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Evaluation of exclusive internal endoscopic drainage for complex biloma with transluminal and transpapillary stenting

Authors
Jun Sakamoto[1], Takeshi Ogura[2], Saori Ueno[2], Atsushi Okuda[2], Nobu Nishioka[2], Akitoshi Hakoda[2], Yuki Uba[1], Mitsuki Tomita[1], Nobuhiro Hattori[2], Junichi Nakamura[1], Kimi Bessho[1], Hiroki Nishikawa[1]

Institutions
1 2nd Department of Internal Medicine, Osaka Medical and Pharmaceutical University, Takatsuki-shi, Japan
2 2nd Department of Internal Medicine, Osaka Medical College, Takatsuki-shi, Japan

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Corresponding author
Dr. Takeshi Ogura, Osaka Medical College, 2nd Department of Internal Medicine, 2-7 Daigaku-machi , 569-8686 Takatsuki-shi, Japan
oguratakeshi0411@yahoo.co.jp

ABSTRACT

Background and study aims Biloma is treated endoscopically with endoscopic retrograde cholangiography (ERCP) or endoscopi ultrasound-guided transluminal biloma drainage (EUS-TBD). However, almost all previous studies have used both internal and external drainage. External drainage has the disadvantages of poor cosmetic appearance and self-tube removal. The aim of the present study was to evaluate the internal endoscopic drainage for complex biloma after hepatobiliary surgery with an ERCP- or EUS-guided approach, without external drainage.

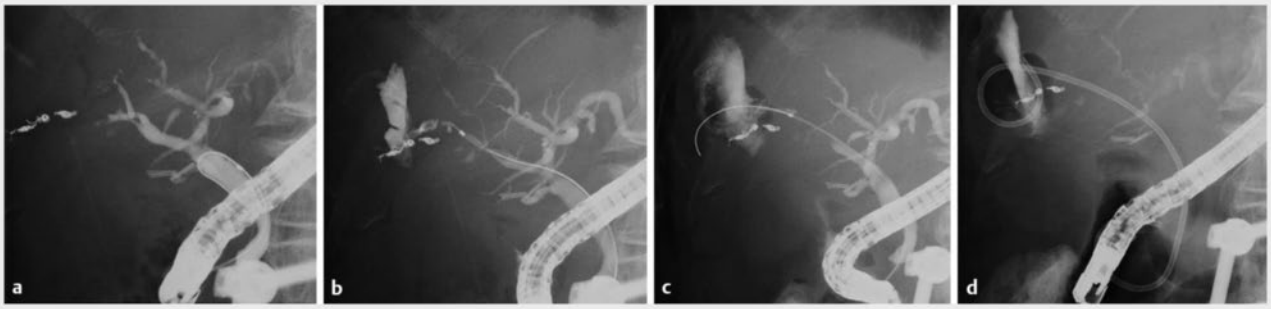
Patients and methods This retrospective study included consecutive patients who had bilomas. A 7F plastic stent was deployed from the biloma to the duodenum in the ERCP group and the metal stent was deployed from the biloma to the stomach in the EUS-TBD group.

Results Forty-seven patients were enrolled. The technical success rate was similar between the groups (ERCP 94% vs EUS-TBD 100%, $P=0.371$); however, mean procedure time was significantly shorter in the EUS-TBD group (16.9 minutes) than in the ERCP group (26.6 minutes) ($P=0.009$). The clinical success rate was 87% (25 of 32 patients) in the ERCP group and 84% (11 of 13 patients) in the EUS-TBD group ($P=0.482$). The duration of median hospital stay was significantly shorter in the EUS-TBD group (22 days) than in the ERCP group (46 days) ($P=0.038$). There was no significant difference in procedure-associated adverse events between the groups.

Conclusions In conclusion, ERCP and EUS-TBD are complementary techniques, each with its own merits in specific clinical scenarios. If both techniques can be performed, EUS-TBD should be considered because of the short times for the procedure, hospital stay. and biloma resolution.

Introduction

Biloma, which is an encapsulated collection of bile juice within the abdominal cavity, can occur after hepatobiliary surgery such as partial liver resection, pancreatoduodenostomy, or laparoscopic cholecystectomy [1, 2]. Although most bilomas resolve with conservative treatment, abdominal pain, fullness, fever, jaundice, or peritonitis may be observed in symptomatic patients [3]. Therefore, drainage should be considered in such cases, selected from among percutaneous, endoscopic, or surgical drainage techniques. Compared with the percutaneous and surgical approaches, endoscopic drainage under endoscopic retrograde cholangiopancreatography (ERCP) has the advantages of being less invasive for the patient and enabling



▶ **Fig. 1** **a** Successful biliary cannulation and deployment of a 0.025-inch guidewire. **b** The contrast medium is injected to evaluate the site of bile leakage. **c** Insertion of the guidewire into the biloma is attempted. **d** Finally, a 7F plastic stent is deployed from the biloma to the duodenum.

evaluation of the point of bile leakage. Conventional endoscopic treatments for biloma include biliary stenting, endoscopic sphincterotomy, and nasal biliary drainage [4]. According to a previous study, success rates for the endoscopic approach range from 90% to 97% [5]; however, this technique is much more challenging in the case of complex biloma, such as the presence of a long bile defect, hilar or intrahepatic leaks, or surgically altered anatomy, for which the mortality rate is reportedly up to 18% [6]. Endoscopic ultrasound (EUS)-guided drainage techniques for biliary obstruction, pancreatic fluid collection, and cholecystitis have recently emerged [7, 8, 9]. EUS-guided transluminal biloma drainage (EUS-TBD) has also been reported [10, 11, 12, 13, 14, 15, 16, 17]. However, almost all previous studies regarding the endoscopic approach have used both internal and external drainage. In addition, a plastic stent is used in EUS-TBD, which is less effective than a self-expandable metal stent (SEMS) in terms of drainage effect. External drainage has the disadvantages of poor cosmetic appearance and self-tube removal. To overcome these issues, we perform endoscopic management using internal drainage alone, and deploy fully covered SEMS (FCSEMS), especially for EUS-TBD. The aim of the present study was to evaluate the feasibility and safety of internal endoscopic drainage for complex biloma after hepatobiliary surgery, by the ERCP- or EUS-guided approach, without external drainage.

Patients and methods

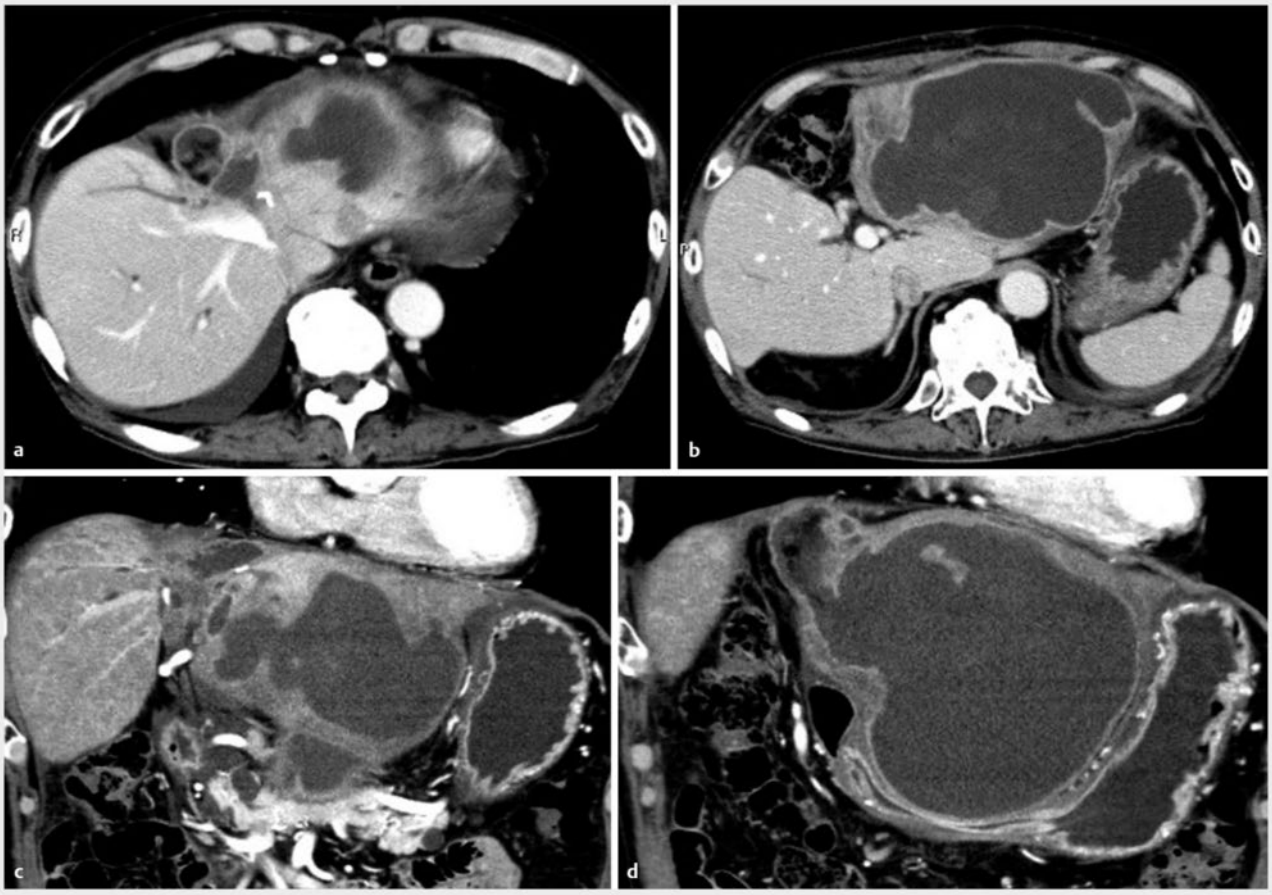
This retrospective study included consecutive patients who had complicated biloma between January 2014 and October 2022. The inclusion criteria were an initial attempt by internal drainage alone and the presence of biloma due to surgery. Patients who underwent external drainage for biloma by any other technique, such as percutaneous drainage, were excluded. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in the a priori approval given by the Human Research Committee at Osaka Medical College (IRB No. 2022–210).

Endoscopic procedures and internal drainage devices

As per our drainage strategy, biloma was evaluated by EUS prior to drainage. If the biloma could be clearly identified on EUS and a safe puncture route could be obtained in patients with surgically altered anatomy, EUS-TBD was the first choice of procedure. If no biloma could be identified, drainage under ERCP guidance was the first choice.

For drainage under ERCP guidance, a duodenoscope (JF260V, Olympus Optical, Tokyo, Japan) was inserted into the duodenum. Biliary cannulation using a standard ERCP catheter (MTW Endoskopie, Düsseldorf, Germany) was then attempted. After successful biliary cannulation and deployment of a 0.025-inch guidewire (VisiGlide, Olympus) (▶ **Fig. 1a**), contrast medium was injected to evaluate the site of bile leakage (▶ **Fig. 1b**). Insertion of the guidewire into the biloma was then attempted (▶ **Fig. 1c**). Finally, a 7F double plastic stent was deployed from the biloma to the duodenum (▶ **Fig. 1d**).

▶ **Fig. 2** shows a computed tomography (CT) image of biloma that occurred after partial hepatectomy. For drainage under EUS guidance, an echoendoscope (UCT 260, Olympus) was inserted into the stomach. The biloma was punctured using a 19G needle (Sono Tip Pro Control 19G; Medi-Globe GmbH, Rosenheim, Germany, or EZ Shot 3 Plus; Olympus) with color Doppler guidance to avoid puncturing any intervening vessels, and contrast medium was injected (▶ **Fig. 3a**). After the 0.025-inch guidewire was deployed within the biloma (▶ **Fig. 3b**), the stomach and biloma wall were dilated using a 4-mm balloon catheter (REN biliary balloon catheter; Kaneka, Osaka, Japan) (▶ **Fig. 3c**). Finally, a fully-covered self-expandable metal stent (FCSEMS) (10 mm×8 cm, Bonastent; Standard Sci Tech, Seoul, South Korea) was deployed (▶ **Fig. 3d**). In all patients who underwent EUS-TBD or drainage under ERCP guidance, biloma size was evaluated by CT on the day after the procedure (▶ **Fig. 3e**). For both procedures, in the case of persistent symptoms with inadequate decrease in the size of the biloma or inadequate resolution of inflammation, additional stenting with a pigtail plastic stent or necrosectomy was considered. Stent removal was considered if clinical success was obtained.



▶ **Fig. 2** Computed tomography imaging of biloma. Huge bimola connected to surgical resection site is observed (**a**, **c** sagittal; **c**, **d** coronal).

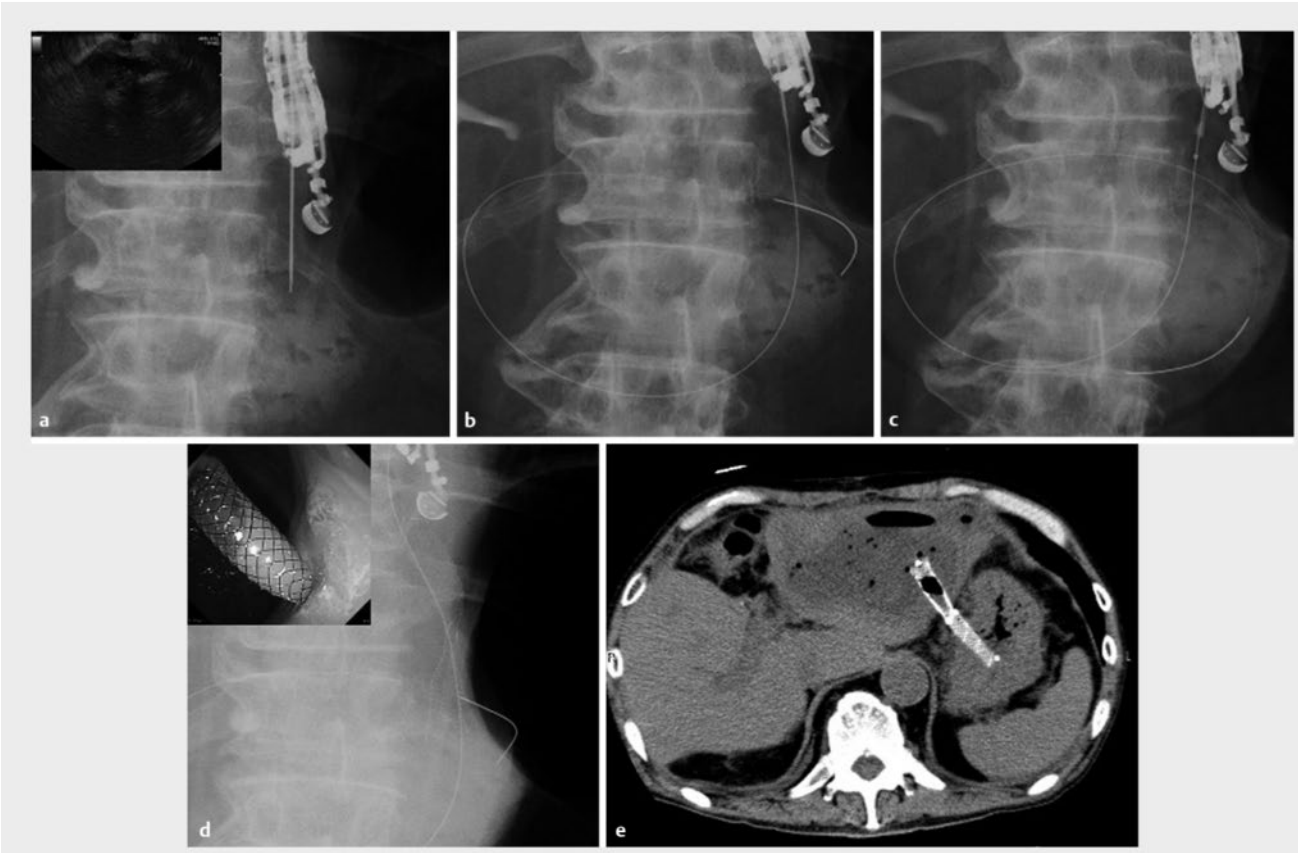
Definitions, outcomes, and statistical analysis

The primary outcome of this study was the technical success rate for endoscopic stenting during ERCP and EUS. Technical success was defined as successful stenting from the biloma to the duodenum in ERCP, and to the stomach in EUS-TBD. Secondary outcomes were the evaluated clinical success rate and the rate of adverse events (AEs) associated with these procedures. The final clinical success rate was defined as a complete or partial decrease in biloma size (>50% reduction in diameter and size < 3 cm in maximum diameter of the biloma on cross-sectional CT) without adding external drainage and disappearance of symptoms such as abdominal pain and fever, with resolution of inflammation on blood examination during clinical follow-up [16, 17]. AEs associated with the procedures were evaluated using the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon [18]. Biloma diameter was measured on CT at the maximum diameter. Procedure time was measured from endoscope insertion to removal. Duration of hospital stay was measured from the day of biloma drainage. The follow-up period was measured from the day of biloma drainage to the last follow-up day. Descriptive statistics are presented as the mean±standard deviation (SD) or as the median and range for continuous variables, and as the frequency for categorical variables. In univariate analysis, the x^2 or Fisher's exact test was used for categorical variables and the Mann–Whitney test or Student's *t* test was used for continuous variables. All data were statistically analyzed using SPSS version 13.0 statistical software (SPSS, Chicago, Illinois, United States).

Results

Patients

A total of 54 patients were enrolled. All patients first underwent EUS. Among them, bilomas could not be identified in 41 patients by EUS; therefore, they underwent ERCP. In this group, bilomas also could not be detected by cholangiogram; therefore, they underwent surgical treatment. In total, 34 patients underwent biloma drainage during ERCP (median age, 73.5 years; 25 males, 9 females; ERCP group). EUS-TBD was successfully performed in 13 patients (median age, 76 years; 8 males, 5 females; EUS-TBD group). ▶ **Table 1** lists patient demographic and clinical characteristics. The primary diseases were hepatocellular carcinoma (n = 18), metastatic liver tumor (n = 11), gallbladder stone (n = 5), and other (n = 13). The main types of surgery prior to complicating biloma were partial hepatectomy (n = 26) and right or left hepatectomy (n = 10). There was no sig-



▶ **Fig. 3** **a** Doppler to avoid puncturing any intervening vessels, and contrast medium is injected. **b** After the 0.025-inch guidewire is deployed within the biloma. **c** The stomach and biloma wall are dilated using a 4-mm balloon catheter. **d** Finally, a fully covered self-expandable metal stent is deployed.

nificant difference in disease type or surgery type between the two groups. There was no significant difference in median biloma diameter between the ERCP group (90 mm) and the EUS-TBD group (93 mm) ($P = 0.700$). Biloma was observed at a median of 20.5 days after surgery in the ERCP group and at 23 days in the EUS-TBD group ($P = 0.626$). The mean values of inflammatory indices prior to biloma drainage were white blood count, 7556.8±4706 and 10803.1±6128.9 /mm^3 ($P = 0.212$) and C-reactive protein, 7.78±6.83 and 11.6±8.89 mg/L ($P = 0.096$) in the ERCP and EUS-TBD groups, respectively. There was no significant difference between the groups in terms of hemoglobin, total bilirubin, aspartate aminotransferase, or alanine aminotransferase.

Procedure outcomes

▶ **Table 2** shows the results of biloma drainage. In the ERCP group, stent deployment was successful in 34 of 36 patients and failed in two patients due to inability to identify the site of bile leakage on cholangiography despite successful biliary cannulation. These two patients underwent percutaneous biloma drainage. Stent deployment was successful in all 13 patients in the EUS-TBD group. Therefore, the technical success rate was similar between the groups ($P = 0.371$); however, median procedure time was significantly shorter in the EUS-TBD group (16 minutes) than in the ERCP group (26 minutes) ($P = 0.009$). There was no significant difference in procedure-associated AEs between the groups and all AEs resolved with conservative treatment.

After initial biloma drainage, median biloma diameter was significantly smaller in the EUS-TBD group (45.5 mm) than in the ERCP group (61.6 mm) ($P = 0.022$). The mean number of endoscopic sessions required was higher in the ERCP group (2.14 times) than in the EUS-TBD group (1.62 times), although the difference was not significant ($P = 0.170$). The median duration of stent deployment was shorter in the EUS-TBD group (32.5 days) than the ERCP group (50 days), which was also not significant ($P = 0.601$). The clinical success rate was 87% (25 of 32 patients) in the ERCP group and 84% (11 of 13 patients) in the EUS-TBD group. Of the patients in the ERCP group for whom clinical success was not achieved, six underwent additional percutaneous biloma drainage and one died due to sepsis. Among the corresponding patients in the EUS-TBD group, one underwent additional percutaneous biloma drainage and one died due to sepsis. The duration of median hospital stay was significantly shorter in the EUS-TBD group (22 days) than the ERCP group (46 days) (P = 0.038). No stent migration or dislocation was observed in any patient in either group prior to

▶ **Table 1** Patient characteristics.

	ERCP	EUS	*P* value
Total patients (n)	34	13	–
Median age (y, range)	73.5 (47–83)	76 (66–90)	0.105
Sex (male:female)	25/9	8/5	0.421
Disease, n			0.234
▪ Metastatic liver tumor	10	1	
▪ Hepatocellular carcinoma	13	5	
▪ Gallbladder stone	4	1	
▪ Others	7	6	
Kinds of surgery			0.217
▪ Partial hepatectomy	16	10	
▪ Right hepatectomy	5	2	
▪ Left hepatectomy	2	1	
▪ Pancreatoduodenostomy	4	0	
▪ Cholecystectomy	7	0	
Median diameter of biloma (mm, range)	90 (31–145.7)	93 (31–153)	0.700
Median days between surgery and drainage (range)	20.5 (7–73)	23 (7–58)	0.626
WBC (/μL, mean±SD)	7756.8 ± 4706.7	10803.1 ± 6128.9	0.212
CRP (mg/dL, mean±SD)	7.78 ± 6.83	11.6 ± 8.89	0.096
Hb (mg/dL, mean±SD)	10.5 ± 1.85	10.7 ± 1.58	0.625
T-Bil (mg/dL, mean±SD)	2.41 ± 3.46	1.62 ± 1.37	0.757
AST (U/L, mean±SD)	65.4 ± 118.0	45.0 ± 25.6	0.830
ALT (U/L, mean±SD)	75.1 ± 158.8	46.2 ± 28.7	0.295

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; WBC, white blood cell; SD, standard deviation; CRP, C-reactive protein; Hb, hemoglobin; T-Bil, total bilirubin; AST, aspartate aminotransferase; ALT, alanine aminotransferase.

▶ **Table 2** Procedure results.

	ERCP	EUS	*P* value
Technical success rate, % (n)	94 (32/34)	100 (13/13)	0.371
Median size of biloma after initial drainage (mm, range)	61.6 (23.7–113.6)	45.5 (20–55.5)	0.022
Median procedure time (min, range)	26 (11–50)	16 (8–21)	0.009
Number of sessions (mean±SD)	2.14 ± 1.44	1.62 ± 0.91	0.170
Clinical success rate, % (n)	87 (25/32)	84 (11/13)	0.482
Median period of stent deployment (day, range)	50 (8–260)	32.5 (12–108)	0.601
Adverse event			0.787
▪ Fever	4	2	
▪ Bleeding	1	0	
Median hospital stay (days, range)	46 (8–102)	22 (14–63)	0.038
Median follow-up period (days, range)	188 (21–2028)	182 (21–2000)	0.168

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound.

stent removal. No recurrence of biloma was observed in either group during clinical follow-up.

Discussion

Small and asymptomatic bilomas generally resolve with conservative treatment. However, in the case of large size and in when patients have symptoms, intervention is required. Recent developments in endoscopic procedures and the high morbidity rates [19] associated with surgical drainage have led to a decrease in surgical treatment. With endoscopic and percutaneous approaches, external and/or internal drainage tube deployment may be the first consideration [20, 21, 22, 23]. Deployment of a drainage tube decreases the internal pressure of the biliary tract, after which the biloma may resolve. However, external drainage requires a percutaneous drainage tube, which has several disadvantages, including self-removal of the tube. More recently, various interventions have emerged that are performed under EUS guidance.

Several reports regarding EUS-TBD have been published to date [10, 11, 12, 13, 14, 15, 16, 17]. In the first published case series, Shami et al described EUS-guided drainage in five patients who had complicated symptomatic biloma [12]. In these patients, the biloma was punctured using a 19G needle under EUS guidance and a 0.035-inch guidewire was then deployed. Tract dilation was performed using a 6- or 8-mm balloon and one or two double-pigtail plastic stents were deployed. After performing these steps successfully, biloma resolution was obtained in all patients without any AEs. Recently, Lorenzo et al conducted a retrospective comparison study between ERCP and EUS-TBD for complex biloma [17]. They enrolled 30 patients with biloma secondary to refractory biliary leak who were treated by ERCP (n = 16) or EUS-TBD (n = 14). The technical success rate was 88% (14 of 16) for ERCP and 100% (16 of 16) for EUS-TBD. During clinical follow-up (median, 33.2 months), clinical success was obtained in 75% of patients who underwent EUS-TBD and in 67% of patients who underwent ERCP. Regarding biloma size, partial biloma regression (>50%, and size <3cm) and complete biloma resolution was obtained in 85% and 59% of patients, respectively, with no significant difference between EUS-TBD and ERCP. Surgical treatment was required in one patient. Serious AEs associated with the procedures occurred in one patient who underwent EUS-TBD and three who underwent ERCP. Based on these favorable clinical results, they concluded that ERCP and EUS-TBD are technically feasible with high clinical success and may avoid the need for additional surgery.

According to these previous reports, EUS-TBD appears to be a safe and effective treatment for biloma. However, most of these reports evaluated EUS-TBD combined with external drainage. Of these, the study with the largest number of patients [17] included deployment of one or two double pigtail plastic stents combined with an endoscopic nasal cyst drainage tube if needed. In addition, previous percutaneous drainage had been performed in 87% (26 of 30), and the drain was placed during initial surgery (n = 6), by interventional radiology (n = 15), or during redo surgery (n = 5). To avoid the influence of external drainage in evaluating the true safety and effectiveness of EUS-TBD, it is necessary to perform a clinical study of EUS-TBD without external drainage. In contrast, Tonozuka et al evaluated the technical feasibility and safety of EUS-guided drainage for infected biloma [16]. Although only six patients were included in their study, the technical success rate was 100% and the clinical success rate at the first session was 83.3% with no procedure-related AEs. Interestingly, they evaluated EUS-TBD performed using either a metal or plastic stent but not in combination with external drainage. However, the study had several limitations, including lack of a historical control group and variation in length of the metal stents.

The major findings of the present study were that EUS-TBD was superior to ERCP in several respects, including short procedure time, biloma size after drainage, and short hospital stay. Although previous reports have mainly used plastic stents, metal stents might be suitable for EUS-TBD, for two reasons. First, drainage might be more effective with the 10-mm diameter metal stent in EUS-TBD than with a plastic stent in ERCP. Second, if no adhesion is created between the biloma and the stomach wall, the complication of leak from biloma into the abdominal cavity may occur due to the gap between the plastic stent and the fistula. In contrast, if FCSEMS is used during EUS-BD, leakage from a biloma into the abdominal cavity may be prevented. Recently, a lumen-apposing metal stent (LAMS) has been developed. Compared with tubular SEMS, a LAMS has a large diameter and strong anchoring force. Therefore, LAMS might be preferable compared with tubular SEMS, although Cassis et al reported successful treatment of biloma with EUS-guided drainage using LAMS [14]. While this treatment might be promising, there are no clinical trials of EUS-guided drainage using LAMS for biloma. Therefore, clinical trials are needed of EUS-guided drainage using LAMS and also assessing different kinds of stents, such as LAMS, tubular SEMS, and plastic stents.

To the best of our knowledge, the present study is the first to report evaluation of endoscopic internal drainage for biloma without additional external drainage and to compare the use of ERCP and EUS-TBD. However, our study also has several critical limitations such as the retrospective nature and small sample size. Because the diameter of SEMS is large compared with plastic stents, a comparison between two groups might not be fair because the difference might influence the drainage effect. Also, because our study period was relatively long, operator technique may have differed during study period. Moreover, our study has selection bias. In our study, EUS-TBD was first considered. If a biloma could not be detected, ERCP was attempted as the next drainage technique. Therefore, more challenging cases might have been included in the ERCP group. This fact influences clinical results for both procedures, and therefore, our result may not be generalizable. Finally, a cost-effectiveness analysis could not be performed. The approximate cost per patient in the ERCP group was $4392 and in the EUS-TBD group was $4821, but because our study period was very long and costs were not definitively documented in our hospital, it was not possible to do an accurate cost analysis.

Conclusions

In conclusion, ERCP and EUS-TBD are complementary techniques, each with its own merits in specific clinical scenarios. If both techniques are feasible for a patient, EUS-TBD should be considered in view of the shorter times for the procedure, hospital stay, and biloma resolution associated with it.

Conflict of Interest

The authors declare that they have no conflict of interest.

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