Long-Term Outcomes of Fully Covered Self-Expandable Metal Stents Versus Plastic Stents in Chronic Pancreatitis

Sang Hoon Lee  
Konkuk University School of Medicine

Yeon Suk Kim  
Gachon University Gil Medical Center

Eui Joo Kim  
Gachon University Gil Medical Center

Hee Seung Lee  
Yonsei University College of Medicine

Jeong Youp Park  
Yonsei University College of Medicine

Seung Woo Park  
Yonsei University College of Medicine

Si Young Song  
Yonsei University College of Medicine

Jae Hee Cho  
Yonsei University College of Medicine

Seungmin Bang (✉ bang7028@yuhs.ac)  
Yonsei University College of Medicine

Research Article

Keywords: medicine, Chronic pancreatitis, patients, plastic stent, FC-SEMS

Posted Date: April 29th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-445308/v1

License: © This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License

Version of Record: A version of this preprint was published at Scientific Reports on August 2nd, 2021. See the published version at https://doi.org/10.1038/s41598-021-94726-z.
Abstract

Chronic pancreatitis (CP) related main pancreatic duct (MPD) stricture has been a challenge for endoscopists. Fully covered self-expandable metal stents (FC-SEMS) has been tried in CP patients, but the efficacy and safety are still controversial. Thus, we aim to compare the long-term clinical efficacy of FC-SEMS vs. plastic stent placement in persistent MPD strictures secondary to CP. Between 2007 and 2018, 80 chronic pancreatitis patients (58 males, median age 49 years), who underwent endoscopic placement of FC-SEMS (n=26) and plastic stent (n=54) for persistent MPD strictures, were retrospectively analyzed during a median follow-up duration of 33.7 months. As a result, MPD stricture resolution rate was statistically higher in FC-SEMS group (87.0% vs. 42.0%, \(p < 0.001\)). Although immediate complications occurred similarly (38.5% vs. 37.0%, \(p = 0.902\)), spontaneous migration (26.9%) and de novo strictures (23.1%) were pronounced delayed complications in FC-SEMS group. Pain relief during follow-up was significantly higher in FC-SEMS group (76.9% vs. 53.7%, \(p = 0.046\)). The total procedure cost was similar in both groups ($1,455.6 vs. $1,596.9, \(p = 0.486\)). In comparison with plastic stent, FC-SEMS placement for persistent MPD strictures had favorable long-term clinical efficacy, with its typical complications like spontaneous migration and de novo strictures.

Introduction

Chronic pancreatitis (CP) is a benign, irreversible, inflammatory pancreatic disorder, which can result in various complications including symptomatic main pancreatic duct (MPD) stricture. In fact, MPD stricture occurred in up to 47% of CP patients who received endoscopic treatment\(^1\). Endoscopic pancreatic duct (PD) stenting with a single plastic stent has been mainly used for treatment of CP patients with symptomatic MPD strictures\(^2\text{-}^4\). However, PD stents cannot be completely removed in approximately one-third of patients because of persistent or recurrent strictures\(^1,^4\text{-}^6\). Therefore, patients with unrelenting symptomatic MPD strictures may require regular plastic stent exchanges indefinitely. Persistent MPD strictures after initial plastic stent placement has been a challenge for endoscopists.

Fully covered self-expandable metal stent (FC-SEMS) placement was lately introduced as an investigated treatment option for refractory MPD strictures, which were defined as symptomatic dominant strictures that persist or relapse after 1 year of single plastic stenting\(^3\). FC-SEMS has advantages including a larger diameter, longer patency duration, and technical ease to release compared with plastic stent\(^7\text{-}^8\). Several published data have recently demonstrated clinical efficacy of FC-SEMS as a 37–88% pain improvement during a 3–4 year follow-up period\(^9\text{-}^11\). However, these pilot studies occurred at a single medical center, and were limited by a small sample size (10–18 patients). To date, no studies have compared FC-SEMS and plastic stent placement for symptomatic CP patients with benign MPD strictures\(^12\). Therefore, we aimed to compare the long-term clinical efficacy of FC-SEMS vs. plastic stent placement in CP patients with persistent MPD strictures in two medical institutions.

Results
Patients’ characteristics and stent feature

Baseline characteristics and stent feature of FC-SEMS and plastic stent group were summarized in Table 1. Median age was 49 years old and 58 (72.5%) patients were male. The majority of the MPD strictures were located in the pancreas head (n=62, 77.5%). Other complications of CP such as PD stones, pseudocysts, and biliary strictures occurred simultaneously in both groups from the beginning, but their incidences were not significantly different between groups. During the median 24.9 and 36.2 months of follow-up, procedures related to these complications were excluded in following analyses.

For the plastic stent group, the maximum stent diameters were described in Table 1. In fact, we failed to upsize the plastic stent diameter in 19 patients (35.2%) in the plastic stent group. The most frequently used length was 6 cm (n=9, 34.6%) for FC-SEMS, and 5 cm (n=18, 33.3%) and 7 cm (n=17, 31.5%) for plastic stents. The types of FC-SEMS are listed in Supplement Table 1.

Procedure-related outcomes

Procedure-related outcomes are summarized in Table 2. Technical success was achieved in all patients of both groups (100%). The total duration of stent placement was significantly shorter in the FC-SEMS group than in the plastic stent group (median 4.9 vs. 7.3 months, \( p = 0.022 \)).

In the FC-SEMS group, almost all patients (n=24, 92.3%) removed the stent, with the exception of two patients who retained the FC-SEMS until the last follow-up (their FC-SEMS placement duration were 0.4 and 2.9 months). However, 31.5% of patients in the plastic stent group continued with MPD stenting (\( p = 0.019 \)). MPD stricture resolution was statistically higher in FC-SEMS group (87.0% vs. 42.0%, \( p < 0.001 \)). (Figure 2).

Immediate complications after stent insertion occurred similarly in both groups (38.5% vs. 37.0%, \( p = 0.902 \)). One-fourth of the FC-SEMS group developed spontaneous migration with median 3.1 months interval after stent insertion, which was more dominant than in the plastic stent group patients (26.9% vs. 3.7%, \( p = 0.002 \)). In addition, other delayed complications such as stent fracture (7.7%) and de novo stricture (23.1%) occurred frequently in the FC-SEMS group (\( p = 0.039 \) and \(<0.001\), respectively).

Clinical outcomes

Clinical outcomes in both groups are shown in Table 3. Two patients without clinical success in the plastic stent group were excluded in following analyses. Compared to the FC-SEMS group, about 20% of the plastic stent group suffered significantly from pain relapse during stent placement (3.8% vs. 19.2%, \( p = 0.066 \)).

The proportion of patients who showed recurrence after stent removal and recurrence-free survival were not statistically different between the two groups (27.3% vs. 43.8%, \( p = 0.587 \); mean 50.1 vs. 51.7 months, \( p = 0.646 \), respectively) (Figure 3). Finally, in our study population, more patients in FC-SEMS group reported experiencing pain relief during follow-up (76.9% vs. 53.7%, \( p = 0.046 \)).
Cost-effectiveness analysis

To compare cost-effectiveness of the stents, we calculated total number of ERCP sessions and summed the total cost of procedures (Table 4). Total number of procedures was significantly lower in the FC-SEMS group (median 2 vs. 3, \( p = 0.014 \)), but the mean cost between the two groups ($1,455.6 vs. $1,596.9, \( p = 0.486 \)) was not different.

Discussion

Our study is the first to describe and compare the long-term clinical efficacy of FC-SEMS vs. plastic stent placements in a clinical setting for treatment of persistent MPD strictures in CP patients. Although FC-SEMS showed typical delayed complications such as de novo stricture and spontaneous migration, its clinical efficacy showed higher MPD stricture resolution rate and considerable sustained pain relief during follow-up.

FC-SEMS not only has a larger diameter and longer patency than a plastic stent, but it is technically easier to release than even a single plastic stent due to its superior “pushability,” with higher flexibility and a lower external diameter of the pushing catheter (7Fr vs. 10Fr).\(^7,8\) Technically, all FC-SEMSs were successful in insertion and removal, including three stent fracture cases and two proximal migration cases. Furthermore, the larger diameter of FC-SEMS can help improve MPD stricture. According to previous studies, stricture resolution was achieved in 83-100% of patients treated with FC-SEMS\(^8-11,13\) and in 9-50% of patients with single plastic stenting\(^5,14-17\). Similarly, we observed more MPD stricture resolution in the FC-SEMS group (87.0% vs. 42.0%, \( p < 0.001 \)), although stent placement duration was significantly shorter in the FC-SEMS group than in the plastic stent group (4.9 vs. 7.3 months, \( p = 0.022 \)).

Temporary placement of FC-SEMS, together with surgery and multiple side-by-side plastic stent placement, is currently considered a treatment option for refractory MPD strictures\(^3\). Clinical results of FC-SEMS obtained from several prospective studies were described in Supplement Table 2. When comparing clinical data of FC-SEMS placement for symptomatic MPD strictures in CP patients, several complicated and discordant issues remain. First of all, clinical indication for FC-SEMS placement is variable. Some early studies enrolled all symptomatic MPD stricture patients, independent of plastic stent placement before FC-SEMS insertion\(^8,13\). By contrast, other studies, including our study, have included only persistent or refractory stricture patients with inclusion criteria of a 3\(^9,11\) or 12 month\(^10\) duration of previous plastic stent placement. When the FC-SEMS group was divided into before and after plastic stent indwelling period of 6 months for subgroup analysis in our results, the FC-SEMS group under 6 months of plastic stent indwelling (n=13, 50.0%) showed comparable clinical efficacy of MPD stricture resolution, recurrence rates and pain relief during follow-up (91.7% vs. 81.8%, \( p=0.484 \); 80.0% vs. 66.7%, \( p=0.484 \); 84.6% vs. 69.2%, \( p=0.352 \), respectively) compared with the remainder subgroup (n=13, 50.0%). Because the evidence for FC-SEMS is currently lacking, further clinical trials is needed on the indications and timing of FC-SEMS placement in CP patients.
Notably, spontaneous migration developed in one-fourth (26.9%) of FC-SEMS group patients, and other delayed complications such as stent fracture (7.7%) and de novo stricture (23.1%) were also prevalent (p = 0.002, 0.039, and <0.001, respectively). However, all of the stent fractures were partially broken and could be endoscopically removed at once. De novo strictures were also clinically manageable by additional plastic stenting in our experience. Reported frequencies of stent migration and de novo strictures for FC-SEMS are 15%–46% and 16%–27%, respectively9,11,13,18 (Supplement Table 2). Tringali et al. reported that the short length of 3 cm-long FC-SEMS may be associated with frequent stent migration11, and Oh et al. suggested that additional anchoring inner plastic stents help to prevent stent migration10. Anti-migration systems have been recently developed and applied to FC-SEMS18,19, but some concerns exist due to its flared end, which may cause stent-induced de novo stricture9,11,13,18.

Our study has several limitations. First, this was a non-randomized retrospective study. Although statistically not significant, patients with active drinking and other CP complications such as PD stones and pseudocysts may suffer more frequently, and relatively long follow-up duration in plastic stent group (36.2 vs 24.9 months, p = 0.237) was likely to be associated with frequent pain aggravation during follow-up. Changes in endocrine and exocrine functions were also not comparable for both groups during the stent placement period. In addition, the stent features of FC-SEMS and plastic stents were not unified, and there was no consistent strategy for choosing FC-SEMS or plastic stents. In the plastic stent group, 19 patients (35.2%) were unable to upsize the diameter of plastic stent, and about three-quarters (74.1%) of patients contained the single plastic stent with a diameter of lesser than 8.5Fr until the last follow-up (Table 1). Larger diameter (10Fr vs. ≤8.5Fr) and multiple plastic stent placements have been considered more effective endotherapies than smaller single plastic stents20-22. Some patients treated with plastic stents sub-optimally can affect less effective clinical outcomes in the plastic stent group. Last, we analyzed cost-effectiveness simply due to our relatively small study population, excluding length of hospitalization and complication rates.

In conclusion, FC-SEMS placement for persistent MPD stricture in CP patients had favorable long-term clinical efficacy with higher MPD stricture resolution rate and sustained pain relief during follow-up than plastic stenting. As typical complications of FC-SEMS such as de novo stricture and spontaneous migration remain major issues, further investigation is needed to resolve these problems.

Methods

Study population

We retrospectively collected data from symptomatic CP patients with persistent MPD strictures after single plastic stent (5-10Fr) placement for at least 2 months in Severance hospital and Gil medical center between January 2007 and December 2018. Patients were included according to the following criteria: (1) dominant MPD stricture located in pancreatic head and neck; (2) initially treated with single plastic stent insertion; (3) persistent MPD stricture with upstream PD dilatation after initial plastic stent removal. Exclusion criteria were as follows: (1) obstructive PD stones without dominant MPD stricture; (2)
concomitant tumor of pancreas and biliary tract; (3) multiple MPD strictures or strictures located at the 
pancreas body/tail; (4) FC-SEMS inserted initially; (5) failure of selective MPD cannulation; (6) previous 
history of PD stenting at another hospital; and (7) improved MPD stricture or follow-up loss after initial 
PD stenting. Finally, 80 CP patients with persistent MPD strictures were included in our analysis.

According to types of secondary PD stents, those were divided into FC-SEMS groups (n=26) and plastic 
stent group (n=54) (Figure 1).

The study protocol conformed to the ethical guidelines of the 1975 Helsinki Declaration and was 
approved by the institutional review board of each institute (Severance Hospital IRB, 4-2019-2196; 
Gachon University Gil Medical Center IRB, GDIRB2019-410). Informed consent was waived due to the 
retrospective study design.

**Procedures**

Experienced endoscopists examined endoscopic retrograde cholangiopancreatography (ERCP). When 
MPD stricture was persistent on subsequent pancreatography after removal of the first inserted plastic 
stent, the physician would try to insert a single plastic stent with a larger diameter, perform multiple 
plastic stent stenting, or use a FC-SEMS. The stent diameter was chosen according to stricture tightness 
and diameter of the upstream-dilated MPD. Stent length was decided based on stricture location and 
MPD morphology.

Stents were exchanged or removed every 3-6 months after placement. When patient's pain relieved and 
MPD stricture was disappeared, stents were removed. Especially in cases of FC-SEMS insertion, we did 
not maintain the FC-SEMS placement for longer than six months. Therefore, if it was necessary to insert 
an additional stent for a remaining stricture or de novo stricture after 6 months of FC-SEMS placement, 
we used a plastic stent.

**Follow-up**

Outpatient follow-up was scheduled at 1, 3, and 6 months after stent insertion or exchange. After stent 
removal, follow-up was continued at 6-month intervals or whenever complications occurred. Physicians 
and registered nurses carefully assessed the pain intensity before stent insertion at an outpatient clinic 
visit, daily during hospitalization for procedure, and at each scheduled follow-up outpatient visit. ERCP 
was considered when the pain was aggravated or when procedure-related complications developed. The 
last follow-up was performed in June 2019.

**Study endpoints**

When analyzing procedure-related outcomes, we regarded the second ERCP after initial plastic stent 
removal as an index procedure. Technical success was defined as successful placement of the stents, 
FC-SEMS or plastic stent during index procedures. MPD stricture resolution was defined as a resolved 
stricture with complete runoff of contrast material on the follow-up pancreatography. We also analyzed 
the immediate and delayed complications such as proximal or distal migration, stent fracture, and stent-
induced de novo stricture. Spontaneous migration was defined as radiological or endoscopic evidence of stent disappearance due to distal movement away from the stricture. A de novo stricture could develop above the intraductal end of the FC-SEMS. Other complications related to ERCP were defined according to the American Society for Gastrointestinal Endoscopy workshop\textsuperscript{23}.

We evaluated clinical outcomes, which were entirely related to patients’ symptoms. Clinical success was defined as a >50% reduction in the visual analog scale (VAS) scale pain score before and after stent placement during hospitalization for the index procedure. Recurrence was defined as a >50% elevation in the VAS scale pain score compared with that after stent removal, or pain aggravation causing hospitalization or therapeutic intervention to the MPD stricture. If such pain aggravation occurred during stent placement, we separately defined it as 'pain relapse', as another parameter of clinical outcomes. Finally, it means that patients with pain relief during follow-up did not experience any pain relapse or recurrence after index procedure for PD stenting.

To compare total cost of placing the FC-SEMS and plastic stent, we calculated the sum of expenses of ERCP with stent insertion, exchange, and removal, including charges for all FC-SEMS and plastic stents used in both groups after index procedure, based on an annual medical fee schedule from Korean National Health Insurance\textsuperscript{24}. These costs were converted from Korean won to U.S. dollars according the annual average exchange rate.

**Statistical analysis**

Data were expressed as the mean ± standard deviation (SD), median (interquartile range (IQR) or range), or n (%), as appropriate. A Student's t-test or Mann–Whitney test was used to analyze continuous variables, and a Fisher's exact test or Pearson's chi-square test for categorical variables. Survival rates were estimated and compared using the Kaplan–Meier method and the log-rank test. A two-tailed P-value of < 0.05 was considered statistically significant. The statistical analysis was performed with SPSS, version 25.0 (PASW Statistics Inc., Chicago, IL, USA).

**Data availability**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Declarations**

**Acknowledgements**

We would like to thank Editage (www.editage.co.kr) for English language editing

**Author contributions**
S.H.L. participated in the conception and design of the study, contributed to collect the data, to the data analysis and its interpretation, and wrote the first draft of the article. Y.S.K., E.J.K., H.S.L., J.Y.P., S.W.P. and S.Y.S. collected the data and contributed to the data analysis. J.H.C. and S.B. conceptualized and designed the study, collected the data, were supervised and responsible for the data analysis and interpretation, and wrote the article.

Additional information

Competing interests: The authors declare no competing interests.

Funding: There was no external funding for this study

References

1. Rosch, T. et al. Endoscopic treatment of chronic pancreatitis: a multicenter study of 1000 patients with long-term follow-up. Endoscopy. 34, 765–771 https://doi.org/10.1055/s-2002-34256 (2002).
2. Adler, D. G. et al. The role of endoscopy in patients with chronic pancreatitis. Gastrointest Endosc. 63, 933–937 https://doi.org/10.1016/j.gie.2006.02.003 (2006).
3. Dumonceau, J. M. et al. Endoscopic treatment of chronic pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline - Updated August 2018. Endoscopy. 51, 179–193 https://doi.org/10.1055/a-0822-0832 (2019).
4. Delhaye, M., Arvanitakis, M., Verset, G., Cremer, M. & Deviere, J. Long-term clinical outcome after endoscopic pancreatic ductal drainage for patients with painful chronic pancreatitis. Clin Gastroenterol Hepatol. 2, 1096–1106 https://doi.org/10.1016/s1542-3565(04)00544-0 (2004).
5. Ponchon, T. et al. Endoscopic stenting for pain relief in chronic pancreatitis: results of a standardized protocol. Gastrointest Endosc. 42, 452–456 https://doi.org/10.1016/s0016-5107(95)70049-8 (1995).
6. Weber, A. et al. Endoscopic stent therapy in patients with chronic pancreatitis: a 5-year follow-up study. World J Gastroenterol. 19, 715–720 https://doi.org/10.3748/wjg.v19.i5.715 (2013).
7. Davids, P. H., Groen, A. K., Rauws, E. A., Tytgat, G. N. & Huibregtse, K. Randomised trial of self-expanding metal stents versus polyethylene stents for distal malignant biliary obstruction. Lancet. 340, 1488–1492 https://doi.org/10.1016/0140-6736(92)92752-2 (1992).
8. Giacino, C., Grandval, P. & Laugier, R. Fully covered self-expanding metal stents for refractory pancreatic duct strictures in chronic pancreatitis. Endoscopy. 44, 874–877 https://doi.org/10.1055/s-0032-1309774 (2012).
9. Matsubara, S. et al. Prospective pilot study of fully covered self-expandable metal stents for refractory benign pancreatic duct strictures: long-term outcomes. Endosc Int Open. 4, E1215–E1222 https://doi.org/10.1055/s-0042-115934 (2016).
10. Oh, D. et al. Long-term outcomes of 6-mm diameter fully covered self-expandable metal stents in benign refractory pancreatic ductal stricture. Dig Endosc. 30, 508–515 https://doi.org/10.1111/den.13041 (2018).
11. Tringali, A. et al. Fully covered self-expandable metal stents to dilate persistent pancreatic strictures in chronic pancreatitis: long-term follow-up from a prospective study. *Gastrointest Endosc.* **88**, 939–946 https://doi.org/10.1016/j.gie.2018.08.019 (2018).

12. Dawod, E. & Kahaleh, M. Management of Benign and Malignant Pancreatic Duct Strictures. *Clin Endosc.* **51**, 156–160 https://doi.org/10.5946/ce.2017.085 (2018).

13. Ogura, T. et al. Placement of a 6 mm, fully covered metal stent for main pancreatic head duct stricture due to chronic pancreatitis: a pilot study (with video). *Therap Adv Gastroenterol.* **9**, 722–728 https://doi.org/10.1177/1756283X16651855 (2016).

14. Cahen, D. L. et al. Endoscopic versus surgical drainage of the pancreatic duct in chronic pancreatitis. *N Engl J Med.* **356**, 676–684 https://doi.org/10.1056/NEJMoa060610 (2007).

15. Cremer, M., Deviere, J., Delhaye, M., Baize, M. & Vandermeeren, A. Stenting in severe chronic pancreatitis: results of medium-term follow-up in seventy-six patients. *Endoscopy.* **23**, 171–176 https://doi.org/10.1055/s-2007-1010649 (1991).

16. Ishihara, T., Yamaguchi, T., Seza, K., Tadenuma, H. & Saisho, H. Efficacy of s-type stents for the treatment of the main pancreatic duct stricture in patients with chronic pancreatitis. *Scand J Gastroenterol.* **41**, 744–750 https://doi.org/10.1080/00365520500383597 (2006).

17. Topazian, M., Aslanian, H. & Andersen, D. Outcome following endoscopic stenting of pancreatic duct strictures in chronic pancreatitis. *J Clin Gastroenterol.* **39**, 908–911 https://doi.org/10.1097/01.mcg.0000180799.18834.99 (2005).

18. Moon, S. H. et al. Modified fully covered self-expandable metal stents with antimigration features for benign pancreatic-duct strictures in advanced chronic pancreatitis, with a focus on the safety profile and reducing migration. *Gastrointest Endosc.* **72**, 86–91 https://doi.org/10.1016/j.gie.2010.01.063 (2010).

19. Isayama, H. et al. Management of distal malignant biliary obstruction with the ComVi stent, a new covered metallic stent. *Surg Endosc.* **24**, 131–137 https://doi.org/10.1007/s00464-009-0537-9 (2010).

20. Sauer, B. G., Gurka, M. J., Ellen, K., Shami, V. M. & Kahaleh, M. Effect of pancreatic duct stent diameter on hospitalization in chronic pancreatitis: does size matter? *Pancreas* **38**, 728–731. https://doi.org/10.1097/MPA.0b013e3181b2bd45 (2009).

21. Costamagna, G. et al. Multiple stenting of refractory pancreatic duct strictures in severe chronic pancreatitis: long-term results. *Endoscopy.* **38**, 254–259 https://doi.org/10.1055/s-2005-921069 (2006).

22. Tringali, A. et al. Long-term follow-up after multiple plastic stenting for refractory pancreatic duct strictures in chronic pancreatitis. *Endoscopy.* **51**, 930–935 https://doi.org/10.1055/a-0959-6163 (2019).

23. Cotton, P. B. et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. *Gastrointest Endosc.* **71**, 446–454 https://doi.org/10.1016/j.gie.2009.10.027 (2010).
Table 1. Comparison of patients’ characteristics and stent feature

|                          | FC-SEMS group (n=26) | Plastic stent group (n=54) | P-value |
|--------------------------|-----------------------|----------------------------|---------|
| Age, median (IQR), years | 47.0 (40.3 - 49.3)    | 57.0 (38.0 - 65.3)         | 0.075   |
| Male, No. (%)            | 19 (73.1)             | 39 (72.2)                  | 0.936   |
| Etiology                 |                       |                            |         |
| Alcohol/Hereditary/Idiopathic, No. (%) | 20 (76.9)/ 4 (15.4)/ 2 (7.7) | 35 (64.8)/ 5 (9.3)/ 14 (25.9) | 0.144   |
| Location of stricture    |                       |                            |         |
| Head/Neck, No. (%)       | 23 (88.5)/ 3 (11.5)   | 39 (72.7)/ 15 (27.8)       | 0.103   |
| Combined complication    |                       |                            |         |
| Pancreatic duct stones, No. (%) | 15 (57.7)             | 22 (40.7)                  | 0.154   |
| Pseudocyst, No. (%)      | 5 (19.2)              | 14 (25.9)                  | 0.510   |
| Biliary stricture at distal CBD, No. (%) | 4 (15.4)              | 6 (11.1)                   | 0.588   |
| Follow-up duration, median (IQR), months | 24.9 (11.4 - 57.7)    | 36.2 (12.7 - 85.6)         | 0.237   |
| Stent feature            |                       |                            |         |
| Diameter*, No. (%)       | 8mm 12 (46.2)         | 5Fr 12 (22.2)              |         |
|                          | 10mm 14 (53.8)        | 7Fr 26 (48.1)              |         |
|                          |                       | 8.5Fr 2 (3.7)              |         |
|                          |                       | 10Fr 14 (25.9)*            |         |
| Length, cm               | 4~8                   | 5~12                       |         |

* For the plastic stent group, the maximum stent diameters were described

* Including 4 patients with multiple plastic stent placement (n=3, 7Fr + 7Fr; n=1, 10Fr + 7Fr)

Abbreviations: FC-SEMS, fully covered self-expandable metal stent; PS, plastic stent; IQR, interquartile range; PD, pancreatic duct; CBD, common bile duct.
Table 2. Comparison of procedure-related outcomes

|                                | FC-SEMS group (n=26) | Plastic stent group (n=54) | p-value |
|--------------------------------|-----------------------|----------------------------|---------|
| Technical success, No (%)     | 26 (100)              | 54 (100)                   | >0.99   |
| Stent exchange, No (%)         | 1 (3.8)               | 25 (46.3)                  | <0.001  |
| Exchange interval, median (IQR), months | 3.0                   | 6.1 (3.4-7.8)             |         |
| Stent placement duration, median (IQR), months | 4.9 (4.0 - 6.5)   | 7.3 (3.7 - 15.2)          | 0.022   |
| Stent removal, No (%)          | 24 (92.3)             | 37 (68.5)                  | 0.019   |
| Spontaneous migration, No (%)  | 7 (26.9)              | 2 (3.7)                    | 0.002   |
| Scheduled removal, No (%)      | 17 (65.4)             | 35 (64.8)                  | 0.960   |
| MPD stricture resolution, No (%) | 20/23* (87.0)        | 21/50** (42.0)            | <0.001  |
| Immediate complications, No (%)| 10 (38.5)             | 20 (37.0)                  | 0.902   |
| Cholangitis, No (%)            | 1 (3.8)               | 2 (3.7)                    | 0.975   |
| Pancreatitis, No (%)           | 5 (19.2)              | 11 (20.4)                  | 0.905   |
| Hyperamylasemia, No (%)        | 6 (23.1)              | 8 (14.8)                   | 0.362   |
| Perforation, No (%)            | 0 (0)                 | 1 (1.9)                    | 0.485   |

Delayed complications

|                                |                       |                           |         |
|--------------------------------|-----------------------|----------------------------|---------|
| Proximal migration, No (%)     | 2 (7.7)               | 1 (1.9)                    | 0.198   |
| Stent malfunction, No (%)      | 0 (0.0)               | 2 (3.7)                    | 0.320   |
| Stent fracture, No (%)         | 2 (7.7)               | -                          | 0.039   |
| De novo MPD stricture, No (%)  | 6 (23.1)              | -                          | <0.001  |

* Excluding 3 patients without follow-up pancreatography after stent removal

** Excluding 4 patients without follow-up pancreatography after stent removal

Abbreviations: FC-SEMS, fully covered self-expandable metal stent; IQR, interquartile range; MPD, main pancreatic duct.

Table 3. Comparison of clinical outcomes
Table 4. Comparison of number of procedure and cost analysis

|                                      | FC-SEMS group (n=26) | Plastic stent group (n=54) | p-value |
|--------------------------------------|-----------------------|-----------------------------|---------|
| Number of ERCP, median (range)       | 2 (1~3)               | 3 (1~10)                    | 0.014   |
| Total cost, mean (SD), US$           | 1455.6 (333.1)        | 1596.9 (1000.8)             | 0.486   |

Abbreviations: FC-SEMS, fully covered self-expandable metal stent; ERCP, endoscopic retrograde cholangiopancreatography.
Figure 1

Flowchart for the study population. Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography; FC-SEMS, fully covered self-expandable metal stent; MPD, main pancreatic duct; PD, pancreatic duct.
Figure 2

Fluoroscopic images of endoscopic retrograde pancreatography. Pancreatography shows a pancreatic ductal stricture in the head (white arrows) with upstream duct dilatation (a). After 7 months of FC-SEMS placement (b), follow-up pancreatography reveals stricture resolution (c). Pancreatography shows a tight pancreatic duct stricture in the pancreas head (black arrows) with upstream duct dilatation (d). After 13 months of single plastic stent placement (e), follow-up pancreatography reveals stricture resolution (f). Abbreviation: FC-SEMS, fully covered self-expandable metal stent.
Figure 3

Kaplan-Meir estimation of recurrence-free survival after stent removal in the FC-SEMS (n=22) and plastic stent group (n=32). There were no significant differences in recurrence-free survival between the FC-SEMS and plastic stent groups (50.1 (95% CI, 31.2 - 69.1) vs. 51.7 (95% CI, 28.7 - 74.7) months, log-rank p=0.646) Abbreviation: FC-SEMS, fully covered self-expandable metal stent; CI, confidence interval.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementTable1.docx
- SupplementTable2.docx