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Original Article

Percutaneous transhepatic balloon dilatation of benign bilioenteric strictures: Analysis of technique and long-term outcome

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ABSTRACT

Background: To retrospectively analyze the technique and outcome of percutaneous transhepatic biliary balloon dilatation (PBBB) used to treat benign bilioenteric strictures in a series of patients who had undergone surgery for various pathologies.

Methods: We retrieved the hospital records of 90 patients with benign biliary strictures and identified 38 patients (male:female = 21:17; mean age, 50.7 ± 16.3 years [range, 13–77 years]) with benign bilioenteric strictures, treated by PBBB between 2000 and 2014. The technique, primary patency, secondary patency, clinical success and complications of PBBB were analyzed.

Results: The bilioenteric anastomoses were performed for postcholecystectomy bile duct injury ($n = 15$, 39.5%), recurrent pyogenic cholangitis ($n = 9$, 23.7%), patients operated for malignancies ($n = 8$, 21.1%), choledochal cyst excision ($n = 5$, 13.2%) and chronic pancreatitis ($n = 1$, 2.6%). All patients presented with clinical features of cholangitis. The average duration of treatment of PBBB was 3.0 ± 1.1 months (range, 1–24 months). Technical success for balloon dilatation was achieved in 33/38 (86.8%). The primary patency period and secondary patency periods were 32.5 ± 7.8 months and 22.5 ± 6.4 months, respectively. Clinical success was achieved in all patients who underwent complete balloon dilatation treatment. The post treatment mean time of follow-up was 31.4 ± 20.1 months (range, 1–140 months; median, 24 months) and was available in all patients who successfully underwent balloon dilatation treatment. Recurrence was observed in 8.1% of patients. The mean symptom-free survival time was 123.4 months (95% confidence interval, 105.8–141.1 months). One year and 2 year clinical success rate was 92.1% and 83.0%, respectively.

Conclusion: Irrespective of the underlying pathology balloon dilatation provides excellent long term relief from symptoms in patients with benign bilioenteric stricture and should be offered as the first line of management in these patients.

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Keywords: Balloon dilatation; Biliary tract; Cholangiogram; Choledochal cyst; Stricture

Introduction

The reported incidence of bilioenteric stricture in patients undergoing biliary enterostomy for various biliary pathologies ranges from 8% to 40%.^{1–4} The inevitable increase in volumes of hepatobiliary surgery for various benign and malignant diseases will also impact the incidence of this complication. If left untreated it can lead to recurrent cholangitis, liver cirrhosis and portal hypertension.² The main objective of treatment is to restore and maintain free flow of bile. Surgical revision of bilioenteric stricture is a challenge because of the very short length of bile duct available for repeat anastomosis and also local fibrosis induced by previous surgeries. The success rates for surgical repair decrease with each

successive surgical intervention.^{5–11} Endoscopic treatment, though widely used in benign biliary strictures, may not be feasible in postoperative bilioenteric strictures with altered upper gastrointestinal or bile duct anatomy.^{12,13} Percutaneous transhepatic management of benign biliary strictures involves repeated balloon dilatations with an indwelling catheter placed for the period of treatment. These techniques are now being widely employed, with varied reported success rates in ductal (76% to 88%) and anastomotic strictures (67% to 73%).¹⁴ Most studies consist of relatively small number of patients with limited long-term patency data or describe a patient populations with a mixture of bilioenteric and primary biliary strictures. The aim of our study is to retrospectively analyze the technique and outcome of percutaneous tran-

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shepatic biliary balloon dilatation (PBBD) used to treat bilioenteric strictures in a series of patients who had undergone surgery for various pathologies. We also tried to assess the effects of PBBD on liver biochemical parameters.

Methods

Patient population

Institutional review board approval was taken for this retrospective analysis (Amrita Institute of Medical Sciences and Research Center, Kochi, India). We retrieved the hospital records of 90 patients with benign biliary strictures and identified 38 patients (male:female = 21:17; mean age, 50.7 ± 16.3 years [range,

Fig. 1. Diagram showing included and excluded patients in the study. PBBD, percutaneous transhepatic biliary balloon dilatation; CCP, chronic calcific pancreatitis.

Fig. 2. Diagram showing the treatment protocol. PTC, percutaneous transhepatic cholangiogram.

13–77 years)) with benign bilioenteric strictures, treated by percutaneous transhepatic balloon dilatations between 2000 and 2014 at Amrita Institute of Medical Sciences and Research Center. Post-liver transplant biliary strictures and benign strictures treated primarily by stenting were excluded from the study (Fig. 1). Clinical records and images were retrieved from electronic medical record and picture archiving and communication system. The technique, primary patency, secondary patency, clinical success and complications of PBBD were analyzed.

Intervention technique (Fig. 2)

All patients were treated with broad spectrum intravenous antibiotics before the procedure. Procedures were performed under intravenous conscious sedation (2.5–5 mg of midazolam and 50–100 mg of fentanyl, administered intravenously). A 10 to 20 mL of 2% lidocaine was administered subcutaneously to achieve local anesthesia. During the procedure, the vital signs of patient were monitored and oxygen was administered if needed. Percutaneous transhepatic cholangiogram was performed by puncturing the bile duct using a 22 G Chiba needle (Cook Inc., Bloomington, IN, USA) under fluoroscopic guidance through a right intercostal approach (right duct) or using ultrasound guidance through an epigastric approach (left duct). After puncturing the duct, iodinated contrast material was injected to opacify the intrahepatic bile ducts and to define the level and nature of obstruction. Based on the percutaneous cholangiogram finding, an appropriate duct was selected and punctured if needed. Using a Neff-set (Cook Inc.) a 0.035-inch guidewire was placed in the system. The stricture was crossed in most cases with a combination of 5 Fr Kumpe catheter (Cook Inc.) and 0.035-inch terumo hydrophilic guidewire

(Terumo, Tokyo, Japan). A microcatheter (Progreat; Terumo) had to be employed to cross the stricture in a few instances (Fig. 3). After crossing the stricture, dilatation was performed with standard angioplasty balloons. The balloon size was decided based on the cholangiogram. Initially dilatation was performed using 6 to 8 mm balloons. In subsequent sessions larger diameter balloons (10–14 mm) were used based on the cholangiographic finding. Balloon inflation time and pressure were not standardized across the study group. The balloon was inflated slowly until the waist disappeared and care was taken never to exceed burst pressures. Finally, an internal-external biliary drainage catheter (8.5–12 Fr size) (Cook Inc.) was inserted with its tip coiled beyond the site of obstruction. After the procedure, the catheter was set initially to gravity drainage (Fig. 4, 5). The patient was discharged when clinically stable with the catheter capped and internalized. At 2 to 6 weeks intervals, patients returned to our institution for re-evaluation of hepatic function and overall clinical status and underwent repeat biliary catheter exchanges and balloons dilatations if necessary. If clinical success had been achieved then the drainage catheter was capped and the catheter was removed after a further two week trial. The functional/clinical outcome of no symptoms and/or stable liver function tests was adopted as a definitive criterion for catheter removal (Fig. 4). In six patients where stenting was performed, we used uncovered balloon expandable or self-expandable metallic stents. Complications were classified as major and minor according to the guidelines of the Society of Interventional Radiology Standards of Practice Committee.¹⁵

Fig. 3. (A-G) A 37-year-old female with recurrent pyogenic cholangitis, post-left hepatectomy and hepatico-jejunostomy stricture presenting with cholangitis. Initial cholangiogram showed stricture in sectoral duct (A, arrowhead) and at hepatico-jejunostomy site (A, arrow). Sectoral duct stricture crossed (B, arrow) and dilated with 6 mm angioplasty balloon (C, arrow). Initial attempt to cross hepatico-jejunostomy stricture failed, later crossed using Progreat (Terumo) microcatheter (D, arrow) and dilated serially with 6 and 8 mm balloons (two sessions) (E-F, arrows). (G) Magnetic resonance cholangio pancreatography 33 months later shows no significant biliary dilatation.

Fig. 4. A 16-year-old female with hepatico-jejunostomy stricture (A, arrow) following choledochal cyst excision. Balloon dilatation of stricture done with 10 mm angioplasty balloon (B, arrow) and 10.2 Fr internal-external drain (C, arrow) left *in situ* across the stricture with tip in the jejunal loop. Check cholangiogram one month later shows no residual stricture with hepatico-jejunostomy site wide open (D, arrow).

Fig. 5. A 58-year-old male with hepatico-jejunostomy site stricture (A, arrow), developed four years after Whipple's procedure for chronic pancreatitis and pseudocyst. Stricture crossed (B) and graded balloon dilatation done using 6 mm, 8 mm, and 10 mm angioplasty balloon (three sessions) (C–E, arrows). Check cholangiogram two weeks after last dilatation shows no residual narrowing and free flow of contrast across anastomosis (F, arrow).

Definition of terms and study endpoints

Terms

A complete treatment is the time period between the first balloon dilatation to the final removal of drainage catheter. A dilatation session is the dilatation of strictures, performed in a single radiological intervention. One treatment can consist of multiple dilatation sessions. One or more dilatations were performed in the initial admission and thereafter, on follow-up, the patient was admitted again for further dilatation sessions if needed.

Study endpoints

Technical success was defined as restoration of normal ante-

grade bile flow across the stricture and resolution of the stricture on cholangiogram. Unsatisfactory dilatation was defined as residual narrowing or poor/absent flow after dilatation requiring further dilatation sessions in the same treatment period to achieve technical success. Clinical success was defined by decrease in pre-procedural elevated total bilirubin and alkaline phosphatase (ALP) levels to normal values after the intervention, as well as the absence of cholangitis in the first month after treatment. The total bilirubin and ALP levels were measured a day before the procedure and 4 to 6 weeks after the completion of treatment. Primary patency was defined as the time interval from drainage catheter removal to the detection of recurrent symptoms or the last follow-up. Secondary patency was defined as the patency following one

Table 1 Summary of Treatment Technique and Outcome in Various Aetiologies

Aetiology	Patient (n = 38)	Balloon dilatation	Balloon dilatation + stenting	Average sessions of dilatations	Average duration of treatment (mo)	Primary patency (mo)	Follow-up (mo)
Post-cholecystectomy	15	11	4	2.3 ± 0.8	2.2 ± 2.6	30.5 ± 29.4	31.4 ± 31.9
Recurrent pyogenic cholangitis	9	9	0	3.0 ± 0.9	4.8 ± 7.5	29.5 ± 44.7	29.6 ± 32.1
Post-choledochal cyst excision	5	4	0	1.5 ± 0.6	1.5 ± 1.4	45.8 ± 28.9	60.0 ± 6.0
Chronic pancreatitis	1	1	0	2	3.4 ± 3.4	24	24
Operated for malignancies*	8	6	2	2.3 ± 0.1	2.9 ± 0.3	33.5 ± 45.7	35.5 ± 40.7

Values are presented as number only or mean ± standard deviation.

GIST, gastrointestinal stromal tumor.

*Hepatectomy (3) for cholangiocarcinoma and pancreaticoduodenectomy procedure (5) for duodenal GIST, 2; periampullary carcinoma, 2; neuroendocrine metastases, 1.

Table 2 Liver Biochemical Parameters before and after Treatment

Aetiology	Total bilirubin (mg/dL)		Alkaline phosphatase (IU/L)	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Post-cholecystectomy	3.23 ± 2.51	1.32 ± 1.37	471.41 ± 409.98	128.30 ± 120.20
Recurrent pyogenic cholangitis	2.10 ± 1.89	0.66 ± 0.40	241.10 ± 118.01	118.40 ± 83.30
Operated for cholangiocarcinoma	12.43 ± 3.89	1.90 ± 1.40	955.00 ± 519.29	138.20 ± 75.50
Operated for malignancies	4.76 ± 4.79	0.76 ± 0.45	519.00 ± 250.26	123.20 ± 90.18
Chronic pancreatitis	13.76 ± 13.94	1.23 ± 1.25	400.00 ± 116.22	107.80 ± 68.22
Post-choledochal cyst excision	8.18 ± 14.44	0.76 ± 0.64	449.80 ± 127.03	95.80 ± 36.28

Values are presented as mean ± standard deviation.

additional percutaneous re-intervention due to clinical relapse of the symptoms. A stricture was considered to have recurred if more than 50% narrowing of treated stricture was seen at imaging done after completion of treatment. Follow-up period was defined as the time from the end of the last treatment until the last known point in time without recurrent stricture or death. Follow-up was done either by imaging (ultrasound, computed tomography, magnetic resonance cholangiopancreatography or cholangiograms) or laboratory investigations (total bilirubin and ALP).

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 20.0 software (IBM Co., Armonk, NY, USA). The data was analyzed using descriptive statistical methods. Comparison between groups was done using Wilcoxon signed-rank test. Differences were considered to be significant if $P < 0.05$. Kaplan-Meier curves were generated to determine the symptom free survival in the patients.

Results

The various causes for which bilioenteric anastomoses were performed in our patients is shown in Table 1. All patients presented with clinical features of cholangitis.

Treatment

Majority of patients (18 patients) underwent two dilatation sessions, eight patients required three sessions, four sessions were required in three patients and four patients were treated with single session of balloon dilatation. The average duration of treatment of PBBD was 3.0 ± 1.1 months (range, 1–24 months) (Table 1).

Technical success and clinical success

Technical success for balloon dilatation was achieved in 33/38 (86.8%). The primary patency period and secondary patency period were 32.5 ± 7.8 months and 22.5 ± 6.4 months, respectively. Clinical success was achieved in all patients who underwent complete balloon dilatation treatment. The mean value of total bilirubin before and after treatment was 7.4 ± 4.8 mg/dL and 1.6 ± 1.7 mg/dL respectively and the mean value of ALP before and after treatment was 501.5 ± 245.9 IU/L and 117.6 ± 13.6 IU/L respectively. Post-treatment statistically significant ($P < 0.001$) decrease in bilirubin and ALP was observed (Table 2). In one patient with bilioenteric stricture following choledochal cyst excision we were not able to cross the stricture (Fig. 6). In another patient with bilioenteric stricture following excision of duodenal gastrointestinal stromal tumor (GIST), the initial balloon dilatations failed to resolve the stricture and therefore stenting was done in the same treatment session (Fig. 7). These two cases were deemed as technical failure. In addition, three patients refused to have the external drain after initial dilatation sessions and stenting was performed after crossing the stricture. Though the PBBD was not complete in these patients they were also considered as technical failure for statistical analysis. With regard to complications, none of our patients had any major procedure related complications like hemobilia requiring blood transfusion, anastomotic rupture (bile leak), sepsis, pneumothorax or death.

Follow-up

The post treatment mean follow-up period was 31.4 ± 20.1 months (range, 1–140 months; median, 24 months) and was available in all patients who successfully underwent balloon dilatation treatment. Long term follow-up (> 24 months) was avail-

Fig. 6. A 13-year-old female with hepatico-jejunostomy stricture (A, arrow) following choledochal cyst excision. Repeated attempts to cross the stricture through right (B, arrow) and left (D, arrow) sectoral ducts failed. Note the external drain in right ductal system (C, arrow). Patient underwent repeat hepatico-jejunostomy.

Fig. 7. A 54-year-old female with hepatico-jejunostomy site stricture (A, arrow) two years post Whipples surgery for duodenal gastrointestinal stromal tumor. Graded dilatation of stricture done with 6 mm, 8 mm, and 10 mm angioplasty balloons (three sessions) over three months period (B, C, arrows). However in view of significant residual stricture (D, arrow) a 7 × 37 mm balloon expandable metallic stent was deployed across the stricture (E, arrow).

able in 20 patients (54.1%). Recurrent symptoms were observed in 3/37 patients (8.1%) treated by balloon dilatation. In one patient with RPC and bilioenteric stricture, recurrence occurred 18 months post-treatment, for which patient underwent repeat balloon dilatation and follow-up period (36 months) was uneventful. In other two patients (postcholecystectomy) technical success was achieved initially with balloon dilatation but later stenting was done due to recurrent stricture at 10 months and 12 months respectively. Applying Kaplan-Meier curves, the mean symptom free survival time was 123.4 months (95% confidence interval, 105.8–141.1 months). Clinical success rate at one year was 92.1% and at two year was 83.0% (Fig. 8).

Discussion

Benign bilioenteric strictures are an uncommon clinical and radiologic problem requiring repeated treatment and long-term follow-up of patients. Percutaneous transhepatic interventional techniques play an important role in management of this challenging problem.¹⁶ In this study we have tried to analyze the technique and outcome of PBBD in various category of patients who have undergone bilioenteric anastomosis. Uniquely we have tried to analyze whether the underlying disease has impact on the outcome. The outcomes were evaluated both in terms of normalization of biochemical parameters and symptom free survival.

Recurrent pyogenic cholangitis (RPC) is a progressive inflam-

matory disease with recurrent episodes of jaundice and cholangitis. It is characterized by intrahepatic biliary strictures and hepatolithiasis. Left untreated cirrhosis develops and there is increased risk of hepatocellular carcinoma and cholangiocarcinoma.¹⁷ In our series 9/38 patients (23.7%) had bilioenteric strictures following surgery for RPC. We observed that a higher number of dilatation sessions (3.0 ± 0.9) and duration of treatment (4.8 ± 7.5 months; range, 0.73–24 months) was required in these patients for treatment completion as compared to other categories (Table 1). This may be due to the very fibrotic nature of stricture as a result of persistent stasis and recurrent cholangitis characteristic of RPC. Excellent technical and clinical success was observed in all these patients with primary patency of 29.5 ± 44.7 months. Yoon et al¹⁸ studied the long term patency of metallic stents in patients with RPC and concluded that metallic stents have high occlusion rates and do not offer a long term solution. The most common cause of stent malfunction is stone or sludge formation inside the stent due to the ongoing disease and bile stasis.

Cholecystectomy is the most common cause of postoperative biliary stricture constituting up to 80% cases in some series.^{19,20} Usually these patients are managed with hepaticojejunostomy. In our series, 15/38 patients (39.5%) belonged to this category. Mean

duration of treatment was 2.2 ± 2.6 months. Technical and clinical success was achieved in 14/15 patients (93.3%) with primary patency of 30.5 ± 29.4 months. Our results are comparable to other studies.^{21–23} One of the problems in patients requiring repeated interventions is the onset and progression of cirrhosis secondary to chronic cholestasis. Percutaneous approach in the presence of cirrhosis and periductal fibrosis can be challenging and metallic stents, despite their limited patency, may become a justifiable option.

Ramos-De la Medina et al²⁴ have observed that percutaneous techniques are more likely to fail in patients operated for malignancy than without malignancy. In our series, eight patients had bilioenteric stricture after surgery for a malignancy (cholangiocarcinoma, 3; duodenal gastrointestinal stromal tumor, 2; periampullary carcinoma, 2; neuroendocrine tumor metastasis, 1). The 6/8 patients (75%) showed good technical and clinical success with primary patency of 33.5 ± 45.7 months. In our series bilioenteric strictures in this category responded well to PBBDD.

The bilioenteric strictures in patients who undergo choledochal cyst excision pose a special challenge because these patients are relatively young and may require repeated interventions and close follow-up lifelong.^{25–27} In our series, the mean age of patients presenting with symptoms was 18.4 ± 4.5 years (13–25 years) and average time between surgery and stricture formation was 42.6 ± 42.9 months (18–108 months). Technical success was achieved in 4/5 patients (80%) with primary patency period of 45.8 ± 28.9 months. We observed that these patients require relatively lesser dilatation sessions (1.5 ± 0.6) and time of treatment (1.5 ± 1.4) as compared to patients with other etiologies and also had better outcome (Fig. 9, Table 1).

Chronic pancreatitis with distal CBD strictures are usually managed successfully by endoscopic approach with good success rate.²⁸ Percutaneous approach may be required in patients with proximal biliary and postoperative bilioenteric strictures. In our series, one patient had developed bilioenteric stricture post-pancreaticoduodenectomy. The patient was managed successfully with balloon dilatation (two sessions) and follow-up period (24 months) was uneventful.

In a recent study, DePietro et al²⁹ showed good long term results by treating the benign biliary strictures with a structured protocol (staged upsizing of internal/external biliary catheters fol-

Fig. 8. Kaplan-Meier curve for symptom free survival time.

Fig. 9. A 13-year-old male with choledochal cyst excision and hepatico-jejunostomy stricture (A, arrow). Stricture dilated with 10 mm (B, arrow), 12 mm (C, arrow) angioplasty balloons (two sessions). Stones in the biliary system (A, arrowhead) cleared with saline flush. Magnetic resonance cholangiopancreatography 54 months later shows wide open hepatico-jejunostomy site (D, arrow).

lowed by cholangioplasty and replacement of optimal size catheter for 6 months). We treated strictures primarily with graded balloon dilatation followed by placement of appropriate sized catheter across the stricture site. Long term patency rates in our study are slightly better as compared to those reported by DePietro et al.²⁹ We used standard angioplasty balloons in all patients. Special high pressure or cutting balloons were not used. The end point of treatment in our study was either cholangiogram which demonstrated no residual stenosis or the absence of cholangitis in the first month after treatment. Biliary manometric perfusion test has been used in some studies to define the end point of the treatment. The manometric perfusion test has shown same efficacy as the clinical findings for predicting long term patency of strictures treated by PBBD.^{30,31} The technical success of PBBD for benign biliary strictures in literature is 93% to 100%.^{21,32-34} We achieved a technical success of 86.8% (33/38). The stricture could not be crossed in only one patient. However the three patients who refused to have the external drain were primarily stented after initial balloon dilatation sessions and were considered as technical failures for purpose of statistical analysis. The reported clinical success rate of PBBD for benign biliary strictures is 75% to 94%.^{21,32,33} In our study clinical success was achieved in all patients who underwent complete balloon dilatation treatment. Though we did not do a formal cost analysis it would be reasonable to assume that the minimally invasive percutaneous approach using standard commonly used devices will be less expensive and definitely less morbid than a major open surgery requiring general anesthesia and intensive postoperative care. Repeated treatment sessions spread over many months, however, demands high degree of patient motivation and compliance.

The limitations of the study are its retrospective nature and lesser number of patients in each category.

Irrespective of the underlying pathology balloon dilatation provides excellent relief from symptoms in patient with bilioenteric strictures. Our long term results cutting across all categories indicate that percutaneous balloon dilatation should be offered as the first line of management in patients with bilioenteric strictures.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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