Metallic biliary drainage: endoscopic ultrasound versus percutaneous approach after failed endoscopic retrograde cholangiopancreatography for distal malignant biliary strictures

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Background and purpose
After failure of endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS)-guided biliary drainage is a feasible and safe alternative to percutaneous transhepatic biliary drainage and surgical bypass for distal malignant biliary strictures (DMBS). The aim of this study was to compare the efficacy, safety, cost, and patency of self-expandable metallic stent insertion by EUS-guided versus percutaneous route for biliary drainage after failure of ERCP.
Patients and methods
A total of 40 patients with DMBS after failure of ERCP were randomized into two groups: group I (20 patients) underwent EUS-BD and group II (20 patients) underwent percutaneous metallic biliary drainage (PMBD); both groups used SEMS.
Results
The technical and clinical success rates for EUS-BD and PMBD groups were 100 and 95% (P=0.897). Nonetheless, complications were more common in the PMBD group (10 vs. 25%, P=0.212). Fever, cholangitis, and mild bile leakage were early complications in both groups, whereas stent migration (one patient) in EUS-BD group and stent obstruction (four patients) (P=0.035) in PMBD group were late complications. Between EUS-BD and PMBD groups, the rate of reintervention was 5 and 20% (P=0.171), and cumulative cost of the procedures was 964.32±79.8$ and 1098.61±84.5$, respectively ($P$=0.035).
Conclusion
When compared with PMBD for DMBS after failure of ERCP, EUS-BD is a technically successful and safe procedure with a shorter fluoroscopy duration, less minor complications, longer stent patency, and a lower cost with fewer re-interventions.

Keywords:
distal malignant biliary stricture, endoscopic retrograde cholangiopancreatography, endoscopic ultrasound guided biliary drainage, percutaneous metallic biliary drainage, percutaneous transhepatic biliary drainage

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Introduction

Biliary obstruction is caused by many causes, including benign and malignant diseases. Approximately two-thirds of cases of distal malignant biliary obstruction are caused by pancreatic head cancer, followed by distal cholangiocarcinoma, ampullary cancer, metastatic lymphadenopathy, and infrequently by hepatic and advanced gastric and duodenal malignancies. Frequently, these tumors are unresectable at the time of diagnosis and only need palliative treatment [1].

The standard method for biliary drainage in these patients is endoscopic retrograde cholangiopancreatography (ERCP) [2]. Nevertheless, in some cases that have gastric outlet obstruction (GOO) or extensive ampullary invasion, biliary cannulation may not be possible [3]. After failure of ERCP, biliary drainage can be achieved by one of the following methods: percutaneous transhepatic biliary drainage (PTBD) (external or internal), combined percutaneous and endoscopic technique (rendezvous technique), endoscopic ultrasound-guided biliary drainage (EUS-BD), or surgical bypass [4,5].

Typically, EUS-BD and PTBD are equivalent to surgical approach regarding feasibility and efficiency. In addition, EUS-BD and PTBD procedures are less invasive in contrast to surgery [6]. In the postoperative period, surgical biliary drainage is associated with high morbidity (9–67%) and up to 3% mortality [7]. External PTBD drainage is related to negative outcomes in 20–77% of cases [8]. Furthermore, external PTBD may negatively affect the patient's quality of life by causing insertion site discomfort, cosmetic issues, and skin inflammation owing to the catheter being retained for a prolonged period. Furthermore, catheter dislocation and bile leakage are frequent complications [9].

Internal biliary drainage either through EUS-BD or internal PTBD with SEMS could then remove these disadvantages of external biliary drainage. Since EUS-BD was introduced by Giovannini *et al.* [10], EUS-BD has been more commonly used as a safe alternative procedure to PTBD for patients with distal malignant biliary stricture (DMBS) after failure of ERCP.

The aim of this study was to compare the efficacy, safety, cost, metallic stent patency, and rate of reintervention between EUS-BD and percutaneous metallic biliary drainage (PMBD) procedures in patients with DMBS after failed ERCP.

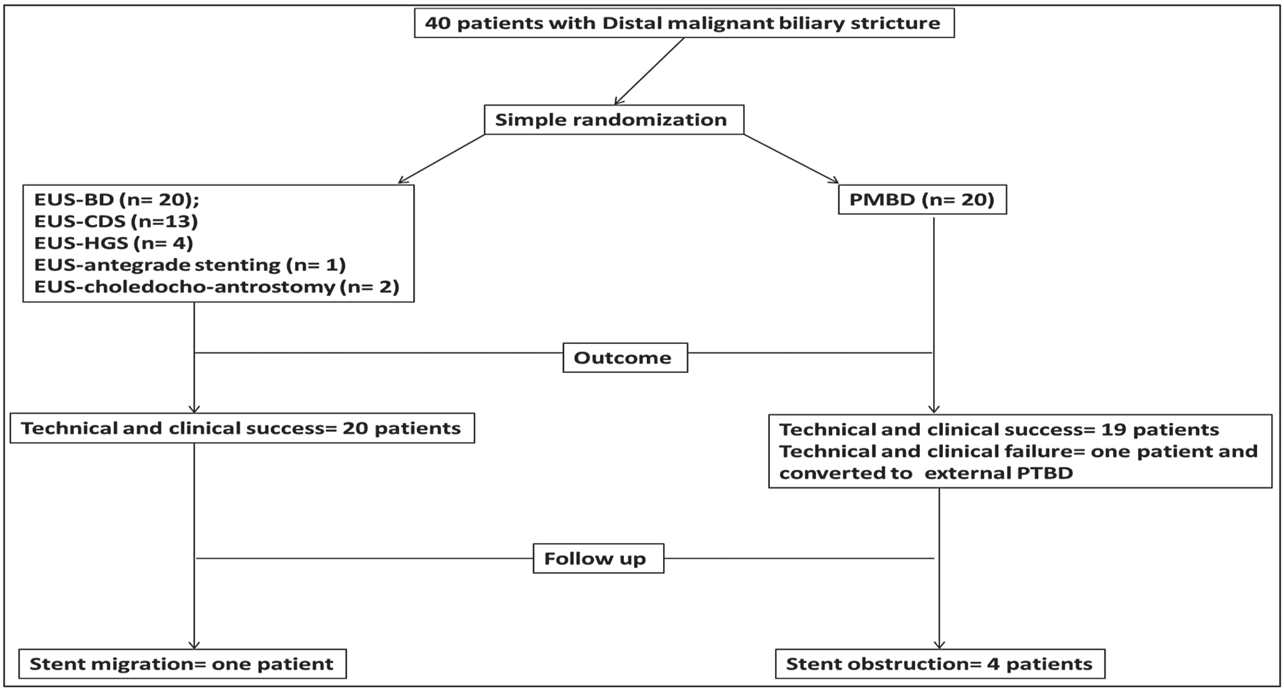
Patients and methods

This was a prospective comparative study that included 40 patients, comprising 22 males and 18 females, with age ranging from 46 to 74 years, with DMBS after failed ERCP attending to two tertiary centers with advanced interventional endoscopy services and advanced interventional Radiology Department over the period between December 2018 and December 2020 (Fig. 1). The diagnosis was confirmed by abdominal computed tomography and/or MRI.

After failure of ERCP, patients were randomly divided into two groups: group I (20 patients), which underwent the EUS-BD procedure, and group II (20 patients), which underwent the PMBD procedure. Allocation was conducted by a biometrician based on a predetermined list generated with a blocked randomization SPSS procedure with a fixed block size. To avoid possible bias, the study personnel involved in the recruitment and baseline assessment did not have access to the randomization lists and were not aware of the block size. On the contrary, the biometrician did not have an effect on the recruitment procedure.

Biliary cannulation was done by insertion of guidewire with sphincterotome via the papillae. The common bile duct (CBD) was visualized on the fluoroscopic image. Difficult of biliary cannulation is defined by one or more of the followings: five or more contact with the papillae attempting to cannulate it, more than 5 min spent to cannulate the papillae, and one or two unintended pancreatic duct cannulation or opacification. Then, precut was done with needle knife sphincterotomy but failed to cannulate the papillae through it [11].

Figure 1



Flow chart of the current study and outcome of both groups. Randomization was done initially after failure of ERCP. ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; EUS-CDS, endoscopic ultrasound-guided-choledochoduodenostomy; EUS-HGS, endoscopic ultrasound-guided-hepaticogastrostomy; PMBD, percutaneous metallic biliary drainage.

Table 1 Baseline characteristic differences among the studied group

	EUS-BD group	PMBD group	*P* value
Mean±SD age (years)	64.14±7.9	55.45±6.6	0.001*
Sex [*n* (%)]			
Female	10 (50)	8 (40)	0.525**
Male	10 (50)	12 (60)	
Causes of biliary obstruction			
Cholangiocarcinoma	0	7 (35)	
Pancreatic cancer	20 (100)	10 (50)	0.041***
Ampullary carcinoma	0	3 (15)	
Causes of ERCP failure			
Papillary infiltration	16 (80)	6 (30)	
Surgical cause	0	2 (10)	0.044***
Duodenal bulb obstruction	4 (20)	6 (30)	
Others	0	6 (30)	

ERCP, endoscopic retrograde cholangiopancreatography; EUS-BD, endoscopic ultrasound-guided biliary drainage, PMBD, percutaneous metallic biliary drainage. *Independent *t* test was used to compare the difference in mean between groups. **χ^2 test was used to compare the difference in frequency between groups. ***Monte-Carlo exact test was used to compare the difference in frequency between groups.

Failure of biliary cannulation after one or two trails of standard ERCP performed by an experienced endoscopist or inaccessible papillae owing to tumor invasion were the main indications for biliary drainage by EUS-BD or PMBD procedures in our study (Table 1).

Exclusion criteria included resectable, borderline, and hilar biliary obstructions involving the main confluence; moderate to tense ascites; coagulation disorders (platelet $<50\times10^3/\mu l$); international randomized ratio of more than 1.5; and/or patient refusal.

Ethical considerations

A written informed consent was obtained from each patient before inclusion into the study after detailed explanation about the intent of the study, the study procedures, potential associated risks, and adverse effects. The study protocol was approved by University Hospital IRB with the approval number IRB: 17200532 and Clinical Trials.gov identifier: NCT03195075.

Procedures

Endoscopic ultrasound-guided biliary drainage group

A single endoscopist specialist in the interventional EUS conducted EUS-BD procedures. With the patient under general anesthesia and in the left lateral position, EUS-BD was performed using a linear echoendoscope (EG-3870 UTK, Pentax, Japan) under fluoroscopic guidance (Table 2).

Table 2 Endoscopic ultrasound-guided biliary drainage related data of the studied patients

Parameters	Category	*N*=20 [*n* (%)]
Access site	Transgastric intrahepatic	5 (25)
	Transduodenal	13 (65)
	Transgastric (EUS-guided choledochoantrostomy)	2 (10)
EUS-BD technique	Antegrade stenting	1 (5)
	Choledochoantrostomy	2 (10)
	Choledochoduodenostomy	13 (65)
	Hepaticogastrostomy	4 (20)
Liver segment targeted	Not determined	1 (5)
	Segment II	2 (10)
	Segment III	2 (10)
Dilatation	Cystotome 6 F	19 (95)
	Mechanical dilatation	1 (5)
Stent length	6 cm	11 (55)
	8 cm	4 (20)
	10 cm	5 (25)

EUS-BD, endoscopic ultrasound-guided biliary drainage.

EUS-BD techniques included the following.

Endoscopic ultrasound-choledochoduodenostomy (13 patients)

The CBD was punctured with a 19-G fine-needle aspiration (FNA) (Wilson-Cook Company, Winston Salem, North Carolina, USA) under ultrasound guidance after visualization of the CBD via the duodenal bulb and absence of the interposing blood vessels using color Doppler. The stylet was extracted, the bile juice aspiration was confirmed, and contrast material for cholangiogram was injected. To prevent bile leakage and CBD collapse, the bile juice was aspirated as little as possible and for a shorter period of time. Afterward, a 0.035-inch guidewire (Wilson-Cook Company) was inserted under EUS and fluoroscopic guidance. FNA was changed for a 6-F cystotome (Endo-flex, GmbH, Voerde, Germany) that was used to dilate the fistulous tract with cut current, followed by insertion of a fully covered metallic stent 6 cm (Wilson-Cook Corporation) in one patient, partially covered metallic stent 6 cm (M.I.Tech, Hanar Stent, Endocare, Korea) in 10 patients, and two half-covered metallic stent in two patients. As an upward orientation was generally preferred with a corresponding decrease in the angle for transmural stent advancement over guidewire into the bile duct, a long scope position was desired to promote this procedure (Fig. 2).

In two patients with GOO, the CBD was punctured from the antrum (EUS-choledochoantrostomy) using a 19-G FNA with insertion of a partially covered metallic stent of 8 cm, using the same instruments used in endoscopic ultrasound-choledochoduodenostomy (EUS-CDS), which is a new technique in patients with GOO.

Endoscopic ultrasound-hepaticogastrostomy (four patients)

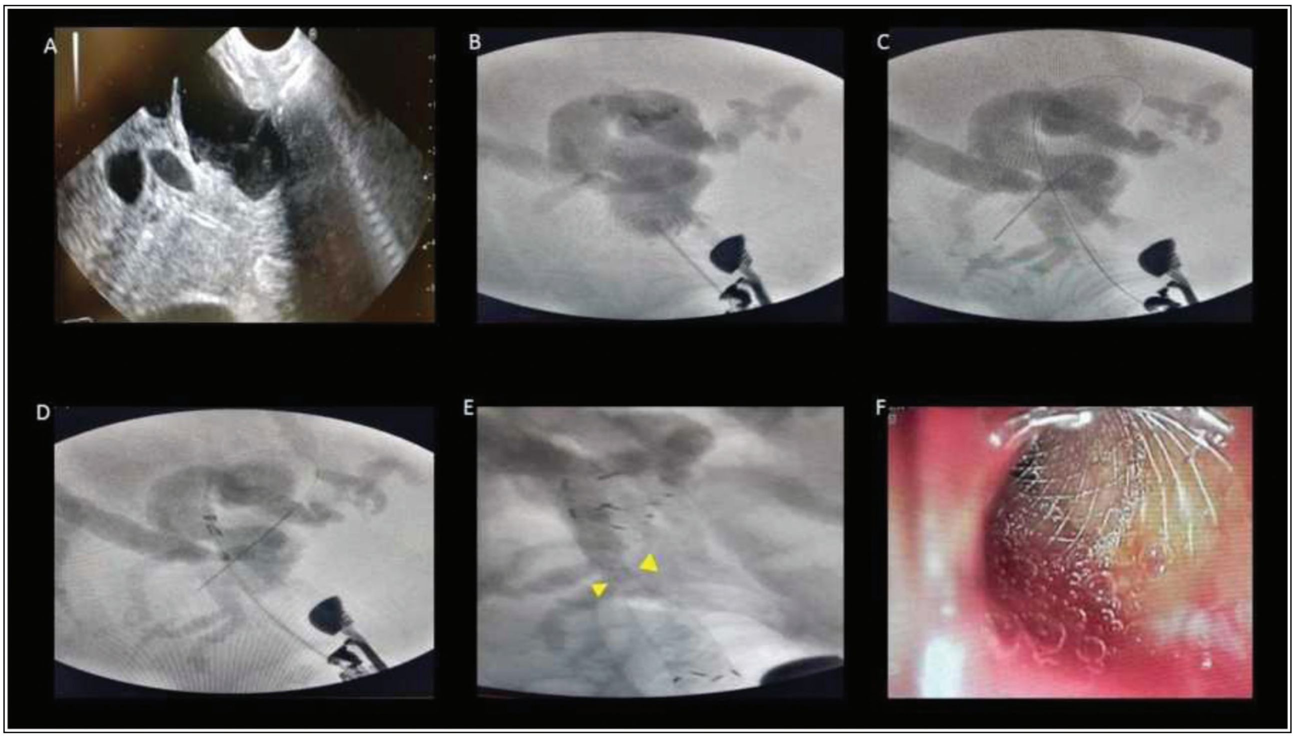
The left intrahepatic bile duct was visualized and punctured through the stomach with a 19-G FNA. Following that, a 0.025-inch guidewire was used in the left intrahepatic bile duct and the CBD. To prevent shearing of the guidewire, we often used a 0.035-inch guidewire with the tissue impaction process. Dilation of the fistulous tract was performed using a 6-F cystotome in three patients and a mechanical Sohendra dilator (Wilson-Cook Corporation) in one patient with insertion of three half-half metallic stents of 10 cm and one special hepaticogastrostomy (HGS) metallic stent (1/3 uncovered and 2/3 covered) 10 cm (M.I.Tech, Hanar Stent) in the other patients. When the luminal length of the stent was 3 cm or more, it was supposed to prevent early stent migration. Therefore, we usually preferred 10-cm metallic stents.

Endoscopic ultrasound-guided antegrade stenting (one patient)

In one patient, where the papilla was not accessible but the guidewire passed through the tumor stricture, EUS-guided antegrading stenting was chosen. The dilated left intrahepatic bile duct was identified transgastrically (B2) and punctured with a 19-G FNA, whereas the scope was placed in the gastric pouch. The use of repeated contrast injections helped to validate small intestine filling and to locate the biliary-enteric junction, which was followed by the insertion of a guidewire into the biliary tree and through the major papillae down to the duodenum. With the aid of a 6-F cystotome, the fistulous tract was dilated. Consequently, a partially covered metallic stent of 6 cm (M.I.Tech, Hanaro Stent) was deployed in an antegrade fashion advancing through the tumor stricture down into the duodenum.

PMBD: under the guidance of ultrasound, PMBD was performed in the fluoroscopy room under local anesthesia (1–2 percent xylocaine) and conscious sedation (midazolam and/or fentanyl). The dilated bile duct was punctured with a 21-18-G Chiba needle (15 cm, Cook Medical, Bloomington, Indiana,

Figure 2



EUS-guided choledochoduodenostomy: (a) EUS-guided targeting the CBD by FNA 19 G; (b) Cholangiogram showed marked dilated CBD and IHBC; (c) Guidewire manipulation deep to IBRD; (d) 6 cm 10 mm partial covered metallic stent was inserted after dilatation of the tract; (e) radiological imaging of the deployed metallic stent; (f) endoscopic imaging of the deployed stent. CBD, common bile duct; FNA, fine-needle aspiration; IHBC, intrahepatic biliary channels.

USA) under ultrasound assistance, and the procedure was continued under fluoroscopic guidance. After insertion of a 6-F short angiographic sheath into the biliary channels, contrast material was injected for cholangiogram. To pass through the tumor stricture and down to the duodenum, we used a 0.035-inch angled hydrophilic guidewire (Radifocus Guide Wire M; Terumo, Tokyo, Japan) with or without an angled angiographic catheter. We put an external drainage catheter 8-F (Ultrathane, Cook Medical) in the CBD for a few days (3–6 days) if the aspirated bile appeared contaminated, which decreases inflammation and edema and increases the chances of passage of the guidewire through the tumor stricture. With the injection of contrast material, the length of the tumor stricture was measured. A high-pressure angioplasty balloon (8 mm in diameter; Wanda, Boston Scientific, Galaway, Ireland) was inflated for 10 s at the tumor stricture to dilate it. A self-expandable, partially covered metallic Wallstent (Boston Scientific Nordic AB, Helsingborg, Sweden) measuring 8 mm×80 mm (14 patients), 10 mm×68 mm (four patients), and 10 mm×94 mm (two patients) was implanted. The distal end of stent was extended with a safety margin (few millimeters) into the duodenum. If we found stent collapse after stent deployment, we performed postdeployment dilatation with the same balloon used for stricture dilatation to achieve adequate drainage with full expansion of the stent (Fig. 3).

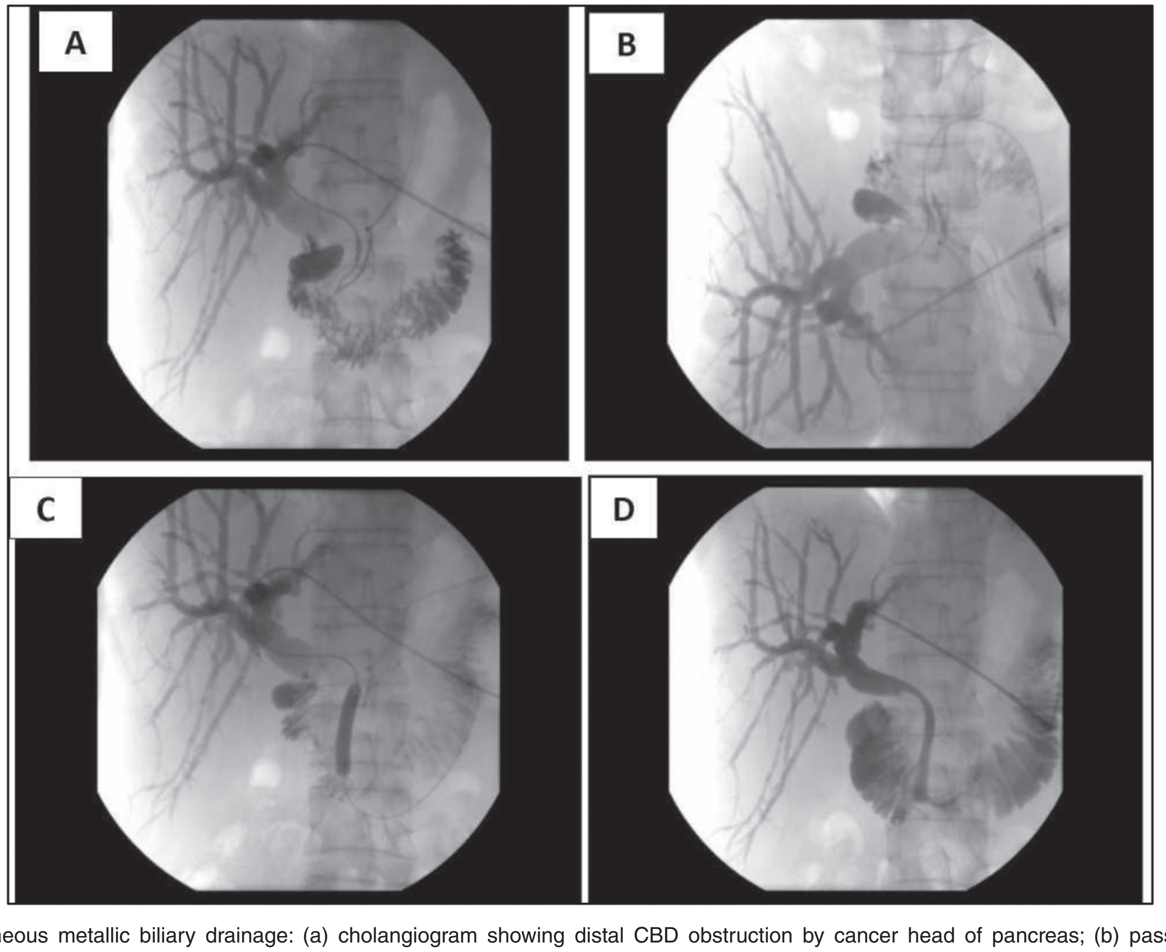
Follow up: all patients were followed up for 6 months after the procedure.

Data management

Endoscopically and/or radiologically determined stent placement into the biliary radicals in the desired position is described as technical success. Clinical success is described as a drop in total serum bilirubin level of more than 50% from the preprocedural level within 14 days of stent placement. Stent patency was described as the time between stent insertion and the need for unplanned reintervention.

Procedure costs, anesthesia, accessories, medications, hospital stay, and all subsequent procedures all contributed to the total cost.

Figure 3



Percutaneous metallic biliary drainage: (a) cholangiogram showing distal CBD obstruction by cancer head of pancreas; (b) passing the duodenum with the guidewire and angiographic catheter through the tumor stricture; (c) balloon dilation; (d) metallic stent placed through the tumor stent. CBD, common bile duct.

Statistical analysis

The researcher checked the data, coded it, and ran it through the Statistical Package for the Social Sciences (IBM-SPSS/PC/ver. 24, Armonk, New York, USA). The following descriptive statistics were calculated: mean SD, frequency, and percentage. χ^2 test and Fisher's exact test of significance were used to compare the differences in frequency distribution among different classes. To test the differences in mean/median for continuous variables between classes, the Student *t* test and Mann–Whitney *U* test were used (parametric and nonparametric). A *P* value of less than 0.05 was deemed significant.

Results

The baseline characteristics of both EUS-BD and PMBD patients are shown in Table 1.

Pancreatic carcinoma was the most common cause of DMBS, followed by distal cholangiocarcinoma and ampullary carcinoma. Failed ERCP was due to papillary infiltration and difficult biliary cannulation in most of cases, gastroduodenal invasion by the tumor, inability to pass through the tumor stricture after successful CBD cannulation, and previous gastroduodenal surgery (Table 1).

Technical success

While all patients in EUS-BD group had technical success, in PMBD group, we had succeeded to insert metallic stents percutaneously except in one (5%) patient due to failure of passage of the guidewire through the stricture due to tight stricture (100 vs. 95%, *P*=0.897), with no statistically significant difference between both groups.

Clinical success

In EUS-BD group, all patients who experienced technical success had comparable clinical success rate (18.72 ± 7.6 vs. 6.15 ± 0.8 mg/dl) (100%). In PMBD group, clinical success was not achieved in one (5%) patient (14.67 ± 3.9 vs. 5.01 ± 0.4 mg/dl) (5%) owing to long-standing biliary obstruction and worsening general condition from the primary disease with no substantial statistical difference between both groups.

Early complications

Endoscopic ultrasound-guided biliary drainage group

Bile leakage was encountered in two patients, which was mild in amount and subhepatic. It was managed conservatively in one patient, whereas percutaneous pigtail drainage was needed in the other patient.

Percutaneous metallic biliary drainage group

Postprocedural cholangitis was identified in four patients, and bile leakage occurred in three patients, which stopped spontaneously after 4 days with only antibiotics (Table 3).

After the procedures, neither group's patients experienced intraperitoneal hemorrhage or major hemobilia.

Cost of the procedure

The mean cumulative cost of EUS-BD procedure was 964.32 ± 79.8$, whereas the mean cumulative cost of PMBD procedure was 1098.61 ± 84.5$. This difference

Table 3 Technique-related data differences among the studied groups

	EUS-BD group	PMBD group	*P* value
Success rates [*n* (%)]			
Technical	20 (100)	19 (95)	0.897*
Clinical	20 (100)	19 (95)	
Mean procedure time (min)	20.27 ± 9.8	37.15 ± 6.4	<0.001**
Complications [*n* (%)]			
No	18 (90)	15 (75)	0.212*
Yes	2 (10)	5 (25)	
Hospital stay (days)	1.65 ± 0.2	3.35 ± 0.3	<0.001***
Cumulative cost (dollar)	964.32 ± 79.8	1098.61 ± 84.5	0.035***
Procedure cost (dollar)	888.89 ± 32.45	670.84 ± 34.34	<0.001***
Stent patency [*n* (%)]			
Stent patent	20 (100)	16 (80)	0.035%
Stent obstruction	0	4 (20)	
Causes of reintervention [*n* (%)]			
Stent obstruction	0	4 (20)	0.171%
Stent migration	1 (5)	0	

EUS-BD, endoscopic ultrasound-guided biliary drainage; PMBD, percutaneous metallic biliary drainage. *χ^2 test was used to compare the difference in frequency between groups. **Mann–Whitney *U* test was used to compare the difference in median between groups. ***Independent *t* test was used to compare the difference in mean between groups. %Fisher's exact test was used to compare the difference in frequency between groups.

Table 4 Technical, clinical success rates, and clinical outcomes in the previous studies

Study (event/total cases)	Technical success		Clinical success		Reintervention		Cost of total procedure	
	EUS-CDS	PTBD	EUS-CDS	PTBD	EUS-CDS	PTBD	EUS-CDS	PTBD
Artifon *et al.* [2]	13/13	12/12	13/13	12/12	NA	NA	USD5673	USD7570
Bapaye *et al.* [15]	23/25	26/26	23/25	26/26	NA	NA	NA	NA
Khashab *et al.* [16]	19/22	51/51	19/19	47/51	3/19	41/51	USD9218	USD18261
Giovannini *et al.* [17]	19/20	17/17	18/19	17/17	NA	NA	NA	NA
Lee *et al.* [18]	32/34	31/32	28/32	27/31	11/32	29/31	NA	NA
Sharaiha *et al.* [19]	43/47	12/13	27/43	3/12	NA	NA	NA	NA

EUS-CDS, endoscopic ultrasound-choledochoduodenostomy; NA, not available; PTBD, percutaneous transhepatic biliary drainage; USD, United States dollar [20].

was related to the hospital stay, which was shorter in the EUS-BD group than in the PMBD group (1.65 ± 0.2 vs. 3.35 ± 0.3 days, P<0.001). Repeated biliary reintervention and restenting after stent obstruction were seen more in the PMBD group (Table 3).

Duration of procedure

The mean duration of EUS-BD procedure was significantly shorter than that of PMBD procedure (20.27 ± 9.8 vs. 37.15 ± 6.4 min with P<0.001) (Table 3).

Late complications

Stent obstruction was identified in four patients in PMBD group at 2, 3, and 5 months after procedure. The causes of stent obstruction were owing to tumor overgrowth (two patients at the proximal end and the other at the distal end of the stent) and biliary sludge inside the stent in one patient. Restenting was done with relief of obstruction. However, in the EUS-BD group, after 2 weeks, one patient in EUS-CDS with fully covered metallic stent experienced stent migration (Table 3).

Discussion

CBD cannulation by ERCP by an experienced endoscopist is achieved in more than 95% of cases with DMBS. When biliary access fails owing to difficult cannulation, distorted papilla, GOO, abnormal anatomy, or periampullary diverticulum [12], EUS-BD has been increasingly used as a less-invasive technique compared with surgery or interventional radiology [5].

To our knowledge, in Egypt, there was only one study reported about EUS-BD technique [13]. This procedure is relatively less common in Egypt owing to high cost and lack of trained centers and accessories. This study is the first Egyptian experience of comparison between EUS-BD and PMBD procedures for DMBS to compare between both procedures regarding technical success rate, clinical success rate, complications, cost, and metallic stent patency.

Both EUS-BD and PMBD procedures are technically and clinically successful procedures, according to the current study, with technical success rates of 100 and 95%, respectively (P=0.897), and clinical success rates of 100 and 95%, respectively, (P=0.897). Although the technical and clinical success rates in EUS-BD were higher than in PMBD, there was no statistically significant difference between both groups.

This agrees with a recent study done by Iwashita *et al.* [14], despite them comparing EUS-antegrade stenting to external PTBD regarding the technical success rate (97.1 vs. 96.6%, respectively; P=1.00) and the clinical success rate (97.1 vs. 93.1%, respectively; P=0.586). Lee *et al.* [18] compared EUS-CDS and HGS with external PTBD for distal malignant biliary obstruction after failed ERCP. Their result was comparable, as the technical success rates were 94.1 and 96.9%, respectively, and the clinical success rates were 87.5 and 87.1%, respectively, but with a higher adverse rate in the PTBD group (8.8 vs. 31.2%) (Table 4).

In comparison with EUS-BD, PMBD has a lower technical success rate, as the guidewire should pass through the tumor stricture before stent deployment, and if the guidewire failed to pass through the stricture owing to tight stricture, the procedure was changed to external percutaneous biliary drainage, as was done in one patient in the current study.

The ability to access the biliary radicles through multiple routes is another benefit of EUS-BD procedures. The dilated intrahepatic bile ducts can be reached through the stomach (EUS-HGS and EUS-guided antegrade stenting), or the CBD can be punctured through the proximal duodenum (EUS-CDS) or the gastric antrum (EUS-choledochoantrostomy), which is a new technique in patients with GOO. Moreover, in patients with mild ascites and liver metastasis, the EUS-BD procedure could be done.

The current study demonstrated that complications were significantly lower in EUS-BD compared with PMBD (10 vs. 25%, P=0.212), which may be owing to two stages of PMBD procedure and repeated biliary drainage owing to stent obstruction. According to Iwashita *et al.* [14], the adverse events in EUS-antegrade stenting and PTBD groups with stenting were 11.7 and 27.6%, respectively (P=0.119), with half of these adverse events due to external drainage catheter complications. In another retrospective study, Sportes *et al.* [21] found no significant difference between EUS-HGS and PTBD for distal malignant obstructive jaundice after failure of ERCP in terms of technical success rate (100 vs. 100%), clinical success rate (86 vs. 83%), or adverse effects (16 vs. 10%).

On average, the PMBD group used longer fluoroscopic time than the EUS-BD group (37.15 ± 6.4 vs. 20.27 ± 9.8 min, P<0.001). This is similar to the study by Sharaiha *et al.* [19], which demonstrated that the PTBD group used longer fluoroscopic time than the EUS-BD group (26.1 vs. 13.8 min, respectively; P=0.002).

Similarly, in our study, the PMBD group had a longer hospital stay than the EUS-BD group (3.35 ± 0.3 vs. 2.0 ± 0.2 days, P<0.001) owing to minor limited complications of the EUS-BD procedure and early discharge of the patients of EUS-BD. In the study by Khashab *et al.* [16], the period of stay was 4.6 days in the EUS-BD group and 4.2 days in the PTBD group (P=0.59). Sharaiha *et al.* [19] conducted another study that found no significant difference in the duration of stay between the two groups. In addition, our study found that the hospital stay in EUS-HGS was longer than in EUS-CDS (3 ± 0.3 vs. 2 ± 0.2 days) to detect early stent migration.

In the current study, the rate of stent obstruction was significantly higher in the PMBD group than in the EUS-BD group (20 vs. 0%, P=0.035), and the rate of biliary reintervention was significantly lower in the EUS-BD group than in the PMBD group (5 vs. 20%, P=0.171). Four patients in the PMBD group needed reintervention owing to stent obstruction through either tumor overgrowth at the proximal or distal end of the stent or biliary sludge. Stent migration occurred in one patient in the EUS-CDS group, with a fully covered metallic stent after 2 weeks of the procedure, here subsequent insertion of a 10-F, 12-cm plastic stent was done by ERCP through the choledochoduodenal fistula. This is in contrast to the study by Khashab *et al.* [16], which demonstrated that the mean stent patency in EUS-BD patients (198 days) was similar to PTBD patients (184 days, P=0.86) and the time to exchange the stent for unplanned events was not different (P=0.3) (Table 4).

The cause of stent obstruction in PMBD group was primarily related to the technique of placement of the metallic stent through the tumor stricture with stent obstruction due to tumor overgrowth at either the proximal or the distal end of the stent. Compared with the PMBD procedure, the higher stent patency in EUS-BD group may be owing to the fact that the stent does not traverse through the tumor stricture as the fistula tract is located outside the tumor stricture, thereby reducing the risk of tumor overgrowth or ingrowth that ultimately leads to stent obstruction and recurrent biliary reintervention unlike PMBD procedures [22].

The patency rate is about 70% at 6 months and 50% at 1 year for uncovered metallic stents [23]. Fully covered metallic stents have a range of disadvantages over partially covered metallic stents, including higher cost, higher rate of stent migration, occlusion of side-branches of biliary radicals with proximal stricture, occlusion of the cystic duct, leading to cholecystitis, and occlusion of the pancreatic duct orifice leading to pancreatitis [24]. Higher rate of stent obstruction of uncovered metallic stent occurred through tumor ingrowth inside the stent [25].

As a result, we preferred to use partially covered metallic stents in PMBD procedures in our study.

Recurrent biliary obstruction owing to stent obstruction in PMBD procedure is a major cause of interruption of treatment in patients undergoing chemotherapy, so EUS-BD is the preferred procedure for biliary drainage in patients with DMBS receiving neoadjuvant or palliative chemotherapy.

In comparison to the cost of both procedures without adding any additional costs such as hospital stay and need to repeated biliary reintervention due to stent obstruction; the cost of EUS-BD procedure was significantly higher than that of the PMBD procedure (888.89 ± 32.45$ vs. 670.84 ± 34.34$, P<0.001).

However, secondary to stent obstruction, longer hospital stay, and a higher rate of reintervention of PMBD procedure in the current study, the cumulative charges of PMBD group were higher than that of EUS-BD group (1098.61$ vs. 964.32$, P=0.035). According to Khashab *et al.* [16], the PTBD group had a significantly higher reintervention rate (scheduled and unscheduled) (80.4 vs. 15.7%, P<0.001), and overall costs, of both index procedure and re-interventions, were more than two times higher than the EUS-BD group (P=0.004) (Table 4).

Internal PMBD has a number of advantages, including long-term catheter-free survival and prevention of external drainage catheter complications such as insertion site discomfort, catheter dislocation or failure, frequent biliary drainages, patient frustration with the appearance of the indwelling external catheter, bile leakage, and retained bile secretion for digestion and nutrient absorption within the gastrointestinal tract.

The widespread experience in PMBD as well as the availability of accessories and possibility of performance under local anesthesia are advantages of it over EUS-BD. Furthermore, unlike the EUS-BD procedure, PMBD maintains the anatomic integrity of the biliary tree and avoids the formation of a fistula.

The ability to penetrate the bile ducts when the papilla is not readily accessible endoscopically is one of the benefits of the EUS-BD procedure. After failure of ERCP, it is possible to convert to EUS-BD in the same session, saving time and preventing delay. The efficacy of EUS-BD in patients with mild ascites, liver metastasis, and GOO as well as the fact that EUS-BD will allow for longer stent patency, all are other significant advantages of EUS-BD over the PMBD procedure.

The cost and nonavailability of accessories such as stent with antimigration properties and guidewire that resist shearing are challenges for endoscopists who perform the EUS-BD procedure. Endoscopic centers with advanced equipment, expertise, and a multidisciplinary team of endoscopist, interventional radiologists, and surgeons are required for the EUS-BD procedure.

This study has some limitations. First, our study only included a small number of patients with EUS-BD and PMBD procedures. Second, as our study focused on patients with DMBS, we were unable to comment on the effectiveness and safety of the EUS-BD procedures in the treatment of proximal biliary stricture or benign biliary obstruction. Third, we preferred to use partially covered metallic stents during PMBD procedures, so larger multicenter randomized trails would be welcome to establish the therapeutic and safety of the partially covered metallic stent before this stent is accepted as a standard stent in PMBD procedures.

Conclusion

After failure of ERCP, EUS-BD and PMBD procedures are both technically and clinically useful methods for biliary drainage in patients with DMBS. Compared with the PMBD procedure, EUS-BD is linked to shorter fluoroscopy duration, less minor complications, longer stent patency, a lower rate of re-interventions, and a lower cost. Our results indicate that for these patients with DMBS after failure of ERCP, EUS-BD is the preferred procedure if qualified endoscopists are available.

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Conflicts of interest

There are no conflicts of interest.

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