—Original Article—

Endoscopic drainage of pancreatic fluid collections using a fully covered expandable metal stent with antimigratory fins

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ABSTRACT

Background and Objectives: Endoscopic drainage is the first consideration in treating pancreatic fluid collections (PFCs). Recent data suggests it may be useful in complicated PFCs as well. Most of the available data assess the use of plastic stents, but scarce data exists on metal stent management of PFCs. The aim of our study to evaluate the efficacy and safety of a metal stent in the management of PFCs. **Patients and Methods:** Data were collected prospectively on 47 patients diagnosed with PFCs from March 2007 to August 2011 at 3 tertiary care centers. These patients underwent endoscopic transmural placement of a fully covered self-expanding metal stent (FCSEMS) with antimigratory fins of 10 mm diameter. **Results:** The stent was successfully placed in all patients, and left in place an average of 13 weeks (range 0.4-36 weeks). Etiology of the PFC was biliary pancreatitis (23), pancreas divisum (2), trauma (4), hyperlipidemia (3), alcoholic (8), smoking (2), idiopathic (4), and medication-induced (1). PFCs resolved in 36 patients, for an overall success rate of 77%. Complications included fever (3), stent migration (2) and abdominal pain (1). **Conclusions:** The use of FCSEMS is successful in the majority of patients with low complication rates. A large sample-sized RCT is needed to confirm if the resolution of PFCs is long-standing.

Key words: Endoscopy, fully covered self-expanding metal stent with antimigratory fins, pancreatic fluid collections, transmural

INTRODUCTION

Pancreatic fluid collections (PFCs) encompass acute peripancreatic fluid collection with solid component, pseudocyst, post-necrotic PFC; and walled-off pancreatic necrosis (WOPN).[1,2]

Pancreatic pseudocysts (PC) usually originate as a complication of an edematous interstitial pancreatitis, a lesion characterized by pancreatic juice that is enclosed within a circumscribed wall of non-epithelialized, fibrous, or granulation tissue, and no necrosis associated.[3] WOPN emerges 2-6 weeks after the onset of pancreatitis and contain liquid and necrotic detritus.[1,2,4]

Majority of the pseudocysts resolve spontaneously or through conservative treatment. However, some symptomatic or enlarging pseudocysts require drainage to avoid complications.[2,3]

The principal indications for drainage are symptoms, complications or rapid increase in diameter of the fluid collection.[3,5]

Contemporary drainage options include surgical,

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percutaneous and endoscopic modalities.[2] Surgical treatment was the gold standard for drainage, but is also associated with elevated morbidity between 7% and 37% and mortality of 6%,[6] while percutaneous drainage depends on an external catheter, which increases the risk of infection or the formation of a cutaneous fistula.[7,8]

With the advent of endoscopy, there has been a major increase in the number of patients undergoing endoscopic drainage since it has been shown to be efficacious and minimally invasive, and hence has become the first preference in treating uncomplicated PFC.[6] Endoscopic drainage can be transpapillary, transmural or both. Transpapillary drainage is now rarely used for small pseudocysts, which communicates with the pancreatic duct.[9,10] Transmural drainage can be done via a transgastric or transduodenal approach;[10-12] which is preeminent for big, infected or collections with necrotic elements.[13] Transmural pseudocyst drainage has median rates of 93.8%, 87.5%, 16.9%, 7.5% for technical success, clinical success, complications and recurrence, respectively.[4,14-17]

Generally, multiple plastic stents are placed for transmural drainage of pseudocysts. However, these stents have a narrow diameter and frequently occlude necessitating repeat stent exchanges or placement of additional stents.[18]

Fully covered self-expanding metallic stents (FCSEMS) have a larger diameter compared to plastic stents. Their advantages might lead to a reduced number of procedures because of longer patency and larger diameter dilation, which results in a shorter period of resolution (6 weeks)[10,13] and reduced morbidity rates.

Penn *et al.* recently reported the combined use of Wallflex stent (FCSEMS, Boston Scientific, MA, USA) and plastic pigtail stents for the treatment of simple pseudocysts. A single 10F or 7F double pigtail biliary stent was placed through the FCSEMS with the internal pigtail inside the cyst cavity and the external pigtail in the GI lumen, to anchor the FCSEMS and reduce the risk of migration.[19]

We evaluated the use of Viabil stents (FCSEMS) composed of nitinol and covered by Gore-Tex expanded polytetrafluoroethylene because it has anchoring fins to prevent migration.[6,20-23]

The aim of this study was to assess the safety and efficacy of FCSEMS for the management of simple pancreatic pseudocysts,[6] and WOPN.

PATIENTS AND METHODS

Patients

Between March 2007 and August 2011, data were collected on 47 patients (29 males, mean age of 59.2 ± 14.8 years) from 3 academic medical centers (University of Virginia, Digestive Associates of Houston, Houston, Texas, Methodist Hospital, Dallas, Texas) with symptomatic PFCs (4 weeks or more) underwent endoscopic transmural drainage with FCSEMS (Viabil, Conmed, Utica) placement. Symptoms included pain, infection, gastric outlet obstruction, etc. Patients were included from established prospective database registries based on the following inclusion criteria:

1. Symptomatic and drainable PFCs (pseudocyst or WOPN).
2. Eligible for endoscopic intervention.

Exclusion criteria included:

1. Poorly organized PFC,
2. Abnormal coagulation, and
3. Cystic neoplasm.

Methods

A single FCSEMS of 10 mm diameter and 6-8 cm in length were placed in all 47 subjects. FCSEMS of 10 mm diameter and 8 cm in length were placed in patients with PFC equal to or larger than 8 cm. All subjects had a history of either acute (n = 37) or chronic pancreatitis (n = 10).

A singular endoscopy session was conducted during which transmural drainage was conducted with the aid of fluoroscopy. The pancreatic duct was evaluated using a pancreatogram for leaks or obstructions and stented if needed, during the same session.

Endoscopic ultrasound (EUS) was used in all but two patients. After size localization and color flow Doppler to assess intervening vasculature, puncture of the fluid collection was performed, and an aspirate sent for culture [Figure 1]. A 19 gauge EUS needle was used to puncture the cavity in 45 patients, and a 10 French cystoenterotome for the remaining two. Balloon dilation of the tract was conducted up to 6-8 mm and a guidewire was coiled into the pseudocyst. The FCSEMS was then deployed into the cavity over the guidewire [Figure 2]. The endoscope was removed after drainage was observed through the FCSEMS [Figures 3 and 4]. Thirteen double pigtail stents were placed through the Viabil stent.

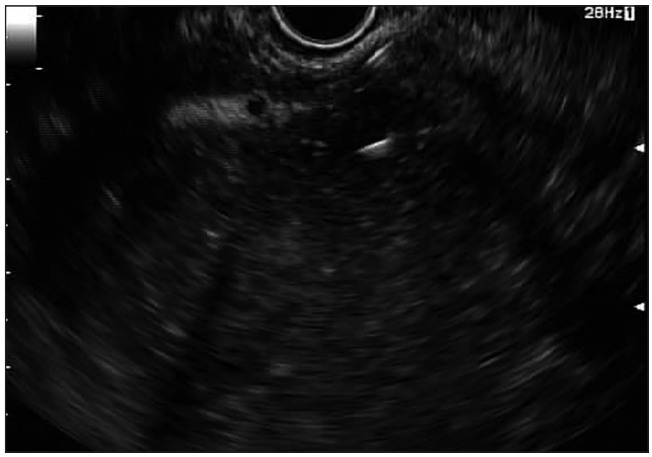

Figure 1. Endoscopic ultrasound image of pancreatic fluid collection

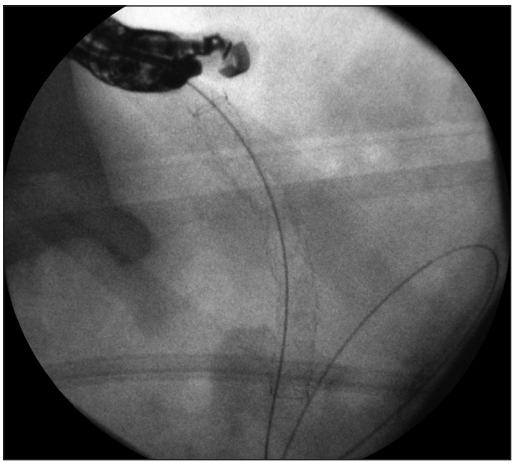

Figure 2. Fluoroscopic image of stent placement

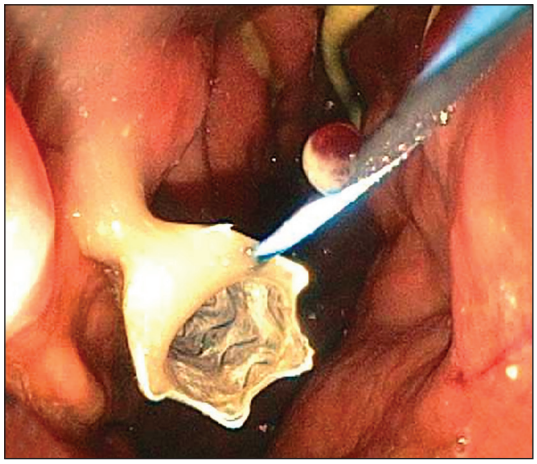

Figure 3. Endoscopic image of drainage visualization post stent placement

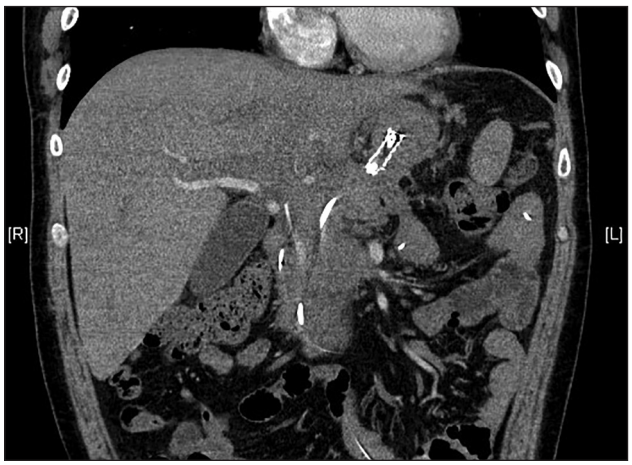

Figure 4. Computed tomography image showing the stent placed with resolution of the pancreatic fluid collection

The majority of the stents were placed on an outpatient basis (n = 25), and the procedure performed under propofol sedation or general anesthesia, all with antibiotics coverage.

Statistical analysis

Institutional review board approval was obtained prior to enrollment and analyses (IRB# 13408, approved on 12/06/2007).

The following variables were collected and considered for both descriptive and analytical statistics: Demographics, etiology, presence or absence of necrosis, dimensions and type of pseudocyst, location of the PFC, puncture site, stent indwelling time, resolution duration, and any complications after stent placement and/or removal. Pancreatogram findings were also collected.

Technical success was based on the successful placement of the FCSEMS through the cavity with appropriate fluoroscopic position. Any complications within 24 h were considered immediate, within 30 days as early complications and late if they occurred after 30 days.

Clinical success was defined as resolution of the PFCs based on the CT or EUS imaging within without the need for surgical, percutaneous or repeat endoscopic drainage.

Logistic regression was conducted using SAS 9.2 (SAS Institute Inc., Cary, NC, USA) to report the predictive factors for success or failure of resolution.

RESULTS

Forty-seven patients (29 males) diagnosed with PFCs were included in a multicenter study from March 2007 to August 2011. Mean age was 49 years (range 17-77 years). Acute pancreatitis occurred in 37, chronic pancreatitis in 10. The PFC was located in the tail in 10, body in 24, head in 8 and body/tail in 5 [Table 1].

Nine subjects had WOPN, while four subjects had infected WOPN.

Four patients had a nasocystic drains placed, and four patients underwent concomitant percutaneous drainage immediately prior to cystenterostomy in cases of extensive necrotic material to provide the ability for flushing similar to the approach reported in Gluck *et al.*[24] 11 had double pigtail stents placed through the Viabil stent, three had two pigtail stents placed.

The FCSEMS was successfully placed in all patients.

Table 1. Characteristics of patients treated for pancreatic pseudocysts (*n* = 47)

Patient characteristics	Resolved 36/47 (77%)
Gender (%)	
Male	29/47 (62)
Female	18/47 (38)
Age	Mean 49 years (range 17-77 years)
Symptoms (%)	
Pain	39/47 (83)
Failure to resolve	4/47 (9)
Suspected infection	4/47 (9)
Symptoms onset to drainage	Mean 14.2 weeks (range 0.5-80 weeks)
Pancreatitis (%)	
Acute	37/47 (79)
Chronic	10/47 (21)
Etiology (%)	
Biliary pancreatitis	23/47 (49)
Alcohol consumption	8/47 (17)
Trauma	4/47 (9)
Idiopathic	4/47 (9)
Hyperlipidemia	3/47 (6)
Pancreas divisum	2/47 (4)
Smoking	2/47 (4)
Medication induced	1/47 (2)
Necrosis (%)	13/47 (28)
Infected	4/47 (9)
Sterile	9/47 (19)
Pseudocyst size	Mean 14.2 cm (range 7-30 cm)
Pseudocyst location (%)	
Body	24/47 (51)
Tail	15/47 (32)
Head	8/47 (17)
Pancreatic duct evaluation (%)	
Main duct leak	10/47 (21)
Obstruction	8/47 (17)
Disruption	2/47 (4)
Divisum	2/47 (4)
Duration of stenting	Mean 13 weeks (range 0.5-40 weeks)
Complications (%)	6/47 (13)
Fever	3/47 (6)
Migration	2/47 (4)
Abdominal pain	1/47 (2)

The stent was placed on an average of 14 weeks (0.5-56 weeks) after symptom onset. The PFC was simple in 34, complex in 13, with a mean diameter of 14.3 cm (7-30 cm). The etiology of the PC was biliary pancreatitis in 23, pancreas divisum in 2, trauma in 4, hyperlipidemia in 3, alcoholic in 8, smoking in 2, idiopathic in 3, and medication-induced in 1.

Pancreatogram in 25 patients revealed a disconnected duct in 10, obstruction in 8 and PD disruption in 2. A pancreatic duct stent was placed in 20 patients, bridging a leak or treating a stricture. Eleven patients had a pancreatic duct leak which was treated prior to PFC drainage with a pancreatic stent placed for 8-10 weeks.

The metal stent for PFC drainage was placed trans-gastrically in 44 patients and trans-duodenally in 3. The stent was left in place an average of 13 weeks (range 0.4-36 weeks). Mean follow-up was 52 weeks (3-180 weeks).

The PFC resolved in 36/47 patients, for an overall success rate of 77%. The success for simple PFC was 79% (27/34) whereas for complex PFC was 69% (9/13). There has not been PFC recurrence in those with the initial resolution after an average observation time of 20 weeks (4-27 weeks).

Six of the failed patients developed an abscess and sepsis requiring surgical drainage, two patients required further endoscopic drainage session and two patients were lost to follow-up (considered a failure). One subject had the metal stent replaced to facilitate endoscopic necrosectomy. Placing plastic stents through the Viabil stent was neither beneficial nor detrimental. One patient had a stent in place for 56 weeks as removal was possible due to cardiac comorbidities (coronary stent placement and anticoagulation) rendering the patient unable to undergo stent removal endoscopy. Of the failed patients, seven had a simple PFC while four had a complex PFC.

Complications included migrations (2), fever (3), and abdominal pain (1). One patient with migrated stent had a very complicated course with bleeding from a pseudoaneurysm and required debridement, with the creation of two additional sites of puncture. One subject had both fever and abdominal pain. Their stent was removed and replaced with a 10F × 6 cm plastic stent. Two subjects with high fever were admitted and underwent surgical drainage.

The addition of plastic pigtail stents in 11 subjects had no effect on migration rates, and was neither beneficial nor detrimental to the safety and efficacy of metal stent management of PFCs.

Logistic regression was conducted to determine if age, gender, etiology, symptom onset to the drainage duration, type of pancreatitis, and location and size of PFC were predictive factors for success or failure of resolution. After adjusting for confounders, none of the above increased or decreased the odds for PFC resolution success [Table 2].

DISCUSSION

Endoscopic drainage of PFCs has been adopted by most tertiary centers.[3,25-29] It offers a safe and minimally invasive alternative to surgery and percutaneous drainage, which are associated with increased morbidity and mortality in this specific indication.[30] Plastic stents are typically placed to create the open conduits between the stomach/intestine and the PFC.[3,15,31] However, the necessity to place many stents to offer the maximal drainage in a least amount of session has led us to seek other options.

Table 2. Predictive factors for successful outcome (*n* = 47)

Predictors	*n* (%)	Adjusted OR* (95% CI) for success (36/47)
Predictor 1: Gender		
Male	29 (62)	1.00 (reference)
Female	18 (38)	0.99 (0.17-5.84)
Predictor 2: Age		
Below 55 years	28 (60)	1.00 (reference)
55 years or above	19 (40)	1.63 (0.34-7.69)
Predictor 3: Etiology		
Biliary pancreatitis	23 (49)	1.00 (reference)
ETOH, medication induced, pancreas divisum, trauma, hyperlipidemia, smoking, idiopathic	24 (51)	0.45 (0.09-2.28)
Predictor 4: Symptoms onset to drainage		
4 weeks or below	17 (36)	0.39 (0.08-1.96)
Above 4 weeks	30 (64)	1.00 (reference)
Predictor 5: Pancreatitis		
Acute	37 (79)	0.25 (0.02-3.29)
Chronic	10 (21)	1.00 (reference)
Predictor 6: Location of pseudocyst		
Body	24 (51)	0.51 (0.09-2.96)
Head or tail	23 (49)	1.00 (reference)
Predictor 7: Size of pseudocyst		
14 cm or below	26 (55)	1.17 (0.27-5.10)
Above 14 cm	21 (45)	1.00 (reference)

*Adjusted for gender, age, symptoms onset to drainage, type of pancreatitis, location and size of pseudocyst. OR: Odds ratio, CI: Confidence interval

The success of expandable metal stent in providing better biliary decompression than plastic stent led to their utilization in PFC.[26,32-37]

Penn *et al*. reported that efficacy was achieved by placing pigtail stents through metal stents (Wallflex, Boston Scientific, Natick, MA, USA) by preventing migration and allowing for drainage along the length of the plastic pigtail stents. Our study demonstrates that is not necessary to place a double pigtail into the FCSEMS to prevent migration. However, they used a different stent, which has a similar design, but doesn't have the anti-migratory fins.[19]

In our study, the pancreatic duct was evaluated, and stents were placed (if needed) in the same endoscopic session of the transmural drainage. With no subsequent recurrence of PFC, we, therefore, believe that diagnosing and treating pancreatic duct disruption does indeed decrease the risk of recurrence.

Treatment success was more likely for patients with simple PFC (pseudocyst) than in complex ones (necrosis). WOPN, due to the need to perform many debridement sessions require the placement of larger than 10 mm metal stent, permitting the insertion of an upper endoscopy.[38]

Despite having a larger sample size, our study has some limitations. Our study had a single cohort of patients, with no control arm or randomization. To confirm and verify the results, we must conduct a randomized trial with two or more arms to compare metal stents with antimigratory fins to conventional placement of plastic pigtail stents; as well as metals stents without antimigratory fins. A multicenter study would ensure large accrual, and help compare if FCSEMSs are indeed superior to plastic pigtail stents.

CONCLUSION

The use of FCSEMS with antimigratory fins is successful in the majority of patients with simple PFC while its efficacy diminishes in patients with necrosis. A large randomized trial comparing this metal stent to plastic pigtail stent in this patient population is needed.

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