

2018

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Ahmed Bolkhir

Washington University School of Medicine in St. Louis

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Bolkhir, Ahmed and et al, "Patient perception and preference of EUS-guided drainage over percutaneous drainage when endoscopic transpapillary biliary drainage fails: An international multicenter survey." *Endoscopic Ultrasound*.7,1. . (2018).
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Patient perception and preference of EUS-guided drainage over percutaneous drainage when endoscopic transpapillary biliary drainage fails: An international multicenter survey

Kwangwoo Nam*, Dong Uk Kim^{1,*}, Tae Hoon Lee², Takuji Iwashita³, Yousuke Nakai⁴, Ahmed Bolkhair⁵, Lara Aguilera Castro⁶, Enrique Vazquez-Sequeiros⁶, Carlos de la Serna⁷, Manuel Perez-Miranda⁷, John G. Lee⁸, Sang Soo Lee⁹, Dong-Wan Seo⁹, Sung Koo Lee⁹, Myung-Hwan Kim⁹, Do Hyun Park⁹

Department of Internal Medicine, Dankook University College of Medicine, ²Department of Internal Medicine, Soonchunhyang University School of Medicine, Cheonan, ¹Division of Gastroenterology, Department of Internal Medicine, Biomedical Institute, Pusan National University Hospital, Pusan National University School of Medicine, Busan, ⁹Department of Internal Medicine, Division of Gastroenterology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; ³First Department of Internal Medicine, Gifu University Hospital, Gifu, ⁴Department of Gastroenterology, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan; ⁵Department of Medicine, Washington University School of Medicine, St. Louis, MO, ⁸Division of Gastroenterology and Hepatology, The University of California Irvine Health, Orange, CA, USA; ⁶Department of Gastroenterology and Hepatology, IRYCIS, University Hospital Ramon y Cajal, Móstoles, Madrid, ⁷Department of Gastroenterology and Hepatology, Rio Hortega University Hospital, Valladolid, Spain

ABSTRACT

Background and Objectives: EUS-guided biliary drainage (EUS-BD) is a feasible procedure when ERCP fails, as is percutaneous transhepatic BD (PTBD). However, little is known about patient perception and preference of EUS-BD and PTBD. **Patients and Methods:** An international multicenter survey was conducted in seven tertiary referral centers. In total, 327 patients, scheduled to undergo ERCP for suspected malignant biliary obstruction, were enrolled in the study. Patients received decision aids with visual representation regarding the techniques, benefits, and adverse events (AEs) of EUS-BD and PTBD. Patients were then asked the choice between the two simulated scenarios (EUS-BD or PTBD) after failed ERCP, the reasons for their preference, and whether altering AE rates would influence their prior choice. **Results:** In total, 313 patients (95.7%) responded to the questionnaire and 251 patients (80.2%) preferred EUS-BD. The preference of EUS-BD was 85.7% (186/217) with EUS-BD expertise, compared to 67.7% (65/96) without EUS-BD

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How to cite this article: Nam K, Kim DU, Lee TH, Iwashita T, Nakai Y, Bolkhair A, *et al.* Patient perception and preference of EUS-guided drainage over percutaneous drainage when endoscopic transpapillary biliary drainage fails: An international multicenter survey. *Endosc Ultrasound* 2018;7:48-55.

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10.4103/eus.eus_100_17

*These authors contributed equally to this work.

Address for correspondence

Dr. Do Hyun Park, Department of Internal Medicine, Division of Gastroenterology, Asan Medical Center, University of Ulsan College of Medicine, 88 Olympic-ro 43-Gil, Songpa-gu, Seoul 05505, South Korea.

E-mail: dhpark@amc.seoul.kr

Received: 2017-11-16; **Accepted:** 2017-11-16; **Published online:** 2018-02-15

expertise ($P < 0.001$). The main reason for choosing EUS-BD was the possibility of internal drainage (78.1%). In multivariate analysis, the availability of EUS-BD expertise was the single independent factor that influenced patient preference (odds ratio: 3.168; 95% of confidence interval, 1.714–5.856; $P < 0.001$). The preference of EUS-BD increased as AE rates decreased ($P < 0.001$). **Conclusions:** In this simulated scenario, approximately 80% of patients preferred EUS-BD over PTBD after failed ERCP. However, preference of EUS-BD declined as its AE rates increased. Further technical innovations and improved proficiency in EUS-BD for reducing AEs may encourage the use of this procedure as a routine clinical practice when ERCP fails.

Keywords: Drainage, endosonography, patient preference, surveys and questionnaires

INTRODUCTION

ERCP with biliary drainage (BD) is a standard procedure for malignant biliary obstruction.^[1,2] However, ERCP may fail in certain patients due to failed transpapillary cannulation or an inaccessible papilla caused by the duodenal invasion of the malignant tumor.^[3–7] The failure rate of ERCP is reported to be up to 7%,^[8] and percutaneous transhepatic BD (PTBD) is a conventional option in such cases. PTBD has been demonstrated to have a high success rate (87%–100%).^[9] However, the requisite external catheter placement is a major drawback, in addition to several adverse events (AEs) including pneumothorax, hepatic arterial injury, bile duct injury, and liver abscess.^[10–12] As a result, many endoscopists sought to identify a less invasive procedure than PTBD.

Since the first report by Giovannini *et al.* in 2001,^[13] EUS-guided BD (EUS-BD) has been reported to be a feasible and effective BD procedure when ERCP fails. EUS-BD has been demonstrated to have a technical success rate of approximately 90% and an AE rate of 17%.^[9,14–18] It has specific advantages over PTBD, as follows: (1) it can be performed in a single session when ERCP has been unsuccessful, (2) it can provide immediate internal drainage with less physical discomfort,^[19] and (3) it is potentially cost-effective, with fewer unscheduled reintervention over long-term follow-up.^[19,20] However, EUS-BD requires experienced endoscopists with advanced endoscopic capabilities and appropriate radiological/surgical backup to manage failed interventions and/or AEs.

Although endoscopists with EUS-BD expertise may prefer EUS-BD over PTBD after failed ERCP due to the potential benefits of EUS-BD including a possible one-stage procedure in the same ERCP unit and internal drainage, patient perception and preference of EUS-BD are not well understood.

Since patients' medical knowledge was limited and personal patient preference had not been incorporated in medical decision-making, it was difficult to make patient-centered decision in real clinical practice. Recently, shared decision-making model between patient and physician has been suggested,^[21,22] and patient decision aids which help appropriate informed choice has been evaluated.^[23] Eliciting the personal preference of the patient then working to align these values and preference with shared decision-making strengthens the therapeutic alliance and is more protective of the provider in a medico-legal context.^[24] Poor communication by the provider and inadequate knowledge on the part of the patient are often precursors for medical liability claim.^[25]

The primary aim of this study was to determine whether patients with suspected malignant biliary obstruction enrolled prefer EUS-BD or PTBD under a simulated scenario (after failed ERCP) with decision aids. The secondary aim was to assess whether altering AEs rates in EUS-BD influenced the patient selection of EUS-BD and/or PTBD.

PATIENTS AND METHODS

Study population

This study was an international multicenter cross-sectional survey of patients scheduled to undergo ERCP for suspected malignant obstruction. Participation in the study was voluntary, and compensation was not provided. An informational booklet describing EUS-BD and PTBD as rescue procedures when ERCP fails, which contained details of the techniques, benefits, and AEs relating to each procedure was provided to the study participants. Once the informational booklet was read, the survey was administered to consecutive patients.

Seven tertiary referral centers in South Korea, Japan, and Spain were participated in this study. Of these, EUS-BD was available in five centers, and PTBD was available at all of them. Participants who preferred EUS-BD were informed as to whether EUS-BD could be performed at their center. Along with the survey, informed consent to undergo any of the available BD procedures (ERCP, EUS-BD, and PTBD) was obtained from the patients before ERCP. The institutional review board for each institution approved the study protocol.

Informational booklet and survey

A third party in the United States created the informational booklet [Supplementary Appendix 1] with visual aids and questionnaire [Supplementary Appendix 2] to minimize selection bias with respect to the endoscopists. The survey was simplified using a subject choice followed by an explanation choice model, and it was written in easily understandable 5th grade US English for patients without medical knowledge. In an attempt to create a reliable and valid questionnaire, the survey was first administered to 34 3rd-year medical students at the University of Ulsan College of Medicine, Seoul, South Korea, and pilot-tested for clarity and internal consistency [Supplementary Appendix 3]. As a result, the questionnaire demonstrated high internal consistency, with a Cronbach's α value of 0.82. The forms then were translated into Korean, Japanese, and Spanish.

The survey was administered to the participants by trained research assistants who read from a standardized script. The patients were allowed sufficient time to read the information booklet and complete the questionnaire. A detailed explanation or discussion of each procedure was not permitted to minimize the risk of selection bias. It was clearly stated that the patient's preference would not be disclosed to the attending physician and it would not affect the treatment plan. The results were blinded to ensure patient anonymity.

The questionnaire started with questions on age, sex, ethnicity, and prior endoscopy, ERCP, and PTBD [Supplementary Appendix 2]. First, participants were questioned as to their preference of a rescue procedure (EUS-BD or PTBD) to be performed in the event of failed ERCP and were asked to provide the reasons for their preference. Choice options listed for EUS-BD were as follows: (1) It can be done at the same time during the ERCP, so you do not have to come back again for another procedure, (2) It has a higher success rate and relatively low AEs, and (3) It

is comfortable, so you do not have drain tube through the skin (such as PTBD). Choice options listed for a PTBD were as follows: (1) It takes less time to place it (quicker), (2) It is cheaper, (3) It is safer (lower AEs), and (4) It is more convenient (easy to perform for the operator). Patients were also permitted to write down any unlisted reasons for their preference.

Patients were then asked whether their opinion would change depending on altering AE rates of EUS-BD compared to those of PTBD (9%–33%). To reduce the chance of selection bias among EUS-BD experts, two centers without EUS-BD experts (two South Korean centers), three centers with EUS-BD experts (one South Korea center and two Spanish centers), and two centers with experts in both EUS-BD and PTBD (two Japanese centers) were invited to participate.

Statistical analyses

The participants were divided into two groups according to the procedure of their choosing (EUS-BD *vs.* PTBD). Statistical analysis was performed using SPSS software version 21.0 (SPSS Inc., Chicago, IL). Continuous variables were reported as the mean and standard deviation and were compared between the groups using the unpaired *t*-test. Categorical variables were reported as frequencies and percentages and were evaluated using Fisher's exact test. The value of $P < 0.05$ was considered to be statistically significant.

To calculate the sample size, it was assumed that two-thirds (66%) of the sample would prefer EUS-BD. A sample size of 75 was identified to determine whether this proportion was significantly different from 50% *a priori*, with an alpha of 0.05 and a power of 80%. Assuming a 30% response rate, we planned to recruit 350 patients (50 patients from each institution).

RESULTS

In total, 327 patients who were scheduled to undergo ERCP due to suspected malignant biliary obstruction were recruited and of these, 313 patients completed the questionnaire (response rate: 95.7%) [Figure 1]. The demographic characteristics of the study participants are shown in Table 1. The mean age was 64 years (range: 34–88 years), and 182 of the respondents (58.1%) were male. The suspected diagnoses of the respondents based on imaging studies (abdominopelvic computed tomography and/or magnetic resonance cholangiopancreatography)

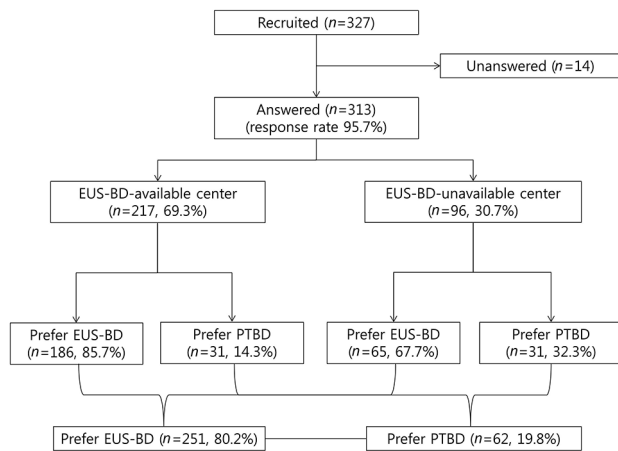


Figure 1. Flow diagram for study

were cholangiocarcinoma in 101 (32.3%), gallbladder cancer in 25 (8%), ampullary cancer in 20 (6.4%), pancreatic head cancer in 93 (29.7%), hepatocellular carcinoma in seven (2.2%), metastatic lymph node in five (1.6%), and indeterminate biliary stricture in 62 (19.8%).

Among these, 258 patients (82.4%) had previously undergone endoscopy, 163 patients (52.1%) had undergone ERCP, and 55 patients (17.6%) had undergone PTBD. There were no differences in preference between EUS-BD and PTBD within three subgroups. EUS-BD was preferred by 186 of 217 participants (85.7%) at the five centers which EUS-BD was available, compared to 65 of 96 patients (67.7%) at the two centers which it was unavailable ($P < 0.001$). There was no significant difference in preference of EUS-BD according to the region (Asia *vs.* Europe) or race (Asian *vs.* non-Asian) [Table 1].

In multivariate analysis, the availability of EUS-BD expertise was the single independent factor that influenced patient preference (odds ratio [OR] 3.168; 95% of confidence interval [CI] 1.714–5.856; $P < 0.001$) [Table 2]. Reasons for selecting EUS-BD included less physical discomfort without percutaneous drain tube placement (196/251, 78.1%), a higher success rate with relatively lower morbidity (110/251, 43.8%), and the ability to be performed at the same time as the ERCP (71/251, 28.3%). By contrast, reasons for selecting PTBD included proven technical safety (43/62, 69.4%), shorter procedure time (18/62, 29%), technical easiness (8/62, 12.9%), and cost-effectiveness (4/62, 6.5%) [Figure 2].

For the second question, preference of EUS-BD decreased as AE rates increased ($P < 0.001$). Two-hundred and one of 217 participants (92.6%) at the five centers with EUS-BD expertise were willing to undergo PTBD if AE rates of EUS-BD were higher than those of PTBD (range: 9%–33%). In contrast, if AE rates of EUS-BD were lower when compared to those of PTBD, 93 of 96 participants (96.9%) at the two centers without EUS-BD expertise were willing to undergo EUS-BD. There was no significant difference in patient preference based on AE rates of EUS-BD according to the availability of EUS-BD expertise [Figure 3a] or the region (Asia *vs.* Europe) [Figure 3b].

DISCUSSION

To the best of our knowledge, this is the first study to focus on the patient preference of BD procedures in patients with suspected malignant biliary obstruction. In this survey, most patients would prefer EUS-BD to PTBD when ERCP fails due to the ability to undergo internal drainage without the need for a percutaneous drain tube. Preference of EUS-BD was significantly higher at centers with EUS-BD expertise compared to centers without EUS-BD expertise (85.7% *vs.* 67.7%, respectively; $P < 0.001$). In multivariate analysis, the availability of EUS-BD expertise was significantly associated with the preference of EUS-BD (OR 3.168, 95% CI 1.714–5.856, $P < 0.001$). In addition, patient willingness to undergo EUS-BD was observed to decline in the context of higher AE rates compared to PTBD.

EUS-BD has been reported to be a feasible BD technique. In a recent randomized controlled trial, EUS-BD was compared with PTBD after failed ERCP in patients with malignant biliary obstruction.^[26] In that study, EUS-BD showed technical success rates comparable to those of PTBD (94.1% *vs.* 96.9%, respectively), and fewer AE rates compared to PTBD (8.8% *vs.* 31.2%, respectively). Although detailed data on EUS-BD are limited, there are clear advantages to EUS-BD, including the possibility of internal drainage without the placement of a percutaneous drain tube, and the fact that EUS-BD can be performed in the same session after failed ERCP provided appropriate informed consent is obtained.

In this study, before ERCP, patients were asked about preferred BD procedure when ERCP fails. This

Table 1. Baseline characteristics of patients and factors influencing the preference for EUS-BD in univariate analysis

Variable	Total (n=313) (%)	Preferred EUS-BD (n=251) (%)	Preferred PTBD (n=62) (%)	P
Age (year), mean±SD	64.0±15.5	64.3±15.0	62.7±17.5	
≥65	160 (51.1)	128 (51.0)	32 (51.6)	0.931
Sex				
Male	182 (58.1)	149 (59.4)	33 (53.2)	0.380
Suspected diagnosis				
Cholangiocarcinoma	101 (32.3)	85 (33.9)	16 (25.8)	0.469
Gallbladder cancer	25 (8.0)	22 (8.8)	3 (4.8)	
Ampullary cancer	20 (6.4)	16 (6.4)	4 (6.5)	
Pancreatic head cancer	93 (29.7)	71 (28.3)	22 (35.5)	
Hepatocellular carcinoma	7 (2.2)	6 (2.4)	1 (1.6)	
Metastatic lymph node	5 (1.6)	5 (1.9)	0 (0.0)	
Indeterminate biliary stricture	62 (19.8)	46 (18.3)	16 (25.8)	
Prior experience				
Prior endoscopy	258 (82.4)	212 (84.5)	46 (74.2)	0.057
Prior ERCP	163 (52.1)	132 (52.6)	31 (50.0)	0.715
Prior PTBD	55 (17.6)	42 (16.7)	13 (21.0)	0.433
Availability of EUS-BD-expertise				
EUS-BD-expertise available	217 (69.3)	186 (74.1)	31 (50.0)	<0.001
(Preference of EUS-BD)	(100.0)	(85.7)	(14.3)	
EUS-BD-expertise unavailable	96 (30.7)	65 (25.9)	31 (50.0)	
(Preference of EUS-BD)	(100.0)	(67.7)	(32.3)	
Region				
Asia	241 (77.0)	197 (78.5)	44 (71.0)	0.208
(Preference of EUS-BD)	(100.0)	(81.7)	(18.3)	
Europe	72 (23.0)	54 (21.5)	18 (29.0)	
(Preference of EUS-BD)	(100.0)	(75.0)	(25.0)	
Race				
Asian	242 (77.3)	198 (78.9)	44 (71.0)	0.183
(Preference of EUS-BD)	(100.0)	(81.8)	(18.2)	
Non-Asian (caucasian, hispanic)	71 (22.7)	53 (21.1)	18 (29.0)	
(Preference of EUS-BD)	(100.0)	(74.6)	(25.4)	

EUS-BD: EUS-guided biliary drainage, PTBD: Percutaneous transhepatic biliary drainage, SD: Standard deviation

Table 2. Factors influencing the preference for EUS-guided biliary drainage in multivariate logistic regression analysis

Variable	OR	95% CI	P
Sex (male vs. female)	0.853	0.479-1.518	0.588
Age (<65 years vs. ≥65 years)	0.710	0.386-1.307	0.272
Previous endoscopy (no experience vs. experience)	1.887	0.955-3.728	0.068
EUS-BD-expertise availability (unavailable vs. available)	3.168	1.714-5.856	<0.001

OR: Odds ratio, CI: Confidence interval, EUS-BD: EUS-guided biliary drainage

process may simulate obtained informed consent for possible EUS-BD before ERCP. Since the prediction of endoscopically inaccessible papilla before ERCP is difficult, unplanned PTBD after failed outpatient ERCP may occur, and it can incur additional hospitalization and an unexpected economic burden on patients and their families. Thus, we adopted an algorithm

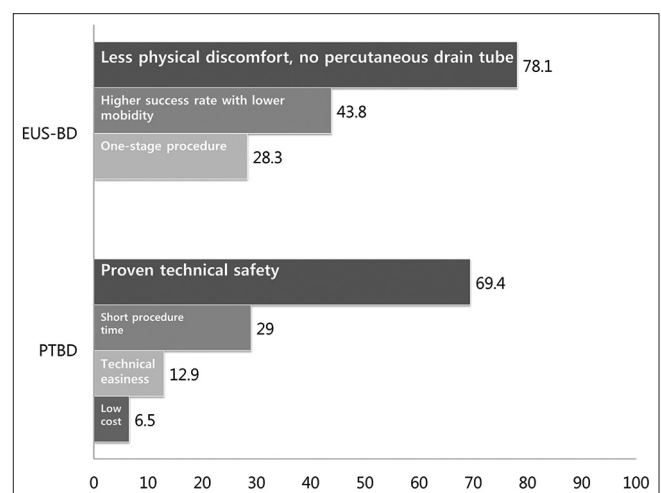


Figure 2. Graph demonstrating the reasons behind patient preference described in our previous studies,^[16,18,26] and routinely obtained informed consent for EUS-BD before ERCP, especially in patients at potential risk of unsuccessful

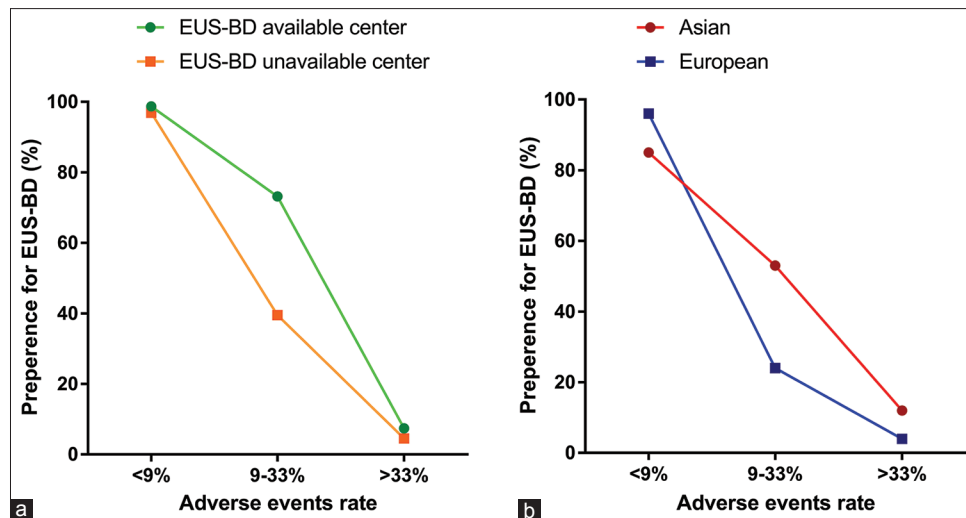


Figure 3. Relationship between patient preference and adverse event rates for EUS-guided biliary drainage depending on (a) the availability of EUS-guided biliary drainage expertise and (b) the region

cannulation. This approach allows the endoscopists to perform timely, one-stage BD, even in the event of the unexpected inaccessible papilla, without the difficulty of obtaining informed consent from the sedated patient in the same ERCP unit.

Due to comparable safety and cost-effectiveness between the inpatient and outpatient procedures, many endoscopists perform ERCP on an outpatient basis in the United States.^[27] However, unplanned admission after outpatient ERCP was reported in 10.7%–25.1% of the cases.^[28,29] EUS-BD has been reported to result in less physical discomfort^[19] and fewer frequent unscheduled reintervention with prolonged hospital stays, which are associated with economic burden, than PTBD.^[26] Thus, EUS-BD after failed ERCP in same endoscopic session may reduce the unplanned admission in the outpatient setting of ERCP. Therefore, treating patients with a preference of EUS-BD prior to ERCP may be more appealing to endoscopists with EUS-BD expertise in the United States who are able to perform outpatient ERCP compared with inpatient setting of ERCP in other country with time availability of scheduled alternative BD procedure on a different session in same day or next day after failed ERCP.

In the present study, age, sex, and prior experience of endoscopy, ERCP, and PTBD were not significantly associated with a preference of EUS-BD. However, the preference of EUS-BD was lower at centers without EUS-BD expertise compared to centers with available EUS-BD expert [Figure 3a]. We believe that patients at centers without EUS-BD expertise preferred PTBD

over EUS-BD because it was perceived to be a safe and readily accessible procedure without an endoscopist with EUS-BD expertise or appropriate radiological/surgical backup. Similarly, patients at centers with EUS-BD expertise preferred EUS-BD over PTBD because it was perceived to be a comfortable and readily accessible endoscopic procedure. Given the close relationship between preference of EUS-BD and its availability at their particular center, we believe that technical advancements and access to EUS-BD experts would improve patient preference and perception of EUS-BD when ERCP fails.

Patient willingness to undergo EUS-BD was shown to increase when AE rates for EUS-BD were less compared to those of PTBD (9%–33%). This suggests that patients may have a fundamentally favorable perception of EUS-BD, regardless of its availability within a given center or their preference of PTBD. In a previous study, patient perception of natural orifice transluminal endoscopic surgery (NOTES), a newly developed endoscopic technique similar to EUS-BD, were evaluated,^[30] and the preference of NOTES was observed to decrease with increased procedural AEs when compared to a more proven procedure (laparoscopic cholecystectomy). Similarly, in our study, the preference of EUS-BD decreased in accordance with an increase in AE rates of EUS-BD compared to those of PTBD. In these circumstances, the patient preference may be affected by the perception of PTBD with proven technical safety and easiness.

We included both Asian and European patients to minimize selection bias with respect to a specific region. In the context of a decrease in AE rates of EUS-BD compared to those of PTBD (<9%), the preferential tendency of EUS-BD in Spanish patients was higher than that in Asian patients without statistical significance. However, with similar or increased AE rates of EUS-BD compared with those of PTBD, the preferential tendency for EUS-BD in Spanish patients was lower than that in Asian patients [Figure 3b]. Differences in the culture and health-care systems between Asia and Europe might have influenced patient preferential tendency of EUS-BD and PTBD according to the degree of AE rates in EUS-BD. Further investigation is necessary to understand these differences.

The response rate to the questionnaire was very high (95.7%). All of the participants were scheduled to undergo ERCP for suspected malignant biliary obstruction. These patients showed interest in the detailed process of the ERCP that they would be undergoing and were concerned about the need for any subsequent procedures in the event of failed ERCP. In general, patients with suspected malignancy wanted to understand their disease and its treatment options. In a previous report, the majority of patients who underwent an EUS-FNA for suspected pancreatic cancer wished to receive the preliminary results on the day of the procedure (96.6%).^[31] Similarly, we found that the participating patients in this study wished to obtain more information on the proposed procedures.

The role of the patients are increasing in medical decision-making, and incorporation of patient preference into treatment is recommended in the context of shared decision-making.^[23] It is reported that shared decision-making process may improve treatment outcome, patient adherence, quality of care, and reduce costs.^[21,22] Although the relationship between patient preference and choice of treatment options was not evaluated in this study, our informational booklet may be useful as a patient decision aid to the patients with malignant biliary obstruction when ERCP fails. Further studies about the shared decision-making process are required to evaluate patient preference and treatment outcome.

There were limitations to this study. First, although we tried to provide the best available information on EUS-BD, our data were limited in terms of the safety

profile and efficacy of EUS-BD, which impaired the patients' ability to make an informed choice. For this reason, we evaluated patient preference according to whether AE rates were higher or lower than PTBD (9%–33%). Second, we did not specifically query patients regarding the type of prior endoscopy (gastroscopy *vs.* colonoscopy), ERCP (diagnostic *vs.* therapeutic), and PTBD (single *vs.* multiple) that they had previously undergone. This may have influenced patient perception of EUS-BD, as their preference could have been based on their previous procedural experience. Third, we did not confirm whether the patients sufficiently grasped the concept of EUS-BD. Although the informational booklet and questionnaire were written in an easily understandable language, patients with older age and a lower educational level might not have understood the questions. Finally, although the questionnaire was tested for internal consistency before its administration, it was not fully independently validated because this was a pilot study on patient preference. Medical students may not have been an accurate representation of the general patient population that was scheduled to undergo BD for malignant biliary obstruction.

CONCLUSIONS

In this international multicenter survey, approximately 80% of the patients preferred EUS-BD to PTBD after being informed of the benefits and risks of both procedures. However, preference of EUS-BD declined as its AE rates increased. Although our survey data are preliminary, patients had favorable perception of EUS-BD due to the possibility of internal drainage without a percutaneous drain tube. Further technical innovations and improved proficiency in EUS-BD for reducing AEs may increase patient preference of EUS-BD and encourage the use of this procedure as a routine clinical practice when ERCP fails.

Acknowledgment

This research was supported by a grant from the Korea Health Technology R7D Project through the Korea Health Industry Development Institute, funded by the Ministry of Health and Welfare, Republic of Korea (HI14C0139).

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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SUPPLEMENTARY APPENDICES

Supplementary Appendix 1

Patient perception and preference of EUS-guided drainage over percutaneous drainage when endoscopic transpapillary biliary drainage fails: an international multicenter survey.

Subject: A survey for the patient perception and preference between draining the bile by placing a biliary catheter through the skin (called percutaneous transhepatic biliary drainage, PTBD) and draining the bile by the use of endoscopy with the help of ultrasonography (called EUS biliary drainage, EUS-BD) in patients with biliary obstruction after unsuccessful biliary drainage with ERCP-guided biliary drainage (ERCP-BD).

When obstructive jaundice occurs in patients with biliary obstruction, the bile is drained by the use of special endoscope called ERCP-BD during which they place a drainage catheter in the bile duct by passing the scope from the mouth to the small bowel then to the bile duct, it is considered as the first treatment option. Its success rate is approximately 95%, whereas its adverse event rate ranges from 1%-5%. If this procedure fails due to duodenal invasion by tumor or prior surgery, there are two alternative treatment options, which are:

1- Draining the bile by placement of biliary drainage catheter through the skin (called percutaneous transhepatic biliary drainage, PTBD);

2- Draining the bile by another special endoscope with the help of ultrasonography (called EUS-guided biliary drainage, EUS-BD).

1. Draining the bile by placing a biliary catheter through the skin (percutaneous transhepatic biliary drainage, PTBD)

PTBD is a procedure to drain the bile ducts through the skin of a patient with obstruction in the bile duct. The classic biliary drainage procedure is performed by the use of special screen, a special dye and an X-ray (called fluoroscopy). During this procedure the skin is injected with local anesthesia then a guide needle and biliary drainage catheter is inserted below the right 10th rib. The procedure takes about 30 minutes

to 1 hour. It is a standard treatment for benign or malignant obstruction in the bile duct after failed draining with ERCP (ERCP-BD). Its success rate ranges from 87% to 100%. The overall incidence of adverse events is about 13% (range 9%-33%). These adverse events include infection, bleeding, and catheter blockage or movement to a different location. The overall incidence of severe adverse event is 8.2% (bile duct injury, and severe bleeding in the bile duct or abdominal cavity) When massive bleeding occurs, emergent procedure will be required such as closing the bleeding vessels by the radiologist with the use of special dye and X-ray (called angiogram) or surgery. The advantage of this procedure is high success rate with relatively shorter procedure time and it is well-established procedure (which has been done successfully many times in the past) after failed ERCP. The disadvantages of this procedure are related to the draining catheter and the canal formed by this catheter, which is related to pain, dislodgment, and tract implantation with tumor in cancer patients.

2. Endoscopic drainage of bile with the help of ultrasonography (EUS-guided biliary drainage, EUS-BD)

EUS is a type of endoscopy with an ultrasonogram attached to the front of the scope. Using EUS, the gastroenterologist can examine the parts which cannot be seen with the usual endoscope. EUS guided biliary drainage is a newly developed procedure used in bile duct obstruction caused by cancer during which a new drainage route is made either by making a route between the liver and the stomach (called hepaticogastrostomy, EUS-HG) or making a route between the bile duct and the duodenum (called choledochoduodenostomy, EUS-CD). It is a newly developed procedure, and its success rate ranges from 75% to 100%, which is comparable to draining the bile through the skin (percutaneous transhepatic biliary drainage, PTBD). The overall incidence of adverse event ranges from 11% to 27%. These adverse events includes leakage of bile to the abdominal cavity causing inflammation (Bile peritonitis), stent migration to a different location, self-limited air leak to the abdominal cavity (Pneumoperitoneum), and bleeding. The advantages

of this procedure are that it can be done at the same time after failed ERCP (bile drainage through the skin by catheter placement PTBD is mostly performed in another session after failed ERCP). Furthermore, no external drain is required. Based on recent studies, the technical and clinical success rate and incidence of overall adverse event is comparable to draining the bile through the skin (PTBD). The

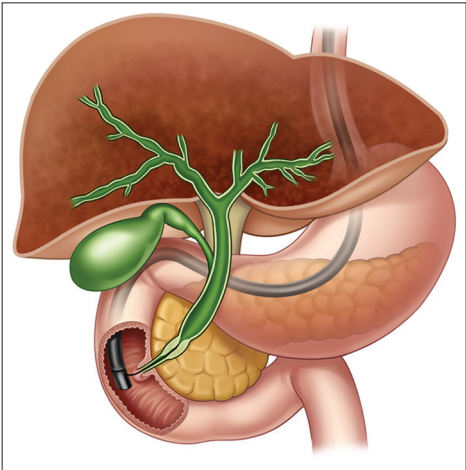
disadvantages of this procedure are that it is a relatively new approach, which should be performed by an expert gastroenterologist. Thus, the overall success and adverse event rate may vary based on the gastroenterologist experience in this field.

*Cost includes only basic procedure and additional cost about stent insertion is possible.

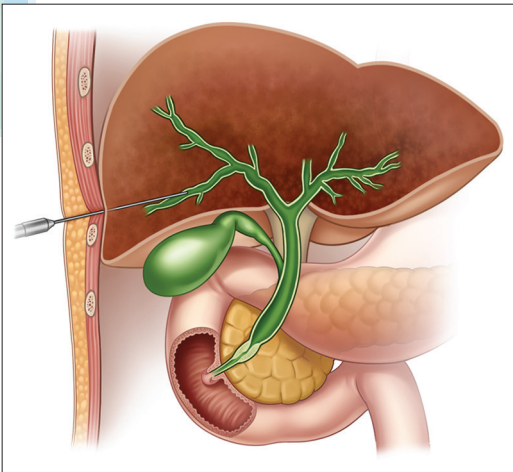
Table 1. The comparison of ERCP-BD, PTBD, EUS-BD

	ERCP-BD*	PTBD*	EUS-BD*
Summary	Using ERCP, insert biliary drainage catheter from inside the small bowel	Using special X-ray called fluoroscopy to insert biliary drainage catheter through the skin	Using EUS, make a new biliary drainage route (liver-stomach, bile duct-duodenum)
Procedure Time	30 minutes - 1 hour	30 minutes - 1 hour	Within 1 hour
Cost*	(Outpatient)	(Outpatient)1 x ERCP-BD	(Outpatient) 1.5 x ERCP-BD
Success Rate	90%-97%	87%-100%	75%-100%
Adverse Event Rate	<10%	9%-33% (Mortality Rate 2%-15%)	~25%
Advantages	Allows diagnosis and treatment simultaneously. Bile drain inside	Shorter procedure time, less procedure-related pain Bile drain outside by catheter through the skin.	Allows immediate procedure after failed endoscopic procedure. Bile drain inside
Disadvantages	Difficulty to approach the bile duct from inside in case of some cancer or surgically altered anatomy. Possibility of bleeding or infection in the bile duct.	Bile drains outside by catheter through the skin, some problems with drain care. Possibility of bleeding or infection in the bile duct.	Operator-dependent procedure needs experiences. Possibility of infection in abdomen (peritonitis), stent migration.

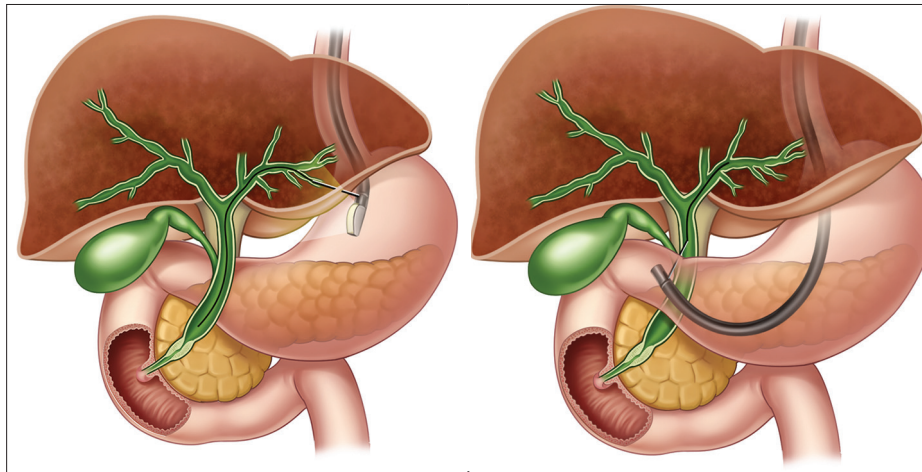
*ERCP-BD, ERCP-guided biliary drainage; PTBD, percutaneous transhepatic biliary drainage; EUS-BD, EUS guided biliary drainage.



Bile drainage by ERCP (ERCP-BD)



Bile catheter placement through the skin (PTBD)



Bile drainage by EUS (EUS-BD)

Supplementary Appendix 2

Patient perception and preference of EUS-guided drainage over percutaneous drainage when endoscopic transpapillary biliary drainage fails: an international multicenter survey.

We will ask you some questions about your preference for draining the bile through the skin (PTBD) or by the use of endoscopy with ultrasonography (EUS-BD) if ERCP drainage fails.

Please provide the following information

- Age: (Year of the Birth: 19____)- Sex: Male / Female
- Race: Caucasian, Hispanic, Asian, *etc* (____)
- Did you have an endoscopy before? Yes / No
- Did you have an upper endoscopy before, where they looked at your bile duct or pancreas (called ERCP) before? Yes / No
- Did you have bile drain placed through the skin (called PTBD) before? Yes / No

Question 1)

- If you should choose to have a bile drain placed, after failing ERCP drainage, would you prefer the drain placed through the skin (PTBD) or you prefer the drainage by EUS (EUS-BD)

(Circle one)

- a) Through the skin (PTBD)
- b) By EUS (EUS-BD)

- If you chose to have a bile drain placed, after failing ERCP drainage, would you prefer the drainage through the skin (PTBD) if

(Circle all that apply)

- a) It takes less time to place it (quicker)
- b) It is cheaper
- c) It is safer (lower adverse events)
- d) It is more convenient (easy to perform for operator)
- e) Other: ____

- If you chose to have a bile drain placed, after failing ERCP drainage, would you prefer drainage by EUS (EUS-BD) if

(Circle all that apply)

- a) It can be done at the same time during the ERCP, so you do not have to come back again for another procedure
- b) It has a higher success rate and relatively low adverse events
- c) It is comfortable, so you do not have drain tube through the skin (such as PTBD)
- d) Other: _____

Question 2)

Would you prefer a drain placed through the skin if,
(Choose Yes/No in each)

- (a) It is safer than EUS drainage (EUS-BD) Yes/No
- (b) It is more dangerous than EUS drainage (EUS-BD) Yes/No
- (c) It has the same risk like EUS drainage (EUS-BD) Yes/No

Supplementary Appendix 3

The results of pilot test for 34 medical students

Table 1. Preference of biliary drainage when ERCP fails and the reason for their preference

Total	34 (100.0%)
Prefer EUS-BD	29/34 (85.3%)
Less physical discomfort (no percutaneous drain tube)	26/29 (89.7%)
Higher success rate with lower morbidity	10/29 (34.5%)
One-stage procedure when ERCP failed	15/29 (51.7%)
Prefer PTBD	5/34 (14.7%)
Proven technical safety	3/5 (60.0%)
Shorter procedure time	3/5 (60.0%)
Technical easiness	2/5 (40.0%)
Low cost	0/5 (0.0%)

Trend of the preference for EUS-BD with varying adverse event rated for EUS-BD ($n = 34$)

