Original Article

A novel technique of percutaneous transhepatic treatment of biliary-enteric anastomotic occlusive strictures with compliant balloon-occluded distal cholangiography and large-bore catheter: a retrospective case series

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Background: Endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic biliary balloon dilatation (PTBD) is a challenge in resolving biliary-enteric anastomotic occlusive strictures (BEAOS) and/or coexisting stones. The biliary-enteric anastomosis (BEA) often cannot be seen because of the surgically altered gastrointestinal anatomy. Here, a technique that combined percutaneous compliant-occluded distal cholangiography and the maintenance of a large-bore catheter is described to resolve this issue.

Methods: A retrospective review of 10 patients who presented with BEAOS with/without coexisting stones who were treated with percutaneous compliant balloon-occluded distal cholangiography, bile duct stone removal, and the maintenance of a large-bore catheter between February 2017 and January 2021 was performed. Treatment response, laboratory examinations, including hepatic function tests, routine blood tests, and blood electrolytes, complications, and imaging data were evaluated. Paired *t*-tests were used to investigate the difference of laboratory examinations before and after the procedure.

Results: All 10 cases were technically successful. A total of 9 stones in 6 patients were successfully removed by the compliant balloon. All catheters were removed after the patency of the stricture was confirmed by percutaneous transhepatic cholangiography (PTHC) 6 months later. No severe adverse events occurred during the perioperative period. There were 2 patients who experienced episodes of cholangitis during the follow-up period (mean, 17 months; range, 4–24 months), and neither BEAOS nor bile duct stones recurred within 2 years after the procedure. White blood cells (WBC), total bilirubin (TB), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) were (6.0±1.4)×10^9/L and (6.0±1.6)×10^9/L (P=0.91), 31.4±15.7 and 29.6±10.3 μmol/L (P=0.74), 50.8±20.0 and 85.8±67.0 U/L (P=0.16), and 42.6±15.2 and 71.8±44.9 U/L (P=0.09) pre and postintervention, respectively.

Conclusions: Percutaneous transhepatic compliant balloon-occluded distal cholangiography and the maintenance of a large-bore catheter probably provide an effective and safe alternative method for resolving BEAOS and/or coexisting stones.

Keywords: Biliary-enteric anastomotic occlusive strictures (BEAOS); compliant balloon-occluded distal cholangiography; large-bore catheter; coexisting stones; interventional procedure

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Introduction

Roux-en-Y hepatico- or choledocho-jejunostomy (RYHJ) is the most common biliary-enteric anastomotic procedure for the reconstruction of the physiological bile excretion pathway after pancreaticoduodenectomy, liver transplantation, or common bile duct (CBD) resection (1). Biliary-enteric anastomotic strictures (BEAS) are common complications caused by biliary-enteric anastomotic fibrosis and scarring after a RYHJ combined with coexisting stones, and these are often noted by endoscopic or percutaneous cholangiographic visualization associated with relative upstream biliary ductal dilatation and are accompanied by elevated hepatic enzymes (1,2). Reports have shown that BEAS are often difficult to manage due to recurrence, which can range from 2.6% to 17% (3). The diagnosis of biliary-enteric anastomotic occlusive strictures (BEAOS) can be made via a percutaneous transhepatic puncture cholangiography biliary-enteric anastomose which can show them as completely broken-off, in which case the contrast media does not inflow from the biliary tract and into the intestinal tract, and no contrast media is visualized in the intestinal tract by percutaneous transhepatic puncture cholangiography due to the upstream bile duct enlargements after RYHJ (4). BEAOS are rare and more severe clinically than BEAS. Most BEAS cases are treated with repeat endoscopic biliary-enteric stricturoplasty or percutaneous transhepatic biliary balloon dilatation (PTBD) (5). Moreover, conventional endoscopic biliary-enteric stricturoplasty and PTBD cannot successfully resolve BEAOS because of the presence of the surgically altered gastrointestinal anatomy (6). A biliary-enteric anastomosis (BEA) often cannot be seen using percutaneous transhepatic puncture cholangiography, and there is no tunnel for the guide wire to navigate through the narrowed anastomosis during a balloon dilatation in endoscopic retrograde cholangiopancreatography (ERCP) or PTBD when BEAOS occurs.

The purpose of this study was to describe a safe and technically efficacious technique that combines percutaneous compliant balloon-occluded distal cholangiography and the maintenance of a large-bore catheter for removing benign BEAOS with/without coexisting stones. We present this article in accordance with the PROCESS reporting checklist (available at https://qims.amegroups.com/article/view/10.21037/qims-23-1693/rc).

Methods

Patient criteria

A retrospective review of patients who presented with BEAOS with/without coexisting stones who were treated with percutaneous compliant balloon-occluded distal cholangiography, bile duct stone removal, and the maintenance of a large-bore catheter between February 2017 and January 2021 was performed in Ruijin Hospital Luwan Branch, Shanghai Jiao Tong University School of Medicine. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Institutional Review Board of Ruijin Hospital Luwan Branch, Shanghai Jiao Tong University School of Medicine (No. LWEC2021007) approved this retrospective study, and written informed consent for treatment was provided by all patients prior to each procedure.

The exclusion criteria were as follows: (I) severe cardiac insufficiency or advanced lung disease, liver disease (Child-Pugh class C), or kidney disease (grade 3 chronic kidney disease); or (II) severe coagulopathy (prothrombin time >17 s or platelet count $<60\times10^9$/L); (III) obvious tumoral recurrences.

Interventional procedure

An 8.5 F drainage catheter (Cook Medical, Bloomington, IN, USA) was therefore left in the CBD after the percutaneous transhepatic biliary drain. An attempt to repair the BEAOS and remove the stones was performed when the symptoms of cholangitis had been controlled, usually, 3–5 days after the drainage. First, cholangiography was performed to delineate the anatomy of the biliary duct and to determine the location of the stones. An 8 F

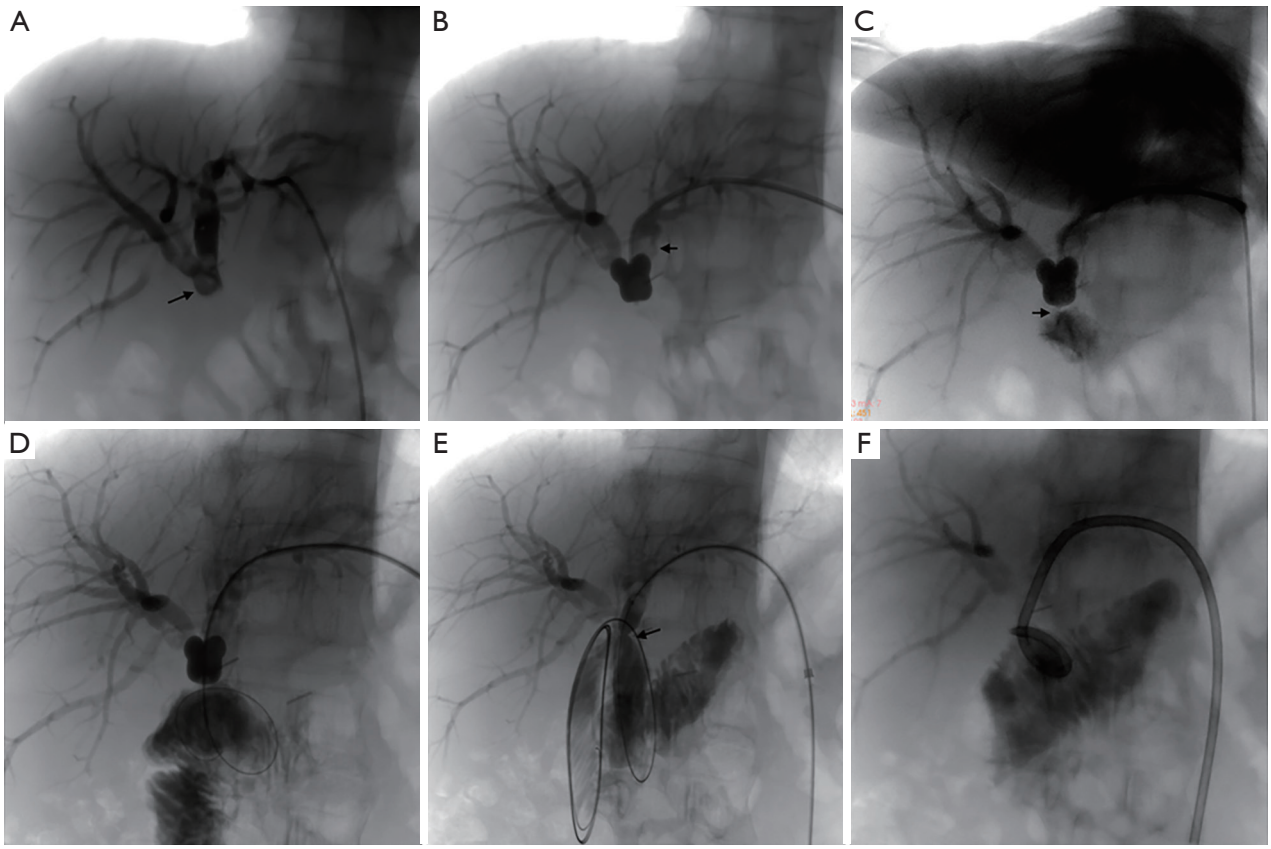

Figure 1 Interventional procedure. (A) Cholangiography was performed to delineate the anatomy of the biliary duct and to determine the location of the stones. (B) A compliant balloon (Fogarty) was inflated by contrast media with balloon diameter to fit the bile duct. (C) High-pressure injection of contrast media was repeated until the contrast media could be seen in biliary-enteric anastomosis and inflow was seen in the intestinal tract. (D) A guidewire passed through the BEAOS through a small channel communicating with the jejunum. (E) The biliary-enteric anastomosis was dilated by high-pressure conventional angioplasty balloons. (F) An 8.5 or 10 F internal/external biliary catheter was left indwelling through biliary-enteric anastomosis and intestinal tracts. Arrows: (A,B) stones; (C,E) BEAOS. BEAOS, biliary-enteric anastomotic occlusive strictures.

introducer sheath (Terumo Medical Corp., Tokyo, Japan) was then inserted into the bile duct (*Figure 1A*). An 80 cm, 7 F compliant balloon (Fogarty, Edwards Lifesciences, Irvine, CA, USA) was passed through the introducer sheath into the CBD (*Figure 1B*). The aforementioned balloon tube was inflated by contrast media (Iodixanol) to fit the bile duct and the diameter of inflated balloon was 14 mm. Then, contrast media (Iodixanol) was injected into the biliary duct through complaint balloon tube with a high pressure (300–500 psi) by contrast media injector. The flow rate was 2–3 mL/s for a total amount of 8–10 mL per injection (*Figure 1C*). The high-pressure injection of contrast media was repeated until the contrast media could be seen in the BEA and flowed into the intestinal tract. Balloon-occluded distal cholangiography was used to better describe the detailed results of cholangiography. A guidewire was used to pass into the BEAOS through a small channel that communicated with the jejunum, as confirmed by the contrast-media injection (*Figure 1D*). An angiographic catheter (Cobra2, Cook), was finally passed into the intestinal tract following the guide wire. A stiff 260-cm-long, 0.035-inch-diameter guidewire (Radifocus Guidewire M, Terumo Medical Corp.) was implanted through the BEA into the intestinal tract, and the angiographic catheter was withdrawn. A conventional angioplasty balloon (Mustang, Boston Scientific, Marlborough, MA, USA) was replaced. The BEA was dilated by high-pressure conventional angioplasty balloons (noncompliant balloons) with a maximum diameter of 8–14 mm per balloon, and the dilation was repeated 2–3 times for each patient (*Figure*

1E). The Fogarty balloon was positioned proximal to the stone and was then partially or fully inflated and used to push the stone into the intestinal tract through the BEAOS. This procedure was repeated several times until all of the stones were expelled from the CBD and into the intestinal tract. An 8.5 or 10 F internal/external biliary catheter was retained in the BEA and intestinal tracts (*Figure 1F*). To reduce the risk of a potential reobstruction of the biliary drainage related to long-term catheterization (which could contribute to an obstruction or sludge formation), additional side holes with an approximate 0.5 cm interval to the biliary drain at large branch points were added, and bile-thinning drugs were given to all of the patients in this case series to prevent bile sludge formation. These primary intra/extra drainage tubes were replaced with 12 to 16 F catheters every 2 months. After 6 months, the catheters were removed after the stricture patency was confirmed by percutaneous transhepatic cholangiography (PTHC).

Postoperative complications and follow-up

The postoperative complications noted in this study were categorized according to published guidelines, and the complications included sepsis, bile leakage, peritoneal hemorrhage, and inflammation or infection (7).

All patients had follow-up laboratory examinations, including hepatic function tests, routine blood tests, and blood electrolytes, 3 days postoperatively. Then, 1–6 months postoperatively, all of the patients underwent follow-up repeat laboratory examinations, routine abdominal computed tomography (CT) scans (8,9) and magnetic resonance cholangiopancreatography (MRCP) at monthly intervals. Any recurrence of BEAOS or CBD stones and any refluxing cholangitis were monitored for 2 years and were considered long term complications.

Statistics

Continuous data are presented as the mean ± standard deviation. We used paired *t*-tests for the same indexes before and after the procedure in the same patient. The statistical analysis was performed using the software SPSS 22.0 (IBM Corp., Armonk, NY, USA). All P values reported were 2-sided with significance level alpha =0.05.

Results

A total of 10 patients (8 men and 2 women) with a mean age of 65 years (ranging from 52 to 74 years) were included in this retrospective descriptive study. Only 1 patient had undergone subtotal gastrectomy, and the others had undergone duodenopancreatectomy. All patients had a RYHJ. All patients presented with features of worsening obstructive jaundice and cholangitis, such as yellow skin pigmentation, icteric sclera, fever, and abdominal distention before the interventional procedure. No patient had abdominal muscle rebound tenderness or tension, and no other significant physical signs were found in the physical examinations of any of the patients. The preoperative laboratory examinations showed elevated total bilirubin (TB), alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (AKP), and gamma glutamyl transpeptidase (GGT). No other elevated hepatic enzymes were observed in any of the cases. No cases had elevations in tumoral biomarkers. Abdominal CT and/or MRCP scans showed biliary-enteric anastomotic calculogenesis and extensive intra/extrahepatic cholangiectasis, and the calculus diameter ranged from 5 to 18 mm. There were no obvious tumoral recurrences in any of the cases and no tumors were noted within biliary-enteric anastomoses in any of the cases. All 10 patients were diagnosed with obstructive jaundice based on the CT findings and the jaundiced skin and sclerosis seen in the patients, and 6 patients were diagnosed with biliary-enteric anastomotic calculogenesis (*Figure 2A,2B*). Patient demographics and baseline clinical profiles are shown in *Table 1*.

A total of 10 BEAOS in the patients were successfully removed by our technique. All 10 cases were technically successful, and surgery was avoided. In 2 of the 10 patients, repeated procedures were performed to cross the BEAOS because of occlusive strictures. A total of 9 stones in 6 patients were successfully removed by a compliant balloon, and the diameters of 9 stones ranged from 5 to 18 mm.

The postoperative laboratory tests showed that all of the liver enzymes decreased after the PTBD. White blood cells (WBC), TB, ALT, AST, AKP, and GGT were $(6.0\pm1.4)\times10^9$/L and $(6.0\pm1.6)\times10^9$/L (P=0.91), 31.4±15.7 and 29.6±10.3 μmol/L (P=0.74), 50.8±20.0 and 85.8±67.0 U/L (P=0.16), 42.6±15.2 and 71.8±44.9 U/L (P=0.09), 585.5±478.3 and 645.0±821.0 U/L (P=0.66), and 461.7±274.1 and 397.4±301.5 U/L (P=0.42) pre and postintervention, respectively. The ALT and AST increased 3 days after placing the compliant balloon-occluded distal cholangiography and large-bore catheter. There was no significant difference between the comparisons. At 1 month

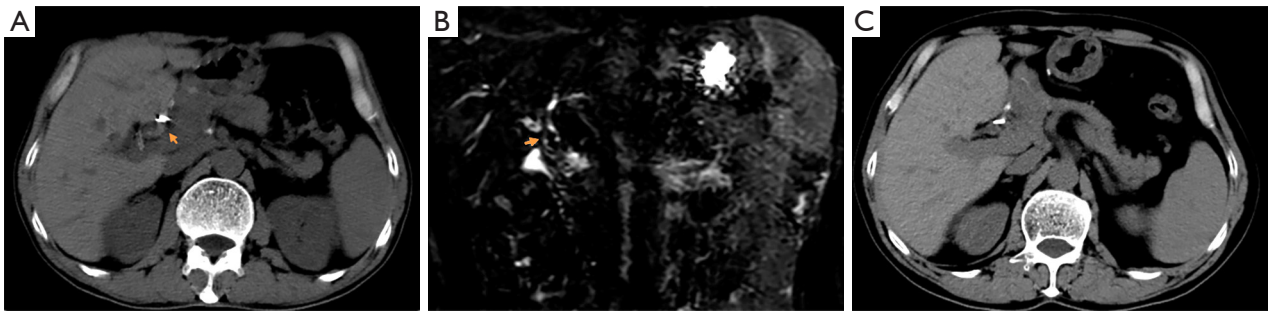

Figure 2 Imaging data pre and postintervention: (A,B) abdominal CT and MRCP scan showing biliary-enteric anastomotic calculogenesis and extensive intra/extrahepatic cholangiectasis; (C) abdominal CT scan showing that the stones were removed and the hepatic cholangiectasis was removed 6 months after the procedure. Arrows: biliary-enteric anastomotic calculogenesis. CT, computed tomography; MRCP, magnetic resonance cholangiopancreatography.

Table 1 Baseline characteristics of patients

No.	Age (years)/sex	Time delay between surgery and index presentation (months)	Number of stones	Diameter of the largest stone (mm)	Technical result	Performed follow-up (months)
1	67/M	8	–	–	Success	24
2*	71/M	44	2	5	Success	18
3	69/M	12	1	10	Success	24
4	69/F	25	–	–	Success	24
5	74/M	13	–	–	Success	24
6	63/M	5	–	–	Success	16
7	62/M	11	3	10	Success	16
8	59/M	61	1	18	Success	13
9	52/F	11	1	12	Success	8
10	62/M	34	1	12	Success	4

*, this patient received subtotal gastrectomy, the other patients had a duodenopancreatectomy. M, male; F, female.

after the procedure, the laboratory parameters (WBC, TB, ALT, AST, AKP, and GGT) were decreased, (5.6±1.8)×10^9/L (P=0.43), 16.9±7.3 (P=0.01), 37.8±26.9 U/L (P=0.07), 42.9±30.1 (P=0.09), 372.8±205.1 U/L (P=0.24), and 153.9±101.5 (P=0.06) compared with 3 days after the procedure (*Table 2*). Compared with the values 1 month postoperatively, the laboratory values were not decreased 2 months or more postoperatively.

All catheters were removed after the patency of the stricture had been confirmed by PTHC 6 months after interventional procedure (*Figure 2C*). No sepsis, inflammation/infection, bile leakage, or hemorrhage was found in any of the patients during hospitalization. No severe adverse events, such as pancreatitis or perforation of the gastrointestinal or biliary duct, occurred during the perioperative period in this case series. During the follow-up period (mean, 17 months; range, 4–24 months), no recurrence of BEAOS or bile duct stones was noted 2 years after the procedure. There were 2 patients who experienced episodes of cholangitis 3 months after the procedure, and 1 patient died of a recurrence of stomach cancer 18 months after the procedure.

Discussion

BEA is an essential surgical procedure to restore the continuity of the biliary-enteric system, and this technique is usually performed for the management of biliary

Table 2 Laboratory tests pre and postintervention

Item	Before PTBD	3 days after PTBD (pretreatment)	3 days after treatment	1 month after treatment	Normal range
WBC (10^9/L)	6.8±4.7	6.0±1.4	6.0±1.6	5.6±1.8	4–11
TB (μmol/L)	72.0±76.5	31.4±15.7	29.6±10.3	16.9±7.3	3–20
ALT (U/L)	135.1.8±154.3	50.8±20.0	85.8±67.0	37.8±26.9	5–40
AST (U/L)	102.2±74.4	42.6±15.2	71.8±44.9	42.9±30.1	8–40
AKP (U/L)	834.8±653.9	585.5±478.3	645.0±821.0	372.8±205.1	40–150
GGT (U/L)	763.7±624.7	461.7±274.1	397.4±301.5	153.9±101.5	11–50

Values are presented as mean ± SD. PTBD, percutaneous transhepatic biliary balloon dilatation; WBC, white blood cell; TB, total bilirubin; ALT, alanine aminotransferase; AST, aspartate aminotransferase; AKP, alkaline phosphatase; GGT, gamma glutamyl transpeptidase; SD, standard deviation.

obstruction or leakage that results from a variety of benign and malignant diseases (3,10). The biliary tree is most commonly anastomosed to the jejunum (either as an RYHJ or a simple loop) (10). Complications secondary to BEA are not rare. Postoperative complications following a BEA include hemorrhage, bile leakage, wound infection, cholangitis, and delayed BEAS (11-14). BEAS is a significant complication in patients with RYHJ, and the complications have an adverse impact on the patient outcomes and can contribute to the long-term morbidity or mortality (10). Hence, the removal of a BEAS is beneficial for decreasing the patients' long-term morbidity and mortality. The first line of management for a BEAS is ERCP, and an interventional operation can be used as a surrogate in ERCP failure patients. In this study, a novel technique combined with percutaneous compliant balloon-occluded distal cholangiography, bile duct stone removal, and the maintenance of a large-bore catheter was performed. All 10 cases were technically successful and avoided surgeries. A total of 9 stones in 6 patients were successfully removed by the compliant balloon. No severe adverse events occurred during the perioperative period.

When considering the results from previous case reports, the calculus diameter, and the life expectancy in these 10 cases, all of these patients were first advised to have an ERCP and endoscopic stone extraction (5,6). The endoscopy showed that fibril scars had formed in biliary-enteric anastomoses, and the biliary-enteric anastomoses were blocked in all of these patients. Meanwhile, it is also difficult to cross BEAOS after percutaneous transhepatic biliary drain. PTHC revealed that there were filling defects located within the biliary tract proximally to the BEA; however, no contrast media was seen in the BEA or the intestinal tract (there was an occlusive stricture at the BEA). Attempted bowel cannulations were unsuccessful. Balloon-occluded distal cholangiography was shown to better describe the detailed results of cholangiography and a guidewire was used to pass into the BEAOS through a small channel that communicated with the jejunum, as confirmed by the contrast-media injection. Repeated percutaneous compliant balloon cholangiographies were performed in patients to cross the BEAOS because of cholangitis, and this could be secondary to the novel techniques utilized. All 10 cases were technically successful, and surgery was avoided.

In this study, 3 key procedure techniques were applied. First, the compliant balloon blocked the upstream distended bile duct of the anastomoses to supply a temporary complete airtight cavea and to prevent reflow of contrast media upon peripheral intrahepatic duct (15). A high-pressure injection of contrast media was completed in the aforementioned temporary complete airtight cavea. Under the high pressure of the contrast media, fiber scars or affixion in the narrowed anastomosis were partly split, and the fissure could be seen after the injection of the contrast media (16). The aim of these procedures was to create a passageway for guidewire access to the aforementioned dilacerated fissure to the intestinal tract. Second, the compliant balloon was partially or fully inflated and was used to push the stone into the intestinal tract through passageways after the BEA dilation (17). Previous reports have shown that percutaneous transhepatic balloon dilation of the ampulla is a safe and effective procedure for CBD stone removal (18,19). The inflated compliant balloons could snuggly fit into the CBD and could achieve a better efficacy for pushing stones into the intestinal tract than conventional angioplasty balloons. Third, the step of maintaining of a large-bore catheter was

initially proposed in the 1970s by Ring *et al.* (20) and is still endorsed by some authors as a successful way to remold the biliary-enteric anastomoses and to prevent biliary-enteric anastomotic restrictures/reobliterations and to prevent reflow of contrast media upon peripheral intrahepatic duct. In a past study (21) that included 47 patients who underwent the placement of a 10 F catheter across the strictures, the catheter was subsequently upsized every 1–2 weeks until a size of 18–20 F was placed for at least 6 months. The primary patency rates were 89.5%. Hence, all the patients in the study who maintained an indwelling 16 F catheter were expected to have the same outcome.

Stent placement is another treatment option. In particular, the use of retrievable covered self-expanding metal stents (CSEMSs) has been proposed as a possible treatment strategy on the basis of the higher expansion force, larger diameter of these stents, and their sustained dilation effect (22,23). In a series of 68 patients who underwent CSEMS placement, Gwon *et al.* (22) reported clinical success in 59 (86.8%) patients after 3 years of follow-up. These studies offer some promising results but highlight that there are still substantial problems to overcome, such as relatively high stent migration and complication rates (24).

In this study, the TB, AKP, and GGT were not significantly lower at 3 days postoperatively, but the ALT and AST increased to 2 times the upper limit of normal, which may have been due to early acute edema of the biliary-enteric anastomotic fibril scars secondary to the balloon dilatation and the high-pressure injection of contrast media. The acute edema of the biliary-enteric anastomotic fibril scars may result in the formation of aggravated strictures (25). In addition, the procedure of flushing the stagnant bile or recanalization and renovation of the cholangiole may require 2 weeks to 1 month. At 1 month postoperatively, the AST and ALT remained within normal limits, the TB and the enzymes that indicate cholestasis (AKP, GTT) were significantly decreased, and the patient's icteric sclera and yellow skin disappeared, which indicated a complete recanalization and renovation of the cholangiole. The bile excretion recovered to the normal levels in the healthy individuals. Compared to 1 month postoperatively, the laboratory examinations were not significantly decreased at 2 months postoperatively or beyond.

In this case series, no procedural-related or postoperative complications were observed. To minimize the risk of sepsis/infection/inflammation secondary to the reflux of bacteria-laden bile into the bloodstream, broad spectrum antibiotics were used before the procedure and overnight during hospitalization after the procedure. Additionally, the delay of the stepwise dilatation procedure and the upsizing with a larger catheter using 1-month intervals in this case series could minimize the bile leakage and peritoneal hemorrhage during the perioperative period.

There are some potential limitations in this case series. First, because this technique was recently introduced for the resolution of BEAOS, only 10 cases were included in this study, and the statistical power was not very robust in this study. A selection bias in the results of the laboratory examinations and postoperative complications was inevitable in this case series. Second, the duration of follow-up was not enough, and late complications for this novel technique were not observed and described.

Conclusions

This technique probably provided an effective and relatively safe treatment for BEAOS with/without coexisting stones combined with compliant balloons and the maintenance of large-bore catheters to avoid additional surgeries. To our knowledge, this case series was the first to introduce a new technique for resolving BEAOS and coexisting stones; hence, the results in this study are preliminary. Other investigations using the same techniques as this case series and with a larger sample size of patients should be conducted to compensate and verify our technique.

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Footnote

Reporting Checklist: The authors have completed the PROCESS reporting checklist. Available at https://qims.amegroups.com/article/view/10.21037/qims-23-1693/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-23-1693/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The institutional review board of Ruijin Hospital Luwan Branch, Shanghai Jiao Tong University School of Medicine (No. LWEC2021007) approved this retrospective study, and written informed consent for treatment was provided by all patients prior to each procedure.

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