

International Journal of Medical Science and Innovative Research (IJMSIR)

IJMSIR : A Medical Publication Hub

Available Online at: www.ijmsir.com Volume – 6, Issue – 6, November – 2021, Page No. : 99 - 108

Outcomes of Endotherapy for Chronic Pancreatitis related Benign Biliary Strictures – A single centre observational study

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Citation this Article: Deepak K Johnson, Ashwin Alexander, Ivan Koshy, Vinod Pillai, "Outcomes of Endotherapy for Chronic Pancreatitis related Benign Biliary Strictures – A single centre observational study", IJMSIR- November - 2021, Vol – 6, Issue - 6, P. No. 99 – 108.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

The aim of the study is to assess the efficacy of Endotherapy in management of chronic pancreatitis related benign biliary strictures using both multiple plastic stents as well as fully covered self-expanding metallic stents and identify predictors of therapeutic success. Thirty four patients who underwent endotherapy for chronic pancreatitis related benign biliary strictures were retrospectively evaluated. Patients underwent ERCPs every 3 months with sequential exchange and addition of multiple plastic stents. Patients who opted for fully covered self expanding metal stents were also included. Diameter of bile duct and length of stricture was calculated at index cholangiography. Stents were kept in situ for twelve months and then removed. Resolution of the stricture

was assessed at the final ERCP done at twelve months. Patients were followed up for 6 months after therapy, interviewed for cholestatic symptoms, and underwent liver function testing at regular intervals. Patients with complete and incomplete stricture resolution were compared. Endotherapy was completed in 31 out of 34 patients. In three patients, recurrent cholangitis necessitated an early surgical intervention. Mean number of ERCP sessions were 4.2 +/- 1 . Mean number of biliary stents was 5.1 +/- 1.2. Complete stricture dilation was achieved in 29 patients (85.2%). A significant improvement in CBD diameter was noted after twelve months of endotherapy (before therapy;13.6 +/- 2.8 mm, after therapy;8.4 +/- 3.5 mm, P= 0.03).A total of five out of thirty four received FCSEMS and four out of five had complete stricture

resolution. Endotherapy using sequential placement of multiple plastic stents or uninterrupted therapy with fully covered self-expanding metallic stent is and effective option for chronic pancreatitis related benign biliary strictures. Presence of pancreatic head calcification and stricture length more than 23 mms were identified as adverse predictors of therapeutic success.

Keywords: Chronic pancreatitis; Benign biliary stricture; Endotherapy; Multiple plastic stenting; FCSEMS; Cholangitis

Introduction

Common bile duct (CBD) stenosis occurs in upto thirty percent of patients with chronic pancreatitis (CP)^[1]. Since the distal bile duct is encompassed within posterior head of pancreas, an inflammatory head mass, fibrosis due to chronic inflammation, pancreatic head cancer as well as a large pseudocyst can cause biliary obstruction. The intrapancreatic portion of the CBD varies in length from 1.5 to 6 cm, which accounts for the variability of stricture lengths seen in clinical practice^[2]. Most cases of benign biliary strictures are incidentally detected on imaging. However, some patients present with abdominal pain, obstructive jaundice, cholangitis or persistently abnormal liver biochemistries. A small proportion ultimately develop secondary biliary cirrhosis^[3].Definitive therapy of benign biliary stricture is surgical by pass by choledochoduodenostomy or choledochojejunostomy. Endoscopic stenting of bile duct is a less invasive alternative to surgery though long term results are inferior. Placement of a single fully covered self expanding metallic stent (FCSEMS) or sequential placement of multiple plastic stents kept for 12 months is the suggested endoscopic approach.

Materials and methods

A total of thirty four patients who visited the gastroenterology department of our teaching hospital during the period March 2016 to April 2021 with a diagnosis of chronic pancreatitis and benign biliary stricture were included. Patients who were less than 18 years old or more than 80 years old, those with underlying pancreatobiliary malignancy, existence of coagulopathy, previous biliary surgery, major medical contraindications for general anesthesia/ERCP (endoscopic retrograde cholangio pancreatography) were not included. Apart from routine tests, all patients had underwent a pancreatic protocol computed tomography (CT) scan at baseline for confirmation of chronic pancreatitis and diagnosing biliary stricture. Written informed consent was obtained from all patients who underwent endotherapy. The study protocol was approved by the institutional review board. At the end of therapy, patients were followed up for cholestatic symptoms and liver function tests (LFT) were done.

Definitions: Diagnosis of chronic pancreatitis was based on history and morphologic abnormalities of the pancreas as seen in computed tomography, magnetic resonance cholangiopancreatography (MRCP) or endoscopic ultrasound^[4]. Diagnosis of benign biliary stricture (BBS) was based on cholestatic symptoms and liver biochemistries, and evidence of upstream biliary dilation on imaging in the absence of pancreatic head mass^[5]. Patients age, sex, duration of chronic pancreatitis, alcohol v/s non alcoholic chronic pancreatitis, Bilirubin, alkaline phosphatase , gamma glutamyl transferase, diameter of bile duct, length of stricture, number of pancreatic stones, location of stones, diameter of largest stone, main pancreatic duct diameter, number of pancreatitis episodes, mean number of ERCPs, mean number of biliary stents used were considered as potential variables that predict success of endotherapy. During follow up, relapse was defined by symptomatic biliary obstruction or episodes of cholangitis.

Procedure: Olympus sideview endoscopes were used for all cases. A biliary sphincterotomy was done during index ERCP.A thorough cholangiography with measurement of length of the stricture and maximal diameter of the common bile duct (CBD) upstream of stricture was noted. A hydrophilic guidewire was placed across the stricture and atleast two seven Fr straight plastic stents placed in first session. ERCP was repeated every three months or earlier based on signs/symptoms of stent block. Stent exchanges and sequential addition of multiple plastic stents were done during the subsequent sessions. All stents were removed after a period of twelve months from index ERCP. Resolution of stricture and diameter of bile duct was measured during the final cholangiography. Patients were followed up for six months from last ERCP to look for symptomatic recurrence of biliary stricture. Patients who opted for therapy with fully covered self expanding metallic stents (FCSEMS) were offered the same.A double pigtail plastic stent was placed through the FCSEMS to prevent migration. The FCSEMS was removed after duration of twelve months only. Stricture was considered to have resolved if an 8.5 mm balloon could be passed across and there was rapid clearance of injected contrast as seen in fluoroscopy ^{[6].} Complications related to ERCP and stent block were meticulously recorded as well.

Outcomes: The main study outcome was to assess the efficacy of endotherapy for chronic pancreatitis related benign biliary stricture. Clinical success was defined by improvement in LFTs, decrease in upstream bile duct diameter and absence of cholangitis. Stricture was considered to have resolved if an 8.5 mm balloon could be passed across and there was rapid clearance of injected contrast as seen in fluoroscopy. Accordingly, patients with adequate stricture dilation as per the above criteria were assigned to the 'complete' group and those with inadequate stricture dilation were included in the 'incomplete ' group.

Statistical methods: Continuous variables were compared with Mann Whitney U test. For comparison of categorical variables, Fishers exact test was used. The differences in the median values of proposed predictors were identified using Wilcoxon signed rank test. A probability value (P value) <0.05 was considered significant. All statistical analysis were done using latest version of SPSS software.

Results

Patients: The baseline patient demography, duration of diagnosis of chronic pancreatitis, duration of therapy as well as follow up, pre procedure imaging findings and interventions of all patients is described in table 1. The ERCP procedures were tolerated well in all thirty four cases. Completion of therapy (12 months with multiple plastic stents/FCSEMS) was achieved in 31 cases (91.1%). In three patients, recurrent cholangitis necessitated an early surgical intervention. Mean number of ERCP sessions were 4.2 +/- 1. Mean number of biliary stents was 5.1 +/- 1.2. Complete stricture dilation was achieved in 29 patients (85.2%). A significant improvement in CBD diameter was noted after twelve months of endotherapy (before

therapy;13.6 +/- 2.8 mm, after therapy;8.4 +/- 3.5 mm, P= 0.03). A total of five out of thirty four received Table 1: Baseline patient characteristics imaging finding

FCSEMS and four out of five had complete stricture resolution (80%).

Table 1: Baseline patient characteristics, imaging findings and interventions before completion of therapy (n=34).

Variable	Value		
Sex, n (%)			
Male	25 (73.5%)		
Female	9 (26.4%)		
Age, mean +/- SD, years	54.3 +/- 7.3		
BMI, mean +/- SD, kg/m ²	21.2 +/- 2.7		
Etiology, n (%)			
Tropical calcific pancreatitis	28 (82.3%)		
Alcohol related	6 (17.7%)		
Duration of CP, mean +/- SD, months	121.3 +/- 76.4		
Treatment period, mean +/- SD, days	372.4 +/- 77		
Follow up period, mean +/- SD, months	7.3 +/- 2.7		
LFT at baseline			
Bilirubin (mg/dl)	7.7 +/- 2.7		
Alkaline phosphatase (U/l)	228 +/- 26.8		
GGT	356 +/- 38.2		
No of pancreatic stones (n, %)			
Single	3 (8.8)		
Multiple	31 (91.7)		
Pancreatic stone location (n, %)			
Head	25 (73.5)		
Body + Tail	9 (26.5)		
Pancreatic stone diameter, mean +/- SD, mm	12.3 +/- 5.7		
Interventions			
No of ERCP sessions, mean +/- SD	4.2 +/- 1		
No of stents, mean +/- SD	5.1 +/- 1.2		
Imaging findings			
CBD diameter, mean +/- SD, mm	13.6 +/- 2.8		
Stricture length, mean +/- SD, mm	23.9 +/-5.7		

Variable	Complete(n=29)	Incomplete(n=5)	P value
Sex (n, %)			
Male	21 (72.4)	4 (80)	
Female	8 (27.6)	1 (20)	
Age, mean +/- SD, years	51.2 +/- 2.4	56.3 +/- 2.3	0.68
BMI, mean +/- SD, kg/m^2	19.2 +/-1.7	22.4 +/- 2.4	0.28
Etiology, n (%)			
Tropical calcific pancreatitis	26 (89.6)	4 (80)	
Alcohol related	3 (10.4)	1 (20)	
Duration of CP, mean +/- SD, months	86.4 +/-21.3	146.3 +/- 36.4	0.25
Treatment period, mean +/- SD, days	397 +/- 26.4	312 +/- 22.3	0.18
LFT at baseline			
Bilirubin (mg/dl)	6.8 +/- 2.2	7.8 +/- 2.4	0.92
Alkaline phosphatase (U/l)	216 +/- 22.4	234 +/- 27.9	0.87
GGT	345 +/- 35.5	362 +/- 40.2	0.94
No of pancreatic stones (n, %)			
Single	2 (11)	1 (6.2)	
Multiple	16 (89)	15 (93.8)	
Pancreatic stone location (n, %)			
Head	10 (52.6)	15 (100)	
Body + Tail	9 (47.4)	0 (0)	
Pancreatic stone diameter, mean +/- SD, mm	9.3 +/- 3.5	14.4 +/- 4.2	0.08
Interventions			
No of ERCP sessions, mean +/- SD	4.3 +/- 1.1	4.2 +/- 0.8	0.95
No of stents, mean +/- SD	5.4 +/-1.2	4.9 +/- 1.1	0.87
Imaging findings			
CBD diameter, mean +/- SD, mm	13.1 +/- 2.4	13.8 +/-2.6	0.82
Stricture length, mean +/- SD, mm	20.5 +/- 3	29 +/-5.1	0.011

Table 2: Univariate analysis of factors predicting complete stricture resolution

Discussion

Chronic pancreatitis is characterized by chronic inflammation and fibrosis of pancreas, leading to slow destruction of parenchyma, manifested by chronic abdominal pain, exocrine and endocrine insufficiency. Chronic pancreatitis related biliary strictures (BBSs) are the most common nonsurgical benign biliary strictures (BBSs) occurring in up to 13-21% of patients ^{[7].} CP related strictures involve the distal CBD and are difficult to treat due to fibrosis, scarring and calcification of bile duct wall. Clinical presentations vary from asymptomatic elevation in liver biochemistries, obstructive jaundice, life threatening cholangitis and rarely secondary biliary cirrhosis.

Diagnosis is made by cross sectional imaging using pancreatic protocol CT or MRI with MRCP. MRCP features of benign biliary stricture include smooth, symmetrical, short segment narrowing. In contrast, malignant strictures are asymmetrical, irregular and longer than 14 mms^[8]. CA 19-9 may not have much diagnostic value since it can be elevated to very high levels in the presence of obstructive jaundice even without cancer. Endoscopic ultrasound (EUS) and targeted biopsy of small pancreatic head tumors or thickened bile duct wall also helps to refine diagnosis. Biliary brush cytology and intraductal forceps biopsy can be used as adjunct techniques to rule out cancer, but are limited in use due to low sensitivity.

Indications for therapy (Frey et al)^[9]:

- 1. Symptomatic cholangitis or infected bile
- 2. Biliary cirrhosis (biopsy proven)
- 3. CBD stones in association with biliary stricture
- 4. Inability to rule out cancer

5. Progression of the CBD stricture based on radiological assessment

6. Persistent jaundice for over a month

7. Persistently elevated alkaline phosphatase (> 3 xULN for more than one month)

Endoscopic therapy is the recommended first line therapy for CP related biliary strictures. Endoscopic therapy for BBSs is safe, effective, repeatable and is less invasive than surgery. But CP related biliary strictures are more refractory to endotherapy compared

other BBSs, especially if pancreatic head to calcifications are present ^{[10].} Endoscopic methods include dilation using over the wire balloon or bougie dilators. Placement of a single plastic biliary stent is associated with dismal long term success rates. Uncovered SEMS are not suitable in BBSs, because reactive tissue ingrowth into the bare wire lattice makes subsequent difficult. removal very Sequential placement of multiple plastic stents has traditionally been used to treat CP related BBSs. Plastic stents are exchanged and added every 3 months and kept for a total duration of 12 months. A systematic review of 47 trials including 1,116 patients with extrahepatic BBS showed that placing multiple plastic stents had higher clinical success (94.3% vs 59.6%) and fewer adverse events (20.3% vs 36.0%) compared with placement of a single plastic stent, respectively^{[11].} According to the ESGE guidelines, if endoscopic therapy is selected for BBS caused by CP, temporary (one year) placement of multiple, side by side, plastic biliary stents is recommended ^[12]. The aim of our study was to assess the efficacy of endotherapy in CP related benign biliary strictures using both multiple plastic stents as well as FCSEMs and to identify the predictors of therapeutic success. In our study, the mean number of biliary stents was 5.1 \pm 1.2 and the mean number of ERCP sessions was 4.2 + - 1, similar to those reported in previous studies [13, 14, 15].

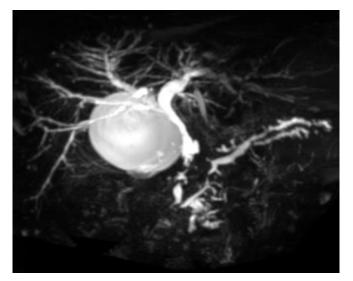


Figure 1a: Distal CBD benign stricture in a chronic pancreatitis patient. Irregularly dilated main pancreatic duct also noted



Figure 2b: Multiple plastic stents (six) deployed by ERCP

World over, alcohol is considered as the most common aetiology of chronic pancreatitis. However in developing countries of the tropical world,Tropical calcific pancreatitis is the most common identifiable aetiology^[16].In our study also, majority of our patients (82.3%) had tropical calcific pancreatitis as the aetiology consistent with previously published data.

Patients with BBS due to chronic pancreatitis in general respond less well to endotherapy compared to other

benign biliary strictures. The presence of calcification in the pancreatic head and stricture location according to the Bismuth classification was used to predict complete stricture dilation in previous studies^[6.].Our study identified presence of pancreatic head stones as well as stricture length more than 23 mms as important adverse predictors of endotherapy success. Hence based on the above factors, a careful patient selection will be helpful in identifying those who will benefit from endotherapy v/s surgical biliary bypass.

In our study, complete stricture dilation was observed in 29 patients (85.2%), consistent with previous studies (44% - 92%) ^{[6,17].} The results suggest that multiple plastic biliary stenting is a useful procedure for treatment of chronic pancreatitis related BBS. In the small group of patients who received FCSEMS, complete stricture resolution was noted in 80% consistent with previous reports.

self-expanding Fully covered metallic stents (FCSEMSs) are increasingly being used due to their larger diameter, ease of placement and need for fewer number of procedures^[18,19]. In a large prospective study of 177 patients with BBSs who received FCSEMS, stricture resolution was noted in 135(76.3%) patients. Removal of the stent was possible in all (n=131) patients scheduled for stent removal, of which 124(94.7%) had no stent removal related adverse events^[20].In another study where FCSEMs were kept for 6 months for CP related BBSs refractory to prior placement of plastic stent, stricture resolution was noted in 70.6% (12 out of 17). No stricture recurrence was noted in the eight patients who completed two year follow up^[19]. FCSEMSs are not without drawbacks either. Inward or outward SEMS migration can occur. Insertion of a double-pigtail plastic stent within an

FCSEMS may help to anchor it, and has been shown to reduce migration and prolong stent indwelling^[21].Recurrent cholecystitis due to obstruction of the cystic duct opening can occur and may necessitate additional salvage procedures. FCSEMSs are unsuitable for hilar located BBSs, since it blocks biliary drainage from opposite hepatic lobe. In our study, a total of five out of thirty four received FCSEMS and four out of five had complete stricture resolution. There was one stent migration in FCSEMS group requiring re intervention.

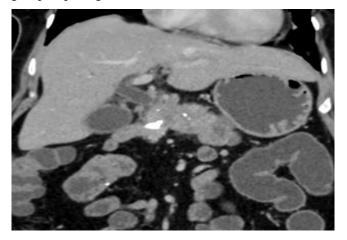


Figure 2a: Distal CBD benign stricture in a chronic pancreatitis patient with big calculi in pancreatic head



Figure 2b: Fully covered SEMS (FCSEMS) deployed at endotherapy across the stricture

A systematic review of data from 25 studies found endotherapy for CP related BBSs resulted in clinical success of 77% with FCSEMS v/s 33% with plastic stents after 12 months of follow up^[22]. The median number of ERCP procedures required to achieve clinical success was lower for SEMSs than plastic stents (1.5 vs 3.9, respectively; P=0.002). In another study of 60 patients with CP-related BBSs, patients were randomized to receive either a single 10 mmdiameter covered SEMS or three initial 10 Fr plastic stents, followed by placement of three more 10 Fr stents after 3 months. All stents were removed after 6 months. The 2-year stricture-free rate was 92% in patients receiving SEMSs and 90% in patients receiving plastic stents (P=0.405)^[23].Overall, the data support the use of covered SEMSs as an effective therapy for the management of CP-related BBS, and these may be considered for first-line use over plastic stents. A small percentage of patients may not respond to endoscopic therapies, and will eventually require surgical biliary drainage.

The limitation of our study is retrospective study design, single centre -single operator study and relatively smaller sample size. Larger multicentre prospective studies would be helpful in confirming our study findings.

Conclusion

Our study identified that endotherapy with multiple plastic stents or FCSEMS is a very effective option for chronic pancreatitis related distal CBD stricture. Presence of pancreatic head calcifications and length of stricture more than 23 mms were identified as adverse predictors of successful endotherapy. Hence consideration of above factors would be helpful in deciding between endotherapy or surgery in CP related benign biliary strictures.

Abbreviations

CBD – Common Bile Duct CP – Chronic pancreatitis ERCP-Endoscopic Retrograde Cholangio pancreatography CT -computed tomography LFTliver function test MRCP- magnetic resonance cholangiopancreatography BBS – Benign biliary stricture GGT – Gamma glutamyl transferase BMI – body mass index EUS – endoscopic ultrasound

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