



Digestive Endoscopy

EUS-guided versus percutaneous biliary access in patients with obstructive jaundice due to gastric cancer



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ABSTRACT

Background: Gastric cancer is sometimes complicated by obstructive jaundice. However, ERCP may be challenging in patients who have advanced gastric cancer, or recurrent gastric cancer after surgical resection that is complicated by obstructive jaundice. In such cases, percutaneous transhepatic biliary drainage (PTBD) is considered. Recently, EUS-guided biliary drainage (EUS-BD) has been developed. We conducted a retrospective study to compare the efficacy of EUS-BD and PTBD in patients with obstructive jaundice due to gastric cancer.

Methods: Patients with gastric cancer complicated with obstructive jaundice who were contraindicated for standard ERCP were enrolled.

Results: A total of 47 consecutive patients were enrolled during the study period. The technical success rates of PTBD and EUS-BD were 88.9% (16/18) and 96.7% (29/30), respectively ($P = 0.64$). The stent patency period, including patient death was equivalent between the two groups (EUS-BD vs. PTBD: 188.4 days vs. 200.9 days, $P = 0.974$). Time to stent dysfunction in the EUS-BD group (391.1 days) was not significantly different as compared to that in the PTBD group (398.1 days) ($P = 0.78$). Adverse events were relatively severe in the PTBD group.

Conclusions: Given the relative severity of adverse events in the PTBD group, EUS-BD might be the procedure of choice for gastric cancer patients with contraindications by inability to perform ERCP.

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1. Introduction

Worldwide, gastric cancer is one of the commonest causes of cancer-related deaths, despite advances in treatment techniques, such as chemotherapy and surgical resection. Only rarely is gastric cancer complicated by obstructive jaundice [1–3]. Performance of continuous chemotherapy in such cases requires biliary drainage. However, endoscopic retrograde cholangiopancreatography (ERCP) may be challenging in patients who have advanced gastric cancer with gastric outlet obstruction, or recurrent gastric cancer after surgical resection that is complicated with obstructive jaundice. In such cases, percutaneous transhepatic biliary drainage (PTBD) is considered the standard treatment. Recently, due to the

need for external drainage with PTBD and the associated cosmetic issue, endoscopic ultrasound-guided biliary drainage (EUS-BD) has emerged as a new alternative [4–9]. This technique is clinically useful in selected patients, although it has a relatively high rate of adverse events. Several studies and meta-analyses have reported comparisons between EUS-BD and PTBD after failed ERCP [10–15]. According to these reports, EUS-BD may be equally efficacious as compared to PTBD. However, the inclusion of heterogeneous causes of obstructive jaundice may be a limitation of these reports, because of different oncological behaviors of the various primary pathologies. In addition, PTBD and EUS-BD were comparatively evaluated as second-line drainage techniques in almost all these studies. To date, there have not been any comparative reports of the clinical efficacy between EUS-BD and PTBD as first-line drainage techniques in patients with obstructive jaundice secondary to gastric cancer.

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Therefore, we conducted a retrospective study to compare the efficacy of EUS-BD and PTBD as the first-line drainage technique in patients with obstructive jaundice due to gastric cancer.

2. Patients and methods

Patients with gastric cancer complicated with obstructive jaundice who were contraindicated for standard ERCP were enrolled in this study between April 2012 and April 2017. The contraindications to ERCP were failure of the endoscope being advanced into the ampulla of Vater due to gastric outlet obstruction or surgical anatomy, such as Roux-en-Y anastomosis. These conditions were evaluated by computed tomography and upper gastrointestinal endoscopy. Therefore, in the present study, ERCP was not attempted in all patients.

This retrospective study was approved by the Institutional Review Board of our hospital. Written, informed consent was obtained from all patients. PTBD was considered the alternative biliary drainage method from April 2012 to September 2014. From October 2014 onwards, EUS-BD was performed as the first-line biliary drainage procedure in patients in whom ERCP was contraindicated.

2.1. Technique of PTBD

PTBD was performed by an experienced gastroenterologist (D.M), as previously described [16]. First, under fluoroscopic and ultrasound guidance, the intrahepatic bile duct was punctured and a guidewire was inserted. After the fistula was dilated, an 8.3-Fr 32 side-hole ring catheter was placed. PTBD revision was performed after 1 to 2 weeks. Finally, a 12-Fr silicone catheter was inserted into the bile duct system. If the site of obstruction was the dis-

tal common bile duct, the silicone catheter was placed across the ampulla of Vater. If the obstruction was in the middle or upper part of the distal common bile duct or in the hepatic hilum, the silicone catheter was placed above the ampulla of Vater.

2.2. Technique of EUS-BD

EUS-BD was performed under conscious sedation. First, an echoendoscope (UCT 260, Olympus Optical, Tokyo, Japan) connected to an ultrasound device (SSD5500; Aloka, Tokyo, Japan) was advanced into the intestine or stomach. Next, the intrahepatic bile duct was visualized. To prevent passage of the puncture needle through the mediastinum, segment 3 (B3) was chosen as the puncture site. If puncture of B3 was difficult, segment 2 (B2) was considered as the secondary puncture site. After puncture of the intrahepatic bile duct using a 19G fine-needle aspiration needle (SonoTip Pro Control; Medi-Globe GmbH, Rohrdorf, Germany), contrast medium was injected and the guidewire (0.025-inch, VisiGlide 1; Olympus Medical Systems, Tokyo, Japan) was advanced into the biliary tract. Next, the puncture site in the small intestine or stomach wall was dilated using a 4-mm balloon catheter (REN biliary dilation catheter, KANEKA, Osaka, Japan). Finally, a covered metal stent (10 mm × 6, 8, 10 cm, Niti-S Biliary Cover Stent; Tae-Woong Medical, Seoul, S. Korea) was placed from the intrahepatic bile duct to the intestine or stomach wall. If the hepatic hilum was obstructed, uncovered metal stent placement (Zilver635 biliary self-expanding stent, Cook Medical, Bloomington, IN, USA) was first performed from the right intrahepatic bile duct to the left intrahepatic bile duct (Fig. 1a, b, c). EUS-guided hepaticogastrostomy (EUS-HGS) was subsequently performed (Fig. 1d).

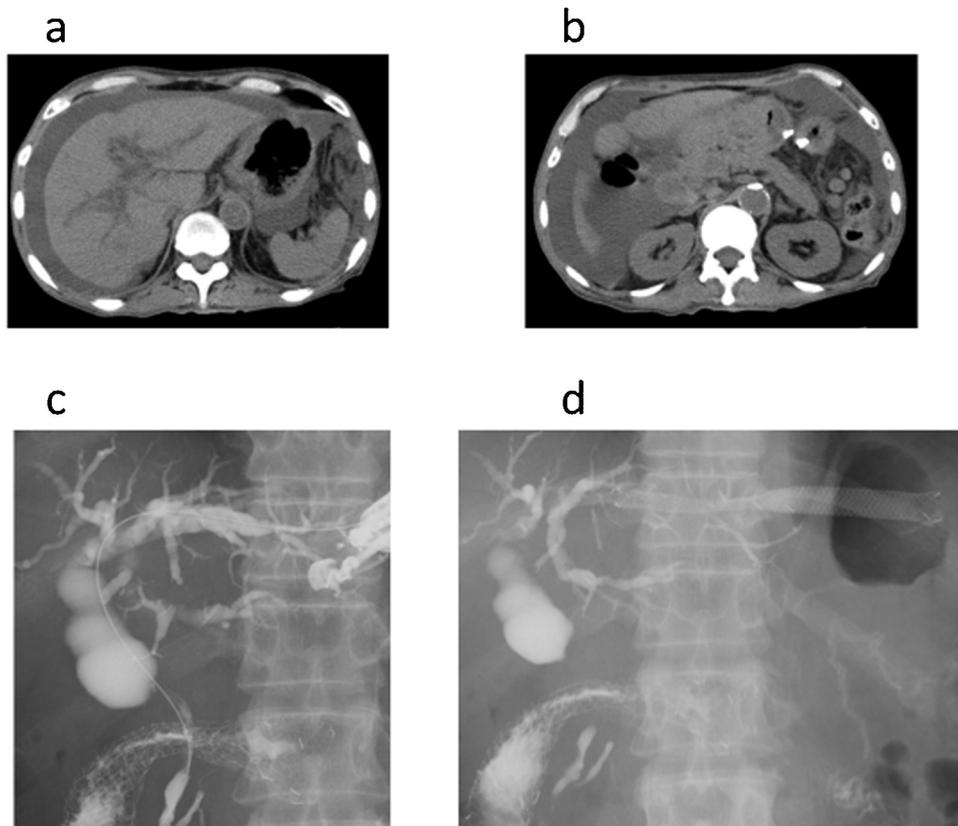


Fig. 1. a. Ascites is seen around the liver. b. Duodenal obstruction due to gastric cancer as a complication. c. Lower bile duct obstruction is seen on EUS-guided cholangiography. d. EUS-guided hepaticogastrostomy is successfully performed.

2.3. Definitions and statistical analysis

In all cases, biliary obstruction was examined using multi-detector computed tomography (MDCT). Overall survival (OS) was measured from the day of metal stent or PTBD tube placement to the time of the patient's death. Stent patency was measured from the day of metal stent or PTBD tube placement until stent dysfunction or patient death or the last follow-up. In addition, time to dysfunction was measured from the day of metal stent or PTBD tube placement to dysfunction. Stent or PTBD tube dysfunction was defined by the presence of cholangitis or recurrence of obstructive jaundice. Technical success was defined as successful metal stent placement in EUS-BD and PTBD tube placement in PTBD cases. Clinical success was defined as resolution of biliary obstruction as assessed by decrease in serum bilirubin levels by 75% at 4 weeks. Adverse events were graded according to the American Society of Gastrointestinal Endoscopy lexicon's severity system [17]. Data collection was performed using a prospectively collected database at our hospital.

Finally, continuous variables were expressed as median values. The proportion of patients who underwent EUS-BD and PTBD was compared using the χ^2 test, Mann–Whitney *U*-test, and Kruskal–Wallis test, as appropriate. Survival curves for OS and stent patency were estimated using the Kaplan–Meier method. Multivariate analysis of technical success was performed using logistic regression analysis. A *P*-value of <0.05 was considered significant. All statistical analyses were performed using SPSS version 13.0 (SPSS, Chicago, IL, USA).

3. Results

A total of 47 consecutive gastric cancer patients were enrolled during the study period (Fig. 2). Among them, PTBD was performed in the first 17 patients, and EUS-BD in the remaining 30 patients. In two of the PTBD patients, the procedure was unsuccessful because of insufficient intrahepatic bile duct dilatation and liver metastasis in the puncture line route, respectively. These two patients subsequently underwent conservative treatment. Adequate biliary drainage could not be achieved in one of the EUS-BD patients, because of difficulty in puncturing the intrahepatic bile duct due to the presence of cancer in the stomach wall at the puncture site. This patient, who instead underwent PTBD, has been included in the PTBD group for analyses. Therefore, the technical success rates of PTBD and EUS-BD were 88.9% (16/18) and 96.7% (29/30), respectively (*P*=0.64). Among the parameters assessed, gender

Table 1
patient's characteristics.

	EUS-BD (n=29)	PTCD (n=16)	P-value
Age, years, median (range)	67.0 (43–84)	71.5 (52–89)	0.43
Gender (male: female)	15: 14	12: 4	0.12
Indication, n (%)			
Surgically-altered anatomy	21 (72.4)	14 (87.5)	0.43
Gastric obstruction	8 (27.6)	2 (12.5)	
Site of bile duct obstruction, n (%)			
Hepatic hilar	9 (31)	7 (43.8)	0.39
Common bile duct	20 (69)	9 (56.3)	
Causes of bile duct obstruction, n (%)			
Lymph node metastasis	12 (41.4)	10 (62.5)	0.66
Direct cancer invasion	8 (27.6)	3 (18.8)	
Peritoneal metastasis	9 (31)	3 (18.8)	
Access route, n (%)			
Right intrahepatic bile duct	0 (0)	4 (25)	0.004
Left intrahepatic bile duct	29 (100)	12 (75)	
Presence of ascites, n (%)	9 (31)	0 (0)	0.01
Pre-biliary drainage laboratory data (mean \pm SD)			
Total bilirubin	6.0 \pm 6.2	5.9 \pm 7.0	0.52
AST	112.5 \pm 82.9	98.5 \pm 71.3	0.51
ALT	140.0 \pm 142.7	83.5 \pm 78.9	0.25
WBC	9427.9 \pm 8587.4	10617.9 \pm 10825.6	0.33
CRP	5.3 \pm 6.3	6.4 \pm 7.8	0.55
Adverse events, n (%)	3 (10.3)	3 (18.8)	0.43
Clinical success, n (%)	26 (89.7)	14 (87.5)	0.78
Overall survival, days (mean)	248.6	272.3	0.875

(*P*=0.063), age (*P*=0.789), site of obstruction (*P*=0.445) and previous surgery (*P*=0.278) were not found to be predictive factors of technical success.

Hence, a total of 45 patients who underwent either EUS-BD (*n*=29) or PTBD (*n*=16) were evaluated. Table 1 shows the patient's characteristics. The indications for EUS-BD or PTBD, which were surgically-altered anatomy or duodenal obstruction, were not significantly different between the two groups (*P*=0.43). Patients were subdivided into two groups based on the site of obstruction: the hepatic hilum and common bile duct. In the EUS-BD group, hepatic hilar obstruction was seen in 9 patients and common bile duct obstruction in 20 patients. On the other hand, in the PTBD group, hepatic hilar obstruction was seen in 7 patients and common bile duct obstruction was seen in 9 patients, indicating no significant differences between the two groups (*P*=0.39). Causes of bile duct obstruction, such as lymph node metastasis, direct invasion, and

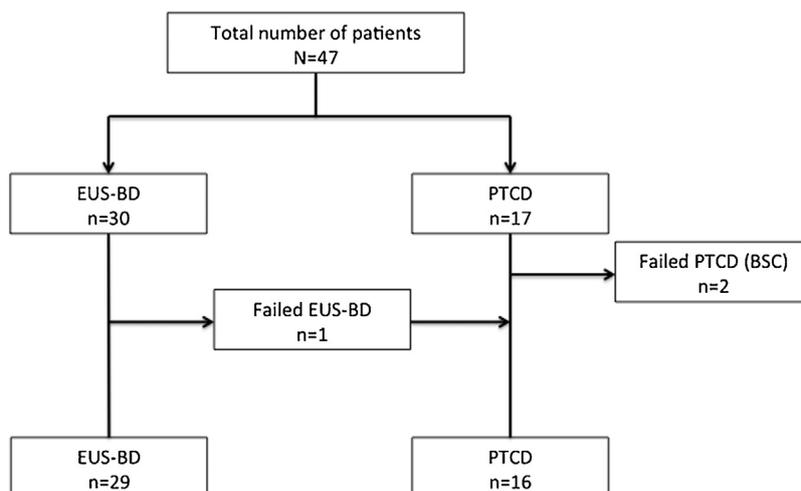


Fig. 2. Patients' flow in this study.

peritoneal metastasis, were also not significantly different between the two groups ($P=0.66$).

However, because EUS-BD could only be performed via the left intrahepatic bile duct, the access route was significantly different between the two groups ($P=0.004$). Also, because PTBD could not be performed for patients with ascites as a complication, presence of ascites was only seen in the EUS-BD group (EUS-BD vs. PTBD: 9 vs. 0, $P=0.01$). Pre-biliary drainage laboratory data, such as total bilirubin, aspartate aminotransferase, alanine aminotransferase, white blood cell count, and C-reactive protein were not significantly different between the two groups. The EUS-BD and PTBD procedures achieved clinical success in 89.7% (26/29) and 87.5% (14/16) of patients, respectively ($P=0.78$).

Mean OS following EUS-BD was 248.6 days [95% confidence interval (CI) 152.6–344.6], which was similar to that in the PTBD group (272.3 days, 95% CI 109.9–434.7, $P=0.88$). Fig. 3 shows mean stent patency, including in patients who died and those who developed stent dysfunction. As seen in the survival curve, stent patency was equivalent between the two groups [EUS-BD vs. PTBD: 188.4 days (95% CI 108.2–268.7) vs. 200.9 days (95% CI 53.646–348.1), $P=0.974$]. In addition, Fig. 4 shows mean stent patency in cases with only stent dysfunction. Mean stent patency in the EUS-BD group (391.1 days, 95% CI 259.1–523.1) was not significantly different as compared to that in the PTBD group (398.1 days, 95% CI 171.1–625.4) ($P=0.78$). The reasons for stent dysfunction in the EUS-BD group were stent obstruction ($n=4$) and cholangitis due to sludge ($n=2$), while that in the PTBD group was tube obstruction ($n=4$). All patients with stent dysfunction in both groups were successfully treated by re-intervention.

Finally, adverse events were seen in three patients each in both groups ($P=0.43$). Three patients in the EUS-BD group developed bile peritonitis that was treated conservatively. On the other hand, compared with the EUS-BD group, adverse events were relatively severe in the PTBD group (bile duct bleeding, acute pancreatitis, and pneumothorax, respectively).

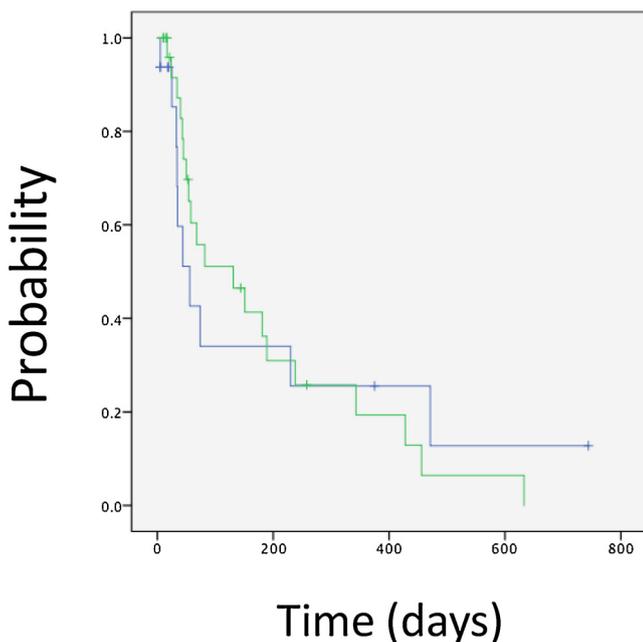


Fig. 3. Kaplan–Meier curves of stent patency including patients who died and stent dysfunction following PTBD and EUS-HGS (green line: EUS-HGS, blue line: PTBD). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

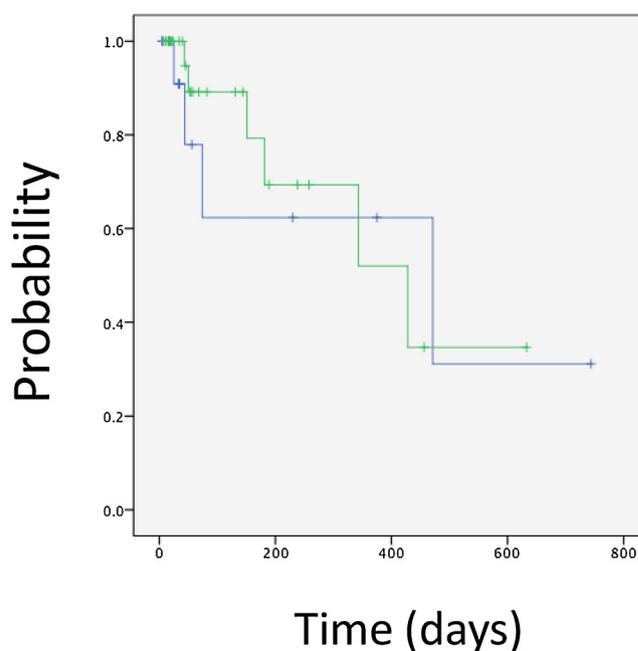


Fig. 4. Kaplan–Meier curves of stent patency including only cases with stent dysfunction following PTBD and EUS-HGS (green line: EUS-HGS, blue line: PTBD).

4. Discussion

Recently, the OS of patients with advanced gastric cancer has improved because of advances in chemotherapy [18–20]. On the other hand, advanced gastric cancer is sometimes complicated by biliary obstruction, which occurs due to direct invasion of the bile duct by the primary tumor, lymph node metastasis around the common bile duct, or peritoneal metastasis. Patients with these complications do not respond well to continuous chemotherapy. Malignant biliary obstruction is usually treated by stent placement under ERCP guidance [21,22]. However, ERCP itself may be challenging in patients with obstruction, because the duodenoscope sometimes cannot be inserted into the ampulla of Vater due to gastric outlet obstruction by the tumor, or due to surgically-altered anatomy, such as following Roux-en-Y esophagojejunostomy. Under these conditions, PTBD is indicated as the alternative gold standard technique. Migata et al. reported the clinical outcomes of bile duct obstruction caused by metastatic gastric cancer, which was treated by metal stent placement through the PTBD route [23]. In their study, obstructive jaundice resolved in 80.6% of patients (29/36), although the rate of adverse events was relatively high [27.8% (10/36 patients)]. Their conclusion was that PTBD with metal stent placement is effective treatment for obstructive jaundice due to gastric cancer, especially in patients in good clinical condition. Similarly, Kasuga et al. also evaluated the clinical outcome of PTBD as a drainage method for obstructive jaundice due to colorectal ($n=32$) and gastric cancer ($n=60$) [24]. Median OS in their study was 273 days after PTBD with subsequent chemotherapy in patients without poor prognostic factors, such as liver metastasis, poor performance status, or ascites. According to previous reports, PTBD is an effective biliary drainage method in selected patients with obstructive jaundice caused by gastric cancer.

Recently, EUS-guided access to the biliary tract has been developed [4–9]. To date, several comparative studies between EUS-BD and PTBD have been reported [11,13–15,25,26] (Table 2). Khashab et al. evaluated EUS-BD and PTBD in patients with malignant distal biliary obstruction and failed ERCP [13]. In their study, the technical success rate was significantly higher in the PTBD group compared with EUS-BD (100% vs 86.4%, $P=0.007$), although clinical success

Table 2
Recent large scale studies comparing EUS-BD and PTBD.

Author (year)	Etiology (n)	Groups	No of patients (n)	Technical success (%)	Clinical success (%)	Adverse events (%)
Khashab et al. [13]	Pancreatobiliary 58	EUS-BD	22	86.4	92.9	39.2
	Metastatic cancer 12	PTBD	51	100	86.4	18.2
	Gastrointestinal cancer 2 Liposarcoma 1					
Sharaiha et al. [15]	Pancreatobiliary 34	EUS-BD	47	91.6	62.2	25
	Metastatic cancer 7	PTBD	13	93.3	25	13
	Gastrointestinal cancer 9					
Lee et al. [14]	Pancreatobiliary 54	EUS-BD	34	94.1	87.5	8.8
	Metastatic cancer 4	PTBD	32	96.9	87.1	31.2
	Gastrointestinal cancer 8					
Sportes et al. [11]	Pancreatobiliary 42	EUS-BD	31	100	86	16
	Metastatic cancer 7	PTBD	20	100	83	10
Télliez-Ávila et al. [26]	Pancreatobiliary 32	EUS-BD	30	90	96	6.6
	Metastatic cancer 3	PTBD	32	78	63	28
	Benign 29					
Nam et al. [25]	Pancreatobiliary 239	EUS-BD	251	87–100%	N/D	9–33%
	Hepatocellular 7	PTBD	62	75–100%	N/D	~25%
	Metastatic cancer 5 Indeterminate 62					

was equivalent. Also, stent patency with EUS-BD (198 days) was equivalent to that with PTBD (184 days) ($P=0.86$). However, since adverse events and total cost were significantly higher with PTBD, they concluded that EUS-BD should be selected as the alternative drainage method, provided it is performed by an experienced interventional endosonographer. More recently, a randomized trial between EUS-BD and PTBD as the alternative biliary drainage method for malignant distal biliary obstruction was reported [14]. In that study, of the 66 patients enrolled, 34 patients underwent EUS-BD and 32 patients underwent PTBD. Technical success was significantly higher in the PTBD compared with the EUS-BD group (96.9% vs. 94.1%, $P=0.008$). On the other hand, procedure-related adverse events, re-intervention rate, and hospital stay were also significantly higher with PTBD. Median stent patency with EUS-BD was 228 days, which was similar to that with PTBD (220 days, $P=0.848$). Therefore, according to their randomized trial, EUS-BD showed similar efficacy as PTBD in terms of technical success, functional success, and quality of life. On the other hand, according to a recent meta-analysis regarding a comparison between EUS-BD and PTBD in 483 patients [10], although technical success was not significantly different between the two procedures (OR, 1.78; 95% CI, 0.69–4.59; $I^2=22\%$), EUS-BD was superior in terms of clinical success rate (OR, 0.45; 95% CI, 0.23–0.89; $I^2=0\%$), fewer adverse events (OR, 0.23; 95% CI, 0.12–0.47; $I^2=57\%$), and lower rate of re-intervention (OR, 0.13; 95% CI, 0.07–0.24; $I^2=0\%$). This meta-analysis concluded that EUS-BD may be preferred over PTBD. Therefore, according to previous reports, EUS-BD can be the second-line biliary drainage method for failed ERCP cases. However, the heterogeneous reasons for obstructive jaundice in previous studies may be a limitation of these reports, because oncological behavior itself can cause different outcomes. In addition, PTBD and EUS-BD were evaluated as second-line drainage techniques in most of these studies. To date, there have been no reports comparing the clinical efficacy between EUS-BD and PTBD as first-line drainage techniques in patients with obstructive jaundice due to only gastric cancer. The present study might be the first study comparing EUS-BD and PTBD as first-line drainage methods for patients with obstructive jaundice secondary to gastric cancer, which is a contraindication for ERCP. However, the present study also has several limitations. First, this study was retrospective in nature with a small sample size. Second, although the technical success rate was not much lower than previously described [15], the PTBD procedures may not have been performed by experienced

operators in our study. This may have led to bias in relation to the number of adverse events.

In conclusion, clinical efficacy, such as technical and clinical success and stent patency, were similar following EUS-BD and PTBD. However, because adverse events were relatively severe in the PTBD group, we recommend that, in expert hands, EUS-BD might be the procedure of choice for biliary drainage in gastric cancer patients with contraindications by inability to perform ERCP.

Conflict of interest

None declared.

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