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Repeated balloon dilatation with long-term biliary drainage for treatment of benign biliary-enteric anastomosis strictures

A STROBE-compliant article

Teng-Fei Li, MD, PhD[a,b], Pei-Ji Fu, MD, PhD[a,b], Xin-Wei Han, MD, PhD[a,b,*], Ji Ma, MD, PhD[a,b], Ming Zhu, MD, PhD[a,b], Zhen Li, MD, PhD[a,b], Jian-Zhuang Ren, MD, PhD[a,b]

Abstract

Percutaneous balloon dilatation for benign biliary-enteric anastomosis stricture has been the most widely used alternative to endoscopic treatment. However, patency results from the precedent literature are inconsistent.

The objective of this study was to evaluate the safety and feasibility of repeated balloon dilatation with long-term biliary drainage for the treatment of benign biliary-enteric anastomosis strictures.

Data from patients with benign biliary-enteric anastomosis strictures who underwent percutaneous transhepatic cholangiography (PTC), repeated balloon dilatation with long-term biliary drainage (repeated-dilatation group; n = 23), or PTC and single balloon dilatation with long-term biliary drainage (single-dilatation group; n = 26) were reviewed. Postoperative complications, jaundice remission, and sustained anastomosis patency were compared between the groups.

All procedures were successful. No severe intraoperative complications, such as biliary bleeding and perforation, were observed. The jaundice remission rate in the first week was similar in the 2 groups. During the 26-month follow-up period, 3 patients in the repeated-dilatation group had recurrences (mean time to recurrence: 22.84 ± 0.67 months, range: 18–26 months). In the single-dilatation group, 15 patients had recurrences (mean time to recurrence = 15.28 ± 1.63 months, range: 3–18 months). The duration of patency after dilatation was significantly better in the repeated-dilatation group ($P = .01$). All patients with recurrence underwent repeat PTC followed by balloon dilatation and biliary drainage.

Repeated balloon dilatation and biliary drainage is an effective, minimally invasive, and safe procedure for treating benign biliary-enteric anastomosis strictures, and provides significantly higher patency rates than single dilatation.

Abbreviations: BEA = biliary-enteric anastomosis, MRCP = magnetic resonance cholangiopancreatography, PTC = percutaneous transhepatic cholangiography, PTCB = percutaneous transhepatic cholangiobiopsy.

Keywords: anastomosis strictures, balloon dilatation, benign

1. Introduction

Anastomotic stricture is a relatively common complication of biliary-enteric anastomosis (BEA), with a reported incidence of between 2.6% and 30%.[1,2] Strictures may lead to biliary infection, jaundice, hepatolithiasis, or biliary cirrhosis and can be associated with significant pain and even death. Surgical revision of these strictures can be difficult and is associated with both a significant morbidity rate of approximately 25% and a mortality rate of between 2% and 13%.[3,4] Revisions can further be associated with increased hospital inpatient stays.[3,4] Benign biliary strictures are commonly managed via an endoscopic approach. Surgically altered anatomy is not considered as a contraindication for endoscopy; however, endoscopy is difficult to perform and is not feasible in some cases.[5,6] Percutaneous transhepatic methods, including percutaneous transhepatic balloon dilatation with or without biliary drainage, have been recommended as potential alternatives to an endoscopic approach. However, the primary patency rates at 24 to 36 months have varied from 62% to 83% in different studies.[7–10] A number of technical aspects of balloon dilatation remains controversial, for example, the size and length of balloon, the frequency of dilatation, and the intra-balloon pressure during dilatation.[8,11] In this retrospective study, we compared repeated balloon with single balloon dilatation, both with biliary drainage. The primary objective of this study was to determine the safety,

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TFL and PJF have contributed equally to this work and share the co-first authorship.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

[a] Department of Interventional Radiology, the First Affiliated Hospital of Zhengzhou University, [b] Interventional Institute of Zhengzhou University, Zhengzhou, China.

[*] Correspondence: Xin-Wei Han, Zhengzhou University, Zhengzhou, Henan, China (e-mail: xinwei_han@163.com).

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Table 1

Patient demographics and clinical characteristics.

	Repeated-dilatation group (n = 23)	Single-dilatation group (n = 26)
Gender		
Male	16	14
Female	7	12
Median age, y	50.6 ± 13.4 (34–67)	52.3 ± 14.3 (34–69)
Clinical manifestations		
Abdominal pain	10	11
Fever	7	9
Chills	6	7
Jaundice	19	22
Pruritus	7	11
Serum biochemistry before PTC*		
ALT, IU/L	229.3 ± 144.7 (27–771)	217.4 ± 137.4 (27–613)
AST, IU/L	183.7 ± 117.3 (25–567)	180.3 ± 107.9 (22–487)
ALP, IU/L	389.9 ± 179.2 (120–922)	377.2 ± 164.5 (50–948)
Direct bilirubin, μmol/L	125.2 ± 104.0 (12.7–334.6)	140.5 ± 87.2 (10.3–317.5)
Total bilirubin, μmol/L	93.9 ± 81.9 (6.1–255.0)	106.3 ± 66.9 (7.1–226.9)
INR	1.1 ± 0.3 (0.6–1.7)	1.1 ± 0.3 (0.6–1.7)
Platelet count, 10^9/L	185.0 ± 57.6 (89.0–342.0)	178.1 ± 57.7 (87.0–341.0)
Primary disease		
Neoplastic diseases	12	14
Cholangiocarcinoma	7	8
Ampullary carcinoma	2	3
Gall bladder carcinoma	3	3
Non-neoplastic diseases	11	12
Iatrogenic bile duct injury (IBDI)	3	4
Choledocholithiasis	5	6
Choledochocele	1	2
Others	2	0
Initial operation		
Choledochoduodenostomy	2	3
Choledochojejunostomy	10	9
Hepaticojejunostomy	11	14

* PTC = percutaneous transhepatic cholangiography; ALT = alanine aminotransferase; AST = aspartate aminotransferase; ALP = alkaline phosphatase; INR = international normalized ratio.

feasibility, and long-term efficacy of repeated balloon dilatation with biliary drainage for benign anastomotic stenosis following BEA. Secondary study objectives were to evaluate long-term anastomosis patency and determine the rates of stricture recurrence following clinically successful balloon dilatation.

2. Materials and methods

2.1. Ethics statement

This retrospective study was approved by the Ethics Committee of Biomedical Research of Zhengzhou University. All procedures were in accordance with the 1975 Helsinki Declaration, as revised in 1983, and written informed consent was obtained from patients before the performance of each procedure.

2.2. Subject selection

All patients (n = 389) who had undergone BEA in our hospital between January 2016 and Oct 2017 for treatment of anastomosis strictures were identified by a review of their case records. Patients were included if they had a benign stricture (confirmed by forceps biopsy of the stenosis or imaging examination); were treated by interventional therapy (balloon dilatation, drainage, and stenting); and had not undergone previous balloon dilatation or stenting. Patients were excluded if they had a malignant stricture; had intractable severe blood coagulation dysfunction; or refused to participate in the study. Finally, 49 patients who met these criteria were enrolled. These patients were treated with repeated balloon dilatation with long-term biliary drainage (repeated-dilatation group; n = 23) or single balloon dilatation with long-term biliary drainage (single-dilatation group; n = 26). All procedures were performed via the transhepatic approach. Before the procedure, the expected curative effect and the risks and cost of the 2 treatments were explained to the patients and/or families and the treatment approach was decided by them. Among these patients, abdominal pain, fever, chills, jaundice, and/or pruritus occurred 2 to 5 months after BEA. Prior to dilatation, patients underwent either diagnostic ultrasonography (n = 49), computed tomography (CT) (n = 43), magnetic resonance cholangiopancreatography (MRCP) (n = 44), and/or percutaneous transhepatic cholangiobiopsy (PTCB) (n = 23). The patients' demographics and clinical characteristics are summarized in Table 1.

2.3. Surgical procedures

All procedures were performed under local anesthesia and conscious sedation with midazolam (Suzhou Enhua Pharmacy Co. Ltd., Suzhou, China) by 2 interventional radiologists (TFL

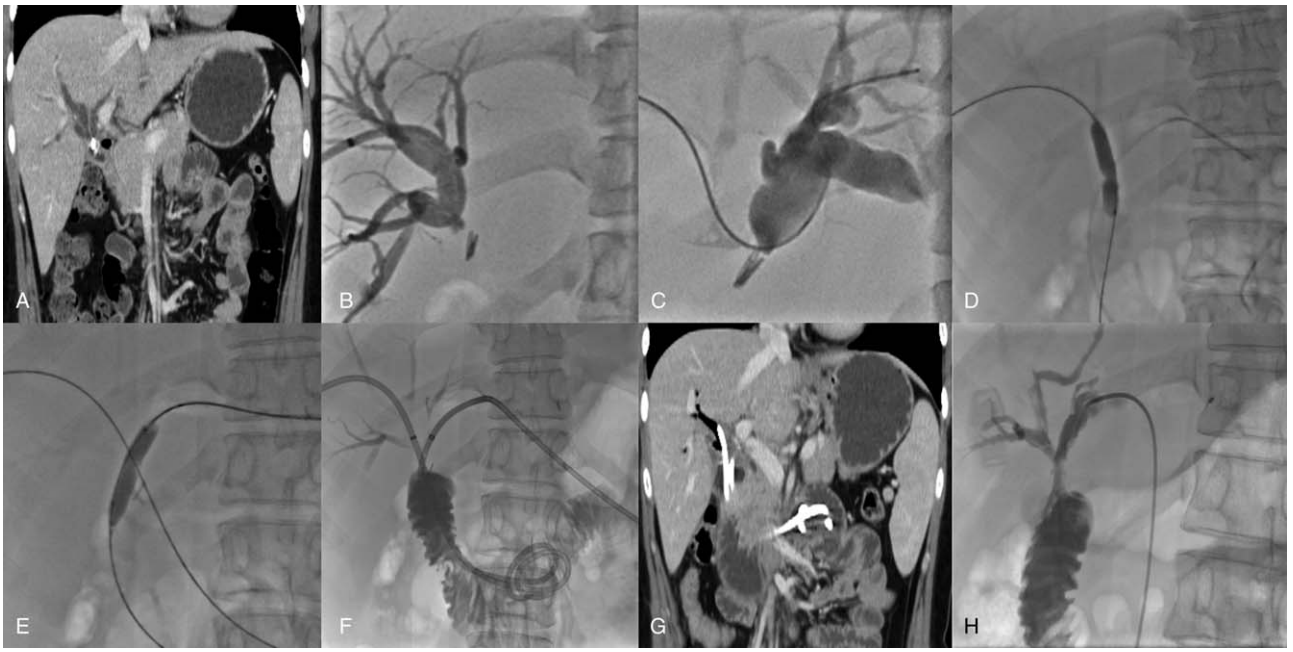

Figure 1. A case of benign anastomotic stricture treated with repeated balloon dilatation with long-term biliary drainage. (A–C) This figure depicts a 26-year-old woman who underwent cholecystectomy, cholangiolithotomy, and hepaticojejunostomy for cholecystocholedo-cholithiasis 6 months previously. Four months following this procedure she presented with abdominal distension and fever. CT and PTC revealed a benign biliary-enteric anastomosis stricture. (D–E) Balloon dilatations were performed in the right and left bile ducts. (F) Post balloon dilatation, 2 8.5F internal and external biliary drainage tubes were implanted at each side. (G) At 6 months postoperatively, CT showed no obvious dilatation of the intrahepatic bile ducts. (H) Repeat biliary angiography showed that the narrowing was cleared, following which the drainage tubes were removed. CT = computed tomography; PTC = percutaneous transhepatic cholangiography.

and HFY, with 12 and 10 years of experience, respectively). Based on the MR/MRCP and CT images, PTC was performed under fluoroscopic guidance, using a 21G Chiba needle (Cook, Bloomington, IN) from the dilated right and/or left bile duct. PTC was performed by the standard micropuncture technique. For the first dilatation, a stiff guidewire (Cook, Bloomington, IN) was inserted through the strictured section until it reached the intestinal tract. A 7F catheter sheath (Cook, Bloomington, IN) was then advanced along the stiff guidewire until the tip was positioned above the stricture. Cholangiography was repeated to qualitatively assess the area of stricture through a 5F Cobra catheter. The catheter was introduced through the sheath and placed beside the stiff guidewire, with its tip above the stricture. Then an 8- to 12-mm balloon (Bard Peripheral Vascular, Inc., Tempe, AZ) was placed at the level of the diseased section, with the diameter tailored to both the location and size of the stricture as appropriate. For example, if the stricture was in an intrahepatic duct, an 8-mm balloon was used at the first dilatation. If the stricture was in the extrahepatic duct, such as at the site of a choledochoduodenostomy, partial choledochojejunostomy, or hepaticojejunostomy, a 10- to 12-mm balloon was chosen for the first dilatation. Stricture dilatation was achieved through inflating the balloon to a pressure of between 6 and 8 kPa and this pressure was maintained for 3 to 5 minutes. After ≥3 minutes, the dilatation process was repeated at least once. If the contrast agent was observed to smoothly pass through the original stricture point into the distal intestine, an 8.5F to 10.2F internal and external biliary drainage tube (Cook, Bloomington, IN) was placed (Fig. 1A–H). This procedure was repeated every month for the first 3 months following the first intervention, and then every 2 months until the biliary drainage tube was removed at the end of 6 months. Over these 6 months the dilatation had been conducted a total of 5 times (Fig. 2). After each procedure vital signs were monitored and abdominal signs and symptoms including rigors, fever, vomiting, and abdominal pain were recorded. In addition, the nature and volume of fluid drainage were documented. The indication for removing the drainage tube is based on a consideration of hepatic and renal function, abdomen ultrasound, MRCP, and/or radiography. In the presence of abnormal clinical parameters, the drainage tube was left in situ and additional dilatation was performed if necessary. Patients in the single-dilatation group underwent only balloon dilatation and biliary drainage, and the tube was removed 6 months later. The balloon type used and technique applied were the same as those used in the repeated-dilatation group.

2.4. Efficacy evaluation, follow-up, and definitions

Patients were administered prophylactic antibiotics and symptomatic treatment as required postoperatively. One week following the dilatation procedure, patients were examined for remission of jaundice and any short-term complications associated with the dilatation procedure. Serum bilirubin concentration was monitored 1 week after the procedure. Following removal of the tube, anastomosis patency and patient survival were assessed via follow-up outpatient visits or telephone interview every month as required. Clinical success of the dilatation procedure was defined radiologically as a <30% residual narrowing at the biliary-enteric anastomosis relative to bile duct caliber as measured from the cranial aspect of the anastomosis on either contrast CT, magnetic resonance imaging

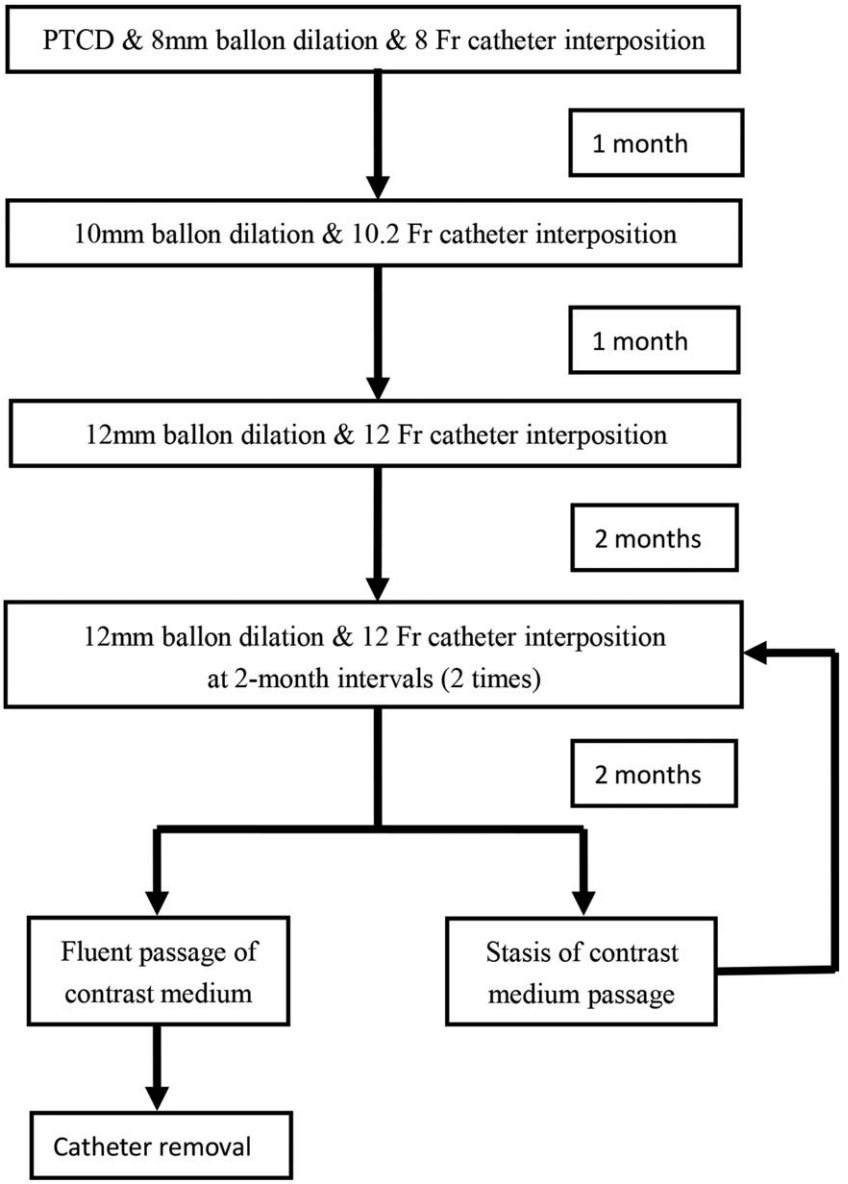

Figure 2. Schematic diagram of our treatment protocol.

(MRI), or ultrasound. Normalization of previously elevated serum bilirubin, pruritus remission (if present), and resolution of other related clinical symptoms were required prior to drainage tubes being removed. Recurrence was defined as the re-development of clinically significant symptoms suggesting re-stenosis such as jaundice and cholangitis, subsequently necessitating intervention. In practice, stricture recurrence was diagnosed based on a combination of clinical symptomatology, serum biochemical tests, and imaging examination.

2.5. Statistical analysis

Biochemical indices were summarized as mean ± SD and compared using the Wilcoxon signed-rank test. Categorical data were analyzed using the Chi-squared or Fisher exact test in the case of small numbers. Anastomosis patency duration and survival rates were compared using the Kaplan–Meier method. For all analyses $P < .05$ was considered significant. All statistical analyses were performed using SPSS for Windows, version 19.0 (IBM Corp., Armonk, NY).

3. Results

3.1. Complications and management

Dilatation procedures were successfully performed in all patients. In order to image the stricture, bilateral PTC was performed in 16 of the repeated-dilatation group patients with the remaining 7 undergoing unilateral PTC. Similarly, bilateral and unilateral PTC was used in 17 and 9 single-dilatation patients respectively. No electrocardiographic abnormality was observed in either group during the intervention. Across both groups no bile duct perforation, peri-biliary sepsis, or hemorrhage occurred intra-operatively. Postoperatively, 3 patients in the repeated-dilatation

Table 2

Decrease in total bilirubin levels and direct bilirubin levels in the 2 study groups (μmol/L).

	Total bilirubin levels				Direct bilirubin levels			
Group	Before intervention	After intervention	*D*-value	*P*	Before intervention	After intervention	*D*-value	*P*
Repeated-dilatation group (n=23)	125.2±104.0	54.5±47.6	70.7±65.1	.82	93.9±81.9	36.6±34.4	57.3±53.8	.92
Single-dilatation group (n=26)	140.5±87.2	65.9±42.0	74.6±51.3		106.3±66.9	50.3±33.5	56.0±39.8	

group and 4 patients in the single-dilatation group subsequently presented with symptoms of cholangitis including abdominal pain, chills, and fever. These resolved with antibiotics and conservative management. Repeat routine blood tests following symptomatic management confirmed all laboratory markers had returned to baseline in these patients.

3.2. Outcomes and follow-up

In both groups, predilatation abdominal distension/pain, fever, chills, pruritus, and loss of appetite were almost completely resolved. There was no difference between surgical groups in either total or direct bilirubin levels at 1-week following the procedure (Table 2).

During the 26-month follow-up period, 3 patients in the repeated-dilatation group had recurrences (mean time to recurrence: 22.84±0.67 months, range: 18–26 months), while 15 patients in the single-dilatation group had recurrences (mean time to recurrence: 15.28±1.63 months, range: 3–18 months). The difference between the groups with regard to the time to recurrence was statistically significant ($P=.01$; Fig. 3).

In the repeated-dilatation group, jaundice recurred in 1 patient at 11 months after the procedure (total bilirubin level: 116 μmol/L, direct bilirubin level: 87 μmol/L). Additionally, 1 patient had recurrent infection at posttreatment 15 months and 1 patient was febrile at 19 months after the procedure. Stricture was confirmed by enhanced CT or ultrasound and treated by repeat balloon dilatation. In the single-dilatation group, there were 15 recurrences. One of these patients had disseminated intravascular coagulation and biliary sepsis secondary to recurrent jaundice and died 3.2 months after balloon dilatation. The other 14 patients improved after repeat dilatations.

4. Discussion

Biliary-enteric anastomosis stricture is a major complication associated with hepatobiliary surgery. Approximately 20% of the strictures occur within 6 months of surgery.[12] The leading causes of benign biliary stricture include intraoperative injury, trauma, cholangitis associated with choledocholithiasis, hepatic artery ischemia, and sclerosing cholangitis. To date, the accepted first-line management of benign biliary strictures is endoscopic resolution. However, an endoscopic approach is generally considered to be inappropriate in patients who have previously undergone bilioenterostomy.[5,6] In such situations, per-oral cholangioscopy-assisted antegrade intervention has been reported as a useful technique. In addition, other novel alternative interventional EUS techniques have been also reported, such as EUS-directed transgastric ERCP in patients with Roux-en-Y gastric bypass.[13,14] Novel devices and tools designed for EUS-guided transluminal interventions allow various new applications and improve the efficacy and safety of these procedures. Specially designed stents and stent insertion devices enable intra- and extra-hepatic bile stenting as well as

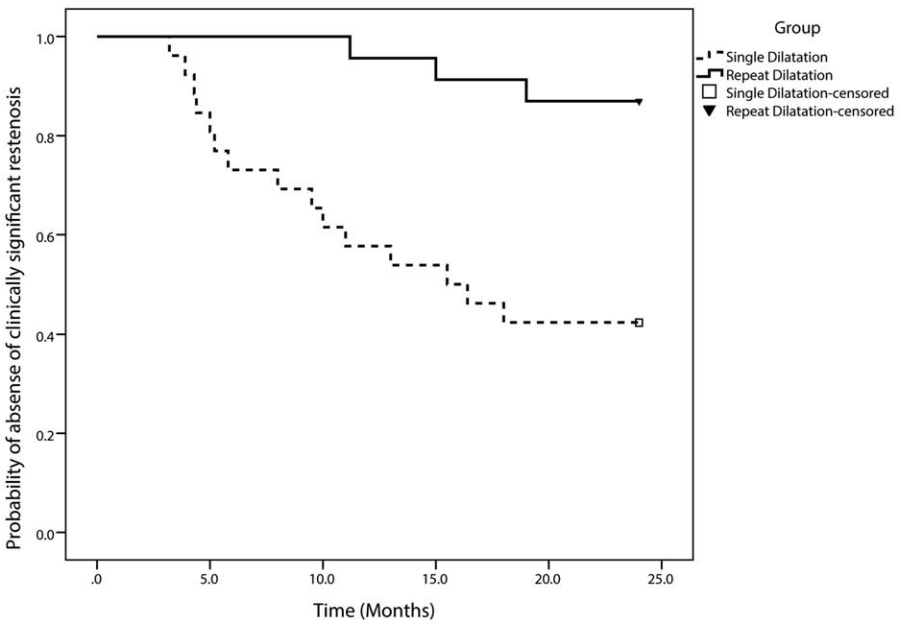

Figure 3. Kaplan–Meier plot of probability of 2 groups having clinically significant restenosis.

gallbladder drainage.[15,16] However, as it relies extremely on experience of the operator, EUS-guided transluminal interventions are restricted in the clinical application. Although the transhepatic approach is invasive, in some difficult cases, percutaneous transhepatic surgical approaches, including percutaneous transhepatic balloon dilatation with or without long-term biliary drainage and stent placement, have been suggested as possible alternatives.[5,6,17] The appropriate placement of a stent to take advantage of both the increased expansive force and prolonged dilatation effect of an in-situ stent may be associated with an increased success rate for the treatment of benign biliary strictures. Placement of non-retrievable, uncovered metallic stents have previously been attempted in patients with refractory benign biliary strictures.[18–20] However, low long-term patency and difficulty removing these stents secondary to hyperplastic tissue in-growth have limited its clinical use.[19,20] The recently developed covered metallic stents may be better for maintaining mid- to long-term patency, and, in addition, they are easier to remove.[21–25] However, in contrast to uncovered devices, covered metallic stents do not integrate into the surrounding tissue and this may in turn be associated with higher migration rates away from their original insertion location. Previous studies of covered stent placement for benign biliary strictures have reported an incidence of stent migration ranging from 2.8% to 25%.[21–25] Biodegradable stents are increasingly being used in the heart and other areas to provide adequate support for stenosis. As these stents degrade completely, the complications associated with stenting are reduced. Although the treatment of benign biliary strictures is still in its initial stages, the use of these stents is an important direction for the future.[26,27]

To date, percutaneous balloon dilatation of benign biliary-enteric anastomosis strictures has been the most widely used alternative to endoscopic treatment.[28–31] However, patency results from the precedent literature are inconsistent.[28–31] In this study, we found that repeated balloon dilatation with long-term biliary drainage was associated with significantly greater long-term anastomosis patency relative to patients undergoing single dilatation. Schwarzenberg et al[32] reported that repeated procedures conducted at 2- to 3-week intervals in 3 patients was associated with persistent biliary patency over a median 6.5 months of follow-up. Luo et al[33] reported that the anastomosis site could be progressively dilated via a balloon left in situ for up to 3 months following surgery; they found that the stricture did not recur, probably because of the support provided by the balloon during the period of wound healing and tissue remodeling at the site of anastomosis. This is consistent with what is known about the final phase of wound healing and scar tissue formation. Broughton reported that wound strength never returns to 100%; from 3% at 1 week to 30% at 3 weeks 30% and approximately 80% after 3 months.[34]

The optimal timing for removing drainage tubes post dilatation is complex and difficult to define. In this study, the biliary long-term drain was left in place after balloon dilatation not only to provide drainage but also for mechanical support of the dilated stricture and for performance of follow-up cholangiography to identify restenosis. If the anastomotic stenosis does not recur within 6 months of the index dilatation, the drain is removed. Some investigators have reported performing percutaneous transhepatic large-diameter (up to 20-F) tube interpositions through the benign bilioenterostomy stricture with long-term drainage.[13] However, the long-term maintenance of Percutaneous transhepatic biliary drainage catheters can result in significant patient discomfort and/or an increased risk of infection.[6] Other surgeons may be more interested in functional or clinical outcomes and end-points. If the patient tolerates the external biliary drain with cap for 1 to 2 weeks, the drain is subsequently removed entirely. Surgeons who prioritize clinical outcomes may lead to patients being asymptomatic for months after an anastomotic stricture has recurred.[35] Despite stricture recurrence, this approach may be associated with an extended period where the patient is "tube-free," an important morbidity consideration for patients. This potential trade-off between prioritizing patient comfort and maximizing patency duration may underscore, at least in part, the wide discrepancy in patency data in balloon dilatation studies. Clinicians who prioritize functional/clinical outcomes tend to report superior patency than those that rely solely on anatomical/cholangiographic outcomes.

Our study has several limitations. First, this was a retrospective study, and a selection bias may be present. Prospective, randomized trials would be required to validate our findings and better control for various imbalances in the distribution of prognostic correlates of our study end-points between treatment groups. Further, there is possibility that our outcome data is incomplete, for example, in patients who developed complications after balloon dilatation, but did not return to our institution for follow-up. However the likelihood of these scenarios are low, as all patients in our study resided locally and were likely to return to the care of their hepatobiliary surgeon in case of a complication.

In conclusion, our findings suggest that repeated balloon dilatation with long-term biliary drainage of biliary-enteric anastomosis strictures may provide a lasting benefit and can prevent the need for a surgical revision of the anastomosis, relative to patients undergoing single dilatation. We recommend that repeated balloon dilatation with long-term biliary drainage should be considered in patients with biliary-enteric anastomotic strictures, who are otherwise inappropriate for endoscopic management.

Author contributions

Conceptualization: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ji Ma, Ming Zhu.
Data curation: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Zhen Li, Jian-Zhuang Ren.
Formal analysis: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ji Ma, Ming Zhu, Jian-Zhuang Ren.
Funding acquisition: Xinwei Han.
Investigation: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ming Zhu, Zhen Li, Jian-Zhuang Ren.
Methodology: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ji Ma, Ming Zhu, Jian-Zhuang Ren.
Project administration: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ji Ma, Jian-Zhuang Ren.
Supervision: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ji Ma, Ming Zhu, Zhen Li, Jian-Zhuang Ren.
Validation: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ming Zhu.
Visualization: Teng-Fei Li, Pei-Ji Fu, Xinwei Han.
Writing – original draft: Teng-Fei Li, Pei-Ji Fu, Xinwei Han.
Writing – review & editing: Teng-Fei Li, Pei-Ji Fu, Xinwei Han, Ji Ma, Zhen Li.

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