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ORIGINAL ARTICLE

A US Multicenter Study of Safety and Efficacy of Fully Covered Self-Expandable Metallic Stents in Benign Extrahepatic Biliary Strictures

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Abstract
Background Endoscopic therapy is considered first line for management of benign biliary strictures (BBSs). Placement of plastic stents has been effective but limited by their short-term patency and need for repeated procedures. Fully covered self-expandable metallic stents (FCSEMSs) offer longer-lasting biliary drainage without the need for frequent exchanges.
Aims The aim of this study was to assess the efficacy and safety of FCSEMS in patients with BBS.
Methods A retrospective review of all patients who underwent ERCP and FCSEMS placement at five tertiary referral US hospitals was performed. Stricture resolution and adverse events related to ERCP and/or stenting were recorded.
Results A total of 123 patients underwent FCSEMS placement for BBS and 112 underwent a subsequent follow-up ERCP. The mean age was 62 years (±15.6), and 57 % were males. Stricture resolution occurred in 81 % of patients after a mean of 1.2 stenting procedures (mean stent dwell time 24.4 ± 2.3 weeks), with a mean follow-up of 18.5 months. Stricture recurrence occurred in 5 patients, and 3 patients required surgery for treatment of refractory strictures. Stent migration (9.7 %) was the most common complication, followed by stent occlusion (4.9 %), cholangitis (4.1 %), and pancreatitis (3.3 %). There was one case of stent fracture during removal, and one stent could not be removed. There was one death due to cholangitis.
Conclusions Majority of BBS can be successfully managed with 1–2 consecutive FCSEMS with stent dwell time of 6 months.

Keywords Benign biliary stricture · Fully covered self-expandable metal stents · Chronic pancreatitis · SEMS · ERCP

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Introduction

Benign biliary strictures (BBSs) can occur due to postoperative bile duct injury or as a consequence of disease processes leading to chronic inflammation. Inflammatory conditions causing BBS include chronic pancreatitis (CP) and primary sclerosing cholangitis (PSC) [1, 2]. Endoscopic therapy has replaced surgery as first-line therapy for the management of BBS [3, 4]. Endoscopic dilatation and placement of plastic stents (PS) have been effective with success rates of 62–89 % [5–7]. However, plastic stents are limited by their short-term patency mandating stent exchange (every 3 months) to avoid complications of stent obstruction

[5]. Multiple procedures (median 5) [8] are therefore required, contributing toward increased expense. Uncovered or partially covered self-expandable metallic stents have shown longer patency in comparison with PS [9, 10] due to larger post-expansion diameters. However, their use has been associated with stent embedment due to epithelial hyperplasia which may make stent removal impossible, and therefore, these stents are not suitable for the use in benign conditions [11]. To overcome the limitations of partially covered self-expandable metallic stents (PCSEMSs) related to tissue hyperplasia, fully covered self-expandable metallic stents (FCSEMSs) were developed. Recent data have highlighted the efficacy of FCSEMS in the treatment of BBS, offering longer-lasting biliary drainage without the need for frequent stent exchanges and risk of tissue ingrowth. However, majority of these were small, single-center studies with relatively short follow-up. Furthermore, many studies only included patients with post-liver transplant anastomotic strictures, while some earlier studies have also included patients who underwent placement of PCSEMS in the patient cohort [1, 12–16]. The aim of this large multicenter study was to assess the efficacy and adverse event rates of FCSEMS placed for the management of BBS.

Methods

Study Design

The study was approved by the Institutional Review Board for Human Research and complied with Health Insurance Portability and Accountability Act regulations at all participating centers. The endoscopy databases at five US tertiary referral centers were searched for patients who underwent ERCP and placement of FCSEMS between January 2009 and April 2013. Patients with BBS [biliary calculi (BC), CP, orthotopic liver transplant (OLT) anastomosis, PSC, ampullary stenosis (AS), post-surgical, and other indications (Table 1)] were included in the study. The presence of a stricture was determined by cholangiography along with clinical evidence of biliary obstruction (cholangitis, jaundice, or cholestatic liver function tests).

Patients were excluded if they had malignant biliary strictures, intrahepatic, or hilar strictures or if they had undergone prior SEMS placement. A detailed chart review was performed to include patient demographics, prior plastic stenting, cholecystectomy status, stricture etiology and length, stricture dilatation, stent type, stricture resolution, and adverse events.

Procedural Details

All procedures were performed by experienced biliary endoscopists using standard video duodenoscopes (TJF-140, 160, 180 series, Olympus America Inc, Center Valley, PA) for patients with conventional anatomy and an adult colonoscope (CF-160, CF-180, Olympus America Inc) for patients with biliary-enteric anastomoses. FCSEMSs were placed as first-line treatment in some patients with a new diagnosis of BBS (Fig. 1) or as second-line treatment in patients who had failed therapy with plastic stents and at the discretion of the endoscopist. Metallic stents used were either Wallflex (Boston Scientific Co, Natick, MA, USA) or Viabil (W.L. Gore and Associates, Flagstaff, Ariz, USA).

Definitions

Stricture resolution was determined by the presence of at least one of the following criteria: absence of waist at cholangiogram, reduction of proximal duct size and improvement of liver function tests, ability to pass a retrieval balloon through the stricture, and drainage of contrast injected proximal to the stricture. Timing of stent removal was at the discretion of the endoscopist at each institution and was performed using a snare or forceps. Stricture recurrence was defined as abnormalities in liver function tests and the need for repeat stent placement after initial stricture resolution and a period of stent removal. Adverse events related to ERCP and FCSEMS placement were recorded.

Statistical Analysis

The primary endpoint analyzed was stricture resolution. Comparative analysis was performed for strictures using the Chi-squared test or Fisher's exact test for proportions and Students' t test or nonparametric Mann–Whitney U test for means. Multiple logistic regression was performed on the following factors potentially predictive of stricture resolution: stricture etiology, previous treatment with plastic stents, number of prior stenting procedures, duration of stricture prior to FCSEMS placement, and type of FCSEMS used. Statistical calculations were performed using SPSS 18.0 (SPSS Inc, Chicago). p values were two-tailed, and the level of significance was set at p value <0.05.

Results

A total of 123 patients with BBS underwent FCSEMS placement during the study period. Mean age was 62 ± 15.6 years, and 57 % were males. Etiology of biliary strictures was BC ($n = 37$, 30.1 %), CP ($n = 30$, 24.4 %), post-OLT (anastomotic) ($n = 16$, 13 %), PSC ($n = 9$, 7.3 %), biliary-enteric anastomotic and post-cholecystectomy strictures ($n = 9$, 7.4 %), AS ($n = 8$, 6.5 %),

Table 1 Patient characteristics and indications for placement of fully covered self-expandable metallic stent in patients with benign biliary strictures ($n = 123$)

Characteristic	Value (%) $n = 123$
Mean age (years)	62 (±15.6)
Sex	
Male	70 (57)
Stricture etiology	
Biliary calculi	37 (30)
Chronic pancreatitis	30 (24.3)
Liver transplant anastomotic	16 (13)
Periampullary diverticulum, AIP, choledochocele	10 (8.1)
Primary sclerosing cholangitis	9 (7.3)
Ampullary stenosis	8 (6.5)
Post-surgical, choledochojejunostomy stenosis	8 (6.5)
Idiopathic	8 (6.5)

periampullary diverticuli ($n = 3$, 2.5 %), autoimmune pancreatitis ($n = 1$, 0.8 %), and idiopathic ($n = 10$, 8.3 %). All strictures were extrahepatic and did not involve the liver hilum (Table 1). Prior ERCP with plastic stent placement had been performed in 71 % of patients, and 15 % had prior stricture dilatation. A total of 27 % of patients had prior cholecystectomy. Mean stricture length was 23 mm (Table 2). Dimensions of FCSEMS were as follows: 10 mm × 60 mm ($n = 70$, 56.9 %), 10 mm × 80 mm ($n = 25$, 20.3 %), 10 mm × 40 mm ($n = 19$, 15.4 %), 80 mm × 60 mm ($n = 4$, 3.3 %), 10 mm × 100 mm ($n = 3$, 2.4 %), 80 mm × 80 mm ($n = 2$, 1.6 %). Wallflex stents were used in majority of patients (Wallflex 101, Viabil 22).

In total, 109 patients had FCSEMS inserted for benign biliary strictures and completed treatment including follow-up ERCP with stent removal. Overall sustained stricture resolution occurred in 88 (81 %) patients (mean stent dwell time 24.4 ± 2.3 weeks) during a mean follow-up of 18.5 months (range 3–49 months). Of these, 70 (80 %) patients had success after single FCSEMS (mean stent dwell time 18.6 ± 1.3 weeks) and 18 (20 %) patients had success after two FCSEMS sessions (mean total stent dwell time 37.2 ± 25 weeks). Stricture resolution rates did not differ between patients with de novo FCSEMS and those who had failed prior plastic stenting (81.2 vs. 80.5 %, $p = 0.9$, respectively). Disposition of the remaining patients is illustrated in Fig. 2: Three patients underwent surgical therapy for BBS, eight patients returned to plastic stenting (stone disease $n = 2$, OLT $n = 1$, periampullary diverticulum $n = 1$, CP $n = 1$, PSC $n = 3$), five patients had stricture recurrence, one patient had an embedded stent that could not be removed, and four patients died.

Stricture resolution was associated with longer SEMS dwell times (24.4 vs. 13 weeks, $p = 0.02$). Stricture etiology, history of prior plastic stenting, duration of stricture prior to FCSEMS placement, stricture length, stricture dilatation, and type of stent (Wallflex vs. Viabil) were not predictors of stricture resolution (Tables 3, 4).

During the follow-up period, stent migration occurred in 12 patients. Proximally migrated stents were removed with a stone-extraction balloon or forceps. Distally migrated stents passed rectally in every case. Cholangitis was seen in five patients prior to scheduled FCSEMS removal (range 1 day–2 months), which was successfully treated medically (antibiotics, intravenous fluids), and stent exchange/stent cleaning. One patient with chronic pancreatitis had an embedded stent which could not be removed despite multiple endoscopic maneuvers. This patient presented with cholangitis 5 months post-FCSEMS placement which was treated with a PS. Four patients developed mild post-ERCP pancreatitis (absence of organ failure). Fracture of a Viabil stent occurred during removal in one patient, but complete stent removal was accomplished. There was one stent-related death in a 50-year-old man with PSC who died secondary to cholangitis 2 months after FCSEMS placement. The remaining three patient deaths were due to unrelated causes (Table 5). Stricture recurrence occurred in five patients after a mean of 17 weeks after single FCSEMS and was subsequently treated successfully with the placement of a second FCSEMS.

Discussion

For many years, surgical biliary-enteric anastomosis was the definitive treatment of BBS. However, endoscopic therapy with the placement of multiple PS is now established as first-line therapy [17]. Although PS have reasonable success rates [3, 4], they are limited by their short patency duration due to occlusion from bacterial biofilm deposition within the stent lumen, necessitating frequent endoscopic procedures for stent exchanges. Although FCSEMS are more expensive than PS, the potential for

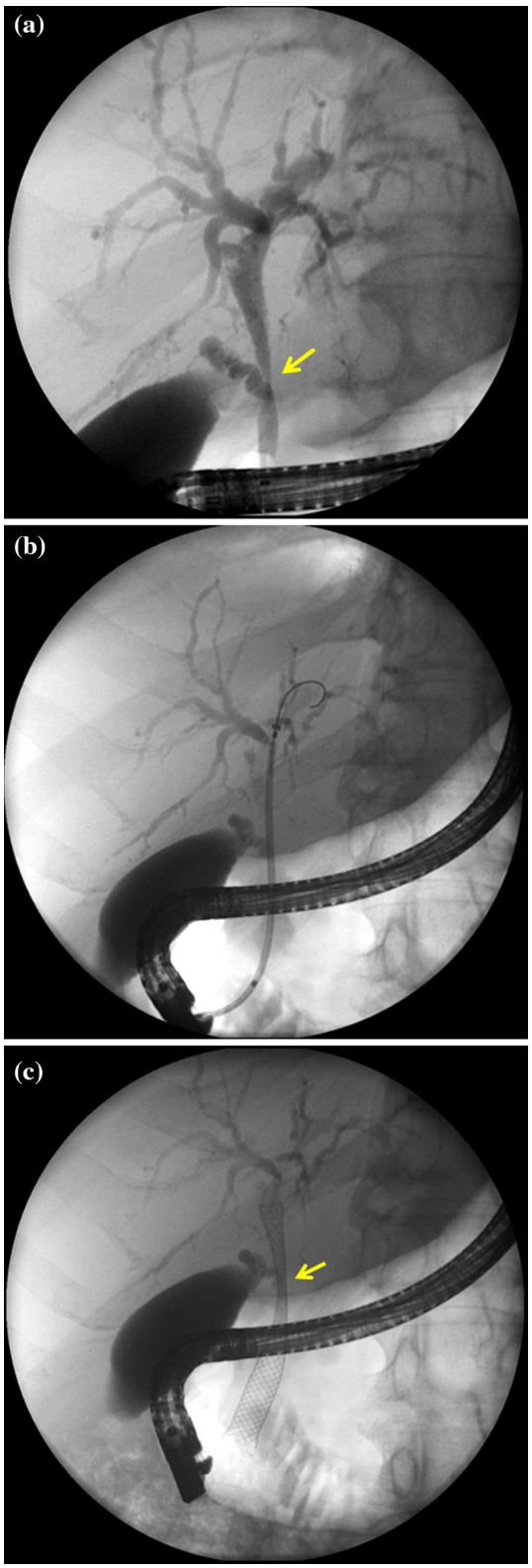

Fig. 1 **a** Benign mid-CBD stricture (*yellow arrow*) in a 52-year-old patient with PSC. **b** A wire is advanced through the stricture, and a FCSEMS is advanced over the wire across the stricture. **c** A waist is seen in the center of the stent at the region of the stricture (*yellow arrow*) after deployment

Table 2 Pre-procedural and procedural characteristics ($n = 123$)

Characteristic	Value (%)
Prior plastic stent	87 (71)
Prior cholecystectomy	33 (27)
Mean stricture length (mm)	23
Type of stent	
Wallflex 10 mm diameter	101
Wallflex 8 mm diameter	4
Viabil 10 mm diameter	16
Viabil 8 mm diameter	2

reduction in number of procedures required may counteract the significantly higher cost [5, 7, 9]. A recent systematic review demonstrated longer stent patency and greater success rates of FCSEMS in comparison with PS for the management of strictures secondary to CP and comparable success rates for all other BBSs [18].

In the current large multicenter study, a wide range of stricture etiologies were well represented, and the overall stricture resolution rate was 81 %, which is comparable to reported rates between 66 and 90 % [18–20]. Mahajan et al. [16] reported a high stricture resolution rate of 83 % in their relatively small ($n = 44$) prospective study of patients with BBS (CP, BC, OLT, AIP, and PSC). However, the follow-up period was short at 3 months. Another prospective, multicenter study [1] of 62 patients demonstrated 90 % stricture resolution rate after 3-month stent dwell time during a mean follow-up of 15 months. The majority (94 %) of the patients in that study had BBS of non-CP etiologies (post-liver transplantation, BC, or biliary surgery). CP-related strictures are thought to be more resistant to remodeling due to the resiliency of pancreatic fibrosis [21, 22].

A significant problem associated with FCSEMS is stent migration. Biliary obstruction (due to distal migration) or difficulty with retrieval (due to proximal migration) can occur. In our study, the stent migration rate was 9 % which falls within the range reported in other studies (0–38 %) [1, 14, 15, 23–28].

The mean stent dwell time in patients with stricture resolution was significantly longer than the non-resolution group (6 vs. 3 months, respectively) and was the only predictor of success in our study. Stricture recurrence occurred in 4.1 % (5/121) of patients in our study; 2 CP, 1 PSC, 1 OLT, and 1 idiopathic. All of these patients had FCSEMS for 3–4 months, and stricture recurrence occurred within 3 months for the CP patients and 6 months for the OLT and PSC patients. The CP patients likely needed longer duration of stenting to allow for adequate stricture remodeling, which may have prevented stricture recurrence. In the PSC patient, recurrence of stricture may

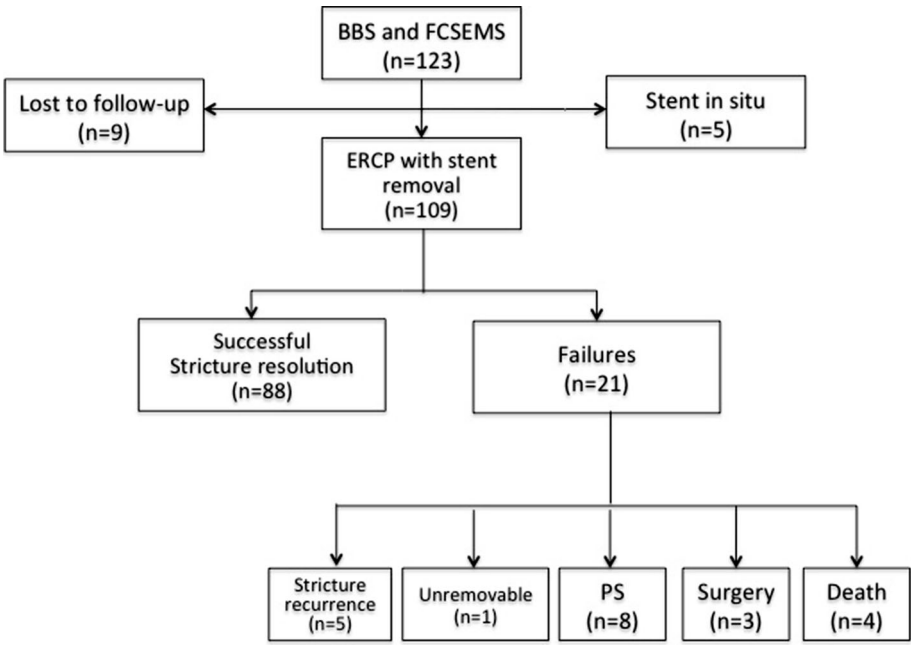

Fig. 2 Patient disposition

Table 3 Adjusted logistic regression analysis for predictive factors for stricture resolution

Factors affecting success	*p* value
Univariate analysis	
Stricture etiology	0.16
Previous plastic stent	0.6
Duration of stricture prior to FCSEMS	0.22
Stricture length	0.33
Stricture dilatation	0.93
Type of stent (8 vs. 10 mm, Wallflex vs. Viabil)	0.86
Overall stent dwell time	0.018

potentially be related to the disease process rather than the failure of stent therapy. In another large study, recurrence rates of 8 % were reported up to 2 years post-stent removal [19], and a recent prospective study reported overall recurrence rates of 14.8 % during 20-month follow-up [28]. Hence, it is possible that recurrence rates may increase during prolonged follow-up. There are currently no guidelines for follow-up post-FCSEMS removal. We recommend regular follow-up with liver function tests every 3 months for the first 2 years post-FCSEMS removal.

The optimal dwell time of FCSEMS in the treatment of BBS is currently unknown. The major risk of longer stent dwell time is cholangitis due to stent occlusion or migration. In our study, four patients (3.3 %) developed cholangitis that was successfully treated with stent exchange, but there was also one patient death due to cholangitis. Although it is clear that longer duration of stenting may be required for BBS to allow for remodeling of fibrosis/scar tissue to occur, extended stent dwell times need to be balanced with the risk of stent occlusion and cholangitis. In a recent multicentre prospective study assessing removability of FCSEMS, mean stent dwell time for CP and post-surgical strictures was 11.3 months, much longer than reported by most other studies. OLT strictures were stented for a mean of 5 months [28]. Overall

Table 4 Proportion of stricture resolution by stricture etiology

Stricture etiology	Non-resolution $n = 21$ (%)	Resolution $n = 88$ (%)
Stone disease	3 (11)	25 (89)
Post-surgery, choledochojejunostomy stenosis	1 (14)	6 (86)
Ampullary stenosis	0 (0)	7 (100)
Chronic pancreatitis	3 (10)	27 (90)
OLT	3 (19)	13 (81)
Periampullary diverticuli, AIP, choledochocele	5 (50)	5 (50)
PSC	5 (62)	3 (38)
Idiopathic	2 (50)	2 (50)

Table 5 Adverse events ($n = 123$)

Adverse events	*n* (%)
Stent migration	12 (9.7)
Stent occlusion	6 (4.9)
Cholangitis	5 (4.1)
Post-ERCP pancreatitis[a]	4 (3.3)
Tissue ingrowth	1 (0.8)
Stent fracture	1 (0.8)
Embedded stent	1 (0.8)
Death[b]	4 (3.3)

[a] Mild pancreatitis

[b] One death related to stent (cholangitis)

migration rates were as high as 35 %, although cholangitis was seen in only 13.9 % of patients (approximately threefold higher than seen in the current study). This is likely due to the longer stent dwell time in Deviere et al.'s prospective study (11.3 vs. 6.1 months in present study) and the prospective nature of their study. The overall stricture resolution rate was 76 % which is slightly lower than 81 % seen in the present study, despite the prolonged stent dwell time in Deviere et al.'s prospective study. The discrepancy is most likely due to the proportion of stricture etiologies in the two studies. Majority of patients in the present study (30 %) had BBS due to BC versus only 9.6 % in the study by Deviere et al. Notably, only 24 % of patients in the present study had BBS due to CP, in comparison with 68 % in the prospective study. It is well recognized that CP strictures are harder to treat, and this is reflected in the disparity between results in the two studies. Nevertheless, longer stent dwell times allowed for longer periods of stricture remodeling, which was evidenced by comparable stricture resolution rates in the CP and non-CP groups (80 vs. 70 %, $p = 0.32$). In our study, 20 % of patients required 2 ERCP and stent placement procedures to achieve successful stricture resolution. Longer stent dwell times may have decreased the need for repeat procedures.

The high success rates seen in our study were across high-volume academic institutions where procedures were performed by experienced endoscopists. Optimal patient outcomes can be likely expected at lower volume institutions provided there is close follow-up of patients after FCSEMS insertion (3-monthly LFTs) with prompt management of adverse events such as cholangitis or stent migration.

Embedding of metallic stents when treating BBS is seen with partially uncovered stents [19]. Successful FCSEMS removal rates of 76–100 % are seen in most studies [1, 12–14, 26–28]. In our study, it was impossible to remove one inwardly migrated FCSEMS. The patient was managed with plastic stenting within the metallic stent. As previously reported for the removal of uncovered or partially uncovered stents, the stent-in-stent technique should be employed for attempted removal of the FCSEMS which have become embedded due to tissue overgrowth [28, 29].

There are many benefits of FCSEMS in comparison with PS. Prior stricture dilatation is not required, and stent exchange interval can be extended out to at least 6 months which allows for fewer repeat procedures with potential for cost savings. Furthermore, the greater radial expansion force of FCSEMS appears to have an advantage in management of fibrotic strictures, such as those related to CP. Reassuringly, no episodes of cholecystitis were seen in our large study which appears to be predominantly associated with malignant strictures involving the cystic duct [30].

Limitations of this study include its retrospective nature, lack of a control group, and inability to standardize the duration of stent dwell time. Furthermore, stricture resolution was determined by the unblinded endoscopist, which also introduces an element of bias.

In summary, this large multicenter study demonstrates the efficacy and safety of FCSEMS in the management of BBS. A longer stent dwell time of 6 months is recommended.

Conflict of interest Payal Saxena is a consultant for Boston Scientific and has received research support from Cook Medical and consultancy fees from Olympus. David L. Diehl is a consultant for Boston Scientific and Olympus. Jonathan M Buscaglia is a consultant for Boston Scientific. Mouen A. Khashab is a consultant for Boston Scientific and Olympus and has received research support from Cook Medical. Anthony Kalloo is a founding Member, equity Holder, and consultant for Apollo Endosurgery. Vikesh K. Singh is a consultant for Abbvie, Santarus, D-Pharm, and Boston Scientific. Anne Marie Lennon is a consultant for Boston Scientific. All other authors have no relevant conflicts of interest to disclose.

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