Gastrointest Interv 2015; 4:1–8

Contents lists available at ScienceDirect

Gastrointestinal Intervention

journal homepage: www.gi-intervention.org

Invited Review Article

Endoscopic approach to benign biliary obstruction

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A B S T R A C T

During the past 30 years, the endoscopic approach to benign biliary strictures (BBS) became the preferred "mini-invasive" treatment modality for benign diseases. Endoscopic plastic or metallic stenting, and balloon dilation represent the gold standard treatment for BBS. Side-by-side insertion of multiple plastic stents is a very effective treatment option for BBS following cholecystectomy or liver transplantation. This strategy has a low recurrence rate on long-term follow-up, with better results than fully covered self-expandable metal stents (FC-SEMS). FC-SEMS seems to have an advantage and higher stricture resolution rate in patients with BBS secondary to chronic pancreatitis. Dilation of dominant biliary strictures in patients with primary sclerosing cholangitis has a lower rate of infective complications than the stenting treatment. Endoscopic retrograde cholangiopancreatography represents a safe and effective approach to BBS, with a very high success rate, especially when such cases are managed in a multidisciplinary setting.

Keywords: benign biliary strictures, ERCP, fully covered, plastic stent, self-expandable metal stent

Introduction

Benign biliary strictures (BBS) can be classified as postoperative and secondary to benign biliopancreatic diseases.

Postoperative biliary strictures can be related to an iatrogenic injury following cholecystectomy or can occur at the biliary anastomosis after liver transplantation. The most common diseases leading to benign biliary strictures are chronic pancreatitis (CP) and primary sclerosing cholangitis (PSC). Rare causes include portal biliopathy, polyarteritis nodosa, radiofrequency ablation, radiotherapy, and tuberculosis.

Endoscopic drainage of BBS is effective to restore bile flow. Multiple plastic stents insertion, and recently introduced fully covered self-expandable metal stents (FC-SEMS) can induce healing of BBS, especially after cholecystectomy, liver transplantation, and those secondary to CP. Endotherapy of PSC-related biliary strictures can obtain temporary improvement of the biliary strictures but chronic disease progression requires repeated treatments.

Endoscopic treatment of benign biliary strictures: plastic and metal stents

Plastic stents

Plastic stents were used for the first time in the late 1970s[1,2] for the endoscopic drainage of malignant biliary strictures. To date a variety of plastic stents are available, and improvement of endoscopes and devices (guidewires, catheters, or dilators) made possible plastic stent insertion in tight and angled strictures as in the setting of BBS.

Plastic stents are available in different lengths (up to 18 cm) and diameters [up to 11.5 French (Fr)]. They are usually tapered on one end to facilitate negotiation of the strictures; 10 Fr is the preferred diameter in BBS because it allows a good bile flow and can be easily pushed into the 4.2-mm working channel of the therapeutic duodenoscope.

Straight stents are the standard design for biliary and pancreatic indications. The choice of the stent depends on the bile duct anatomy and stricture features. Straight stents are usually slightly bent to conform to the anatomy of the biliary ducts. They may have side holes for better drainage, and are provided with side flaps to avoid displacement and migration.

The choice of the stent length is related to the distance between the proximal end of the stricture and the papilla of Vater, which can be measured by graduated catheters.

The availability of different plastic stent size, shape, and diameter permit to "tailor" the stent case by case, according to BBS characteristics. Plastic stents make also possible the treatment of postcholecystectomy BBS involving the main hepatic confluence.

Materials

Three different polymers were used for biliary and pancreatic stents: polyethylene, Teflon, and polyurethane.

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Received 1 March 2015; Revised 14 April 2015; Accepted 16 April 2015
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2213-1795
http://dx.doi.org/10.1016/j.gii.2015.04.001

Despite promising preliminary studies, none of these materials provided any definite advantage in terms of longer patency, when compared to standard polyethylene stents in clinical practice.[1,3–9]

Polyethylene is the material most commonly used for plastic stents.

Plastic stents insertion

In the setting of BBS, the biliary sphincterotomy is recommended to facilitate repeated stent exchange, insertion of multiple plastic stents, and possible retreatment. Angle- or straight-tip fully hydrophilic guidewires are recommended to negotiate tight BBS. Following mechanical or balloon dilation, the plastic stent can be inserted. Usually two or more plastic stents are placed side by side to dilate BBS. A good coordination between operator and assistant is required to place multiple plastic stents (MPS) and to avoid intrabiliary stent migration; this fact does not represent a clinical problem because bile can flow alongside the stents, but can make stent removal difficult during retreatments.

Two or more plastic stents for BBS?

Dilation of BBS was attempted by insertion of two 10 Fr plastic stents with planned exchange every 3 months for 1 year; at the end of 1-year treatment stents were removed, but stricture recurrence was high (20%).[2] An "aggressive" approach to obtain a progressive dilation of BBS was proposed in 2001[10] by insertion of an increasing number of plastic stents every 3 months until complete morphological stricture resolution; this approach lead to an 11% stricture recurrence rate after a very long-term mean follow-up of 13.7 years.[11] The main limitation of plastic stenting for BBS is the need for repeated endoscopic retrograde cholangiopancreatography (ERCP; usually 3–4) for a long period (at least 1 year).

Self-expandable metal stents

Self-expandable metal stents (SEMS) with a 30 Fr diameter, were developed in the early 1990s. Uncovered SEMS finds an indication in the setting of malignant biliary strictures, since are not removable. FC-SEMS have an indication in BBS due to their removability. A variety of SEMS are commercially available.

Most commonly used SEMS are made of a nickel-titanium alloy (nitinol). Nitinol has at least two unique properties: shape-memory and elasticity. Thermal shape-memory enables nitinol implants to be compressed for insertion into small caliber delivery systems and upon deployment *in situ*, at body temperature are restored to their original shape. Elasticity is advantageous when flexibility, constancy of applied stress, and large expansion or deformation ratios are needed. Because of this property, nitinol stents are more flexible than stainless-steel SEMS. Nitinol is nonferromagnetic with a very low magnetic susceptibility; thus, nitinol SEMS are compatible with magnetic resonance imaging.

Fully covered SEMS

SEMS with a plastic polymer covering were developed to resolve the problem of tissue ingrowth and to allow removability in the setting of BBS. SEMS covering membranes need to be durable to ensure removability. Usually FC-SEMS have flared distal ends to reduce the risk of migration. FC-SEMS are available in an 8- and 10- mm diameter and 4 cm, 6 cm, and 8 cm lengths. No specific mesh design demonstrated to facilitate or impair removability.

Removability of FC-SEMS in the setting of postoperative biliary strictures and chronic pancreatitis related biliary strictures was evaluated with good results in several studies.[12–20] Optimal time for FC-SEMS removal is maybe between 4 months and 6 months, unless there are not enough data.

Deployment

SEMS deployment is currently a standardized maneuver. SEMS deployment does not usually require any previous stricture dilation. SEMS introducers have a diameter varying from 8.5 Fr to 10 Fr, like the standard plastic stents. In the delivery system, the SEMS are constrained between an inner catheter (that allows the passage of the guidewire) and an outer sheath. The delivery system is advanced over the guidewire and positioned across the stricture. Because some SEMS significantly shorten after deployment, the appropriate SEMS length should be evaluated on preliminary cholangiography using appropriate graduated catheters.[21] FC-SEMS are released extending about 5–10 mm beyond the papilla into the duodenum for an easier removability with foreign body forceps or snares. After the delivery system is in position, the SEMS is released by carefully pulling back the outer sheath. This maneuver must be monitored by fluoroscopy to permit minor adjustments of the SEMS position before final release. In case of erroneous placement or inappropriate SEMS length, the stent can be reconstrained into the delivery system before it has been totally deployed.

Postcholecystectomy biliary strictures

BBS following cholecystectomy were treated by complex surgical repair with related morbidity and mortality[11]; a "mini-invasive" endoscopic approach is advisable in patients with iatrogenic lesions of the bile ducts[10,22] (Fig. 1). Our experience with 164 patients treated with multiple plastic stents over a 22-year period reported a 9.3% stricture recurrence rate after a mean follow-up of 7 years; endoscopic retreatment of stricture recurrences was always feasible and successful.

Postcholecystectomy strictures are short fibrotic scars and are typically located in the upper third of the common bile duct and can involve the main hepatic confluence. The bile duct below the stricture is usually not dilated. These features may limit the use of SEMS for a number of reasons. Correct positioning of partially covered SEMS strictures near the hilum may be technically challenging, with possible damage to the normal mucosa of the confluence. SEMS tend to stretch the nondilated distal common bile duct below the stricture, and this fact may have unpredictable consequences on accurate positioning of a foreshortening stent. Last, a high stent migration rate for FC-SEMS may limit its utility when compared to progressive placement of plastic stents. Further comparative studies with longer follow-up are needed before a firm recommendation can be made in favor of either approach. It is also noteworthy that SEMS removal may be technically challenging.[23]

Furthermore reported cases of postcholecystectomy biliary strictures treated with FC-SEMS are very rare (Table 1).[17,24–28]

Anastomotic biliary strictures following liver transplantation

In the past decades biliary strictures following orthotopic liver transplantation (OLT) were managed by surgical repair or percutaneous balloon dilation.[29–31] More recently, ERCP and endoscopic biliary plastic stent placement have been the primary therapeutic approach for such lesions.[32–38]

Anastomotic strictures may occur at the level of any biliary anastomosis, either duct-to-duct or hepatico-jejunostomy, in

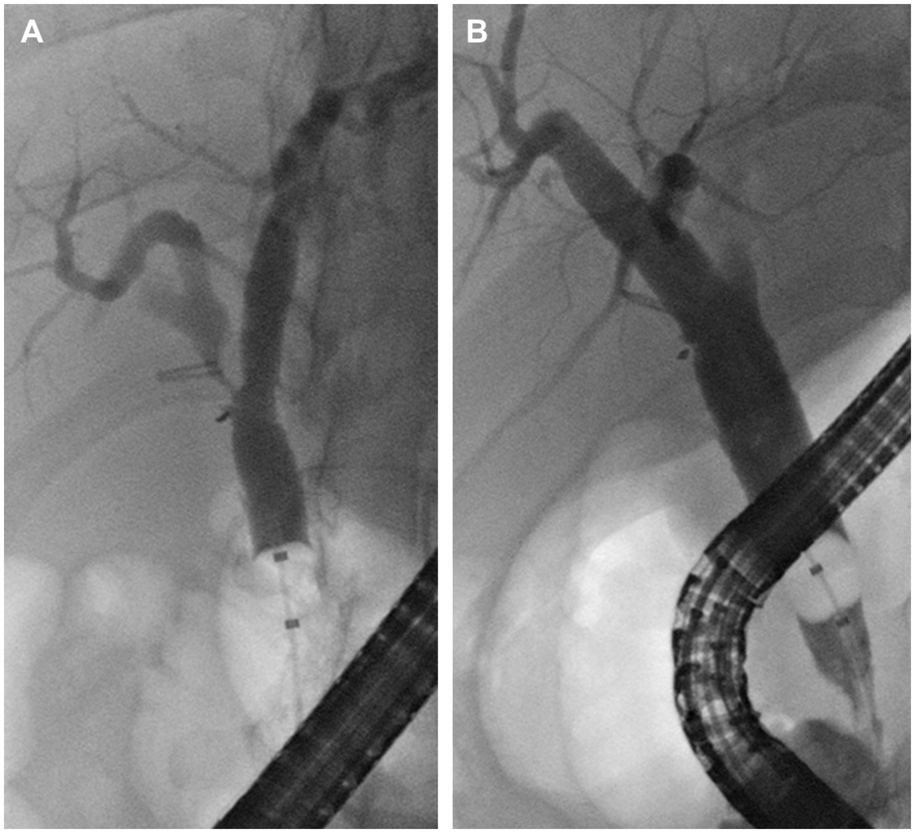

Fig. 1. Postcholecystectomy biliary stricture before (A) and after (B) treatment with four plastic biliary stents.

deceased- or living-donor OLT; duct-to-duct anastomosis are amenable for endoscopic treatment.

A characteristic of biliary strictures after OLT is that, also in the case of tight strictures, the transplanted liver bile ducts do not display the same degree of proportional dilation as non-transplanted livers. This peculiar behavior of transplanted liver has not been completely clarified; however, the presence of fibrosis leading to less pliable ducts has been suggested as a possible etiology.[39] Nevertheless, the absence of substantial dilation for the bile ducts may limit the number of stents to be placed side to side for the initial dilation of the stenosis.

Pneumatic balloon dilation of anastomotic biliary strictures without any stent placement is successful in $<$ 50% of cases.[40–42] In a retrospective study on 25 biliary anastomotic strictures it was found that clinically relevant stricture recurrences are more frequent in a group of patients treated with balloon dilation only (recurrence 62%) than in those treated with stents (recurrence rate 27%).[42] Other authors found a single balloon stricture dilation effective in 31% of the patients only, whereas 34.4% required more than one session of balloon dilation and another third of the patients required stenting.[41]

Post-OLT anastomotic biliary strictures are usually dilated with balloons (4–6 mm) followed by the placement of MPS (Fig. 2). This approach appears to be successful with a durable outcome.[11,33,43,44] The majority of patients with anastomotic biliary strictures after liver transplantation require several endoscopic interventions. Recurrences have been variably reported in about 7–13% of the cases for deceased donor living transplantation after a 1–5-year mean follow-up; stenting of anastomotic strictures is relatively easy when the whole liver has been transplanted from a deceased donor, because the biliary anastomosis is usually at the level of the middle common bile duct, far from the main biliary confluence. In the setting of living donor-liver transplantation the biliary anastomosis is close to the hilum and reported strictures recurrence is 21% after a 6-year follow-up (Table 2).[44–46]

Anastomotic biliary strictures recurrence can be usually managed conservatively by endoscopic restenting.

Table 1 Endoscopic Therapy of Postoperative Biliary Strictures

Series of patients treated with fully covered removable metal stents			
Study	Etiology	Patients (n)	Patients with postoperative stricture (excluding OLT)
Kahaleh et al, 2008[17]	CP, stones, OLT, PO, AI	65	3
Mahajan et al, 2009[24]	CP, stones, OLT, AI, PSC	41	0
Moon et al, 2012[25]	CP, stones, OLT, PO, PSC, post- traumatic, vascular, pancreatic cystic neoplasm	21	4
Tarantino et al, 2012[26]	CP, stones, OLT, PO, PSC	62	9
Poley et al, 2012[27]	CP, cholecystectomy, papillary stenosis	23	9
Devière et al, 2014[28]	CP, cholecystectomy, OLT	187	18

AI, autoimmune pancreatitis; CP, chronic pancreatitis; OLT, orthotopic liver transplantation; PO, postoperative; PSC, primary sclerosing cholangitis.

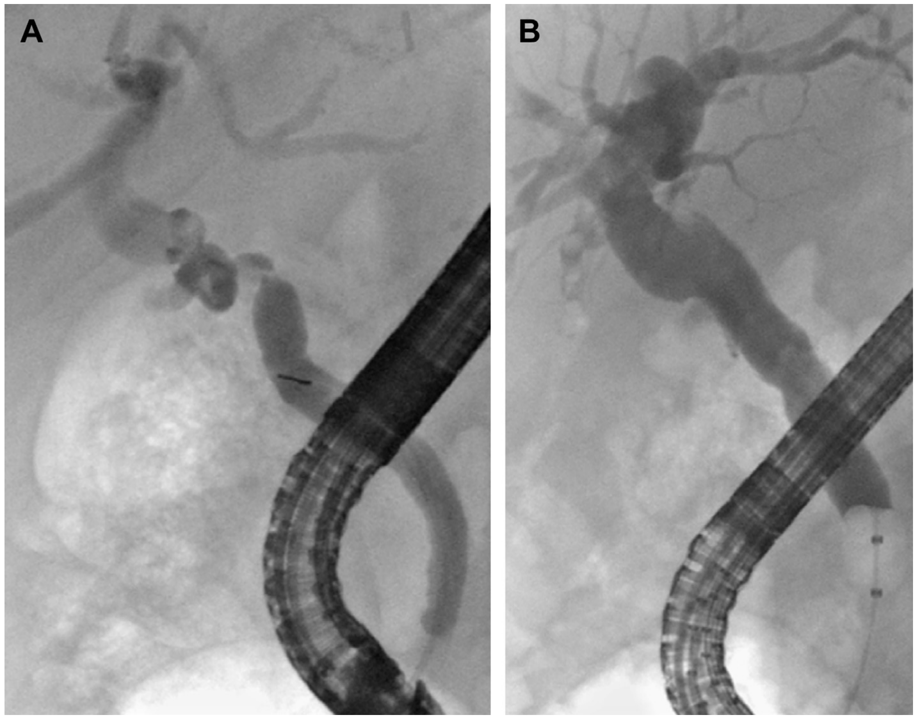

Fig. 2. Anastomotic biliary stricture following liver transplantation (A) before and (B) after dilation with seven plastic stents.

Patients with anastomotic strictures after OLT require long-term surveillance because strictures may recur after years from stent removal. Long-term surveillance by liver function test monitoring and bile ducts imaging is advisable. Some authors have observed that anastomotic strictures diagnosed within 6 months after OLT, usually have a better prognosis and good response to nonsurgical therapy.[33]

FC-SEMS have been proposed to dilate anastomotic strictures following OLT because their removability was safe and possible in almost all cases; results are still under evaluation due to the high incidence of stents migration and the high stricture recurrence rate at the 2-year follow-up (Table 3).[26,28,47,48]

Biliary strictures secondary to chronic pancreatitis

Chronic pancreatitis (CP) is an inflammatory process characterized by destruction of pancreatic parenchyma and ductal structures with subsequent formation of fibrosis.[49] Strictures of the common bile duct (CBD) can be found in 3–46% of patients with advanced CP.[50–57] The incidence of CP-related CBD stricture is widely variable because not all patients present with jaundice, which is also frequently transient.[58]

The nature of the stricture depends on the anatomical relationship of the CBD within the head of the pancreas. Fibrotic CBD strictures occur as a consequence of recurrent acute inflammatory state of the pancreas, which may finally result in a permanent periductal fibrotic invasion.[59] CBD strictures can also be a result of an acute inflammatory process of the pancreatic head, or be secondary to a compression from a pancreatic pseudocyst.[60] In these two conditions the CBD stricture usually resolves after healing of the acute inflammatory process or drainage of the pseudocyst.

The clinical presentation varies from asymptomatic cholestasis to symptomatic jaundice or cholangitis. In a small number of cases, the stricture can lead during years to secondary biliary cirrhosis.[61] Regression of liver fibrosis was found by Hammel et al[62] in patients with CP-related CBD stricture after biliary drainage. The clinical course of the disease is variable and usually characterized by exacerbations and remissions.

CP-related CBD strictures are much more difficult to dilate compared to CBD strictures related to other benign causes.[17,24] In some clinical scenarios, CBD strictures due to CP may resolve with time, but in the majority of patients they should be considered as permanent. Sooner or later, any plastic stent will occlude, leading to a recurrent sign of biliary obstruction and cholangitis. The real indication to endoscopic plastic stent placement in these patients should be carefully evaluated. The definitive therapy of CP-related CBD strictures, especially in younger patients who presumably

Table 2 Endoscopic Therapy of Anastomotic Biliary Strictures Following Liver Transplantation

Results with multiple plastic stents						
Study	Patients (*n*)	Mean of ERCPs (*n*)	Mean stent (*n*)	Stenting duration (mo)	Mean follow-up after stent removal (y)	Stricture recurrence (%)
Morelli et al, 2008[45]	38	3.5	2.5	3.6	1	13
Tabibian et al, 2010[44]	69	4.1	NA	15	1	8
This study	62	3.3	4.2	10	5	7
Hsieh et al, 2013[46]	38*	4	3	5.3	6	21

* All living donor transplantation.

Table 3 Endoscopic Therapy of Anastomotic Biliary Strictures Following Liver Transplantation

Results with fully covered removable metal stents							
Study	Patients (*n*)	Median stenting duration (mo)	SEMS migration (%)	Success in SEMS removal (%)	Stricture resolution (%)	Stricture recurrence (%)	Mean follow-up after SEMS removal (mo)
Chaput et al, 2010[47]	22	2	27	100	86	47	12
Hu et al, 2011[48]	12	5	0	100	92	9	13
Tarantino et al, 2012[26]	54	2	37	100	67	16	18
Devière et al, 2014[28]	42	4–6	74	100	68	27	20

have a longer lifespan, is surgical drainage by Roux-en-Y hepatico-jejunostomy.[50,63]

Endoscopic stenting of CBD strictures due to CP is indicated in patients who are unfit for surgery because of severe comorbidities or in those who refuse surgery. Endoscopic plastic stenting can also be performed as a "bridge to surgery" in patients who refuse an operation in the first instance, or more often, in case of severe jaundice, when surgery has to be delayed.

Despite the peribiliary fibrosis, these strictures can be easily passed with guidewire and guiding catheter. The placement of a 10 Fr or 11.5 Fr stent is not substantially difficult and does not require special skills. Pneumatic balloon dilation before stent placement is seldom necessary.

Unfortunately, endoscopic treatment of these strictures with a single plastic stent is effective only in the short term; in fact, the long-term results are disappointing: almost 70% of the strictures ineluctably recur after stent removal.[64,65] The presence of calcifications in the pancreatic head parenchyma is associated with a worse long-term prognosis.[65,66]

A prospective nonrandomized trial[32] compared results of single versus multiple plastic stents to dilate CP-related CBD strictures; after a 4-year mean follow-up period, results were significantly better in the multiple stents group than in the single stent group (92% vs. 24%, respectively; $P < 0.01$). Pozsár et al[67] reported successful outcomes at 1-year follow-up in 60% of the patients after multiple plastic stenting for CP-related biliary strictures.

Despite the encouraging outcomes of some published papers, endoscopic biliary plastic stenting, including multiple stent placement, remains a marginal therapy for few selected patients with chronic pancreatitis, who might better benefit of a permanent biliary drainage by surgery.

Results of FC-SEMS to dilate CP-related biliary strictures reported satisfactory success in $>$ 70% of the cases after a 2-year follow-up (Table 4, Fig. 3).[24,28,68–70] A recently published prospective trial confirmed this promising result in a large cohort of 147 patients.[28]

Primary sclerosing cholangitis: Balloon dilation or stenting?

PSC is a chronic cholestatic hepatic disease characterized by progressive fibrosing inflammatory involvement of the intrahepatic and extrahepatic bile ducts, leading to cholestasis and progressive cirrhosis. No effective medical therapy has been found for this disease, which sooner or later will cause end-stage liver disease and need for transplantation. Endoscopy plays a role in the management of patients with PSC, when they present with clinical and biochemical deterioration and severe cholestasis, sustained by a dominant biliary stricture involving the CBD or the right or left main intrahepatic ducts.[71]

Current knowledge on endoscopic therapy of PSC is based on a retrospective small series. Often in these patients, the choice of the treatment is based more on local preferences and expertise than on available evidence.

Dominant strictures in symptomatic patients may be treated by balloon dilation or stents. Nevertheless, the real efficacy of endoscopic stenting remains to be established, the effects of stenting on patient survival are controversial and doubtful.

The gastroenterological community is divided in "stent supporters" and "stent detractors".[72–76]

In 1996, a European group[73] reported on favorable outcomes in 25 patients treated by temporary stent placement. Endoscopic stent placement was technically successful in 21/25 patients (84%), with a median number of three procedures. Despite the need for retreatment, prevalence of jaundice decreased from 62% to 14%, pruritus from 52% to 5%, and fever from 38% to 10%. Because of the high risk of stent clogging and complication rate, the same group experimented with a protocol of stenting for a very short time (mean 11 days). Two months after short-term stent therapy, cholestatic complaints had improved in 83% of patients after a 35-month median follow-up, and at 1 year and 3 years 80% and 60% of patients, respectively, did not required repeated treatments.[77]

More recently Gluck et al[72] reported their experience with endoscopic therapy on symptomatic PSC over a 20-year period. Eighty-four patients with dominant strictures underwent 291 ERCP for acute cholangitis unresponsive to antibiotic treatment, worsening jaundice, pruritus, or pain. Of the 84 patients, 70% had balloon dilations on one or more occasions; temporary stents were placed in 51% of the patients. ERCP-related complications occurred in 7.2% of procedures, and included pancreatitis in 3.4%, worsening cholangitis in 1%, sepsis in 1% and in a minor percentage ductal perforation, bleeding, and liver abscess.[72]

Table 4 Bile Duct Strictures in Chronic Pancreatitis

Results with fully covered removable metal stents							
Study	N°	Stent design	Median time to SEMS removal (mo)	Stricture resolution rate at SEMS removal (%)	Migration rate (%)	Complications (%)	Median follow-up after stent removal (mo)
Cahen et al, 2008[68]	6	FC-SEMS	5.5	67	33	67	20.5
Behm et al, 2009[69]	20	PC-SEMS	5	80	5	4	22
Mahajan et al, 2009[24]	19	FC-SEMS	NA	58	5	16	NA
Perri et al, 2012[70]	7	UE-SEMS	6	43	100	57	24
	10	FE-SEMS		90	40	10	
Devière et al, 2014[28]	127	FC-SEMS	11.3	79	NA	NA	20.3

FC, fully covered SEMS; FE, flared ends stems; PC, partially covered SEMS; SEMS, self-expandable metal stents; UE, unflared ends SEMS.

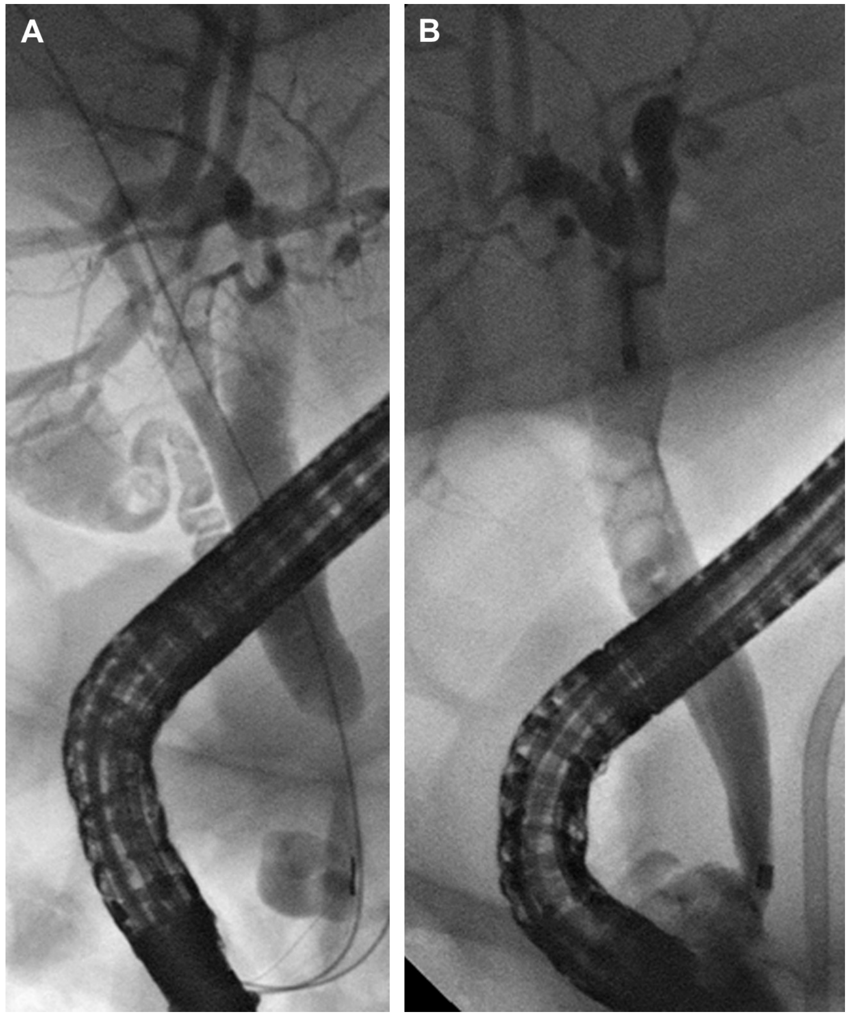

Fig. 3. Chronic pancreatitis related biliary stricture (A) before and (B) after dilation with fully covered self-expandable metal stents.

Another study retrospectively compared the outcomes of stent placement and balloon dilation in patients with PSC.[74] In this study, 34 patients underwent endoscopic balloon dilation of the dominant stricture (4- to 8-mm balloons) and 37 patients underwent endoscopic or percutaneous stent placement. Endoscopically placed stents were exchanged every 3–4 months. Complications and cholangitis were significantly more common in the stent group compared to the balloon dilation group and there were more complications related to percutaneous than endoscopic stent placement. However, there was no substantial difference between the two groups with regard to cholestasis improvement and symptoms resolution.[74]

Balloon dilation for the management of PSC-related dominant strictures can be supported because it has a lower infective complication rate than endoscopic stent placement, despite a similar clinical benefit.

Other authors reported on 500 balloon dilations and five stent placements in 96 patients with dominant strictures, who were followed for a median period of 7.1 years. ERCP-related complications were rare (pancreatitis 2.2%, acute cholangitis 1.4%, and bile duct perforation 0.2%). Liver disease led to the need for OLT in 22.9% of patients. Patient survival free of liver transplantation was 81% after 5 years and 51% after 10 years.[75]

ERCP should be performed carefully and only when strictly indicated in patients with PSC.[76] Balloon dilation may be the preferred therapeutic option due to the lower complications rate than the stent insertion strategy.

Conclusion

Postoperative strictures are effectively dilated by multiple plastic stents. Results of FC-SEMS are promising for BBS secondary to chronic pancreatitis. PSC-dominant strictures seems to have lower infective complications after balloon dilatation than stent insertion.

Multiple plastic stenting has the advantage to obtain a persistent biliary stricture dilation on long-term follow-up and permit treatment of strictures involving the main hepatic confluence, but requires multiple procedures repeated over an extended period of time, which is not patient friendly and is expensive.

FC-SEMS give the opportunity for stricture dilation in a shorter time by two ERCPs only, but not all the strictures can be treated, especially if located too close to the main hepatic confluence because of the risk of occlusion of the major intrahepatic ducts; further long-term follow-up are not yet available.

Endoscopic approach to BBS is currently the first-line approach and needs to be “tailored” case by case.

A multidisciplinary evaluation (surgeon, gastroenterologist, radiologist, and interventional radiologist) and detailed discussion with the patient are the key aspects for a successful treatment.

Conflicts of interest

Vincenzo Bove, nothing to disclose.

Andrea Tringali had a consulting agreement for Boston Scientific Corporation (Animal lab in 2012–2013, Speaking and teaching in 2014)

Guido Costamagna is a consultant for Olympus, Boston Scientific Corporation, Cook Inc., Covidien and Taewoong Medical Inc.

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