROYUKI ASAMA[1], HIROSHI SHIMIZU[1], KENTARO SATO[1], REI OHIRA[1], JUN NAKAMURA[1,2], MIKA TAKASUMI[1], TSUNETAKA KATO[1,2], TAKUMI YANAGITA[1,2], MITSURU OTSUKA[1], TAKUTO HIKICHI[2] and HIROMASA OHIRA[1]

[1]Department of Gastroenterology, School of Medicine, Fukushima Medical University, Fukushima, Fukushima 960-1295, Japan; [2]Department of Endoscopy, Fukushima Medical University Hospital, Fukushima, Fukushima 960-1295, Japan

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Abstract. Endoscopic ultrasound-guided biliary drainage (EUS-BD) is performed as a second drainage method when endoscopic retrograde cholangiopancreatography-guided biliary drainage fails. There are several severe adverse events in EUS-BD, and avoiding technical failure is desirable. Although EUS-BD is a skilled endoscopic treatment, the appropriate conditions for EUS-BD beginners are not well known. The present study aimed to clarify the appropriate cases for EUS-BD beginners. The present retrospective cohort study included patients with malignant biliary obstruction who underwent EUS-BD, which was performed by beginners between March 2005 and June 2024. Factors associated with successful EUS-BD performed by beginners were evaluated by multivariate logistic regression analysis. The performance of each factor was evaluated via a receiver operating characteristic (ROC) curve. According to multivariate analysis, the diameter of the punctured bile duct was associated with successful EUS-BD performed by beginners (odds ratio, 1.34; 95% CI, 1.03-1.75; P=0.031). The area under the ROC curve for the diameter of the punctured bile duct was 0.79, and the cutoff value was 6.7 mm (71% sensitivity and 81.8% specificity). The diameter of the punctured bile duct might be associated with successful EUS-BD procedures performed by beginners. When a beginner performs EUS-BD, a diameter of the targeted bile duct >6.7 mm might be desirable for successful procedures.

Correspondence to: Dr Mitsuru Sugimoto, Department of Gastroenterology, School of Medicine, Fukushima Medical University, 1 Hikarigaoka, Fukushima, Fukushima 960-1295, Japan
E-mail: kita335@fmu.ac.jp

Abbreviations: EUS-BD, endoscopic ultrasound-guided biliary drainage; ROC, receiver operating characteristic; MBO, malignant biliary obstruction; ERCP-BD, endoscopic retrograde cholangiopancreatography-guided biliary drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-AGS, EUS-guided antegrade stenting; EUS-FNA, EUS-guided fine needle aspiration; SEMS, self-expandable metallic stent; OR, odds ratio

Key words: EUS-BD, beginner, EUS-CDS, EUS-HGS, EUS-AGS

Introduction

For a number of years, endoscopic retrograde cholangiopancreatography (ERCP)-guided biliary drainage (ERCP-BD) has been the first choice for the treatment of malignant biliary obstruction (MBO). However, this drainage method can be difficult when the duodenoscope cannot reach the Vater papilla because of duodenal obstruction or if biliary cannulation is impossible. Recently, endoscopic ultrasound-guided biliary drainage (EUS-BD) is widely used as a second biliary drainage method for MBO in patients for whom ERCP-BD fails (1). EUS-BD methods include EUS-guided choledochoduodenostomy (EUS-CDS), EUS-guided hepaticogastrostomy (EUS-HGS), EUS-guided antegrade stenting (EUS-AGS), and combination of EUS-HGS and EUS-AGS. In recent meta-analyses, the technical success and clinical success of these EUS-BD techniques were reported to be comparable to those of ERCP-BD (2,3). Therefore, EUS-BD has become the first-line biliary endoscopic treatment. However, EUS-BD is a skilled endoscopic treatment. Several severe adverse events, such as bleeding, bile leakage, and dislocation (4,5), which are sometimes fatal (6,7), have been reported in previous reports and avoiding technical failure is desirable. Despite the risk, EUS-BD can be performed by endoscopists without sufficient experience. For these reasons, ERCP-BD is successful in most cases, and EUS-BD is a relatively novel treatment (8). On the other hand, which EUS-BD procedures are appropriate for beginners is unknown. In this study, we aimed to clarify the factors for successful EUS-BD performed by beginners and to determine which EUS-BD cases are suitable for beginners.

Materials and methods

Study design, patients, and ethics. This was a retrospective study that investigated methods for selecting MBO cases that are suitable for EUS-BD beginners. This study was approved by the Institutional Review Board of Fukushima Medical University (approval number: REC 2023-201). Patients with

histologically diagnosed MBO who underwent EUS-BD at Fukushima Medical University between March 2005 and June 2024 were enrolled in this study. The need to obtain informed consent was waived because this was a retrospective study of anonymized clinical data. The details of the study can be found on the homepage of Fukushima Medical University.

Definition of EUS-BD beginners. All EUS-BD procedures were performed by endoscopists, who have performed more than 300 cases of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA). EUS-BD beginners were defined as endoscopists who had performed fewer than 20 procedures according to a previous report written by Hara *et al* (9).

EUS-BD procedures. EUS-BD procedures were started after MBO patients were sufficiently sedated by midazolam. EUS-BD was performed as follows: the puncture point of the target bile duct was determined via consultation with an expert. The common bile duct or intrahepatic bile duct was punctured via the duodenal bulbus or stomach via an EUS-FNA needle, and the biliary tract was enhanced via the injection of contrast medium. After a sufficient length of guidewire was placed in the biliary tract, fistula dilation was performed via a dilation catheter. Finally, a biliary stent was placed via the duodenum or stomach. When the puncture route or the guidewire could not be observed on the monitor, the echo image was modulated under expert guidance. If an EUS-BD beginner could not complete the procedure, an expert completed the procedure.

The selection of an appropriate EUS-BD method was as follows: For lower biliary strictures without duodenal bulb obstruction, EUS-CDS was performed. For hilar biliary strictures or long CBD strictures, EUS-HGS was performed. When a guidewire was sufficiently inserted into the duodenum, EUS-AGS was combined with EUS-HGS. EUS-HGS was also performed for patients who underwent partial gastrectomy.

The echoendoscope used was a GF-UCT260, GF-UC240P-AL5, or GF-UCT240-AL5 (Olympus Medical Systems, Tokyo, Japan). The echo device used was an EU-ME1, an EU-ME2 (Olympus Medical Systems), a Prosound SSD α10, or an SSD5500 (Hitachi Alocha Medical, Tokyo, Japan). The FNA needles used were 19G SonoTip (Medi-Grobe, Rosenheim, Germany), 19G Echotip Ultra (Cook Medical, Tokyo, Japan), 19G NA-11J-KB (Olympus Medical Systems), 19 or 22G Expect (Boston Scientific Japan, Tokyo, Japan), or 19 or 22G Ez shot3 plus (Olympus Medical Systems) needles. The guidewire used was a 0.018 Fielder 18, 0.025 VisiGlide, VisiGlide 2 (Olympus Medical Systems), 0.025 or 0.035 Jagwire, or 0.025 EndoSelector (Boston Scientific Japan). The dilator used was a 6-Fr Cysto-Gastro-Set (Endo-Flex GmbH, Voerde, Germany), an ES dilator (Zeon Medical Co., Tokyo, Japan), an MTW ERCP tapered catheter (MTW endoskopie, Wesel, Germany), a Tornus ES (Olympus Medical Systems), or a 4 mm Hurricane RX Biliary Balloon Dalation Catheter (Boston Scientific Japan). The biliary plastic stent used was a 7 Fr Flexima Plus (Boston Scientific), 7 Fr IT (Gadelius Medical Co., Ltd., Tokyo, Japan), or 7 Fr double pig-tail stent (Cook Medical). The biliary self-expandable metallic stent (SEMS) used for EUS-CDS or EUS-HGS was a 10 mm Niti-S COMVI, an 8 mm Niti-S covered Spring Stopper (Taewoong Medical, Gyoenggi-do, Korea), or a 10 mm partially covered WallFlex Biliary RX stent (Boston Scientific). The biliary SEMS used for EUS-AGS was a 10 mm Zilver 635 (COOK Medical), an 8-10 mm BileRush (PIOLAX, Kanagawa, Japan), or a 10 mm Niti-S Large Cell slim delivery (Taewoong Medical).

Outcomes. The main aim of this study was to identify predictive factors for successful EUS-BD performed by beginners. The potential predictive factors were selected according to previous reports (10-13). The patient characteristics included age, sex, history of gastrectomy, disease status (primary or metastatic), biliary stricture location, and use of a duodenal stent before EUS-BD. The factors related to EUS-BD procedures included the puncture length, diameter of the punctured bile duct, use of an EUS-FNA needle (19 G or 22 G), type of dilator used (cautery or mechanical), type of EUS-BD (CDS or HGS, with or without AGS), and type of stent used (plastic stent or metallic stent).

The puncture length and diameter of the punctured bile duct were measured via echo imaging. When an appropriate echo image was not available, these parameters were measured via X-ray imaging. The definition of technical success was stent deployment from the stomach or duodenum to the target bile duct. The definition of clinical success was an improvement in alanine transaminase or total bilirubin values to normal values or half of the pretreatment values.

Sample size. The primary aim of this study was to clarify the factors associated with successful EUS-BD performed by beginners. To achieve this aim via multiple logistic regression, 10 events per explanatory variable were needed. Two variables were evaluated in the multivariate analysis; therefore, 20 patients with successful EUS-BD were necessary. According to the results below, the expected technical success for beginners is approximately 70%. Therefore, at least 29 patients were included in this study.

Statistical analysis. Continuous variables that were normally distributed are presented as the means ± standard deviations. Continuous variables that were not normally distributed are reported as medians (ranges). Nominal variables are reported as n or n (%). The potential factors for successful EUS-BD performed by beginners were determined via multiple logistic regression. The determined factors were evaluated via receiver operating characteristic (ROC) curves. A P value <0.05 was considered statistically significant. All the statistical analyses were performed via EZR version 1.68 (Saitama Medical Center, Jichi Medical University, Saitama, Japan).

Results

Participants. The flowchart of the participants is shown in Fig. 1. EUS-BD was attempted in 52 patients with MBO. Among these patients, 45 underwent EUS-BD performed by beginners. Three patients with a history of pancreaticoduodenotectomy and biliojejunostomy were excluded from this study because they underwent EUS-BD via a forward-viewing echoendoscope. Overall, 42 patients who underwent EUS-BD

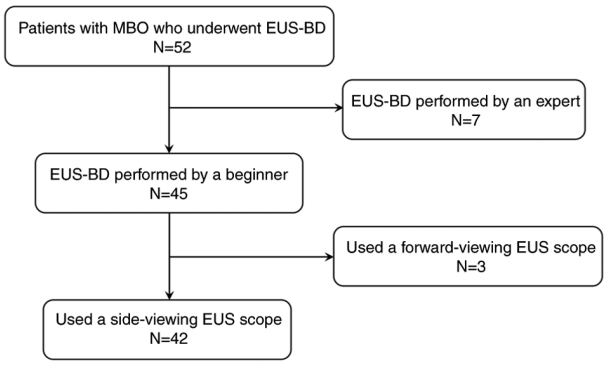

Figure 1. Flowchart of the participants. MBO, malignant biliary obstruction; EUS-BD, endoscopic ultrasound-guided biliary drainage.

performed by beginners with the use of a side-view echoendoscope were included in this study.

Summary of patient characteristics and EUS-BD procedures. The patient characteristics and EUS-BD procedures performed by beginners are shown in Table I. The mean age was 71.7±9.4 years. Twenty-seven (64.3%) patients were male. Three patients underwent gastrectomy (Billroth-I: 1 patient, Billroth-II: 2 patients), 38 MBO patients had primary disease, and 4 MBO patients had metastatic disease. Distal biliary stricture was observed in 39 (92.9%) patients. Fourteen (33.3%) MBO patients underwent EUS-CDS, and 28 (66.7%) patients underwent EUS-HGS. In 10 patients, EUS-AGS was added to the procedure. The final technical success rate for the experts was 95.2% (40 patients), and the technical success rate for the beginners was 73.8% (31 patients). The reasons for technical failure for beginners were puncture failure (n=9), dilation failure (n=1), and stenting failure (n=1). The adverse events were bile leakage (n=1) and bleeding (n=1).

Predictive factors for successful EUS-BD performed by beginners. The results of the multivariate analysis are shown in Table II. According to the univariate analyses, the diameter of the punctured bile duct was the only significant factor for successful EUS-BD performed by beginners (odds ratio (OR): 1.35, 95% confidence interval (CI) 0.33-5.30, P value=0.026). According to the reasons for the technical failure of beginners, puncture failure was the main cause (Table I). According to previous reports, the determination of the tumor position via EUS monitoring is a risk factor for puncture failure (14). Therefore, the puncture length, which is a factor affecting the tumor position, and the diameter of the punctured bile duct were included in the multivariate analysis. Finally, the diameter of the punctured bile duct was a significant predictor of successful EUS-BD performed by beginners according to multivariate analysis (OR: 1.34, 95% CI: 1.03-1.75; P value=0.031). The cutoff value of the punctured bile duct diameter was 6.7 mm (area under the ROC curve: 0.79; sensitivity: 71%; specificity: 81.8%), as shown in Fig. 2.

Discussion

This study revealed that the diameter of the punctured bile duct was associated with successful EUS-BD performed by

Table I. Summary of patient characteristics (n=42) and EUS-BD performed by beginners.

Parameters	Value
Mean age ± SD, years	71.7±9.4
Sex, n (%)	
Male	27 (64.3)
Female	15 (35.7)
History of gastrectomy, n (%)	3 (7.1)
Billroth-I, n	1
Billroth-II, n	2
Diagnosis, n (%)	
Primary disease	38 (90.5)
Pancreatic cancer	29
Biliary tract cancer	9
Metastatic disease	4 (9.5)
Bladder cancer, n	1
Urothelial cancer, n	1
Retroperitoneal liposarcoma, n	1
Lymph node metastasis of unknown origin, n	1
Biliary stricture location, n (%)	
Distal	39 (92.9)
Hilar	3 (7.1)
Duodenal stent before EUS-BD, n (%)	11 (26.2)
Mean puncture length ± SD, mm	17.2±7.5
Median diameter of the punctured bile duct (range), mm	7.3 (1.7-20.0)
Type of needle used, n (%)	
19 G	25 (59.5)
22 G	17 (40.5)
Type of dilator used, n (%)	
Cautery dilator	6 (14.3)
Mechanical dilator	36 (85.7)
EUS-CDS, n (%)	14 (33.3)
EUS-HGS, n (%)	28 (66.7)
Addition of EUS-AGS, n (%)	10 (23.8)
Type of stent used, n (%)	
Plastic	30 (71.4)
SEMS	10 (2.4)
Stent placement failure	2 (4.8)
Technical success, n (%)	40 (95.2)
Technical success for beginners, n (%)	31 (73.8)
Reasons for technical failure of beginners, n	
Puncture failure	9
Dilation failure	1
Stenting failure	1
Clinical success, n (%)	40 (95.2)
Adverse events, n (%)	2 (4.8)
Bile leakage, n	1
Bleeding, n	1

EUS-BD, endoscopic ultrasound-guided biliary drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-AGS, EUS-guided antigrade stenting; SEMS, self-expandable metallic stent.

Table II. Univariate and multivariate analyses of predictive factors that might be associated with successful EUS-BD performed by beginners.

	Univariate			Multivariate		
Variable	OR	95% CI	P-value	OR	95% CI	P-value
Age	0.93	0.85-1.02	0.12			
Sex, male	2.93	0.71-12.10	0.14			
History of gastrectomy	0.69	0.06-8.45	0.77			
Primary disease	0.93	0.09-10.00	<0.96			
Distal biliary duct stricture	<0.01	0-infinity	<0.99			
Duodenal stent before EUS-BD	0.93	0.20-4.38	0.92			
Puncture length	0.95	0.87-1.04	0.29	0.99	0.89-1.11	0.89
Diameter of the punctured bile duct	1.35	1.04-1.75	0.03	1.34	1.03-1.75	0.03
19 G needle used	1.32	0.33-5.30	0.70			
Cautery dilator used	$5.10x10^7$	0-infinity	0.99			
EUS-HGS (vs. CDS)	0.31	0.057-1.67	0.17			
Addition of EUS-AGS	1.57	0.28-8.83	0.61			
Plastic stent used	<0.01	0-infinity	0.99			

EUS-BD, endoscopic ultrasound-guided biliary drainage; OR, odds ratio; HGS, hepaticogastrostomy; CDS, choledochoduodenostomy; AGS, antegrade stenting.

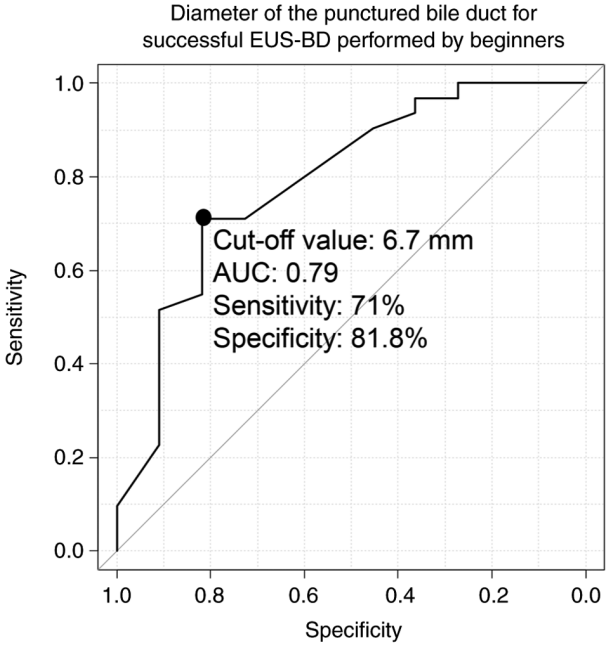

Figure 2. Receiver operating characteristic curve for the evaluation of the influence of the punctured bile duct diameter on successful EUS-BD performed by beginners. EUS-BD, endoscopic ultrasound-guided biliary drainage; AUC, area under the receiver operating characteristic curve.

beginners. The recent meta-analysis by Barbosa *et al* (15) included six randomized controlled trials (577 patients) and compared the treatment outcomes between patients who underwent EUS-BD and those who underwent ERCP-BD. For EUS-BD, the technical success rate, clinical success rate, and adverse event rate were 93.0% (95% CI: 89.3-95.5), 89.0% (95% CI: 80.9-93.9), and 8.33% (95% CI: 4.30-15.53), respectively. For ERCP-BD, the technical success rate, clinical success rate, and adverse event rate were 88.0% (95% CI: 79.1-93.4), 88.0% (95% CI: 83.3-91.5), and 15.6% (95% CI: 10.9-21.9), respectively. These treatment outcomes are not significantly different, and EUS-BD could be the first choice for the endoscopic treatment of MBO. EUS-BD procedures are being refined and are becoming more popular. However, the clear conditions for EUS-BD that are appropriate for beginners are not well known.

In previous reports, puncture and opacification, guidewire manipulation, and fistula dilation emerged as representative and definitive factors for predicting EUS-BD failure. Vila *et al* (16) reported the initial experience of EUS-BD and EUS-guided pancreatic drainage for 125 patients in Spain. Puncture and opacification were successful in 113 patients, and guidewire manipulation was successful in 94 patients. Oh *et al* (10) reported failure in 129 patients who underwent EUS-HGS. Among these patients, 46 experienced EUS-HGS failure (puncture and opacification failure: 11 patients; guidewire manipulation failure: 15 patients; fistula dilation failure: 20 patients). With respect to the steps after guidewire manipulation, not only the technique of the endoscopist but also the technique of the assistant is important. This report indicated that bile duct puncture might be the most critical step of EUS-BD procedures for beginners.

For EUS-BD to the thin bile duct, a procedure involving the use of 22 G needles, a new 0.018 guidewire, and a dedicated dilator was reported. According to the report written by Iwashita *et al* (17), the technical success rate was 100% (26/26) for the median 5 (interquartile 3-6) mm diameter bile duct. Ogura *et al* (18) also performed EUS-BD using 22G needles in 18 patients. Although the diameter of the bile duct was very thin, ranging from 0.5-1.3 mm, the technical success rate

was 88.9%. These new devices can contribute to overcoming the difficulty of EUS-BD in patients with thin biliary ducts. However, excellent results have been achieved by very skilled experts. In this study, 22G needles, a 0.018 guidewire, and a dedicated dilator were used for some patients. Therefore, the diameter of the bile duct is still a factor affecting the difficulty of EUS-BD for beginners.

There were several limitations in this study. First, this was a retrospective study performed at a single institution. In the future, a multicenter prospective study is needed to confirm the findings of this study. Second, several types of EUS-BD procedures were evaluated. However, the rates of technical success, clinical success, and adverse events were comparable between the EUS-HGS and EUS-CDS procedures in a recent meta-analysis. In this study, the EUS method was not associated with EUS-BD failure among beginners.

In conclusion, the diameter of the punctured bile duct might be associated with successful EUS-BD procedures performed by beginners. When a beginner performs EUS-BD, a diameter of the targeted bile duct >6.7 mm might be desirable for successful procedures.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

MS wrote the paper, and designed and performed the study. TT and HO designed and oversaw the study. RS, HA, TH, JN, MT, HS, KS, RO, TK, TY and MO performed analysis and interpretation of data. MS and TT confirm the authenticity of all the raw data. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The present study was approved by the Institutional Review Board of Fukushima Medical University (approval no. REC 2023-201; Fukushima, Japan). The requirement for informed consent was waived because this was a retrospective study of anonymized clinical data.

Patient consent to publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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