# Preliminary study of a modified, nonflared, short, fully covered metal stent for refractory benign pancreatic duct strictures (with videos)

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**Background and Aims:** Fully covered self-expanding metal stents (FCSEMSs) are considered to be more effective than plastic stents for the treatment of main pancreatic duct (MPD) strictures associated with chronic pancreatitis (CP) because of their larger diameter and exertion of a radial expansion force. However, the current FCSEMSs have several limitations. To overcome these, a novel modified nonflared FCSEMS was developed. In this study we conducted a prospective long-term follow-up evaluation of the efficacy of the novel FCSEMS for the treatment of refractory benign PD strictures in patients with CP.

**Methods:** Consecutive patients with symptomatic CP associated with refractory MPD strictures were enrolled prospectively in this single-arm study. The nonflared FCSEMS was placed intraductally or transpapillary according to the location and length of the stricture. Stent removal was performed at 3 months after placement. The primary outcome was the resolution of the pancreatic ductal stricture.

**Results:** Endoscopic placement of modified nonflared FCSEMSs was technically successful in all 25 patients. Intraductal FCSEMS placement was performed in 14 patients (56.0%). Stents of diameter 8 mm were used in 17 patients (68.0%). Stents of lengths 3 and 5 cm were inserted in 22 (88.0%) and 3 (12.0%) patients, respectively. In 1 patient (4.0%), stent migration developed. All other stents were removed successfully. After stent removal, resolution of the MPD stricture was confirmed in all patients, and no FCSEMS-related de novo stricture was observed. During the follow-up period (median, 34 months; interquartile range, 25-56) after the stents had been removed from the 25 patients, reintervention for recurrence of MPD stricture with abdominal pain was performed in 2 patients (8.0%).

**Conclusions:** Endoscopic placement of a novel modified nonflared FCSEMS resulted in long-term stricture resolution with pain relief and reduced the rate of stent-related adverse events, particularly stent migration and stent-induced de novo MPD stricture. (Clinical trial registration number: UMIN000035681.) (Gastrointest Endosc 2020;91:826-33.)

*(footnotes appear on last page of article)*

Endoscopic transpapillary placement of a single plastic stent has been used as an initial treatment for symptomatic chronic pancreatitis (CP) associated with main pancreatic duct (MPD) strictures.[1] Although it reduces pain in most patients, a subset experience recurrence of pain because of persistent or recurrent pancreatic stricture after stent removal.[2-5]

Multiple plastic stent placement, which is used to resolve refractory benign PD stricture (BPS), led to promising results in terms of persistent stricture dilation during

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long-term follow-up.[6] However, multiple endoscopic sessions were required in some patients, and the available data are limited to a small series in a single study. Because fully covered self-expanding metal stents (FCSEMSs) can be of larger diameter than plastic stents and are more easily inserted than multiple plastic stents,[7] their efficacy for the treatment of refractory BPS has been investigated. However, use of the FCSEMS designed for other applications is limited by the high frequency of stent migration for pancreatic ductal stent placement.[8] Subsequently, modified flared FCSEMSs were developed to reduce stent migration, but these tended to induce de novo strictures with stent-induced ductal change.[9] In addition, classic transpapillary placement of FCSEMSs such that the distal segment is in the duodenal lumen requires coverage of the MPD lumen by the FCSEMSs, particularly for proximally located strictures. Also, FCSEMSs can induce pancreatic infection and/or sepsis by occluding side branches of the MPD.[7,9-11]

To overcome these limitations, a modified nonflared FCSEMS was developed. The newly modified nonflared FCSEMS has several structural characteristics such as a central saddle-like stent form for preventing stent migration and a round margin without open flares at both ends for reducing stent-induced ductal change. In addition, the short length and intraductal location of the modified nonflared FCSEMS prevents duodenopancreatic duct reflux and also minimizes covering of side branch as compared with a conventional FCSEMS. In this study we conducted a prospective long-term follow-up evaluation of the efficacy of a newly modified nonflared FCSEMS for the treatment of refractory BPS in patients with CP.

## METHODS

### Patients

Consecutive patients with symptomatic CP associated with refractory BPS were prospectively enrolled in this study. Inclusion criteria were (1) painful focal MPD stricture in the pancreatic head or body, which was initially treated with pancreatic sphincterotomy and single plastic stent insertion; (2) improvement of abdominal pain during single plastic stent placement; (3) recurrence of a painful stricture within 6 months or stricture persistence after plastic stent removal; (4) upstream pancreatic ductal dilatation >6 mm; (5) no evidence of pancreatic neoplasia in CT and/or EUS; (6) age >18 years; and (7) ability to provide informed consent. Patients with multiple MPD strictures, MPD stricture in the pancreatic tail, active alcohol abuse, and pancreatic pseudocyst and/or walled-off necrosis were excluded.

### Study design

This was a prospective single-arm study in a single tertiary referral university hospital. Our Institutional Review Board approved the study, and written informed consent was obtained from all patients. This study was registered in the UMIN Clinical Trial Registry (UMIN000035681).

### Newly modified nonflared FCSEMS

The modified FCSEMS (BONASTENT M-Intraductal; Standard Sci Tech Inc, Seoul, South Korea) is made of nitinol wire and fully covered with a silicone membrane. The FCSEMS has a saddle-like form and is available in the following sizes: proximal and distal portions, 8- or 10-mm diameter; central portion, 6- or 8-mm diameter and 1- to 3-cm length. The central saddle consists of a cross-wired structure, and the other portion of the stent has a fixed-hook and cross-wired structure. To facilitate stent placement at the center of a stricture, spiral-shaped radiopaque markers are located at the central saddle portion of the stent. The stent has a round margin without open flares at both ends to reduce the risk of ductal injury. In addition, radiopaque markers are placed at both ends to assist accurate intraductal stent placement. A lasso 7 cm in length is attached to the distal end to facilitate stent retrieval (Figs. 1 and 2). The FCSEMS is available in total lengths of 3, 4, 5, 6, and 7 cm. The stent is contained in a standard 8F, pull-back delivery system. The expected shortening rate of 3-cm length modified FCSEMS with 8- and 10-mm diameter is 30%.

### Endoscopic interventions using the modified FCSEMS

All procedures were performed according to standardized protocols by 3 experienced investigators using a standard duodenoscope (TJF-260V; Olympus Medical Systems, Co, Ltd, Tokyo, Japan). Standard techniques were used to cannulate the PD, and contrast was injected to identify the location and length of the stricture. Endoscopic pancreatic sphincterotomy was performed previously in all patients, and endoscopic biliary sphincterotomy was performed if there was no history of biliary sphincterotomy. As needed, the PD stricture was dilated using a Soehendra biliary dilatation catheter (Cook Medical, Winston-Salem, NC, USA) or a balloon dilation catheter (Hurricane; Boston Scientific Corp, Marlborough, Mass, USA). Stent diameter was determined on the basis of the diameter of the dilated upstream duct proximal to the stricture. The length was selected such that .5 to 1 cm of each end of the FCSEMS extended beyond the stricture segment and the FCSEMS was as short as possible to reduce the risk of side-branch obstruction. The stent was placed under fluoroscopic guidance so that the central saddle portion was located at the center of the stricture in the MPD irrespective of the exposure of the distal end to the duodenal lumen (Video 1, available online at www.giejournal.org). Therefore, the fully deployed FCSEMS was placed inside the PD, and only the long lasso was exposed to the duodenal lumen in some patients, depending on the location and length of the stricture (Video 2, available online at www.giejournal.org).

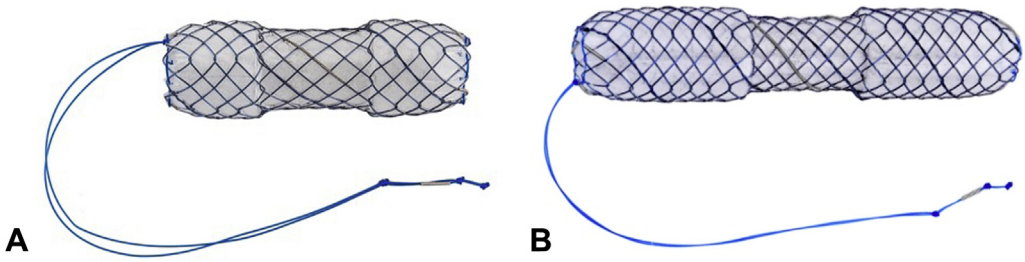


**Figure 1.** A newly modified nonflared fully covered self-expandable metal stent. **A,** 8-mm diameter and 3-cm length. **B,** 8-mm diameter and 5-cm length.

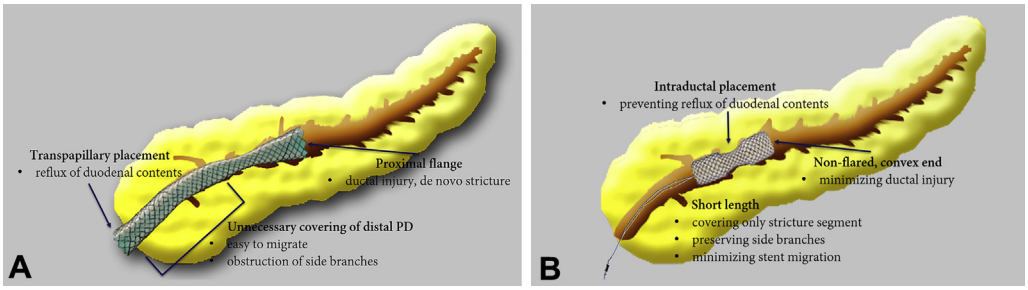


**Figure 2.** Comparison of fully covered self-expandable metal stent (FCSEMS) for the treatment of refractory benign pancreatic duct stricture (BPS). **A,** A conventional FCSEMS placed across the duodenal papilla. **B,** Newly modified nonflared FCSEMS placed above the papilla in the BPS. *PD*, Pancreatic duct.

Stent removal was performed at 3 months after stent placement. The FCSEMS was removed through the working channel of a therapeutic duodenoscope after grasping the lasso using forceps (Videos 3 and 4, available online at www.giejournal.org). After removal, a balloon-occluded pancreatogram was obtained to evaluate stricture resolution and development of de novo strictures (Figs. 3 and 4).

## Follow-up

Serial plain abdominal radiographs were taken before the procedure and at 1, 2, 7, 30, and 90 days thereafter to evaluate stent migration. The serum levels of pancreatic enzymes were assayed and liver function tests performed on the same schedule. After stent removal, patients were scheduled to visit the hospital every 6 months. The intensity of abdominal pain was evaluated using a visual analog scale before and after FCSEMS placement and at 6-month intervals after its removal.

## Definitions of events and assessment of outcomes

The primary outcome was the resolution of the pancreatic ductal stricture, defined as resolution or marked improvement of PD strictures together with a decreased diameter of the upstream duct as observed in a pancreatogram after stent removal and when complete runoff of contrast material was observed and an extraction balloon could be passed through the PD.[4] Secondary outcomes were technical success rate, pain relief, FCSEMS-related adverse events, FCSEMS removability, recurrence of pain, and the need for endoscopic reintervention during follow-up.

Technical success of endoscopic pancreatic ductal stent placement with the FCSEMS was defined as exact positioning of the stent along the entire length of the stricture with free flow of contrast material through the stent. Pain relief was defined as a reduction in the visual analog scale pain score of >50% compared with that before stent placement. Stent migration, stent occlusion, development of FCSEMS-related MPD strictures, and pancreatic sepsis were evaluated as FCSEMS-related adverse events. Stent migration was defined as movement of the entire FCSEMS above or below the stricture site. After stent removal, occurrence of a new pancreatic ductal stricture at the locations of the ends of the FCSEMS was defined as development of FCSEMS-related MPD stricture. Pancreatic sepsis was defined as clinical sepsis at the time of FCSEMS placement and retrieval.[12] Other adverse events after ERCP were recorded according to the guidelines of the American Society for Gastrointestinal Endoscopy.[13]

## Statistical analyses

Categorical parameters are expressed as frequencies and proportions and continuous variables as medians with interquartile ranges (IQRs). All statistical analyses were performed using SPSS software (version 18.0; IBM Corp, Armonk, NY, USA).

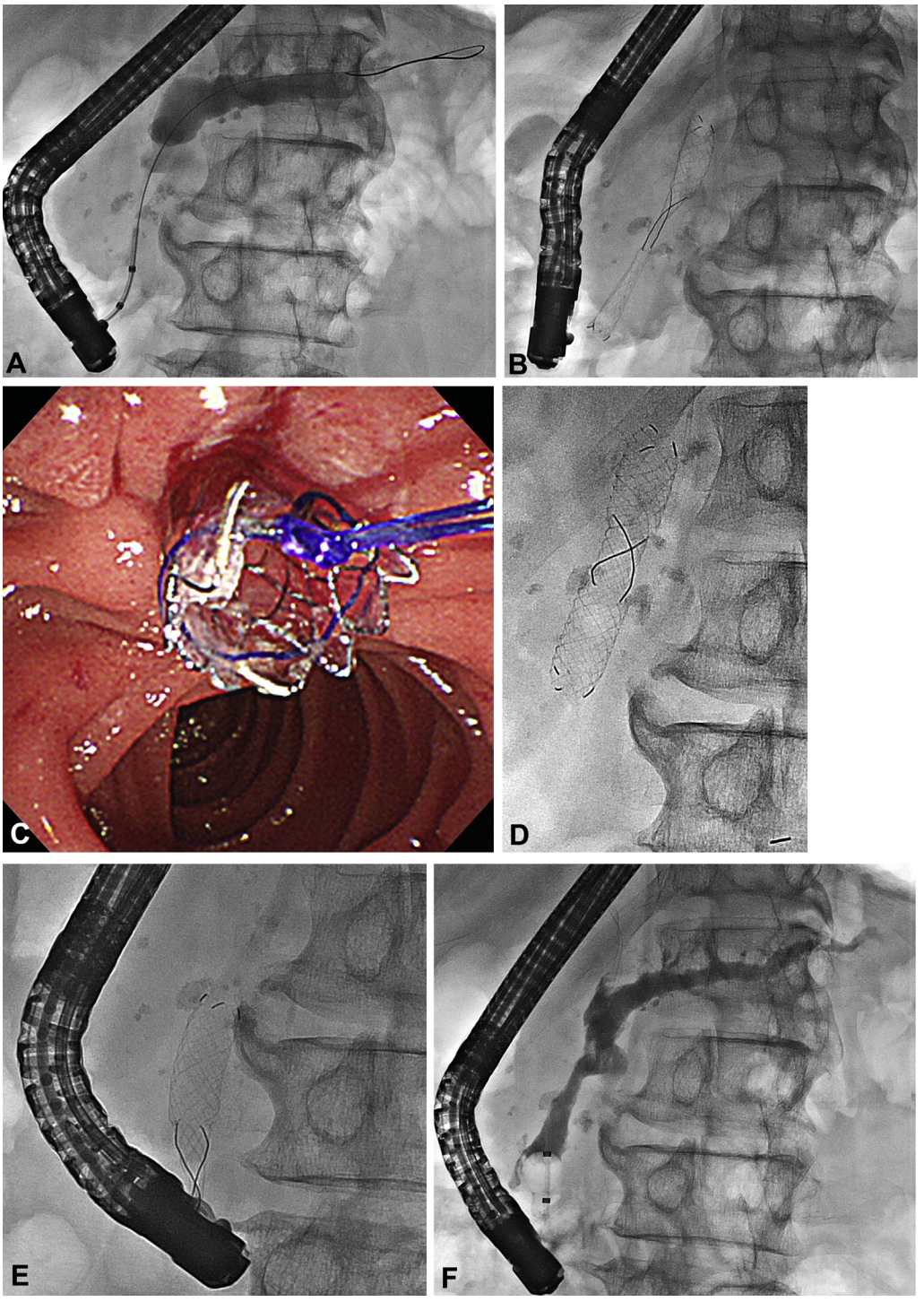


**Figure 3.** Refractory benign pancreatic duct stricture (BPS) managed by endoscopic transpapillary placement of a modified, nonflared, fully covered, self-expandable metal stent (FCSEMS). **A,** Pancreatogram showing a tight stricture at the pancreatic head with upstream duct dilatation. **B,** Fluoroscopic image with successful transpapillary deployment of an FCSEMS in the BPS. **C,** Endoscopic view showing the distal end of the stent and the lasso. **D,** Fully expanded configuration of the modified nonflared FCSEMS **E,** Fluoroscopic view showing stent retrieval through the working channel of the duodenoscope. **F,** Pancreatogram showing resolution of the BPS and improvement of upstream dilation after stent removal.

## RESULTS

From August 2012 to December 2017, 29 patients were screened; 4 were excluded for multiple MPD strictures (n = 2), pancreatic pseudocyst (n = 1), and refusal to participate (n = 1). The remaining 25 patients (21 men; median age, 53 years [IQR, 46-56]) were enrolled in the study. Most MPD strictures (84.0%) were located at the

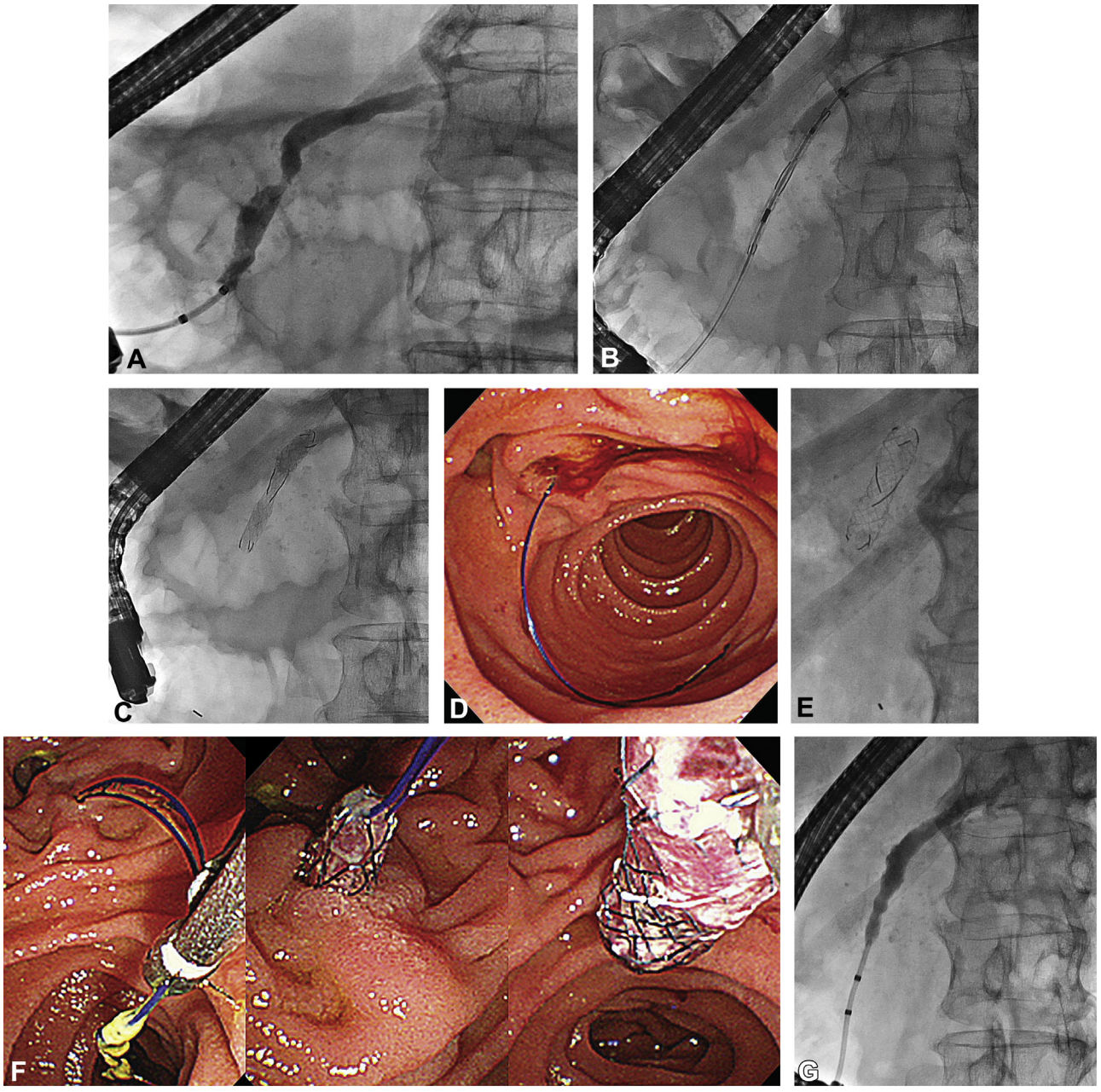


**Figure 4.** Refractory benign pancreatic duct stricture (BPS) managed by endoscopic intraductal placement of a modified, nonflared, fully covered, self-expandable metal stent (FCSEMS). **A,** Pancreatogram showing a short segmental stricture at the pancreatic head with upstream duct dilatation. **B,** Fluoroscopic image showing successful intraductal placement in the BPS. **C,** Fluoroscopic image showing deployment of an FCSEMS in the BPS. **D,** Endoscopic view of a lasso facilitating retrieval of a stent with an obscured distal end in the duodenal lumen. **E,** Fully expanded configuration of the modified nonflared FCSEMS. **F**, Endoscopic view showing removal and retrieval of the FCSEMS through the working channel of a duodenoscope by grasping the lasso using forceps at 3 months after placement. **G,** Pancreatogram showing resolution of the BPS after stent removal.

pancreatic head. The median total in situ duration of a previous plastic stent was 14 months (IQR, 8-24) (Table 1).

## Technical outcomes of FCSEMS placement

Endoscopic placement of the modified nonflared FCSEMSs was technically successful in all patients. Intraductal placement of the FCSEMS was performed in 14 patients (56.0%). Stents of 8-mm diameter were used in 17 patients (68.0%). Stents of lengths 3 and 5 cm were inserted in 22 (88.0%) and 3 (12.0%) patients, respectively (Table 2).

## Stricture resolution and FCSEMS-related adverse events

After FCSEMS placement, pain relief was achieved in all patients. Asymptomatic complete distal migration of stent occurred in 1 patient (4.0%), but no additional procedure was required because the MPD stricture had already been

**TABLE 1. Baseline characteristics of patients (n = 25)**

| Characteristic | Value |
|---|---|
| Median age, y (interquartile range) | 53 (46-56) |
| Sex, male/female | 21/4 |
| Etiology of chronic pancreatitis | |
| Alcohol | 19 (76.0) |
| Idiopathic | 6 (24.0) |
| Median duration of chronic pancreatitis, mo (interquartile range) | 25 (16-39) |
| Location of stricture | |
| Head | 21 (84.0) |
| Neck | 4 (16.0) |
| Median length of pancreatic duct stricture, mm (interquartile range) | 10 (9-12) |
| Pancreatic stones | 21 (84.0) |
| Median duration of previous plastic stent placement, mo (interquartile range) | 14 (8-24) |

Values are n (%) unless otherwise defined.

**TABLE 2. Technical outcomes of endoscopic placement of modified nonflared FCSEMSs**

| Characteristics | Value n (%) |
|---|---|
| Technical success | 25 (100) |
| Location of FCSEMS | |
| Intraductal placement | 14 (56.0) |
| Transpapillary placement | 11 (44.0) |
| Length of FCSEMS | |
| 3 cm | 22 (88.0) |
| 5 cm | 3 (12.0) |
| Diameter of FCSEMS | |
| 8 mm | 17 (68.0) |
| 10 mm | 8 (32.0) |

*FCSEMS*, Fully covered self-expanding metal stent.

**TABLE 3. Outcomes of endoscopic placement and removal of modified nonflared FCSEMSs**

| Characteristic | Value |
|---|---|
| Median duration of FCSEMS placement, days (interquartile range) | 109 (91-126) |
| Pain relief | 25 (100) |
| Stent removability | 24/24 (100)* |
| Resolution of pancreatic ductal stricture | 25 (100) |
| FCSEMS-related adverse events, | |
| FCSEMS-related MPD stricture | 0 |
| Stent migration | 1 (4.0) † |
| Pancreatic sepsis | 0 |
| Cholestatic liver dysfunction | 0 |
| Stent removability | 24/24 (100)* |

Values are n (%) unless otherwise defined.
*FCSEMS*, Fully covered self-expanding metal stent; *MPD*, main pancreatic duct.
*Excluding 1 case of stent migration.
†No additional intervention was required because the pancreatic duct stricture was resolved.

resolved. The stents were removed successfully from the remaining 24 patients. The median interval between FCSEMS insertion and removal was 109 days (IQR, 91-126). After stent removal, resolution of MPD stricture was confirmed in all patients. No FCSEMS-related de novo stricture was observed on pancreatography (Table 3).

### Long-term outcomes after FCSEMS removal

The 25 patients underwent follow-up for a median of 34 months (IQR, 25-56) after stent removal. Pain recurred in 3 patients (12.0%), among whom recurrence of MPD stricture was confirmed in 2 (18 and 24 months after FCSEMS placement, respectively). One patient with pain recurrence was a heavy active drinker but had no evidence of MPD stricture recurrence on magnetic resonance imaging. Finally, reintervention for recurrence of MPD stricture was performed in 2 of 25 patients (8.0%) who achieved stricture resolution by FCSEMS placement (Fig. 5). The 2 recurred MPD strictures were managed with endoscopic placement of multiple plastic stents.

## DISCUSSION

FCSEMSs are considered to be more effective than plastic stents for the treatment of MPD stricture associated with CP because they are larger in diameter and exert a radial expansion force. However, endoscopic treatment of MPD stricture using FCSEMSs has several limitations and may lead to undesirable outcomes, as shown in previous studies.[8-10,14] Therefore, development of a novel FCSEMS was required to overcome the limitations of conventional FCSEMSs for the treatment of benign MPD strictures.

First, the specially designed FCSEMS was evaluated for the treatment of MPD stricture in 13 patients with CP, and stricture resolution was found after stent removal in all patients; however, stent migration developed in 5 patients (39.0%).[8] To prevent stent migration, the FCSEMS was modified to be flared at both ends or to have different radial forces segment by segment.[9] However, FCSEMS-induced de novo strictures on MPD occurred in 16% to 27% of patients after the removal of a flared FCSEMS because of ischemic injury related to the excessive outward radial pressure exerted by the flared ends of the stent.[7,9,10] In addition, modified FCSEMSs still showed a high stent migration rate of 25% to 54% even after an installation of the flared end.[7,10,15]

A newly modified nonflared FCSEMS was designed to overcome the limitations of previous FCSEMSs for the management of BPS. The nonflared FCSEMS has a central saddle portion with a diameter 2 mm less than that

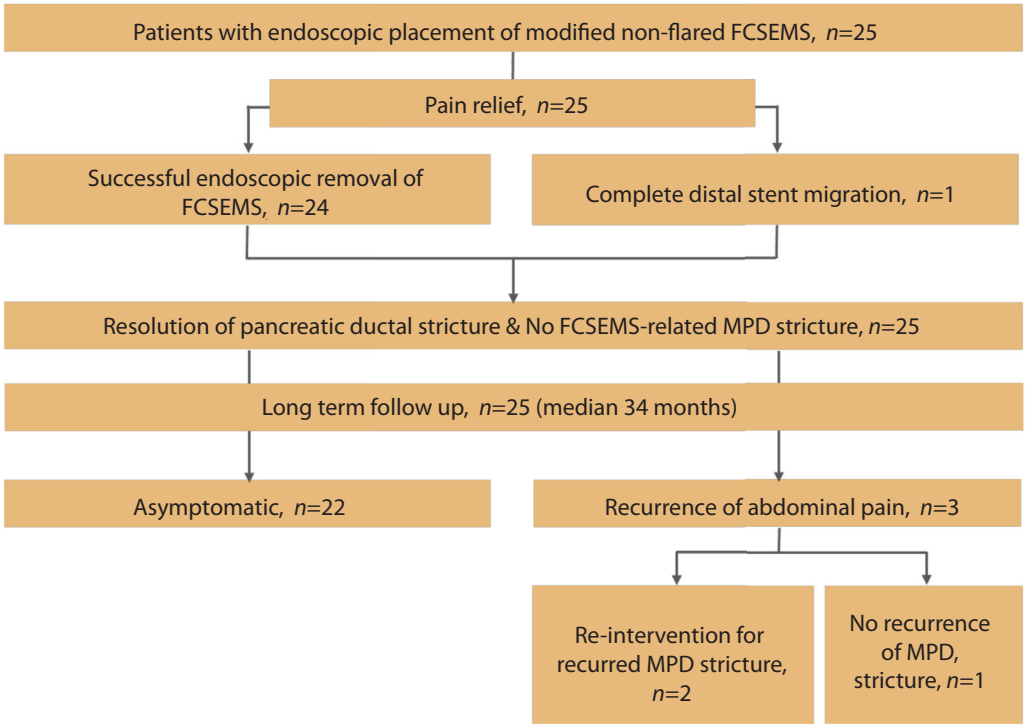


**Figure 5.** Flow chart of patient enrollment. *FCSEMS*, Fully covered self-expandable metal stent; *MPD*, main pancreatic duct.

of the proximal and distal portions to prevent stent migration. Therefore, this stent does not need a flared end. The nonflared structure of the new FCSEMS reduces the incidence of FCSEMS-related de novo strictures after stent removal. In this study, the newly modified nonflared FCSEM was inserted for management of refractory BPS in 25 patients with CP and resulted in pain relief and stricture resolution in all of them. In addition, stent migration occurred in only 1 patient (4.0%), and no FCSEMS-related de novo stricture was noted.

Another concern regarding FCSEMS placement in the PD is the development of pancreatic sepsis or infection associated with side-branch obstruction by the covering membrane of the FCSEMS. To reduce the risk of side-branch obstruction, FCSEMSs of lengths sufficient to cover only the stricture segment of the MPD are used.[8,9] Tringali et al[7] inserted a 3-cm-long FCSEMS in 12 patients with CP and refractory MPD strictures; however, complete distal migration developed in 7 patients (58.3%). The authors suggested migration of the 3-cm-long stent could be related to its instability, which was caused by it not extending sufficiently above and below the stricture. In this study, we inserted a modified nonflared FCSEM of as short a length as possible to reduce the risk of side-branch obstruction. A 3-cm-long nonflared FCSEM was inserted in 22 patients (88.0%); among them, stent migration occurred in only 1 patient (4.5%). A short nonflared FCSEM was placed intraductally in 14 patients (56.0%). All intraductally placed stents were successfully removed using a 7-cm-long lasso. Intraductal placement of the FCSEM can decrease the risk of sludge formation inside the stent by preventing duodenopancreatic ductal reflux. Intraductal FCSEMS placement also avoids obstruction of the bile duct orifice and reduces the risk of cholestatic liver dysfunction.

The long-term maintenance of MPD stricture resolution is essential to decrease repetitive treatments during the course of CP. However, pain relief during a median follow-up of 35 months was sustained only in 37.5% of patients (3/8) after removal of the FCSEMS.[10] In a recent study, 89% of patients (8/9) with refractory MPD strictures were asymptomatic during a mean follow-up of 3.2 years.[7] In this study, during a median follow-up of 34 months, 92.0% of patients (23/25) exhibited no recurrence of pancreatic pain-related MPD stricture. The newly modified nonflared FCSEMS shows promise for the endoscopic treatment of refractory MPD stricture associated with CP.

This study has several limitations. First, it had a relatively small sample size and did not include a control group. Especially, further comparative studies with previous conventional FCSEMSs are needed to confirm the advantages of the structural characteristics of modified nonflared FCSEMSs showed in this study. Second, the efficacy of intraductal placement of the FCSEMSs was not compared with that of transpapillary placement. We expected intraductal placement of a FCSEMS to decrease the rate of duodenopancreatic ductal reflux, but this

was not examined. Third, all patients underwent endoscopic sphincterotomy; thus, whether nondevelopment of cholestatic liver dysfunction was because of intraductal placement of FCSEMSs was unclear. Fourth, we did not perform multiple plastic stent placement before placement of the FCSEMS. Therefore, a further study on the effectiveness of multiple plastic stent placement versus the modified nonflared FCSEMS for the treatment of refractory BPS is warranted. Fifth, the stent indwelling period (median, 109 days) was shorter than that in previous studies. Stent removal was planned 3 months after placement to avoid the development of adverse events such as tissue hyperplasia and stent migration because of long-term stent indwelling. Sixth, selection bias may have occurred because only patients with improvement of abdominal pain during previous single plastic stent placement were enrolled. However, the origin of pain is multifactorial in patients with CP. Therefore, we selected the above patients to further clarify the effectiveness of endoscopic placement of the FCSEMS in relieving abdominal pain in patients with CP. Finally, a bias in the assessment of pain relief after endoscopic stent placement may have occurred because it was performed by endoscopists.

In conclusion, endoscopic placement of a novel modified nonflared FCSEMS provided long-term stricture resolution with pain relief and reduced the rate of stent-related adverse events, particularly stent migration and stent-induced MPD stricture. Further randomized, controlled trials involving larger cohorts are required to confirm the benefits of this novel FCSEMS for the treatment of refractory MPD strictures.

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*Abbreviations: BPS, benign pancreatic duct stricture; CP, chronic pancreatitis; FCSEMS, fully covered self-expanding metal stent; IQR, interquartile range; MPD, main pancreatic duct; PD, pancreatic duct.*

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