Anchoring flap versus flared end, fully covered self-expandable metal stents to prevent migration in patients with benign biliary strictures: a multicenter, prospective, comparative pilot study (with videos)

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Background: Recently, placement of fully covered self-expandable metal stents (FCSEMSs) has been proposed as an alternative treatment for the management of benign biliary strictures. However, the major limitations of FCSEMSs are frequent migration and removal complications.

Objective: We conducted this study to compare the antimigration effects, complication rates, and short-term efficacy of 2 FCSEMSs with either an anchoring flap (AF) or a flared end (FE) at the proximal end of the stent.

Design: A multicenter, prospective comparative pilot study.

Setting: Two tertiary referral centers.

Patients: A total of 43 patients with benign biliary stricture who were candidates for placement of FCSEMSs were assigned to the AF (n = 22) or the FE group (n = 21).

Interventions: Predefined duration of placement and removal of FCSEMSs.

Results: After a median period of placement of 6 months (interquartile range 4-6), no patients in the AF group and 33% of patients (7 of 21, 1 in proximal and 6 in distal) in the FE group had stent migration (P = .004). The removal rate of the FCSEMSs was 100% in both groups (per protocol, n = 22 in the AF group and n = 17 in the FE group). Immediate improvement of biliary stricture was 91% (20/22, per protocol) in the AF group and 88% (15/17, per protocol) in the FE group. All stents were removed without difficulty.

Limitations: Short-term follow-up after the removal of FCSEMSs.

Conclusions: With regard to the antimigration effect of FCSEMSs for benign biliary stricture, the AF design may be superior to the FE. For up to 6 months, both FCSEMSs can be endoscopically removed without complications. (Clinical trial registration number: NCT00945516.) (Gastrointest Endosc 2011;73:64-70.)

Benign biliary strictures may occur as a result of various causes, such as chronic pancreatitis, bile duct injury after surgery, anastomotic site strictures after liver transplantation, and choledocholithiasis.[1] Benign biliary strictures may have adverse outcomes, such as chronic cholestasis, jaundice, recurrent cholangitis, and secondary biliary cir-

Abbreviations: AF, anchoring flap; FCSEMS, fully covered self-expandable metal stent; FE, flared end; PEP, post-ERCP pancreatitis.

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rhosis.[2,3] Thus, proper and prompt management of benign biliary strictures is essential. Endoscopic management was proposed as a first-line treatment in those patients with benign biliary strictures and an endoscopically accessible bile duct because of its less-invasive nature compared with open surgery.[4-7]

Recently, fully covered self-expandable metal stents (FCSEMSs) have been introduced to treat benign biliary and pancreatic ductal strictures.[4,8-10] This modality may have several advantages over placement of multiple plastic stents. Multiple stenting with multiple numbers of plastic stents has been advocated for dilation of refractory benign biliary ductal strictures. However, a substantial mean number of procedures were required in a previous study.[11] Moreover, multiple endoscopic sessions may be impractical for some patients.[9,12,13] FCSEMSs might offer longer-lasting drainage of the bile duct and dilation of the stricture without the interval stent changes required when using multiple plastic stents. Partially covered metal stents may have a major disadvantage over FCSEMSs because partially covered metal stents may have tissue ingrowth through the uncovered stent mesh, making it difficult to remove the stent later.[9,14,15] Primary placement of an FCSEMS may therefore be an attractive option for benign biliary strictures. However, in early reports, stent migration was common because of the nature of an FCSEMS.[9,10,16] Although an FCSEMS with anchoring fins for antimigration has become available, removal may be problematic because of these multiple anchoring fins, which can cause ulceration and bleeding from the mucosa as the FCSEMS is extracted.[4,17] Therefore, the ideal stent design of an FCSEMS to improve stent removability without increasing stent migration after the intended duration of stent placement has not been described. To date, several designs for antimigration properties of FCSEMSs have been developed.[18-20] We studied the antimigration effects, removal ease and complications, and short-term efficacy of 2 newly designed and commercially available FCSEMSs. The stents contained either an anchoring flap (AF) or a flared end (FE) at the proximal portion. We conducted this comparison as a multicenter, prospective, comparative pilot study.

Take-home Message

- Placement of fully covered self-expandable metal stents (FCSEMSs) has been proposed as an alternative treatment for the management of benign biliary strictures. In this multicenter, prospective pilot study comparing the antimigration properties of FCSEMS (anchoring flap versus flared end at the proximal end of the stent) for benign biliary stricture, the anchoring flap at the proximal end of the stent appears to be superior to the flared end (0% vs 33%, respectively; $P = .004$). Both types of FCSEMSs can be removed endoscopically without complications 4 to 6 months after placement.

PATIENTS AND METHODS

The inclusion criteria for enrollment were (1) age 18 years or older, (2) clinical symptoms of biliary obstruction such as biliary pain with cholestatic liver test or jaundice,[4] and (3) biliary strictures or ampullary stenosis with treatment failure on biliary sphincterotomy with or without previous placement of single or double plastic stents (10F or double 10F), with regular stent change intervals of 3 to 6 months in the common bile duct.

The exclusion criteria were (1) patients for whom endoscopic procedures were contraindicated, (2) refusal of the study protocol, (3) patients with peripheral or hilar biliary strictures, and (4) patients with suspected malignant strictures. Between January 2009 and March 2010, 49 consecutive patients were invited to participate in this study. Six patients were not enrolled because of refusal to participate (n = 3), advanced liver cirrhosis (n = 1), and suspicious malignant stricture (n = 2). Patients were considered for entry before the procedure. Finally, 43 patients with benign biliary strictures met the eligibility criteria. These patients were assigned to the AF or the FE group by means of computer-generated numbers. No patient was lost during follow-up.

All endoscopic procedures were performed by 5 therapeutic endoscopists expert in performing ERCP (D.H.P, T.H.L, S.S.L. D.-W.S, S.-K.L). Two independent observers (H.J.K, C.H.R), who had no clinical information on this study, evaluated stricture resolution, migration, and complications after FCSEMS placement and removal.

Routine transpapillary biopsy of the biliary strictures for exclusion of malignancy was performed during ERCP. The Institutional Review Board at the University of Ulsan College of Medicine, and the Ethics Committee at the Soonchunhyang University Cheonan Hospital approved the study protocol. Written informed consent was obtained from all patients.

FCSEMSs

Both FCSEMSs are made of a nitinol wire with a silicone-covered membrane. Both FCSEMSs have the FE at the distal portion of the stent to prevent proximal migration. To prevent distal migration, an FCSEMS with an AF (M.I. Tech, Seoul, South Korea) has 4 anchoring flaps at the proximal end of stent. This portion is flexible and has a rounded tip covered with a silicone membrane to reduce bile duct injury. An FCSEMS with both ends flared (Standard Sci Tech, Seoul, South Korea) was considered the standard type of FCSEMS because this type of stent had shown an antimigration effect in previous studies (Fig. 1).[19,20]

FCSEMS placement and removal. After an overnight fast, all patients underwent ERCP in the prone position with a standard duodenoscope (TJF 240; Olympus Optical,

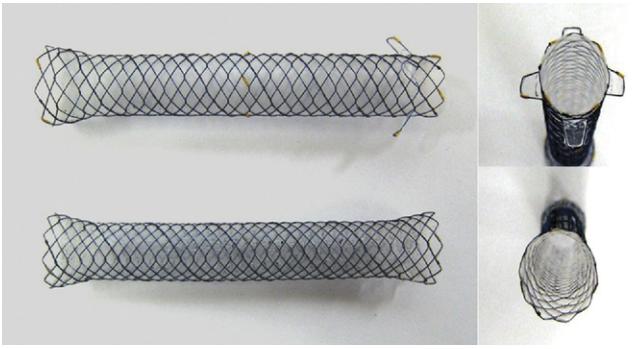

Figure 1. Two types of FCSEMS (upper, FCSEMS with an AF at the proximal end of the stent; bottom, FCSEMS with an FE at the proximal end of the stent).

Tokyo, Japan) after sedation with intravenous midazolam (0.05 mg/kg) or propofol (0.5 mg/kg). Prophylactic antibiotics and analgesics were permitted. FCSEMSs with a proximal AF (M.I. Tech) or FE (Standard Sci Tech) were 10 mm in diameter and fully covered. After biliary cannulation, the length of the biliary stricture was measured. The FCSEMS delivery system was advanced above the biliary stricture over a guidewire where the FCSEMS (40, 50, 60, 80, or 100 mm) was partially deployed and positioned within the stricture before complete deployment. In cases in which it was anticipated that the cystic duct would be covered by the FCSEMS, a gallbladder stent was not routinely placed. The distal end of the FCSEMS was routinely placed across the papilla. Radiography of the simple abdomen to identify the position of the stent, and liver function and serum pancreatic enzyme tests were performed before stent placement and 1 and 2 days after stent placement. During the follow-up period, patients were seen in the outpatient clinic at 1-month intervals. At each visit, a plain abdominal radiograph was obtained to monitor stent position, and liver function tests and serum pancreatic enzyme tests were performed. When distal migration was suspected from the plain abdominal radiograph (eg, stent was placed in the distal bile duct below the stricture), a follow-up duodenoscopic evaluation was also done.

Four or 6 months after FCSEMS placement, stent removal was performed with a side-viewing duodenoscope and rat-tooth forceps (FG-8L-1 or FG-14P-1; Olympus) (Videos 1 and 2, available online at www.giejournal.org).[21] If possible, the stent was removed through the working channel of the endoscope. If resistance was encountered, the stent was fixed to the tip of the duodenoscope with the forceps, and the duodenoscope and stent were withdrawn. After removal of the stent, a cholangiogram for the evaluation of the stricture and possible ductal injury was obtained.

Definitions

Biliary stricture for inclusion criteria was defined as the difficulty to pass an extraction balloon through the stricture and delayed drainage of contrast injected upstream of the stricture after removal of the plastic stent.[9]

Patients were considered to have stricture resolution if symptoms resolved and a follow-up CT scan did not demonstrate biliary dilation at 3 months after removal or migration of an FCSEMS. We planned to place another metal stent if stricture recurred, and if the patient had clinical symptoms of biliary obstruction after removal or migration of an FCSEMS.

Immediate stricture resolution or improvement was defined as the disappearance of the stricture waist and a rapid drainage of contrast from above the stricture on the cholangiogram during FCSEMS removal.[9] The length of the stricture was measured from the stricture to the dilated upstream segment of the common bile duct after correction for the magnification by use of the known diameter of the duodenoscope on the cholangiogram.

Clinical success was defined as a clinical resolution of the stricture without the need for repeat stent placement based on normal results on liver function tests and the absence of jaundice and abdominal pain during the follow-up period after removal or migration of the FCSEMS. Definition of stent removal without difficulty was that attempts at stent removal were made only using rat-tooth forceps, were limited to a 5-minute duration, and invasive methods such as piecemeal extraction were not used.[21]

Complications were reported separately for FCSEMS insertion and removal. Poststenting pancreatitis was defined by the consensus criteria.[22]

Proximal stent migration was defined as any migration of the FCSEMS into the bile duct, preventing its easy removal.[22] Distal stent migration was classified as spontaneous or duodenal migration. Spontaneous migration was defined as distal migration without becoming lodged in the bowel. Duodenal migration was defined as the stents impacting in the distal (downstream) bile duct below the stricture or in the duodenal wall opposite the papilla.[23,24] Any stent migration after placement of an FCSEMS served as the primary endpoint measure. A second endpoint was procedural complications related to FCSEMS placement and removal.

Statistical analysis

Because the FCSEMS with AF has no preliminary data regarding stent migration and this pilot study was intended as a proof-of-concept study, no formal power calculation was presented. Statistical analysis was performed by using SPSS 12.0 (SPSS, Inc, Chicago, Ill), and for the final analysis, a 2-tailed P value $<.05$ was considered statistically significant. Variables in the 2 groups were analyzed with a Student t test or Mann-Whitney U test according to the continuous data with normal or non-normal distributions. Differences in categorical variables were analyzed by the χ^2 and Fisher exact tests.

TABLE 1. Patient characteristics

Characteristics	AF (n = 22, group I)	FE (n = 21, group II)	*P* value
Age, y, mean (SD)	63 (13)	60 (13)	.47
Male sex, no. (%)	10 (45)	13 (62)	.28
Etiology, no. (%)			.44
CP	5 (23)	6 (28)	
BS*	15 (68)	11 (52)	
OLT	0	2 (10)	
PS	2 (9)	2 (10)	
Previous common bile duct plastic stenting, no. (%)	20 (91)	19 (90)	1.00
Length of stricture, mm, no. (IQR)	12 (8-16)	10 (7-12)	.14
Location of stricture			.27
Distal	20	16	
Mid	0	2	
Proximal	2	3	

AF, Anchoring flap; *FE,* flared end; *SD,* standard deviation; *CP,* chronic pancreatitis; *BS,* biliary stone disease; OLT, orthotopic liver transplantation; *PS,* post-surgery, *IQR,* interquartile range.
*Included choledochal cyst, recurrent pyognenic cholangitis, and post-endoscopic biliary sphincterotomy strictures with accompanying choledocholithiasis.

RESULTS

Patient characteristics

There was no difference in baseline characteristics between AF and FE group (Table 1).

Of 43 patients, 39 (91%) had a previous plastic stent placed. Of 39 patients with a previous plastic stent, 14 (36%) had at least 2 sessions of plastic stenting. Median duration of FCSEMS placement was 6 months (interquartile range 4-6 months) (Table 2).

Technical success

Technical difficulties during stent placement were not encountered in any enrolled patients (100% technical success).

Stent migration and removability

Of 22 patients in the AF group, 0% and 33% (7 of 21 patients) in the FE group had stent migration (P = .004: proximal migration in 1 and distal migration in 6 in the FE group). In terms of proximal stent migration, the stent migrated to the intrapancreatic portion of the common bile duct. This migrated position was identified on duodenoscopic and cholangioscopic findings. With regard to the distal migration (4 spontaneous migrations and 2 duodenal migrations with persistent biliary stricture), it occurred at 2 or 3 months after FCSEMS placement according to monthly plain abdominal radiographs or endoscopic findings. Per protocol analysis, the removal rate of FCSEMSs was 100% in both groups (22/22 in the AF group and 17/17 in the FE group). In patients with proximal stent migration (in the FE group), stent removal was successfully performed by using rat-tooth forceps under fluoroscopic guidance.

Profiles of other complications after FCSEMS placement

The rate of poststenting pancreatitis was 18% (4/22, mild grade) in the AF group and 10% (2/21, mild grade) in the FE group. It was managed conservatively, and these patients had an uneventful recovery. There was no significant difference in poststenting pancreatitis between the 2 groups (P = .66). Of 43 patients, 26 (60%) had gallbladders. FCSEMSs were placed below the cystic duct insertion in 18 of 26 patients (69%) with a gallbladder. FCSEMSs were placed across the cystic duct in the remaining 8 patients (31%). There was no poststenting cholecystitis in any of the enrolled patients. During the follow-up for stent placement, 1 patient in each group had cholangitis. During endoscopic stent removal, sludge impaction without liver dysfunction was observed in 2 patients from each group (2/22 [9%] in the AF group and 2/17 [10%] in the FE group; P = 1.0). There were no removal complications (Table 3). During cholangiography, no new FCSEMS-induced biliary strictures were seen.

Short-term clinical success and follow-up

During FCSEMS removal with follow-up cholangiogram, immediate improvement in the biliary stricture was 91% (20/22, per protocol) in the AF group and 88% (15/17, per protocol) in the FE group. With regard to this per-protocol analysis, 4 excluded patients in the FE group had a complete distal stent migration on follow-up plain abdominal radiograph in the outpatient clinic. Thus, follow-up cholangiography was not done in these patients. The remaining 3 patients had 1 proximal and 2 distal migrations (stent lodged the duodenal wall). In these 3 patients, we evaluated the status of biliary strictures after removal of FCSEMSs with follow-up cholangiography.

During the follow-up period (median 4 months, interquartile range 3-5 months) after removal or migration of FCSEMSs, recurrence of the initial biliary stricture (16%, 7/43) in both groups occurred in 4 patients with chronic pancreatitis (n = 11), 2 with biliary stones (n = 26), and 1 with a liver transplant (n = 2). These patients underwent repeat metal stenting. Of the 7 patients who had recurrence of symptomatic biliary stricture, 3 patients were in the AF group and 4 patients were in the FE group (14% vs 19%, respectively; P = .7). Two of 6 patients in the FE group who had a distal stent migration had a recurrence of

TABLE 2. Treatment characteristics

Treatment characteristics	AF (n = 22, group I)	FE (n = 21, group II)	*P* value
Length of stent, mm, 40/50/60/80/100, no. (%)	8 (36)/8 (36)/5 (23)/1 (5)	6 (29)/9 (43)/4 (19)/2 (9)	.86
Duration of stent placement, mo (SD)	5.2 (1)	4.6 (1.4)	.076
Follow-up after stent removal, mo (SD)	3.6 (2.4)	4.2 (2.1)	.43

AF, Anchoring flap; *FE*, flared end; *SD*, standard deviation.

TABLE 3. Clinical outcomes and complications after placement of FCSEMS

Clinical outcomes and complications	AF (n = 22, group I)	FE (n = 21, group II)	*P* value
Stent migration, no. (%), proximal/distal	0	7 (33) 1/6	.004
Removal rate of stent (%) as per protocol	22/22 (100%)	17/17 (100%)*	1.00
Poststenting pancreatitis, mild form, no. (%)	4 (18%)	2 (10%)	.66
Pain after stent placement	0	0	
Removal complication			
Pain	0	0	
Post-ERCP pancreatitis	0	0	
Stent occlusion without cholangitis, no. (%)	2 (9.5)	2 (10)	1.00
Cholangitis	1	1	1.00
Immediate resolution rate of stricture as per protocol, no. (%)	20/22 (91)	15/17 (88)*	1.00
Recurrence, no. (%)	3 (14)	4 (19)	.7

FCSEMS, Fully covered self-expandable metal stent; *AF*, anchoring flap; *FE*, flared end.
*Four patients who had a spontaneous migration were excluded.

a biliary stricture at 3 and 4 months after FCSEMS migration. These 2 patients had distal biliary strictures caused by chronic pancreatitis. No biliary stricture recurred in the remaining patients during the follow-up period.

DISCUSSION

Stent migration of FCSEMSs has been reported to range from 4% to 38% in benign biliary stricture.[4,10,16,17,25,26] Proximal (upstream) stent migration may be problematic. If the stent is unable to be retrieved, it may permanently damage or obstruct the biliary tree.[10] Distal (downstream) stent migration may lead to inadequate dilation of the stricture and a decrease in treatment efficacy.[27] It may also lead to biliary obstruction if the stents impact the distal (downstream) bile duct below the stricture or in the duodenal wall opposite the papilla. Appropriately timed distal migration of FCSEMSs may lead to improved cost-effectiveness of this procedure if a stent removal procedure is not required and the stricture responds to a single stent placement and migration. Various FCSEMS designs have been studied that would prevent migration in pancreaticobiliary diseases.[4,8,18-20] To date, FCSEMSs with antimigration anchoring fins have become available and are well studied in benign biliary stricture, bile leak, and pancreatic ductal stricture in chronic pancreatitis.[4,14,17] Stents with anchoring fins at both ends may prevent stent migration; however, the anchoring fins can cause ulceration and bleeding of the mucosa as the FCSEM is extracted.[4,17] Moreover, in a long-term follow-up study,[28] complications during placement of FCSEMSs were observed in a substantial portion of patients, including pain, post-ERCP pancreatitis, and bleeding. Complications during stent removal also occurred in a substantial portion of patients, including post-ERCP pancreatitis, pain, stent unraveling, bile duct leak, bleeding, and bacteremia. Cholangitis also developed on removal. This disappointing experience has encouraged the development of a new type of FCSEMS to prevent stent migration and placement and removal complications.

Our prospective study compared the 2 types of FCSEMSs with different designs to prevent stent migration in patients with benign biliary strictures.

Placement of FCSEMSs with an AF resulted in no stent migration compared with one third of patients with stent

TABLE 4. Studies on covered metal stent placement for benign biliary strictures

Study	No. of patients	Stent design	Etiology	Time to removal	Clinical success (%)	Migration rate (%)	Other complications related to stent (no. of patients)
Cantu et al[26]	14	PCSEMS	CP	21 mo (range 18-33)	37.5*	14	Cholestasis (7), cholangitis (5), cholecystitis (1)
Kuo et al[25]	3	FCSEMS	OLT	32 d (range 1-28)	100†	0	Septicemia
Kahaleh et al[14]	79	PCSEMS	CP/OLT/BS/IM/PS	4 mo	90†	14	Misplacement (1), stricture (6), pain (2)
Cahen et al[10]	6	FCSEMS	CP	3-6 mo	66†	33	Recurrent stricture (1)
Mahajan et al[4]	44	FCSEMS	CP/OLT/BS/IM/PS	3.3 mo	83*	4	Pain (3), post-ERCP pancreatitis (6), bleeding (1), occlusion (1), unravel during removal (1)
Traina et al[16]	16	FCSEMS	OLT/LRLT	2 mo	81*	38	PEP (1)
Current study	43	FCSEMS	CP/OLT/BS/PS	6 mo	84*	0(AF)/33 (FE)	PEP (6), stent occlusion without cholangitis (4), cholangitis (2)

PCSEMS, Partially covered self-expandable metal stent; *CP,* chronic pancreatitis; *FCSEMS,* fully covered self-expandable metal stent; *OLT,* orthotopic liver transplantation; *BS,* biliary stone disease; *IM,* inflammatory; *PS,* post-surgery; *LRLT,* living-related liver transplantation; *PEP,* post-ERCP pancreatitis; *AF,* anchoring flap; *FE,* flared end.
Modified from Mahajan et al.[4]
*Clinical success at removal.
†Clinical success after postremoval follow-up.

migration with FCSEMSs with an FE. Previous studies have similar results for stent migration of FCSEMSs with an FE (Table 4).[10] An FCSEMS with an FE had no or minimal migration in our patients with malignant biliary obstruction (data not shown) and our EUS-guided biliary drainage with transluminal stenting.[19,20] Therefore, FCSEMSs with an FE at both ends of the stent may be adequate for conditions with very tight strictures. With regard to the benign biliary strictures, the stricture will usually resolve while the stent is in place. This explains why, in this study, distal stent migration may occur at 2 or 3 months after placement of the stent. Most patients in this study had a previous plastic stent placed or an endoscopic sphincterotomy. Thus, after dilation of the stricture by the FCSEMS, the stent in place may be vulnerable to migration.

With regard to the prevention of proximal migration, both FCSEMSs had an FE at the distal portion of stent. However, the FCSEMS with an FE had 1 proximal migration. The design of the proximal end of the FCSEMS may therefore be essential for the prevention of proximal and distal stent migration.

In this study, placement of both types of FCSEMSs had a few poststenting events. According to our recently published and previous articles,[15,29] placement of a self-expandable metal stent may be associated with post-ERCP pancreatitis (PEP) However, the overall rate of poststenting pancreatitis in this study is higher than that in previous studies (14% vs 6.1%-6.9%).[15,29] In our patients, a biliary sphincterotomy was performed in all patients before FCSEMS placement. Moreover, most patients had undergone previous ERCP with plastic stent placement. Therefore, the frequency of poststenting pancreatitis in this study may not be related to the ERCP procedure per se during FCSEMS placement. There are a few factors contributing to PEP after FCSEMS placement in patients with benign biliary strictures. One is that occlusion of the pancreatic orifice can occur because of the covering membrane of the FCSEMS with the FE design. This may be a risk factor for poststenting pancreatitis. Second, the rate of PEP in patients with benign biliary strictures after FCSEMS placement may be more frequent than that in patients with distal malignant biliary strictures because PEP might not occur in patients with complete obstruction of the pancreatic duct, such as in pancreatic cancer, which might destroy pancreatic function, including pancreatic juice secretion.[15]

Despite no statistical significance, there seems to be a difference in the rate of PEP between the 2 groups (18% in the AF group vs 10% in the FE group; $P = .66$). Different radial force values of these groups (9.7 N for the AF group vs 9 N for the FE group at a 4-mm diameter of the FCSEMS; unpublished data) may be related to the discrepancy in the rate of PEP in these groups because a high radial force value could exert excessively high stress to the opening of the pancreatic duct.[15,29,30] For the issue of the rate of PEP after placement of an FCSEMS, the ideal radial force of the FCSEMS to prevent PEP without sacrificing patency may be evaluated. Further study will determine whether protective pancreatic duct stenting is needed.

Our primary endpoint is the evaluation of 2 types of FCSEMSs for the prevention of stent migration. Because this study is a proof-of-concept study on stent migration, our short-term follow-up after stent removal does not evaluate the long-term efficacy of intended placement of FCSEMSs for benign biliary strictures.

Based on our promising results of the antimigration properties and easy removal of FCSEMSs with an AF, a long-term study with this device in benign biliary strictures is warranted.

In conclusion, with regard to the antimigration properties of FCSEMSs for benign biliary strictures, an AF at the proximal portion of the stent appears to be superior to the FE. In our trial, both types of FCSEMSs can be removed endoscopically at 4 to 6 months without complications.

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