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ORIGINAL RESEARCH

EUS-Guided Biliary Drainage for Unresectable Malignant Biliary Obstruction: 10-Year Experience of 99 Cases at a Single Center

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Abstract

Purpose To evaluate clinical outcomes of endoscopic ultrasound (EUS)-guided biliary drainage (EUS-BD) for unresectable malignant biliary obstruction for cases in which endoscopic retrograde cholangiopancreatography (ERCP) failed at a high-volume center.

Methods All 99 EUS-BD cases of unresectable malignant biliary obstruction at Sendai City Medical Center between February 2007 and September 2017 were retrospectively evaluated. ERCP is strictly prioritized over EUS-BD during the study period, and EUS-BD was performed in cases wherein ERCP was impossible or ineffective. Technical success, clinical success, adverse events, and time to recurrence of biliary obstruction were evaluated.

Results EUS-BD was technically successful in 98% of the patients (97/99). The clinical success rate was 93% (90/97). Adverse events that were definitely related to the procedure were observed in ten patients (10%; peritonitis in six, acute cholecystitis in four). Of six patients with bile peritonitis, four suffered from mild localized peritonitis that improved with conservative treatment, whereas two developed pan-peritonitis that improved with additional intervention. Other three patients with a poor performance status succumbed shortly after the successful EUS-BD, with a possible association between the procedure and death. In the 68 patients with a bilioenteric stent, the median time to recurrence of biliary obstruction was 339 days (95% confidence interval (CI), 14–664 days) during the mean follow-up period of 136 ± 173 days.

Conclusion EUS-BD was found to be feasible. However, there were a few patients with an unfavorable course after successful EUS-BD.

Keywords Endosonography · Choledochoduodenostomy · Hepaticogastrostomy · Indication · Adverse event

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has been the standard technique for relief of jaundice induced by an unresectable malignant stricture, which requires permanent biliary drainage. Although transpapillary biliary drainage always follows the success of endoscopic biliary cannulation, it often fails for various reasons. When transpapillary drainage fails, endoscopic ultrasound (EUS)-guided drainage can be an alternative option.

Since EUS-guided biliary drainage (EUS-BD) was first reported by Giovannini et al. [1], a large number of reports on EUS-BD have been published [2–6]. However, there have been few reports on detailed outcomes of a large number of cases from a single center, in which indications for that intervention were strictly defined. In multicenter studies, it is difficult to estimate the frequency of EUS-BD performance in a setting where ERCP was attempted as much as possible because indications for the intervention would be substantially different between institutions. Studies with a prospective setting would also not reveal such a frequency because of selection bias. In comparison, retrospective studies at a single center would provide real-world evidence.

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At our institution, indications for EUS-BD have been limited to cases in which the transpapillary route is absolutely unavailable even with expert techniques. On the other hand, we have proactively performed EUS-BD in ERCP-failed cases for 10 years, it being superior to percutaneous drainage and surgical bypass. We herein report results of 10 years of EUS-BD experience at such an institution.

Material and methods

Patients

All patients who underwent EUS-BD for unresectable malignant biliary obstruction at Sendai City Medical Center between February 2007 and September 2017 were included in this study. Certain cases were excluded as follows: (1) cases of EUS-guided gallbladder drainage, (2) cases wherein EUS-BD was performed for benign etiologies, (3) cases of intervention via the bilioenteric anastomosis that had previously been created by bilioenteric stenting at another institution, (4) cases wherein just EUS observation was performed without loading a EUS-guided fine needle aspiration (FNA) in the scope, and (5) cases without sufficient clinical records. Such case extraction was carried out using a prospectively maintained database for EUS-guided intervention at our center. The performance status was estimated according to the Eastern Cooperative Oncology Group (ECOG) criteria [7].

We adhered to ERCP for the first intervention. Even if EUS-guided drainage seemed technically easier, the transpapillary approach was prioritized when it could be safely performed. For biliary cannulation, we performed direct cannulation or contrast-assisted cannulation wherein contrast was injected from a cannula roofing the biliary orifice, rather than using the wire-guided technique. To achieve biliary cannulation, the pancreatic guidewire technique, the double-guidewire technique, and the precut sphincterotomy were utilized in difficult cases.

Since the first case of EUS-BD in February 2007, EUS-BD has been considered to be the alternative option for ERCP. When performance of EUS-BD did not seem reasonable for reasons of safety or technical difficulty, the percutaneous approach was performed instead.

Procedures of EUS-BD

Before the procedure, puncture routes were carefully considered based on computed tomography (CT) and abdominal ultrasonography. After insertion of the echoendoscope (GF-UC240P or GF-UCT260, Olympus Co., Tokyo, Japan), an appropriate route without any vessels was punctured with a 19-gauge needle dedicated for EUS-guided FNA (EchoTip, Cook Japan, Tokyo, Japan; Expect, Boston Scientific Japan K.K, Tokyo, Japan; or EZ Shot 3 Plus, Olympus). Successful puncture was confirmed through aspiration of bile and contrast injection. Subsequently, a guidewire was advanced toward the liver hilum through the needle. After withdrawal of the needle, a dilation device, including a bougie dilator (7-Fr ES Dilator, Zeon Medical, Tokyo, Japan; 7-Fr tapered catheter, Gadelius Medical Co., Tokyo, Japan; 5-Fr tapered catheter, Gadelius Medical), a balloon dilator (MaxForce, 4 mm in diameter, Boston Scientific; REN, 4 mm in diameter, Kaneka Co., Tokyo, Japan), and a cautery dilator (6-Fr Cyst-Gastro set, Cook), and a needle knife (single use three-lumen needle knife V, Olympus) were utilized along the guidewire. Finally, a plastic stent (7-Fr Flexima, Boston Scientific; 7-Fr single pigtail stent, CX-R stent type IT, Gadelius Medical) or a metal stent (fully covered Zeostent, Zeon Medical, Tokyo, Japan; fully covered X-Suit NIR, Olympus; partially covered Niti-S, Century Medical Co., Ltd., Tokyo, Japan; or uncovered Zilver/Zilver 635, Cook) was deployed at the puncture site or in a malignant stricture.

The standard route was considered to be a transduodenal route into the extrahepatic bile duct (choledochoduodenostomy (CDS)) (Fig. 1). When CDS seemed difficult (e.g., cases with a tumor involving the duodenal bulb or gastric antrum, cases with a tumor spreading to the bile duct at the liver hilum, or cases with an occluded metal stent in the extrahepatic bile duct which was previously deployed but no longer accessible), transgastric routes were alternatively selected (hepaticogastrostomy (HGS)) (Fig. 2).

Essentially, a stent was placed at the punctured site. When an intrahepatic bile duct was punctured, antegrade stenting at the biliary stricture was considered if the guidewire passed through the stricture. Even when antegrade stenting was successful, a stent would be additionally deployed at the puncture site to avoid bile leakage (Fig. 3). When the duodenal papilla was accessible but transpapillary cannulation failed, the rendezvous technique could be applied at endosonographer's discretion.

In the early period of this study, plastic stents were used because of a lack of covered metal stents with a thinner delivery system which could insert through the working channel of the echoendoscope. After covered metal stents with a thinner delivery system became available, fully covered metal stents were used for bilioenteric anastomosis in CDS, partially covered metal stents which have a 10-mm uncovered portion on its distal end were used for bilioenteric anastomosis in HGS, and uncovered metal stents were used for antegrade stenting. In cases with a thin target duct, a plastic stent was considered alternatively.

The procedures were all performed by one of nine expert endoscopists with experience of > 1000 ERCP

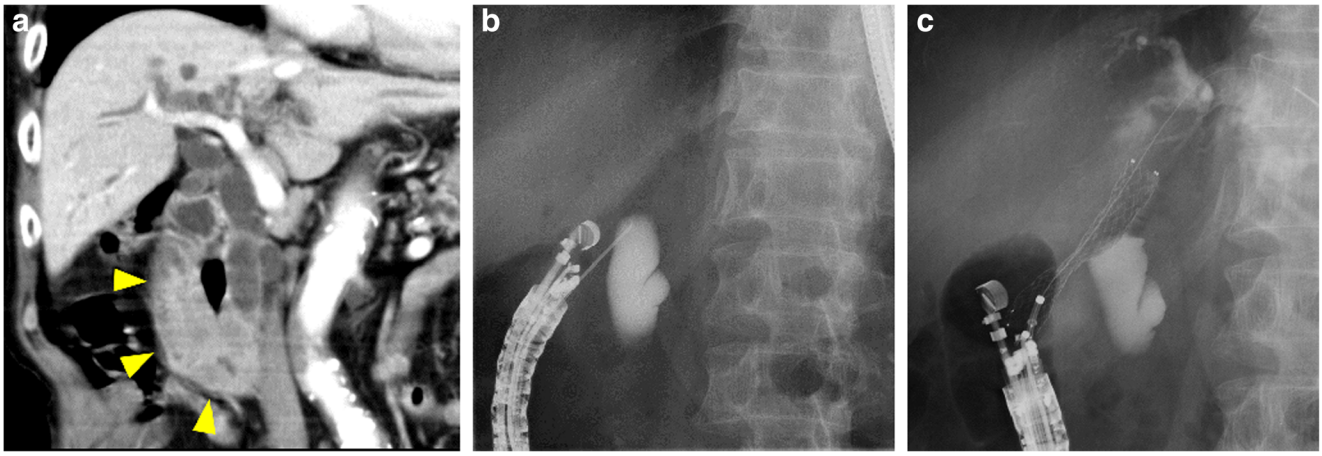

Fig. 1 EUS-guided choledochoduodenostomy (CDS). **a** CT revealed ampullary cancer (arrow heads) which occupied the duodenal lumen. **b** After biliary puncture with a 19-gauge needle through an echoendoscope, successful puncture was confirmed through aspiration of bile and contrast injection. **c** After dilation of the puncture tract with a bougie dilator and a balloon dilator, a laser cut-type fully covered metal stent (X-Suit NIR, Olympus) was deployed

sessions, > 1000 EUS examinations, and > 100 EUS-guided FNA procedures as a main operator. Some of the experts or well-experienced trainees assisted the procedures.

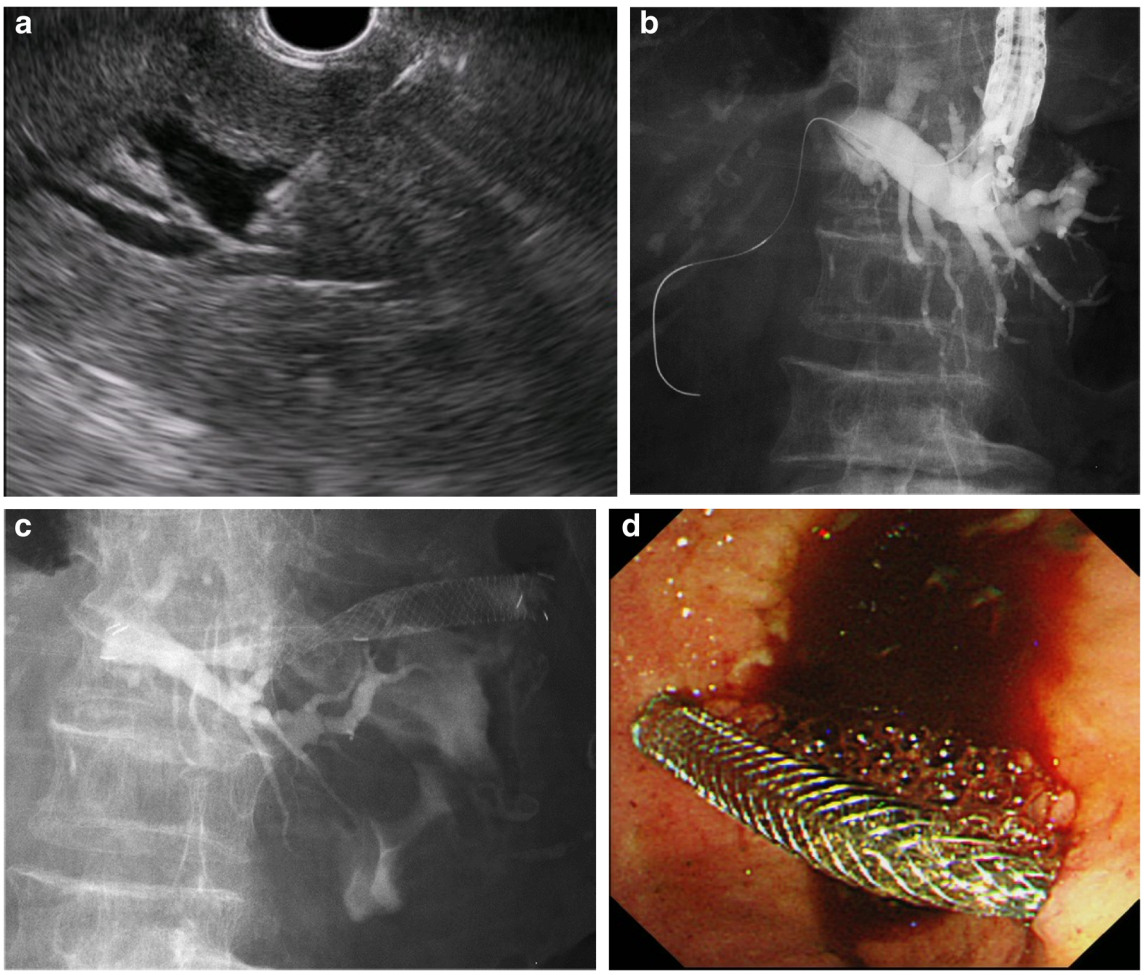

Fig. 2 EUS-guided hepaticogastrostomy (HGS). **a** An intrahepatic bile duct was punctured under EUS guidance. **b** After confirmation of successful puncture, a guidewire was inserted. **c** After dilation of the puncture tract with a bougie dilator, a weave-type partially covered metal stent (Niti-S, Century Medical) was deployed. **d** Sufficient length of the proximal part of the stent was located in the stomach

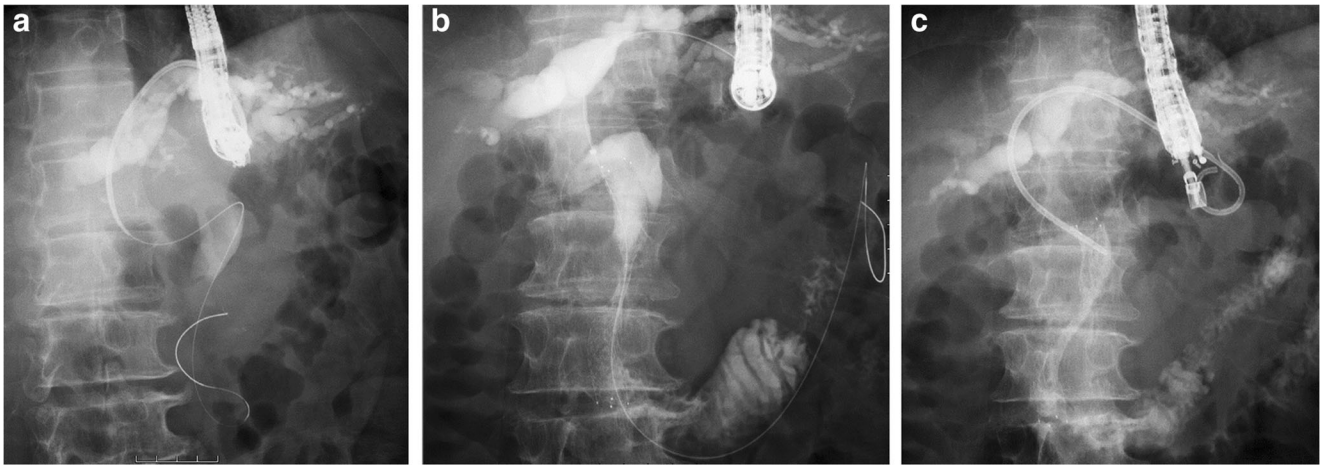

Fig. 3 EUS-guided antegrade stenting with HGS. **a** After puncture of the intrahepatic bile duct, a guidewire was inserted through the stricture at the extrahepatic bile duct. **b** After dilation of the puncture tract and the stricture, an uncovered metal stent (Zilver 635, Cook Japan) was deployed at the stricture. **c** Finally, a single pigtail plastic stent with multiple side holes and a flap at the proximal end, 15 cm long (type IT, Gadelius Medical), was placed at the puncture site

Outcome Measurements and Definitions

After identification of all EUS-BD cases, cases which met the aforementioned exclusion criteria were eliminated. The remaining cases were retrospectively evaluated.

Short- and long-term outcomes of EUS-BD were retrospectively evaluated. Such outcomes included technical success, clinical success, adverse events related to the procedure, recurrence of obstructive jaundice or infectious cholangitis, and survival period. Technical success was defined as successful drainage that was planned before the procedure. Clinical success was defined as improvement of a serum total bilirubin level to a normal level (< 1.2 mg/dL) or less than half of the level before the procedure. Adverse events were defined as any clinically important events that required additional treatment, such as endoscopy, surgery, radiological intervention, medication, prolongation of fasting period, and blood transfusion. Bile peritonitis was defined as abdominal pain that newly emerged after the procedure accompanied with elevation of the serum C-reactive protein (CRP) level.

Regarding long-term outcomes, the overall survival period and time to stent dysfunction were analyzed. Dysfunction of the deployed stent was separately evaluated from procedure-related adverse events. Stent dysfunction was defined as the recurrence of obstructive jaundice and/or segmental acute cholangitis that required additional intervention, even without jaundice.

The recurrence of obstructive jaundice was defined as re-elevation of the serum total bilirubin level or biliary infection indicated through the CRP, alkaline phosphatase (ALP), or gamma-glutamyl transpeptidase (GTP) level. Re-elevation of the total bilirubin level was defined as an increase to greater than 3.0 mg/dL in cases which had improved to a normal level after EUS-BD or as an increase of greater than 2.0 mg/dL from the lowest level in cases which had not improved to a normal level. Elevation of such data that were not derived from stent occlusion or cholangitis but rather from multiple organ failure was not considered stent dysfunction.

Statistics

Fisher's exact test and the Kaplan-Meier method with or without the log-rank test were applied for analyses.

A p value of less than 0.05 was considered to be statistically significant.

SPSS software (version 24; IBM Japan, Ltd., Tokyo, Japan) was used for all analyses.

Results

After elimination of cases with the aforementioned exclusion criteria, EUS-BD was attempted in 99 patients during the study period. Baseline characteristics of these patients are shown in Table 1. During the approximate 10-year period, 6873 cases of ERCP, including 1034 cases involving patients with a naïve papilla who suffered from malignant biliary obstruction, were performed at our center. Of the 1034 cases, 75 patients received EUS-BD after an ERCP attempt and 24 patients underwent EUS-BD without an ERCP attempt because the papilla was not accessible.

Table 1 Baseline demographics of the patients

Age, years, mean ± SD	75.0 ± 10.9
Sex, male/female	55:44
Etiology	
Pancreatic cancer	50
Extrahepatic cholangiocarcinoma	13
Intrahepatic cholangiocarcinoma	12
Ampullary cancer	7
Gallbladder cancer	6
Metastatic lymph nodes	11
Surgically altered anatomy	
Distal gastrectomy, Billroth I reconstruction	9
Distal gastrectomy, Billroth II reconstruction	4
Distal gastrectomy, roux-en-Y reconstruction	4
Total gastrectomy, roux-en-Y reconstruction	6
Pancreatoduodenectomy, PD-II reconstruction	1
Palliative hepaticojejunostomy	9
Previous cholecystectomy	26
Performance status	
0	18
1	24
2	32
3	15
4	8

Technical and Clinical Success

EUS-BD was technically successful in 98% of the patients (97/99) (Table 2). In one case of unsuccessful EUS-BD, a guidewire could not be inserted into the thin intrahepatic bile duct, although needle puncture was successful, and the contrast was injected into the duct. This patient had extremely advanced perihilar cholangiocarcinoma which had previously been treated with seven metal stents and two plastic stents. Additional transpapillary drainage was judged to be ineffective, and EUS-HGS was attempted. After EUS-BD failed, the patient abandoned further intervention and received medication. In another case of unsuccessful EUS-BD, in which the patient had pancreatic cancer which induced a duodenal stenotic deformity, an intrahepatic bile duct, 5 mm in diameter, was successfully punctured, but the guidewire was not inserted, similar to the first failed case. This patient underwent percutaneous drainage. Both patients did not suffer from procedure-related adverse events.

Of 97 successful patients, puncture was performed from the duodenal bulb in 46 patients, from the stomach in 44, from the jejunum in four, and from the abdominal esophagus in three. Although transesophageal puncture was unintendedly performed in the earlier study period, it was avoided for ease of maintenance and prevention of bile esophagitis in the later period. The extrahepatic bile duct was punctured in 46 patients from the duodenum, whereas the intrahepatic bile duct was punctured in other patients. A stent was placed at the puncture site in 90 patients, of whom six patients additionally underwent antegrade placement. Five patients received simple antegrade stenting without bilioenteric anastomosis (stenting at the puncture site), and two underwent the rendezvous technique.

Of the patients who experienced technically successful EUS-BD, clinical success was achieved in 93% (90/97). Three patients succumbed before jaundice sufficiently improved, as mentioned in the following section. In three patients, jaundice did not improve possibly because it derived from liver failure, or because the drained cavity was insufficient in the highly segmented biliary tree. The remaining patient could not be followed up after hospital discharge.

Adverse Events

Adverse events that were definitely related to the procedure were observed in ten patients (10%). Of six patients with bile peritonitis, four suffered from mild localized peritonitis that improved with conservative treatment, whereas two developed pan-peritonitis. In one of the two pan-peritonitis cases, the distal edge of a metal stent (fully covered Zeostent) which was attempted to be placed, bridging the extrahepatic bile duct and duodenum, was erroneously placed outside the bile duct. Although another covered metal stent was attempted to be additionally inserted through the first stent, only an uncovered metal stent (Zilver stent) was able to be inserted. Further stenting with a fully covered stent was attempted, but the procedure was abandoned because of deterioration of the respiratory condition of the patient. On the next day, percutaneous biliary drainage was performed in order to lessen bile leakage. Two days after the first intervention, the third metal stent (fully covered WallFlex, Boston Scientific) was additionally deployed in the two previously placed stents. Bile leakage resulted in biloma around the bile duct, which was treated with percutaneous drainage. After such interventions, the patient recovered and was discharged without any external drainage tubes. Another patient with pan-peritonitis, in whom a cautery dilator (8.5-Fr Cyst-Gastro-set) was utilized because of difficulty in dilation, recovered conservatively.

Acute cholecystitis occurred in four patients because of occlusion of the cystic duct by the choledochoduodenal fully covered metal stent. All of them recovered with percutaneous drainage.

In one patient, a metal stent which was attempted to be placed at the choledochoduodenal puncture site was dislocated toward the bile duct side during the procedure,

Table 2 Outcomes of endoscopic ultrasound-guided biliary drainage (EUS-BD)

Reason for EUS-guided biliary drainage	
Biliary cannulation impossible due to invasion to the papilla	33
Papilla inaccessible due to intestinal deformity	19
Biliary branches difficult to selectively drain via the papilla	16
Papilla inaccessible because of surgically altered anatomy	14
Metal stent placed at the duodenum	9
Biliary cannulation impossible due to the difficult papilla	6
Frequent occlusion of transpapillary stents	2
Punctured site	
Esophagus	3
Stomach	44
Duodenum	46
Jejunum	4
Stenting technique	
Bilioenteric anastomosis	90
Antegrade stenting	11
Rendezvous technique	2
Deployed stent	
Plastic stent	41
Metal stent	61
Procedure time, min, mean ± SD	36 ± 18
Technical success rate	98% (97/99)
Clinical success rate	93% (90/97)

and its proximal edge moved outside the duodenum. An additional metal stent was deployed in the same session. In another five patients, a guidewire which was successfully inserted into the bile duct was unexpectedly bounced off outside the bile duct during dilation procedures, but EUS-BD was achieved after re-puncture. These six patients did not suffer from any adverse events, including peritonitis.

Three patients succumbed shortly after the procedure, following rapid deterioration of their condition (Table 3). One patient (no. 1 in Table 3) developed liver failure after the procedure (aspartate aminotransferase (AST), 50 to 6531 IU/L; alanine aminotransferase (ALT), 40 to 4384 IU/L) without biliary enzyme deterioration (total bilirubin, 12.2 to 11.5 mg/dL; ALP, 1076 to 712 IU/L). He had atrial fibrillation, but he did not receive anticoagulant therapy because of his low performance status owing to his age. Given a severely elevated lactate dehydrogenase (LDH) (321 to 5333 IU/L), sudden thromboembolic events might have occurred. Subsequently, he developed disseminated intravascular coagulation, suffered from multiple organ failure, and finally succumbed. Another patient (no. 2 in Table 3) underwent EUS-BD because pancreatic cancer severely invaded into the papilla and spread along the biliary tree toward the liver. Huge metastatic liver masses highly segmented the biliary tree into several cavities. She received EUS-BD with a plastic stent because the targeted bile duct was not sufficiently dilated. Acute respiratory distress syndrome (ARDS) occurred the next day after the successful procedure. Intensive medication, including steroid pulse therapy, was performed, but she finally succumbed 10 days after the procedure. In the other patient with right paresis derived from an old cerebral infarct (no. 3 in Table 3), EUS-BD was performed at her desire after 9 days of cessation of antiplatelet agents. Although her consciousness level had been clear before the procedure, it never recovered after the successful procedure performed under deep sedation with propofol and pentazocine. Her respiration gradually decreased after the successful procedure, resulting in her death 2 days after the procedure. Although the definite mechanism for death was not known in all three patients, EUS-BD could have been directly related to their death.

All types of adverse events, such as bile peritonitis, acute cholecystitis, and death in the short term after the procedure, occurred in both early and late study periods irregularly.

Long-Term Outcomes

Among 84 patients in whom a stent was placed at the puncture site without antegrade stenting, the stent was endoscopically removed in two patients and was exchanged in a planned manner in nine. Of the remaining 73 patients, spontaneous stent dislodgement occurred in two without recurrence of jaundice (plastic stent in one, metal stent in one) and in three with such recurrence (plastic stent in one, metal stent in two). In the remaining 68 patients with a bilioenteric stent (plastic stent in 20, metal stent in 48), the median time to recurrence using the Kaplan-Meier method was 339 days (95% confidence interval (CI), 14–664 days) during the mean follow-up period of 136 ± 173 days (Fig. 4a). Such recurrence occurred in 11 patients (2/20 cases with a plastic stent, 9/48 cases with a metal stent, $p = 0.49$). The median time to recurrence based on the Kaplan-Meier method was 125 days (95% CI, not available) in the plastic stent group and 339 days (95% CI, not available) in the metal stent group, without a statistically significant difference ($p = 0.61$) (Fig. 4b).

The median overall survival period was 142 days (95% CI, 100–184 days) in all 99 patients who underwent EUS-BD (Fig. 5).

Discussion

A meta-analysis reported feasibility of EUS-BD for unresectable malignant biliary obstruction in comparison with percutaneous transhepatic biliary drainage [8]. This meta-analysis included 483 cases from three randomized trials and

Table 3 Patients who succumbed possibly because of the EUS-BD procedure

	Age	Sex	PS	Causative malignancy	Previous EBS	Coexisting disease	EUS-BD technique	Stent position	Deployed stent	Procedure time (min)	Cause of death	Day of death (after the procedure) (days)	Certainty of relation between the procedure and the death
1	86	M	3	Ampullary cancer	No	Atrial fibrillation, Alzheimer's disease, depression	CDS	Puncture site	7-Fr Flexima	14	Liver failure	3	Possible
2	73	F	4	Pancreatic cancer	No	None	CDS	Puncture site	Single pigtail stent, type IT	60	ARDS	10	Possible
3	78	F	4	Pancreatic cancer	No	Right paresis after old cerebral infarct	CDS	Puncture site	7-Fr Flexima	12	Respiratory failure	2	Probable

PS performance status, *EBS* endoscopic transpapillary biliary stenting, *CDS* choledochoduodenostomy, *ARDS* acute respiratory distress syndrome

six retrospective comparative studies. There was no difference in technical success between two procedures (odds ratio (OR), 1.78; 95% CI, 0.69–4.59), whereas EUS-BD was associated with better clinical success (OR, 0.45; 95% CI, 0.23–0.59), fewer adverse events (OR, 0.23; 95% CI, 0.12–0.47), and lower re-intervention rate (OR, 0.13; 95% CI, 0.07–0.24). Another meta-analysis, which included non-comparative studies, and multicenter studies have reported sufficiently acceptable feasibility of EUS-BD [9–12].

EUS-BD has become a feasible option in cases of failed ERCP. However, there have been few retrospective studies which reported real-world data with a large population. Prospective studies have a risk of selection bias because of their strict inclusion/exclusion criteria, resulting in somewhat atypical data that differs from outcomes in the real world. Patients with better performance status, those having sufficient time to obtain full informed consent before the procedure, those with a trusting relationship with their doctors, and those with a high comprehension level are easy to include in prospective studies. Because retrospective observational studies can include other patients, such studies are worth evaluating in detail with a large sample size.

This study showed the acceptable success rate of EUS-BD (98%) in cases wherein ERCP had not been applicable. If this procedure can be safely performed, it can possibly be a more reasonable option for such patients in comparison with percutaneous intervention or surgical treatment because of its advantages, such as no pain and uncomfortableness at the skin, no need of external drainage tubes, and physiological bile flow which would prevent deterioration of nutritional status and immunity. However, three patients who succumbed shortly after the procedure were encountered. Although the definite association between the procedure and their death was unclear, this study revealed that there can be such an unfavorable result, even when EUS-BD was successful in patients with a poor condition status. In these three patients, the performance status had deteriorated to ECOG 3 or more because of coexisting diseases, causative malignancy, and/or infectious cholangitis. If further accumulation of patients reveals an evident relationship between a poor performance status and poor outcomes, indications for EUS-BD can be appropriately limited. On the other hand, it is often difficult to determine the performance of an invasive treatment in patients with a poor condition status. Because there were patients who recovered by EUS-BD even with a poor performance status, performing this procedure is sometimes required when it seems to have some chance of saving a patient's life and is considered the best choice among all options, including medication without interventional treatment.

Total outcomes shown in this study were found to be relatively reasonable, but they were achieved with utmost caution and preparation at the institution with a high volume of ERCP and EUS. Because the technology of EUS-BD has not been

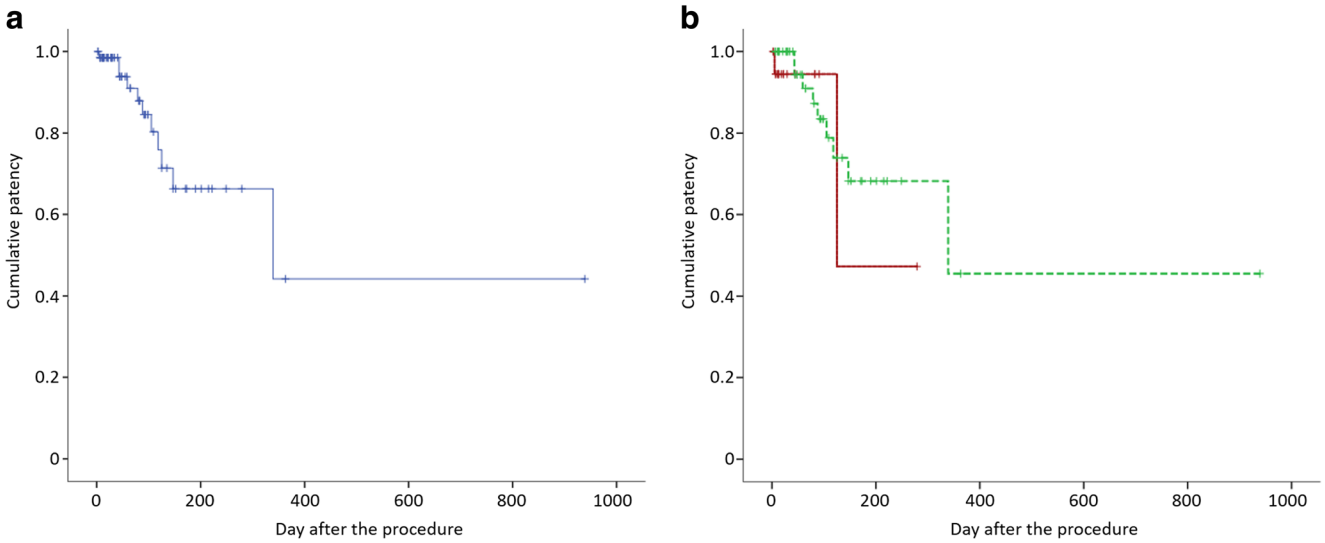

Fig. 4 **a** Kaplan-Meier curve of cumulative patency of the stent deployed at the puncture site ($n = 68$). The median time to recurrence of biliary obstruction was 339 days (95% confidence interval (CI), 14–664). **b** Time to recurrence was not different between a plastic stent (brown line; $n = 20$; 125 days; 95% CI, not available) and a metal stent (green dashed line; $n = 48$; 339 days; 95% CI, not available)

fully established, similar outcomes would not be available in other settings without experienced technicians. On the other hand, scopes and many devices have been improved during the study period, and technical methodology is also being established at an accelerating pace. Echoendoscopes and ultrasound processor systems have improved in image quality. Capability of needles to puncture hard tissues and to advance straight has increased. Additionally, a dedicated dilator developed [13]. Fully covered metal stents with a thin delivery system which enables placement through echoendoscopes became available. Such development must have reduced technical difficulty and adverse events, although the reduction cannot be proved in this study due to the relatively small population.

Further development has been reported in several studies. Lumen-apposing metal stents (LAMSs) improve technical simplicity and safety of EUS-BD [14–16]. The placement of LAMS has been facilitated in EUS-guided drainage of pancreas cysts and a gallbladder. Tsuchiya et al. reported feasibility of a LAMS with a cautery-enhanced delivery system for EUS-guided CDS [16]. In all 19 patients, stent deployment was technically

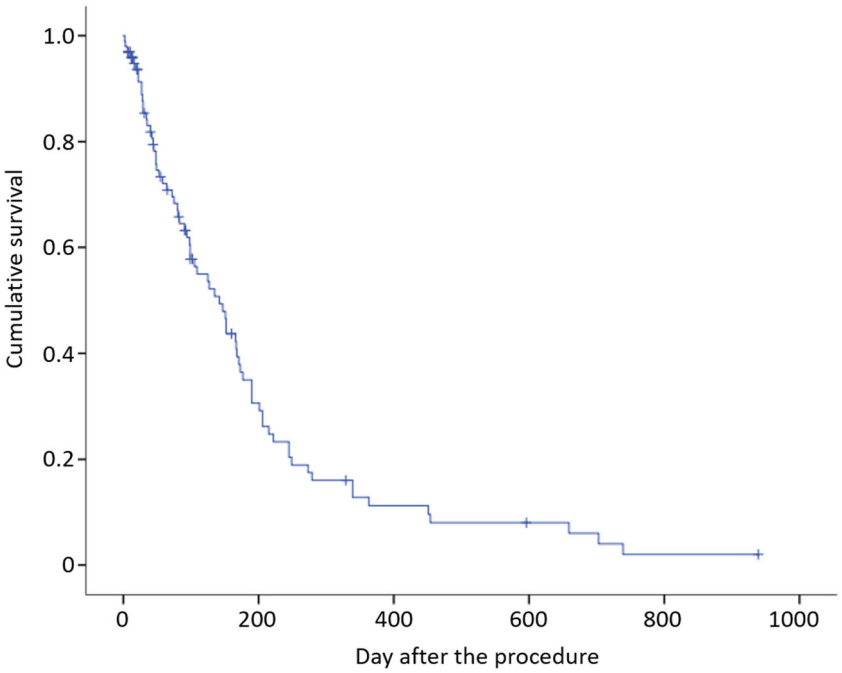

Fig. 5 Kaplan-Meier curve of cumulative overall survival after EUS-guided biliary drainage. The median survival period was 142 days (95% confidence interval, 100–184) in 99 patients

successful with the mean procedure time of 16 ± 7 min. This feasibility study did not show superiority to traditional stents in terms of safety and patency. Further evaluation is needed for generalizing the application of this stent for EUS-CDS. However, this stent cannot be utilized in HGS. Additional inventions for EUS-HGS are desired.

In conclusion, this retrospective study showed the acceptable success rate, clinical rate, adverse events rate, and long-term outcomes in the real-world setting at a single high-volume center where ERCP is highly prioritized over EUS-BD, similar to previous prospective studies and multicenter studies. However, a few patients with a poor performance status succumbed shortly after successful EUS-BD with a possible association between the procedure and death. Further evaluation with a larger sample size is desired.

Author Contribution All authors had access to the study data and reviewed and approved the final manuscript.

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Compliance with Ethical Standards

Both the EUS-BD procedure and this study were approved by the Institutional Review Board of Sendai City Medical Center. Written informed consent for EUS-BD was obtained with presenting risks and benefits in comparison with other possible options from all patients before the procedure.

Conflict of Interest The authors declare that they have no conflicts of interest.

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