

# Endoscopic treatment of large pancreatic fluid collections (PFC) using self-expanding metallic stents (SEMS) – a two-center experience

## Authors

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submitted 24. June 2014  
accepted after revision  
7. July 2014

## Bibliography

DOI <http://dx.doi.org/10.1055/s-0034-1390796>  
Published online: 29.10.2014  
Endoscopy International Open 2014; 02: E224–E229  
© Georg Thieme Verlag KG  
Stuttgart · New York  
E-ISSN 2196-9736

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**Background/study aim:** During the last several years, endoscopic ultrasound (EUS)-guided pancreatic fluid collections' (PFC) drainage has evolved into the preferred drainage technique. Recently, self-expanding metallic stents (SEMS) have been used as an alternative to double pigtail stents, with the advantage of providing a larger diameter fistula, thereby decreasing the risk of early obstruction and also allowing for direct endoscopic exploration of the cavity. The aim of this study was to evaluate the technical and clinical success, safety, and outcome of patients undergoing EUS-guided drainage of complex PFC using SEMS.

**Patients/materials and methods:** The study was conducted at two tertiary hospitals from January 2010 to January 2013. All patients with PFC referred for endoscopic drainage were enrolled in a prospective database. The inclusion criteria were: (1) patients with pseudocysts or walled-off necrosis based on the revised Atlanta classification; (2) symptomatic patients with thick PFC; (3) PFC

that persisted more than 6 weeks; and (4) large PFC diameter ( $\geq 9$  cm). The exclusion criteria consisted of coagulation disorders, PFC bleeding or infection, and failure-to-inform written consent.

**Results:** A total of 16 patients (9 females, 7 males; mean age 52.6, range 20–82) underwent EUS drainage with SEMS. There were 14 cases of pseudocysts and 2 cases of walled-off necrosis. The etiologies of the PFC were mainly gallstones (8 of 16 patients, 50%) and alcohol (5 of 16 patients, 31%). Technical success was achieved in 100% of the cases. All patients had a complete resolution of the PFC.

**Conclusion:** Transmural EUS-guided drainage of complex PFC using SEMS is feasible, appears safe, and is efficacious. However, the exchange of the UC (uncovered)-SEMS for plastic stents is mandatory within 1 week. Future prospective studies, preferably multicenter studies, comparing SEMS versus traditional plastic stents for the drainage of PFC are warranted.

## Introduction

The current therapeutic modalities for symptomatic pancreatic fluid collections (PFC) include surgical, endoscopic, and percutaneous drainage [1, 2]. During the last several years, endoscopic ultrasound (EUS)-guided PFC drainage with double pigtail plastic stents has evolved into the preferred drainage technique [3, 4].

Although EUS-based drainage is potentially associated with less bleeding and perforation, the main complication of this technique is infection, which is generally caused by stent obstruction, especially when the fluid collection is thick or it has adhered necrotic tissue. Therefore, to maintain the patency of the enterocystic fistula, placing multiple double pigtail stents into the collection cavity is recommended [1, 2, 5, 6]. The main limiting factor to inserting larger diameter stents

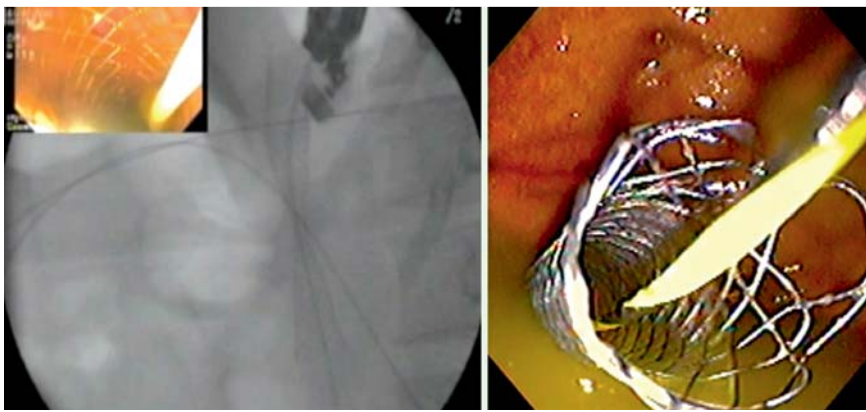
into the collection cavity is the small diameter of the working channel of the endoscope, which ranges from 2.8 to 3.2 mm. This diameter is generally insufficient to guarantee the drainage of thick material. However, even several plastic stents may be insufficient to drain fluid containing necrotic material and debris.

Recently, self-expanding metallic stents (SEMS) have been proposed as an alternative to double pigtail stents for the drainage of PFC [7–9], with the advantage of providing a larger diameter fistula, thereby decreasing the risk of early obstruction and also allowing for direct endoscopic exploration of the cavity [7–9].

The aim of this study was to evaluate the technical and clinical success, safety, and outcome of patients undergoing EUS-guided drainage of complex PFC using SEMS.

## License terms





**Fig. 1** Fluoroscopic view confirming the coiling of the wire inside the pancreatic fluid collection (PFC) and self-expanding metallic stent (SEMS) inserted into the cavity.

## Patients/materials and methods

The study was conducted from January 2010 to January 2013 at two tertiary hospitals with approval of their ethics committees. Patients with PFC who were referred for endoscopic drainage and presented with all four inclusion criteria were enrolled in a prospective database. The inclusion criteria were: (1) patients with pseudocysts or walled-off necrosis based on the revised Atlanta classification [10]; (2) symptomatic patients with thick PFC (pain, abdominal discomfort, nausea, post-prandial vomiting); (3) PFC that persisted more than 6 weeks; and (4) large PFC diameter ( $\geq 9$  cm). The exclusion criteria consisted of coagulation disorders, PFC bleeding or infection, and failure-to-inform written consent.

The EUS-guided drainage monitored sedation was administered by a senior anesthesiologist, according to the patient clinical condition; a combination of intravenous (IV) midazolam, fentanyl, and propofol or general anesthesia was used. A prophylactic antibiotic (ciprofloxacin 400 mg, IV) was administered before the procedure, and this (ciprofloxacin 500 mg, twice daily by mouth) was maintained for at least 1 week.

Using a 3.7-mm channel, linear echoendoscope (GFUCT160, Olympus Medical Systems Corp., Tokyo, Japan; or FUJIFILM Medical Co., Ltd., Tokyo, Japan), the best side to access the PFC was identified. Color Doppler ultrasound was used to determine the presence of vascular structures within the planned drainage tract. The PFC was punctured using a 19-gauge needle (EUSN-19-T, Cook Endoscopy, Winston-Salem, NC, USA). A fluid sample was aspirated and sent for microscopic analysis. A 0.035-inch guidewire was then threaded through the needle into the cavity. Fluoroscopic imaging was used to confirm the coiling of the wire inside the PFC. The needle was withdrawn and a cystotome (8.5-Fr or 10-Fr Cysto-Gastro-Set, Endo-flex, Düsseldorf, Germany) was placed over the wire to cut through the puncture site in the gastric wall, using pure cut current with 70 W (ERBE Erbotom ICC 200 unit, Surgical Technology Group, Hampshire, England, UK). Then the metal stent was inserted into the cavity (Fig. 1). We used eight uncovered (UC) SEMS Zilver Biliary Stent (Cook) in three cases, and WallFlex Biliary Stent, (Boston Scientific, Natick, MA, USA) in the remaining five cases and eight partially covered (PC) SEMS (WallFlex Biliary Stent, Boston Scientific), with a 10-mm diameter and 6- or 8-cm length, through the fistula without any dilation procedure.

Eight patients were drained with PC-SEMS and eight with UC-SEMS, according to endoscopist preference. After the PC-SEMS placement in seven patients, in order to prevent migration, a single 8.5-Fr double pigtail stent (Endo-flex or Cook) was placed



**Fig. 2** Pancreatic fluid collection (PFC) flushing session and debridement of necrotic content.

through the metallic stent over the same guidewire, thereby anchoring the SEMS. The length of the double pigtail stent was similar to the SEMS length used in each case.

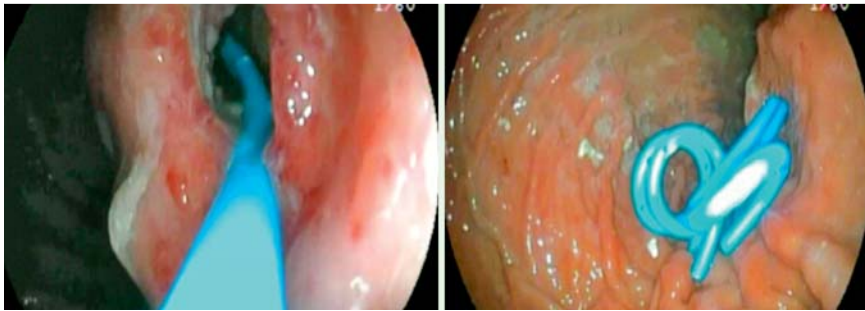
A second endoscopic procedure to remove the SEMS was based on the echoendoscopic aspect of PFC, clinical outcome of the patients, and the type of SEMS used. Patients with necrosis were scheduled to have a late removal of the stent. They underwent additional prophylactic endoscopies with washing of the cavity by the insertion of the endoscope at the PFC and the flushing with 300 to 400 mL of saline solution followed by complete suction. This washing procedure was performed until the PFC remained clear (Fig. 2). Patients in whom the SEMS were removed, and who did not have resolution of the PFC, underwent placement of two double pigtail plastic stents (Fig. 3).

Scheduled endoscopic controls were performed at 15 and 45 days and between 2 and 3 months. Any complication occurring 1 week after the procedure was considered a late complication. Before the last endoscopic control, a computed tomography (CT) scan of the abdomen was performed to analyze the PFC. If a complete resolution of the PFC was documented by CT scan and confirmed by EUS, the stents were removed during the same procedure.

## Results

A total of 16 patients (9 females, 7 males; mean age 52.6, range 20–82) underwent EUS drainage with SEMS. There were 14 cases of pseudocysts and 2 cases of walled-off necrosis.

The etiologies of the PFC and the symptoms that indicated a requirement for drainage are shown in Table 1. Three patients



**Fig. 3** Placement of double pigtail plastic stents after the removal of self-expanding metallic stents (SEMS).

had undergone unsuccessful previous drainage with radiology (percutaneous) ( $n=2$ ) or surgery ( $n=1$ ). The mean PFC diameter was 12 cm, ranging from 9 to 28 cm. The mean time between the initial pancreatitis episode and PFC drainage was 15.6 weeks, ranging from 7 to 48 weeks.

Technical success was achieved in 100% of the cases. UC-SEMS were used in eight patients (50%), and PC-SEMS were utilized in the remaining eight cases (50%). In one case, after the use of an 8.5-Fr cystotome, the pigtail deployment was difficult due to the collection fibrotic wall.

There were no early complications. The mean procedure time was 32.5 minutes, ranging from 20 to 60 minutes. The patients were discharged home from 2 hours up to 7 days after the procedure, based on their clinical condition. They were instructed to take daily oral antibiotics and to avoid solid food for 1 week. Two patients were kept on enteral nutrition by nasojejunal tube, one for 15 days and the other for 30 days. In these two cases, we performed necrosectomy.

In a late complication, one patient developed bleeding from the PFC cavity 3 weeks after drainage with PC-SEMS. This patient had a good outcome after surgery with suturing of the bleeding vessel and maintenance of the transgastric drainage. Nine patients (56.5%) experienced fever. Two of these patients additionally developed leukocytosis ( $>20000$  leukocytes), with clinical and laboratory improvement after antibiotic treatment and flushing sessions of the PFC cavity. In both cases, the fever and leukocytosis presented 1 week after the UC-SEMS removal. The first patient had a large PFC of 16 cm in diameter. The second patient had a significant necrotic solid content in the PFC cavity – more than 50% of its internal volume, consistent with a walled-off necrosis. In this case, it was necessary to perform three endoscopic washing sessions of the cavity, each one with an interval of 1 week.

UC-SEMS were used in the first three patients and replaced by double pigtail plastic stents after 5, 4, and 2 weeks of the drainage. The stents that were removed at 5 and 4 weeks fractured during their removal. In the stent removed at 2 weeks, we inflated a CRE dilation balloon (Boston Scientific) inside the UC-SEMS, aiming to release the stent from the PFC wall and to prevent its fracture.

All patients (100%) had a complete resolution of the PFC, as assessed by CT scan and EUS analysis. The mean time until PFC resolution was  $35 \pm 29$  days (range 15–120 days). The mean follow-up was  $9.5 \pm 3$  months, ranging from 3 to 23 months. The results are summarized in **Table 1**.

## Discussion/conclusion



Endoscopic transmural drainage is now the preferred route to drain PFC, with success rates ranging from 79 to 94% and morbidity from 9 to 17%, without mortality [11–13]. EUS-guided drainage may increase technical success and decrease incidence of complications [4]. EUS has the additional advantage of permitting cavity access in cases without gastric or duodenal compression by the PFC [4,14,15]. However, drainage success depends not only on cavity access, but also on the ability of the PFC contents to drain into the lumen. This is determined primarily by the diameter of the enterocystic fistula. Because current endoscopes only allow for the insertion of small-diameter plastic stents, several stents must be inserted into the cavity to promote drainage, especially in cases with thick collections or the presence of debris.

Our institution guidelines for PFC drainage are based on the literature recommendation, in which the pseudocyst drainage is indicated for symptomatic collections bigger than 6 cm and persisting for more than 6 weeks. The asymptomatic can be observed for up to 1 year. The EUS-guided technique is preferred; however, in cases with gastric or duodenal bulging the conventional blinded technique may be employed.

In this paper, we present our experience with larger diameter SEMS to drain PFC. Our study demonstrates that EUS-guided PFC drainage by the use of SEMS is technically feasible. In addition, the procedure is safe and efficient, leading to long-term resolution of the PFC in most patients, including those with necrosis and debris. Nonetheless, some patients still develop fever due to insufficient drainage of the thick collections. This does not dismiss the utility of SEMS, but mainly reflects the problem with the sticky and debris-rich collections that occur as a consequence of pancreatitis.

Our study adds to the existing literature on the use of SEMS to drain PFC. There are several case reports and series documenting the efficacy of SEMS drainage of PFC [7–9,15–18]. However, only 4 previous studies have enrolled more than 10 patients [7,15,16,18]. Thus, our series is one of the largest experiences published so far. The importance of our study evaluating SEMS for PFC is underscored by several aspects. First, confirmatory studies are always important to document potential efficacy of a new method. We have confirmed the findings of other authors. Despite a SEMS being more expensive, it has inherent characteristics that may prove beneficial in the PFC drainage. Its larger caliber provides specific advantages over plastic stents: a faster drainage; almost no risk of early obstruction; and access into the PFC cavity through the stent orifice with lesion debridement or washing, even after SEMS removal. Only large PFC diameters were selected for our study because, in our experience, these PFC are the collections that have more complications and usually

**Table 1** Clinical and endoscopic data of the patients submitted to pancreatic and/or peripancreatic fluid collection drainage.

Gender	Pancreatitis Etiology	Size (cm)	Location	Wall Thickness (mm)	Contents	SEMS type	Pigtail Anchoring	Endoscopic Sessions	SEMS duration (wks)	Over-growth	SEMS complications	Clinical complications
1 Male	Alcohol	9	Body	4	Debris	UC 6 cm x 10 mm	No	2	5	Yes	Obstruction, SEMS fracture	No
2 Male	Alcohol	14	Body	5	Debris	UC 6 cm x 10 mm	No	2	4	Yes	Obstruction, SEMS fracture	No
3 Male	Idiopathic	12	Head	5	Debris	UC 6 cm x 10 mm	No	2	2	Yes	Obstruction	Fever
4 Female	Alcohol	13	Body	3	Debris	PC 8 cm x 10 mm	No	3	3	No	No	Abdominal pain, fever, late bleeding
5 Female	Gallstone	11	Body	5	Debris	PC 8 cm x 10 mm	Yes	2	5	No	Obstruction	Abdominal pain, fever
6 Female	Gallstone	9	Body	5	Debris	PC 8 cm x 10 mm	Yes	2	1	No	Obstruction	Fever
7 Female	Gallstone	12	Body	4	Thick Liquid	UC 8 cm x 10 mm	No	2	1	No	No	No
8 Male	Gallstone	15	Body	6	Thick Liquid	UC 6 cm x 10 mm	No	2	1	No	No	Fever
9 Female	Partial pancreatectomy	16	Body	5	Thick Liquid	UC 6 cm x 10 mm	No	3	1	No	No	Abdominal pain, fever, leukocytosis
10 Female	Gallstone	12	Body	4	Necrotic tissue	UC 6 cm x 10 mm	No	2	1	No	No	Fever
11 Female	Gallstone	9	Body	5	Necrotic tissue	UC 6 cm x 10 mm	No	4	1	No	No	Fever, leukocytosis
12 Male	Alcohol	11	Body	8	Debris	PC 6 cm x 10 mm	Yes	2	4	No	No	Fever
13 Female	Gallstone	28	Head	10	Thick Liquid	PC 6 cm x 10 mm	Yes	2	4	No	No	No
14 Female	Idiopathic	9	Tail	12	Debris	PC 6 cm x 10 mm	Yes	2	4	No	No	No
15 Male	Gallstone	14	Body	10	Liquid	PC 6 cm x 10 mm	Yes	2	2	No	No	No
16 Male	Alcohol	9	Head	11	Thick Liquid	PC 6 cm x 10 mm	Yes	2	2	No	No	No

SEMS: Self-expandable metallic stent; UC: Uncovered; PC: Partially covered.

take a longer time to resolve with double pigtail stent drainage. The procedure is technically easier and faster than using plastic stents because of the SEMS easy introduction and deployment into the PFC cavity. It also does not require fistula balloon dilation, reducing procedure time, and theoretically decreases the risk of bleeding and separation of the PFC wall from the gastric or duodenal walls.

Second, using different SEMS is important. Our study has the advantage of having used widely available SEMS. Most studies report on the use of custom-made or investigational stents [7–9, 17, 18]. Indeed, some of the stents used no longer exist [19]. We used biliary stents with an outer diameter of 10 mm. We encountered problems with UC-SEMS and thus do not recommend their further use for draining PFC for more than 1 week, once the cases that took longer than this evolved with SEMS complication removal and occlusion. The first three cases in which we used UC-SEMS evolved with late stent obstruction due to granulation tissue growth inside the stent lumen, making their removal difficult, with stent fracture in two cases. After that, we concluded that UC-SEMS should be removed after 1 week. Even employing PC-SEMS some patients also developed fever, and it was necessary to remove these stents earlier than expected. We decided to use UC-SEMS because it was not necessary to also employ pigtail stents to prevent migration, making the procedure faster and less expensive.

Third, we found that using an inner anchoring with a double pigtail stent prevented migration of the SEMS. In the first case treated with PC-SEMS, we did not utilize a pigtail stent. This patient presented with fever and three episodes of PFC delayed bleeding, and was referred to surgery. We believed that bleeding was caused by a trauma from the uncovered portion of the stent. In endoscopy controls, it was noted that the stent could be easily moved and did not migrate into the PFC because its distal part was anchored in the contralateral PFC wall, and its length was 8 cm. Previous studies have not consistently used this technique and there have been several reports of migration [9, 15]. In another study, Penn et al. also documented the utility of placing an anchoring stent within the SEMS [16].

Fourth, we provided information on the potential use of sequential flushing of the cavity. Of the 16 patients, 3 needed more than one session to wash the PFC cavity. All these patients had necrosis and debris, including small recesses within the cavity that made spontaneous drainage difficult. In this latter case, despite a great amount of granulation tissue and partial collapse of PFC, it was resolved with only one washing session.

Fifth, we carefully documented any potential complications. Despite their larger diameter, obstruction and infection still may occur. In the study by Talreja et al. the complication rate was 44% including superinfection, bleeding, and inner migration [7]. Most recently, Penn et al. reported 20 cases, in which only 2 had a major complication and 1 had a minor complication [16]. However in their study, Penn et al. mainly drained acute and chronic pseudocysts [16]. In our study, we included a significant amount of patients with necrosis and debris. Despite this, we only had two cases with severe infection and one case of bleeding. Nonetheless, we believe that using larger diameter SEMS is important to achieve adequate drainage. This was recently demonstrated by Itoi et al. The authors utilized a novel, fully covered SEMS with a dual-anchoring mechanism [18]. Due to the anchoring mechanism, their stent will obviate the need for insertion of double pigtail plastic stents.

Our study has some potential limitations that need further comment. Foremost, we are tertiary centers practicing advanced endoscopy and our results may not be replicated in other centers. However, we believe that patients with complex PFC should be treated in tertiary centers. In addition, our study was not randomized and the sample size was relatively small. Ideally, a larger randomized study with a control arm receiving traditional endoscopic drainage with plastic stents compared with SEMS should be conducted.

In summary, we have demonstrated that transmural EUS-guided drainage of complex PFC using SEMS is feasible, appears safe, and is efficacious. Future prospective studies, preferably multicenter studies, comparing SEMS versus traditional plastic stents for the drainage of PFC are warranted, especially in patients with complex PFC and those containing necrosis and debris. Despite being a case series with a small sample, in our study we found that the use of SEMS in large PFC drainage is easy, fast, and secure. However, we do not recommend long-term placement of SEMS.

**Competing interests:** None

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