



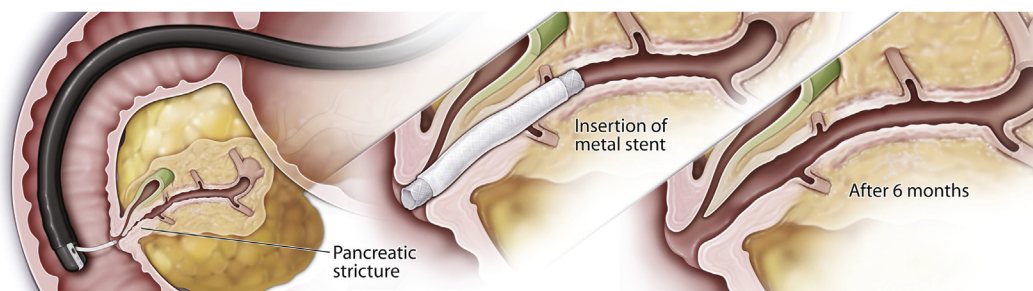
Fully covered self-expandable metal stents to dilate persistent pancreatic strictures in chronic pancreatitis: long-term follow-up from a prospective study



Andrea Tringali, MD, PhD,^{1,2} Salvatore Francesco Vadalà di Prampero, MD, PhD,^{3,4} Rosario Landi, MD,^{2,4} Vincenzo Bove, MD,^{2,4} Pietro Familiari, MD, PhD,^{2,4} Jun Hamanaka, MD,^{4,5,6} Fabia Attili, MD,^{2,4} Guido Costamagna, MD, FACP^{1,2,7}

Rome, Udine, Italy; Yokohama, Japan; Strasbourg, France

GRAPHICAL ABSTRACT



Background and Aims: Symptomatic main pancreatic duct (MPD) strictures secondary to chronic pancreatitis (CP) may benefit from endoscopic insertion of single or multiple plastic stents. MPD stricture resolution after single plastic stent removal is uncommon. The use of removable fully covered, self-expandable metal stents (FC-SEMSs) to dilate MPD strictures secondary to CP was evaluated.

Methods: Patients with CP and symptomatic MPD stricture located in the head of the pancreas persisting for 3 months or more after placement of a single plastic stent were enrolled in a prospective single-arm trial. A nitinol FC-SEMS was inserted and removed after 6 months. The FC-SEMS diameter and length were chosen according to the stricture anatomy and MPD diameter above the stricture. Our primary objective was FC-SEMS removability. Secondary outcomes were MPD stricture resolution rate and adverse events.

Results: Between December 2012 and October 2014, 15 patients (10 male, mean age 60 years) were enrolled. Pancreatic calcifications were present in 6 (40%) patients. Four patients (27%) had a history of alcohol abuse. In 10 patients, the FC-SEMS was inserted through the major papilla, whereas 5 patients (3 pancreas divisum, 2 dominant dorsal duct) received the stent through the minor papilla. One patient developed cholangitis after 24 hours due to occlusion of the biliary sphincterotomy from the FC-SEMS; cholangitis resolved after insertion of a plastic biliary stent. Complete distal migration of the FC-SEMS was reported in 7 patients (47%) (5 asymptomatic, 2 symptomatic with recurrence of pancreatitis). All migrations occurred with the 3-cm-long FC-SEMS. Four patients (27%) developed de novo stricture induced by the FC-SEMS at the level of the flared end and were excluded from the follow-up; 1 patient with FC-SEMS migration had failed stricture resolution. One patient was lost to follow-up. Finally, 9 patients with MPD stricture resolution had a mean follow-up of 38.9 months (range, 5.3-55.3 months), and 89% were asymptomatic.

Conclusions: FC-SEMS removability from the MPD in CP was feasible in all cases, and 90% of the patients were asymptomatic after 3 years. Migration seems more frequent with the 3-cm-long FC-SEMS. Occurrence of FC-SEMS-induced pancreatic strictures is a major issue and deserves further assessment. According to our experience, pancreatic FC-SEMSs have promising results, but a careful evaluation in the setting of clinical trials is needed. (Gastrointest Endosc 2018;88:939-46.)

(footnotes appear on last page of article)

INTRODUCTION

Main pancreatic duct (MPD) strictures in the course of chronic pancreatitis (CP) occur in up to 47% of patients.^{1,2} The usual endoscopic modality of treatment of symptomatic patients with MPD strictures is single plastic stent placement.^{1,3} Although adequate stent placement will relieve pain in most patients,⁴⁻⁶ stents cannot be definitively removed in approximately one-third of the patients because of persistent or recurrent strictures.^{2,7-10} As a consequence, patients with unrelenting symptomatic MPD strictures may need periodical plastic stent exchange for an indefinite period of time. Latero-lateral pancreaticojejunostomy is a definitive option, but it is often refused by the patients due to its invasiveness and related adverse events.¹¹

New strategies to dilate benign MPD strictures after CP are under evaluation. Insertion of multiple plastic stents obtained satisfactory results, but data are limited to a small series from a single study.¹² Fully covered self-expandable metal stents (FC-SEMSs) seem promising but are still under investigation according to some authors.¹

The aim of our study was to evaluate FC-SEMS placement to dilate MPD strictures in CP in a prospective single-center study with long-term follow-up.

PATIENTS AND METHODS

Patients

Consecutive patients with symptomatic MPD strictures secondary to CP persisting after single plastic stent (8.5F-10F) placement were treated by FC-SEMSs. Initial pain was assessed using the Izbicki score.¹³ Patients were enrolled according to the following inclusion criteria: dominant MPD stricture located in the pancreatic head, initially treated with pancreatic sphincterotomy and single plastic stent insertion; pain relief during single pancreatic plastic stent placement; persistence of the MPD stricture after single plastic stent removal; pancreatic duct dilation >6 mm; no evidence of pancreatic neoplasia on CT scan and/or EUS performed before the first ERCP. Patients with active alcohol abuse, multiple MPD strictures, previous treatment by multiple plastic stents, pancreatic pseudocyst, or concomitant bile duct stricture secondary to CP were excluded.

Refractory MPD stricture was defined as a definite narrowing of the pancreatic duct creating obstruction to pancreatic flow, with persistence of contrast medium in the dilated duct of the body and tail for more than 5 minutes after stent removal.¹²

Endpoints

The primary endpoint was assessment of the pancreatic FC-SEMS removability 6 months after placement. The secondary endpoints of the study were evaluation of FC-



Figure 1. The Taewoong Bumpy pancreatic fully covered self-expandable metal stent.

SEMS-related adverse events (pain, migration, cholangitis, development of de novo stricture), the need for endoscopic re-intervention due to SEMS malfunction, the rate of MPD stricture resolution and recurrence after FC-SEMS removal, and pain relief after 3 years of follow-up.

Pancreatic FC-SEMS features

All patients included in the study were treated with a Niti-S Bumpy Stent (Taewoong Medical, Gimpo-Si, South Korea). This pancreatic FC-SEMS is braided with nitinol wire, has flared ends to reduce migration, and is fully covered with silicone (flared end) and polytetrafluoroethylene (body portion); the middle portion of the stent has irregular cell sizes resulting in different segmental radial forces to prevent migration and provide high conformability (Fig. 1). The stent introducer size is 8.5F. The Bumpy stent is available with diameter of 6, 8, or 10 mm and different lengths (4-12 cm). A 3-cm-long stent was customized at the investigators request specifically for this study to reduce the amount of potentially occluded side branch.

Endoscopic treatment with pancreatic FC-SEMS

Patients with pancreatic stones obstructing the MPD received extracorporeal shock-wave lithotripsy followed by ERCP with extraction of stone fragments; a pancreatic plastic stent was inserted to drain an MPD stricture if present, and to assess pain relief after ductal drainage. Antibiotic prophylaxis with cefazolin (2 g, intravenously) was given; rectal indomethacin (100 mg) was administered before ERCP to prevent post-ERCP pancreatitis.

ERCP was performed with the patient under deep sedation with propofol or general anesthesia at the discretion of the anesthesiologist. The endoscopic treatment protocol included the following steps:

- (1) removal of the single pancreatic stent;
- (2) dilation of the stricture with an 8.5F mechanical Soehendra dilator to assess the possibility of advancing the introduction device of the SEMS; 4-mm balloon dilation was performed in case of failure to pass the stricture with the 8.5F dilator;
- (3) insertion of a 6- or 8-mm-wide and 3-, 4-, or 5-cm-long FC-SEMS (diameter of the stent was chosen according

TABLE 1. Characteristics of pancreatic fully covered self-expandable metal stents

	n	%
Diameter		
6 mm	7	47
8 mm	8	53
Length		
3 cm	12	80
4 cm	2	13
5 cm	1	7

to the MPD diameter above the stricture, whereas stent length was decided according to stricture extension and MPD morphology);

(4) removal of the FC-SEMS 6 months after placement.

After pancreatic stent removal, stricture resolution was defined according to the following criteria:

- easy passage of a 10-mm extraction balloon;
- absence of pain during continuous saline solution perfusion (1000 mL/24 hours) through a 5F to 7F nasopancreatic catheter inserted after stent removal;
- free flow of contrast medium alongside the nasopancreatic catheter on a check pancreatogram 24 hours later.

In case of failed MPD stricture resolution, a single plastic stent was placed to guarantee ductal drainage and the patient was evaluated for surgery.

The protocol was approved from the Ethical Committee of the Catholic University of Rome on 6 December, 2012 (P/1134/CE/2012).

Follow-up

Follow-up started after removal of the FC-SEMS until death or last contact. The clinical condition of the patients was evaluated every 6 months for the first 2 years and then annually by telephone interview, focusing on general condition, pain relief/recurrence, pancreatitis recurrence, and the need for endoscopic re-treatment. A minimum of 3 years of follow-up was the target. Pain was evaluated using the Izbicki score.¹³ Radiologic investigations (CT scan, magnetic resonance pancreatography) were not performed systematically, but at physician's discretion based on clinical evaluation. Last follow-up was performed in April 2018.

Statistical analysis

Continuous data were reported as the mean (standard deviation [SD]); categorical data were reported as the count and percentage. Continuous variables were compared using the Student t test. Nominal *P* values are reported; 2-sided *P* values less than .05, were considered significant. MedCalc Statistical Software version 14.8.1 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2014) was used for statistical analyses.



Figure 2. Obstruction of the biliary orifice (arrow) by the pancreatic fully covered self-expandable metal stent.

TABLE 2. Results of placement and removal of pancreatic fully covered self-expandable metal stents (FC-SEMSs)

	n	%
Patients	15	–
FC-SEMS removability	8/8	100
FC-SEMS complete distal migration	7/15	46
Asymptomatic	5/7	71
Symptomatic	2/7	29
FC-SEMS-induced MPD stricture	4/15	27
FC-SEMS-related cholangitis	1/10*	10
MPD stricture resolution	14/15	93
Asymptomatic after a mean follow-up of 3.2 years	8/9	89

MPD, Main pancreatic duct.

*Patients who received FC-SEMS through the major papilla.

RESULTS

Between December 2012 and October 2014, 15 patients (10 men; mean age, 60 years; range, 19-85 years) were enrolled in the study. Four patients (27%) had a history of

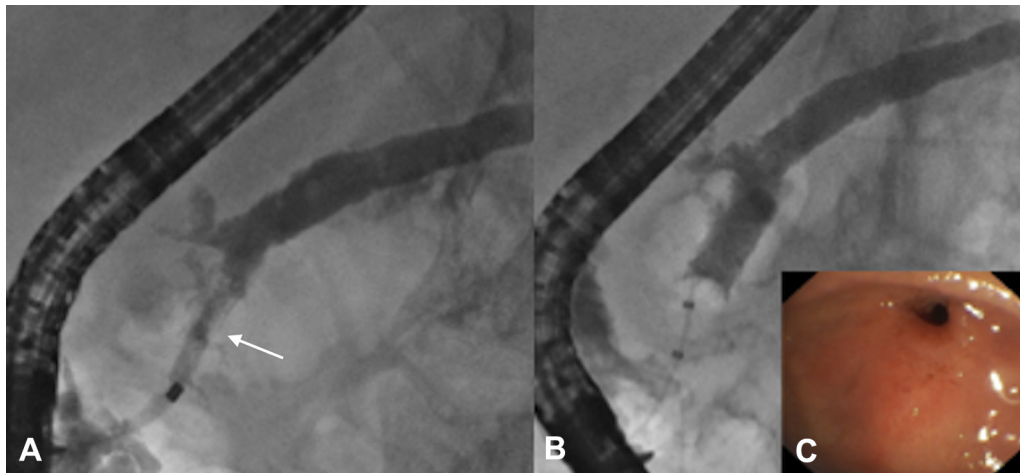


Figure 3. Main pancreatic duct stricture (A) (arrow) resolved (B) after metal stent removal (C, endoscopic view).

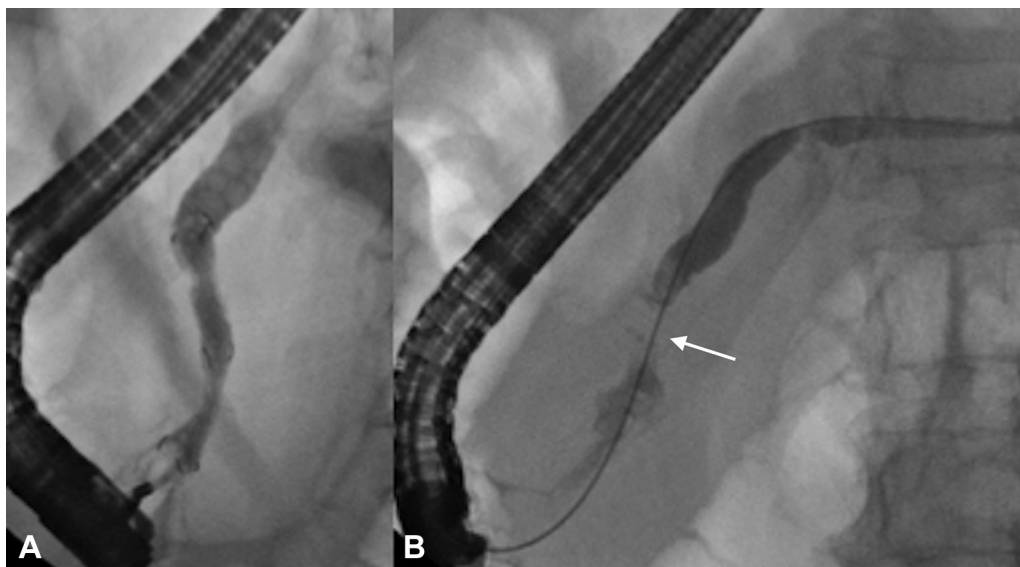


Figure 4. Fully covered pancreatic metal stent after deployment (A); occurrence of a de novo pancreatic duct stricture (arrow) after stent removal (B).

long-lasting alcohol abuse. Six (40%) patients had pancreatic calcifications and, before plastic stent placement, 4 received extracorporeal shock-wave lithotripsy to fragment calcified stones obstructing the MPD in the pancreatic head.

Mean Izbicki score at the time of plastic stent insertion was 45.2 (SD, ± 14.1). Twelve of 15 patients (80%) received a 3-cm-long (customized) pancreatic FC-SEMS; the stent diameter was 6 or 8 mm, distributed equally among the patients (Table 1).

The FC-SEMS was placed through the major papilla in 10 of 15 patients (67%) and through the minor papilla in the remaining 5 patients with a pancreas divisum ($n = 3$) or a dominant dorsal duct anatomy ($n = 2$). All patients had a previous pancreatic sphincterotomy (10 major, 3 minor, 2 both major and minor) at FC-SEMS placement.

After FC-SEMS insertion, no cases of pancreatitis were recorded. In all patients, postoperative pain was successfully controlled by nonsteroidal anti-inflammatory drugs with resolution after 24 to 48 hours. One patient developed cholangitis 24 hours after FC-SEMS insertion due to occlusion of the biliary sphincterotomy from the pancreatic FC-SEMS (Fig. 2); cholangitis resolved after a further ERCP with biliary plastic stent insertion.

Planned FC-SEMS removal occurred after a mean time of 7.1 months (SD, ± 1.4 months; range, 5.8-10.3 months) in 8 patients: pancreatic FC-SEMSs were still in place in 8 of 15 patients (54%), and removal was feasible in 7 cases by gentle pulling with foreign body forceps. One patient had proximal (intraductal) FC-SEMS migration, and the stent was removed easily with foreign body forceps after

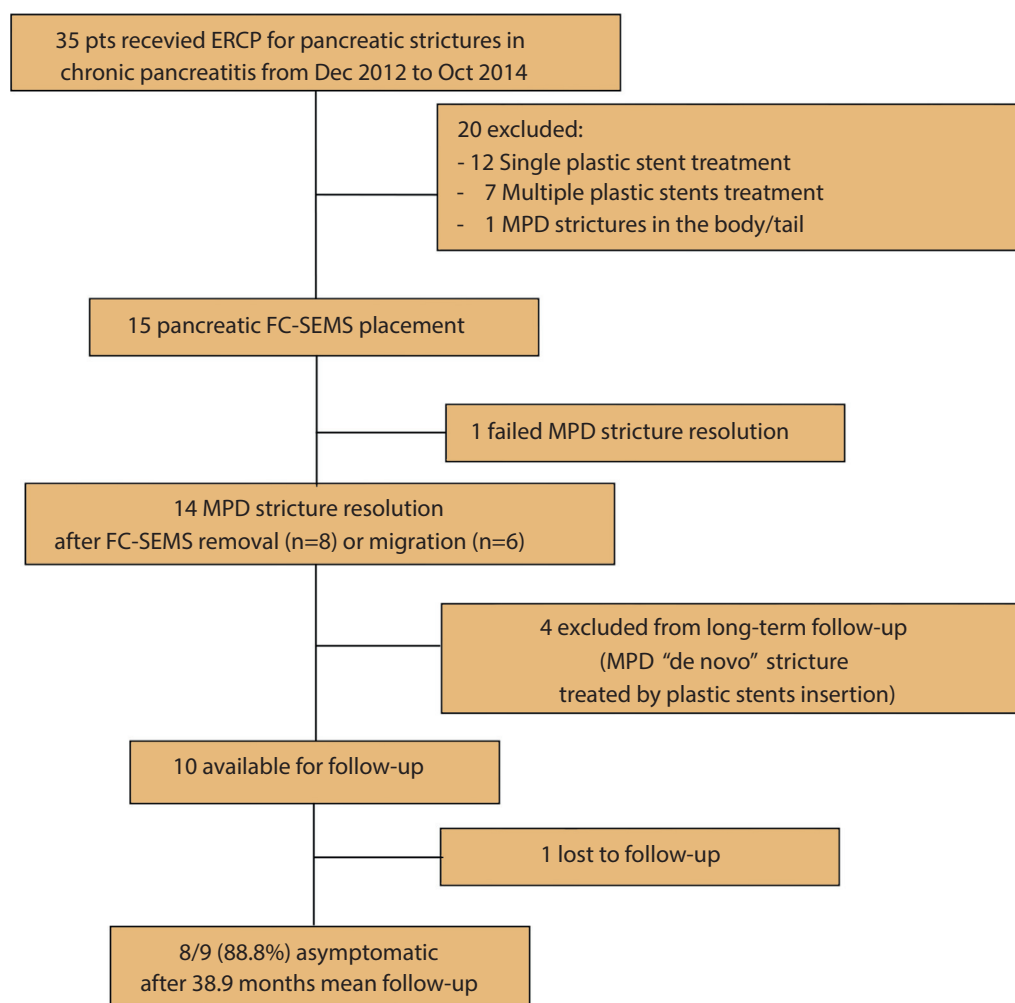


Figure 5. Study flowchart. *FC-SEMS*, Fully covered self-expandable metal stent; *MPD*, main pancreatic duct.

balloon dilation of the papilla. Asymptomatic complete distal migration was found in 5 patients; FC-SEMS migration was diagnosed in 2 patients because of pancreatitis occurrence after a mean of 4.5 months (SD, ± 0.7 months) since placement (Table 2): an 85-year-old patient had persistence of MPD stricture and accepted annual exchange of a single pancreatic plastic stent; the second patient had MPD stricture dilatation but developed a de novo stricture. Overall, original MPD stricture resolution was achieved in 93.3% of patients (14 of 15) (Fig. 3).

De novo MPD stricture (Fig. 4) just above the intraductal end of the FC-SEMS was observed in 4 of 15 patients (27%). In 3 patients, de novo stricture diagnosis was incidental at the time of planned FC-SEMS removal, whereas 1 patient had pancreatitis 5 months after FC-SEMS placement. Results are summarized in Table 2. These de novo MPD strictures were short (≤ 1 cm) and narrow; in 3 patients they were managed by insertion of a single 7F or 10F plastic stent left in place for a mean of 5.3 months. In one case, passage of the

stricture was possible only after EUS-guided rendezvous; this patient was treated by insertion of a single 10F plastic stent for 12 months and then by the insertion of four 10F stents. After plastic stent removal, all the de novo strictures healed, without recurrence during the follow-up.

The 4 patients with a stent-induced stricture were excluded from the long-term follow-up to avoid misleading factors; one had failed MPD stricture resolution. One patient was lost to follow-up. Follow-up data were thus evaluated in 9 patients: 8 of 9 (89%) remained asymptomatic at a mean follow-up of 38.9 months (SD, ± 16.8 months; range, 5.3-55.3 months) (2 died during follow-up after 5 and 11 months due to pancreatic and lung cancer). The mean Izbicki score at the end of follow-up was significantly lower than at the baseline (6.0; SD, ± 10.5 ; $P < .0001$). The patient with pain recurrence was an active drinker and underwent magnetic resonance imaging without evidence of pancreatic stricture recurrence. Study enrollment and results are summarized in Figure 5.

TABLE 3. Published results of pancreatic fully covered self-expandable metal stents (FC-SEMSs) in chronic pancreatitis (prospective studies)

Reference and stent type	N	Diameter (mm)	Length (cm)	Pain relief with stent in place (%)	Planned stent removal (months)	Stricture resolution (%)	Need for surgery (%)	Follow-up (months)	Pain relief during follow-up (%)	FC-SEMS-related adverse events
Park et al, 2008 ¹⁵ Niti-S, D-type, unflared	13	6-8	5-7	100	2	100	0	5 (median)	100	31% distal migration 8% proximal migration 23% mild pancreatitis 15% cholestasis
Sauer et al, 2008 ¹⁶ Viabil	5	8-10	–	100	3	40	0	–	–	Absent
Moon et al, 2010 ¹⁷ Niti-S, Bumpy, flared	32	6-8-10	4-8	100	3	100	3	5 (mean)	91	16% de novo strictures (asymptomatic)
Giacino et al, 2012 ¹⁸ BSCL, Wallflex, flared	10	8-10	4-6	90	6	100	0	20 (mean)	90	20% cholestasis 20% SEMS for removal
Ogura et al, 2016 ¹⁹ Niti-S, S-type, unflared	13	6	6-8	92	6	100	0	9 (median)	85	15% migration 8% severe pain (SEMS removed)
Matsubara et al, 2016 ²⁰ Niti-S, Bumpy, flared	10	8-10	5-7	100	3	40	0	35 (median)	37	30% severe pain 25% migration 25% ductitis 25% de novo strictures
Present study Niti-S, Bumpy, flared	15	6-8	3-4-5	100	6	93	0	39 (mean)	89	46% migration 27% de novo strictures 10% cholangitis

DISCUSSION

MPD stricture is still a challenging adverse event of CP because of its blockage of pancreatic juice with subsequent continuous pain which is difficult to manage with medical therapy only. These days, there are 2 main options to drain MPD strictures: surgery and endoscopy. Surgical treatment of CP (derivative or resective) is considered a definitive solution with better results than endoscopy,³ but it can be refused by the patient due to the perception of its invasiveness. Furthermore, some patients with CP are not eligible for surgery because of their comorbidities.

Endoscopy is another option to manage MPD strictures: transpapillary drainage of the MPD by ERCP is historically considered the main option and is still widely used. Transgastric EUS-guided drainage of the MPD is limited to case reports, and its success rate appears to be low.¹⁴ Two types of stents can be used to drain the MPD by ERCP: a plastic stent and FC-SEMS. Until now, single plastic stent placement is the main option with a high technical and clinical success rate in the short term; the main limitations of the single plastic stent are the failure to obtain permanent MPD stricture dilation and the high rate of stricture recurrence.³ To get permanent dilatation of the MPD strictures related to CP, temporary multiple plastic stent insertion

has been proposed with promising results on a small cohort of patients (94% of stricture dilation, 84% pain free after 3 years of follow-up).¹²

FC-SEMSs can reach a larger diameter than plastic stents, and the insertion is easier compared with multiple plastic stents. Some concerns regarding the insertion of the FC-SEMS into the pancreatic duct are occlusion of the side branches and the trauma of the MPD secondary to the radial force of the metal stent. Small series¹⁵⁻²¹ using pancreatic FC-SEMSs in CP were published recently: adverse events (migration, development of de novo strictures, hyperplasia, severe pain, cholestasis) are the main issues; however, sustained pain resolution after pancreatic FC-SEMS removal was reported in 85% to 100% of patients during a short-term follow-up (mean, 5-20 months) (Table 3).

Pancreatic FC-SEMS migration was reported in 15% to 30% of cases in previous studies (Table 3). In our series, a complete distal migration of the FC-SEMS occurred in nearly half of the patients (46%); the length of the migrated stent was 3 cm in all cases, whereas no migration was observed in patients who received a 4- to 5-cm-long stent. A reason for FC-SEMS migration can be the stricture resolution, especially in asymptomatic cases; in our series, migration of the 3-cm-long stent can be related also to the instability of the stent, which did not extend enough above and below the stricture.

FC-SEMS-induced MPD strictures requiring endoscopic re-treatment were a problem (27%) in our series. A de novo MPD stricture above the intrapancreatic end of the stent is probably secondary to reactive hyperplasia secondary to compression from the flared end of the Bumpy stent (Fig. 4). A shorter duration of the FC-SEMS indwelling time could reduce the incidence of de novo MPD strictures; nevertheless, 2 studies using the same Bumpy stent^{17,20} for a 3-month period reported a 16% to 25% rate of de novo strictures.

In our study, 3-cm-long, customized FC-SEMSs were used with the supposed advantage of reducing the possibility of side branch occlusion and to cover the MPD stenosis exactly, avoiding possible damage over the normal MPD. Nevertheless, 3-cm-long FC-SEMSs did not have any advantage over available stents; furthermore, the 3-cm-long stent had a very high migration rate.

Pain improvement during indwelling FC-SEMSs was achieved in all of our patients, as shown by the improvement of the Izbicki score ($P < .0001$). MPD stricture resolution after FC-SEMS removal was 93.3%, similar to that reported in the literature (Table 3).

A long-term follow-up is the key to understand the evolution of patients affected by CP, which requires repeated treatment during the course of the disease. Previous studies report results on short-term follow-up with >85% of the patients pain free after FC-SEMS removal; this figure decreases to 37% in a study with a median follow-up of 35 months (Table 3).²⁰ In our long-term follow-up (mean, 3.2 years), 89% of patients were asymptomatic; these data are promising, but the role of FC-SEMSs in CP needs to be defined in the setting of clinical trials¹ due to the high migration rate and the occurrence of FC-SEM-induced strictures.

The present study confirms that the removability of pancreatic FC-SEMSs is possible in all cases, which represents an important safety point for future evaluation. The main limitations of this study are the small sample, single-center enrollment, and the absence of a control group. The role of pancreatic FC-SEMSs is therefore still under evaluation. Future studies should also focus on a modified FC-SEMS design to avoid migration and the occurrence of de novo MPD strictures. A prospective multicenter evaluation with a comparison between multiple plastic stents and FC-SEMSs would be desirable.

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Abbreviations: CP, chronic pancreatitis; FC-SEMS, fully covered self-expandable metal stent; MPD, main pancreatic duct.

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Current affiliations: Digestive Endoscopy Unit, Fondazione Policlinico Universitario Agostino Gemelli - IRCCS, Catholic University, Rome, Italy

(1); CERTT, Centre for Endoscopic Research, Therapeutics and Training – Catholic University, Rome, Italy (2); Department of Gastroenterology and GI Endoscopy, University Hospital of Udine, Italy (3); Digestive Endoscopy Unit, Fondazione Policlinico Universitario Agostino Gemelli - IRCCS, Rome, Italy (4); Department of Gastroenterology, Yokohama City University Graduate School of Medicine, Yokohama, Japan (5); Department of Gastroenterology, Yokohama Minami Kyosai Hospital, Yokohama, Japan (6); Digestive Endoscopy, IHU-USIAS, University of Strasbourg, Strasbourg, France (7).

Reprint requests: Andrea Tringali, MD, PhD, Dipartimento Scienze Gastroenterologiche, Endocrino-Metaboliche e Nefro-Urologiche, Istituto di Clinica Chirurgica Generale e Terapia Chirurgica, Fondazione Policlinico Universitario A. Gemelli IRCCS – Università Cattolica del Sacro Cuore, Rome, Italy (Largo Agostino Gemelli, 8, 00168 Roma RM, Italy).

If you would like to chat with an author of this article, you may contact Dr Tringali at andrea.tringali@unicatt.it.

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