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Relationship between stent characteristics and treatment outcomes in endoscopic transmural drainage of uncomplicated pancreatic pseudocysts

Ji Young Bang · C. Mel Wilcox · Jessica M. Trevino · Jayapal Ramesh · Muhammad Hasan · Robert H. Hawes · Shyam Varadarajulu

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Abstract
Background Transmural stents are placed at endoscopy to drain pancreatic fluid collections. This study evaluated the relationship between stent placement and treatment outcomes in patients undergoing endoscopic transmural drainage of uncomplicated pancreatic pseudocysts.
Methods This is a retrospective study of all patients who underwent endoscopic drainage of uncomplicated pancreatic pseudocysts over a 10-year period. After dilating the transmural tracts in the range of 8–15 mm, single or multiple, 7 or 10Fr double-pigtail plastic stents were deployed. The main outcome measure was to evaluate the relationship between stent characteristics and the number of endoscopic interventions required to achieve resolution of the pancreatic pseudocyst (treatment success).
Results Of 122 patients, 45 (36.9 %) had 10Fr stents of which 30 patients (66.7 %) had more than one stent; the remaining 77 (63.1 %) patients had 7Fr stents of which 56 (72.7 %) had more than one stent. The overall treatment success was 94.3 %. Treatment was successful in 102 patients (83.6 %) with one intervention; 13 patients (10.7 %) required re-intervention for successful drainage and 7 patients (5.7 %) failed endoscopic treatment. There was no significant difference in the number of interventions required for treatment success between patients with 7 or 10Fr stents (one intervention required in 87.7 vs. 90.5 %, respectively; $p = 0.766$) and between patients with 1 or >1 stent (one intervention required in 88.9 vs. 88.6 %, respectively; $p = 0.999$). On multiple logistic regression analysis, the stent size (OR 1.54; 95 % CI 0.23–10.4) and number (OR 1.15; 95 % CI 0.25–5.25) were not associated with the number of interventions required for treatment success when adjusted for pseudocyst size, location, drainage modality, the presence or absence of pancreatic duct stent and luminal compression.
Conclusions There appears to be no relationship between the number of interventions required for treatment success and stent characteristics in patients undergoing endoscopic transmural drainage of uncomplicated pancreatic pseudocysts.

Keywords Pancreatic pseudocysts · Endoscopic drainage · Stents · Treatment outcomes · EUS-guided drainage

Endoscopic drainage is a clinically effective and safe technique for the treatment of peripancreatic fluid collections (PFCs) [1–3]. The procedure entails the creation of a fistula between the PFC and the gastric or duodenal lumen followed by the placement of a stent and/or a nasocystic drainage catheter. The clinical outcomes of endoscopic drainage are directly related to the type of PFC being treated with outcomes being excellent for pancreatic pseudocysts and marginal for walled-off pancreatic necrosis (WOPN). Treatment failure in WOPN is ascribed mainly to inadequate decompression and ineffective evacuation of necrotic contents [1, 2]. To overcome this limitation, different techniques such as the creation of multiple internal channels for improved drainage, hybrid approaches using laparoscopy or percutaneous routes for better debridement of necrosis, and deployment of novel endoprosthesis for improved access to the necrotic cavity have been proposed as measures to

J. Y. Bang · M. Hasan · R. H. Hawes · S. Varadarajulu (✉)
Center for Interventional Endoscopy, Florida Hospital, 601 East Rollins Street, Orlando, FL 32803, USA
e-mail: svaradarajulu@yahoo.com

C. Mel Wilcox · J. M. Trevino · J. Ramesh
Division of Gastroenterology-Hepatology, University of Alabama at Birmingham, Birmingham, AL, USA

improve clinical outcomes [4–7]. While these measures are likely critical for improved outcomes in patients with WOPN, it is unclear whether this complex treatment approach is necessary for patients with symptomatic, uncomplicated pseudocysts. To our knowledge, there are no studies that have evaluated the relationship between stent characteristics and treatment outcomes in patients undergoing endoscopic transmural drainage of pancreatic pseudocysts.

The objective of the present study was to evaluate the relationship between stent characteristics and the number of interventions required for treatment success in patients undergoing endoscopic transmural drainage of uncomplicated pancreatic pseudocysts.

Materials and methods

Patients

This is a retrospective study of all patients with pancreatic pseudocysts who underwent endoscopic transmural drainage over a 10-year period at the University of Alabama at Birmingham (July 2003 to June 2012) and Florida Hospital, Orlando (July 2012 to June 2013). In this study, pseudocysts were defined as a fluid collection in the pancreatic or peripancreatic area that had a well-defined wall and contained no solid debris or recognizable parenchymal necrosis [8]. Included in the study were all patients with (i) symptomatic, uncomplicated, acute or chronic pseudocysts measuring >6 cm in size and located adjacent to the stomach or duodenum and (ii) gastric outlet or biliary obstruction secondary to the mass effect from the pseudocyst. Excluded from the study were (i) patients with WOPN, (ii) infected pseudocysts (previously termed as 'abscess' by the 1992 Atlanta classification) [9], (iii) pseudocysts located >1.5 cm from the gastrointestinal lumen, (iv) patients with coagulopathy, (v) patients who underwent only an endoscopic retrograde cholangiopancreatogram (ERCP) for pancreatic duct stent placement, and (vi) patients with follow-up of less than 90 days. Informed procedural consents were obtained from all patients. This study received approval from the Institutional Review Board of the University of Alabama at Birmingham and Florida Hospital, Orlando.

Procedural protocol

Prior to endoscopic drainage, a contrast-enhanced computed tomogram (CT) was obtained at either institution. Intravenous ciprofloxacin (400 mg) was administered to all patients prior to the procedure and was continued for 48 h or until discharge. An ERCP was performed prior to transmural drainage to define the communication between the main pancreatic duct and the pseudocyst. In patients with partial duct disconnection, a bridging stent was placed as long as the proximal duct could be accessed with a guidewire; no pancreatic duct stents were placed in patients with a complete disconnected pancreatic duct syndrome (DPDS). ERCP was not performed in patients with DPDS that was diagnosed by a prior MRCP.

Procedural technique

Following ERCP, in patients with a luminal compression, transmural drainage was undertaken using a standard duodenoscope. The luminal compression was punctured using a needle-knife catheter, and after dilating the fistula, single or multiple, 7 or 10Fr double-pigtail stents (4 cm in length) were deployed. In patients without an obvious luminal compression, transmural drainage was undertaken using a therapeutic echoendoscope. At endoscopic ultrasound (EUS), the pseudocyst was accessed using a 19G FNA needle. After coiling a 0.035-inch guidewire and sequentially dilating the transmural tract, single or multiple 7Fr stents were deployed. For transmural dilation, if the size of the pseudocyst was 80 mm or less, an 8- to 10-mm balloon was used; for pseudocysts greater than 80 mm, a 12- to 15-mm dilating balloon was used. As the biopsy channel of the echoendoscope (Olympus UCT140T) is smaller than that of a standard duodenoscope, only 7Fr stents were placed during EUS-guided procedures. The number of stents placed was at the discretion of the endoscopist.

Postprocedure protocol

A CT scan of the abdomen was obtained in all patients at 8 weeks following patient discharge from the hospital. If the pseudocyst had resolved, the transpapillary pancreatic duct stents and transmural stents were removed if the follow-up pancreatogram revealed an intact main pancreatic duct. In patients with persistent leak or strictures, exchange of the transpapillary pancreatic duct stent was undertaken until the leak resolved. Our practice pattern for the management of transmural stents in patients with DPDS evolved over time. While we removed all transmural stents routinely following resolution of the pseudocyst during the initial years, of late, we have been leaving at least one transmural stent in place indefinitely, to decrease the risk of pseudocyst recurrence [10].

Definitions

Treatment success was defined as complete resolution or decrease in the size of the pseudocyst to ≤2 cm on follow-

up CT scan performed eight weeks after an endoscopic intervention. *Treatment failure* was defined as (i) persistence/worsening of symptoms in association with a residual pseudocyst measuring >2 cm on follow-up CT scan despite repeat endoscopic interventions, with subsequent need for surgery or percutaneous drainage or (ii) occurrence of a complication following endoscopic intervention that resulted in death or required surgical/interventional radiology management. *Reintervention* was defined as the need to undertake more than one endoscopic intervention as the initial attempt at drainage failed to achieve pseudocyst resolution.

Primary outcome measure

To evaluate the relationship between stent characteristics and the number of interventions required for treatment success in patients undergoing endoscopic transmural drainage of uncomplicated pancreatic pseudocysts.

Statistical analysis

The baseline characteristics of patients, pancreatic pseudocysts, and procedure details were initially summarized for all patients. Continuous variables were summarized as means (with standard deviation) and medians (with interquartile range and range), whereas categorical variables were summarized as frequencies and percentages. 12 variables of interest were then compared using the χ^2 or Fisher's exact test as indicated between two groups—patients who required only one intervention against those who required more than one intervention for endoscopic pseudocyst drainage, in order to identify factors which may be associated with the need for single intervention only. Multiple logistic regression and reverse stepwise multivariate logistic regression analyses were then conducted in order to identify factors that are significantly associated with the need for only one intervention during successful pancreatic pseudocyst drainage.

Statistical significance was determined as p value <0.05. Datasets were compiled using Microsoft Excel, and all statistical analyses were performed using Stata 13 (Stata Corp, College Station, TX).

Results

Of a total of 318 patients referred for endoscopic drainage of PFCs over a 10-year period, 171 were diagnosed with pancreatic abscess or necrosis; 25 patients were further excluded: due to an alternative diagnosis of cyst neoplasm

Table 1 Summary of patient and procedure characteristics (total no. of patients = 122)

Age (years)	
Mean (SD)	46.7 (16.4)
Median	49
IQR	39–58
Range	1–77
Gender *n* (%)	
Female	59 (48.4)
Male	63 (51.6)
Ethnicity *n* (%)	
Black	26 (21.3)
Caucasian	94 (77.0)
Hispanic	2 (1.6)
Serum white cell count ($\times 10^9$/L)	
Mean (SD)	9.7 (4.6)
Median	7.8
IQR	6.8–11.8
Range	3.8–25.8
Serum albumin (g/dL)	
Mean (SD)	3.1 (0.9)
Median	3.1
IQR	2.3–3.7
Range	1–6.7
Etiology of pancreatitis *n* (%)	
Alcohol	46 (37.7)
Gallstones	23 (18.9)
Post-procedure	15 (12.3)
Idiopathic	25 (20.5)
Other[a]	13 (10.7)
Type of pseudocyst *n* (%)	
Acute	29 (23.8)
Chronic	93 (76.2)
Size of pseudocyst (longest diameter in mm)	
Mean (SD)	99.0 (41.5)
Median	90
IQR	70–120
Range	40–350
Location of pseudocyst *n* (%)	
Head	24 (19.7)
Uncinate	2 (1.6)
Body	58 (47.5)
Tail	38 (31.1)
Luminal compression present on endoscopy *n* (%)	
Yes	50 (41.0)
No	72 (59.0)
Method for pseudocyst drainage *n* (%)	
CTD	36 (29.5)
EUS	86 (70.5)

Table 1 continued

Stent diameter *n* (%)	
7 Fr	
1 stent	21 (27.3)
>1 stent	56 (72.7)
10 Fr	
1 stent	15 (33.3)
>1 stent	30 (66.7)
No. of stents placed *n* (%)	
1	36 (29.5)
2	84 (68.9)
3	1 (0.8)
4	1 (0.8)
Pancreatic duct stent placed *n* (%)	
Yes	41 (33.6)
No	81 (66.4)
Permanent stent placed *n* (%)	
Yes	23 (18.9)
No	99 (81.1)
No. of drainage procedures performed in a single patient	
1	106 (86.9)
2	16 (13.1)
Treatment success *n* (%)	
Yes	115 (94.3)
No	7 (5.7)
Complications *n* (%)	
Yes	8 (6.6)
No	114 (93.4)

CTD conventional transmural drainage, *EUS* endoscopic ultrasound, *IQR* interquartile range, *SD* standard deviation

[a] Other causes of pseudocyst include hypertriglyceridemia, hereditary, and trauma

($n = 9$), the PFCs were beyond the reach of the echoendoscope ($n = 7$), the PFCs had spontaneously resolved or decreased in size at time of procedure ($n = 8$), or extensive gastric collaterals were present that precluded endoscopic drainage ($n = 1$). The remaining 122 patients with pseudocysts met inclusion criteria and constituted the study cohort.

51.6 % of patients were male, and the median age of the study cohort was 49 years. Alcohol was the most common etiology and 47.5 % of the collections were located in the pancreatic body. The median size of the pseudocyst was 90 mm and 70.5 % were drained under EUS guidance. 91 of 122 (74.6 %) patients had a pancreatogram prior to endoscopic drainage that revealed a normal main pancreatic duct in 27, duct leak in 41, and disconnected gland in 23. The pancreatic duct leaks were treated by placement of transpapillary stents bridging the site of the leak (Table 1). The patient and clinical characteristics of the study cohort are shown in Table 1. Of the 122 patients, 45 (36.9 %) had 10Fr stents of which 30 patients (66.7 %) had more than one stent; the remaining 77 (63.1 %) patients had 7Fr stents of which 56 (72.7 %) had more than one stent.

Overall endoscopic treatment was successful in 115 of the 122 (94.3 %) patients. Treatment success was achieved in 102 of 122 (83.6 %) patients with one intervention, 13 of 122 (10.7 %) patients required more than one intervention for successful pseudocyst drainage, and seven (5.7 %) failed treatment. Reintervention was necessary in 16 patients due to persistence of symptoms and the pseudocyst on follow-up imaging. Additional stents were deployed in 13 of these patients with successful clinical outcomes, including one patient who developed an infection following the initial endoscopic drainage which was then successfully endoscopically managed by placement of additional stents. Two of the patients who failed repeat endoscopic drainage required surgery, where both were found to have pancreatic necrosis, and one patient developed bleeding during the second endoscopic procedure, which was managed by interventional radiology-guided coil placement.

Treatment was unsuccessful in seven patients who required either surgical or interventional radiology-guided therapy due to the development of procedural complications. Perforation was encountered in two patients with pseudocyst in the uncinate region of the pancreas that was drained via the transgastric route; both patients underwent surgical repair of the perforation with cystogastrostomy. Infection developed in two patients, which was initially managed by additional stent placements ($n = 1$) or by creation of more internal transmural fistulae ($n = 1$). This however failed in both the patients, and they subsequently underwent surgery where necrosis was identified and treated by internal debridement with cystogastrostomy. Bleeding was identified in two patients intra-procedurally following transmural dilation; one patient was managed by interventional radiology-guided coil placement and the other patient required surgery to over-sew an ulcer at the drainage site. One patient died due to delayed bleeding, and autopsy revealed varices within the pseudocyst wall.

There was no difference in patient or clinical characteristics between patients who underwent one or more than one endoscopic intervention for pseudocyst drainage (Table 2). There was also no difference in the size or number of transmural stents placed, the presence or absence of transpapillary pancreatic duct stent placements or placement of permanent transmural stents between both patient cohorts. Additionally, there was no difference in the number of interventions required for treatment success between patients with 7 or 10Fr stents (one intervention required in 64 (87.7 %) of 7Fr vs. 38 (90.5 %) of 10Fr group; $p = 0.766$) and between patients with 1 or >1 stent

Table 2 Comparison of patients requiring 1 versus 2 interventions during pancreatic pseudocyst drainage

Variable	No. of interventions		*p* value
	1 ($n = 106$)	2 ($n = 16$)	
Age *n* (%)			
≤50 years	44 (41.5)	8 (50.0)	0.593
>50 years	62 (58.5)	8 (50.0)	
Gender *n* (%)			
Female	51 (48.1)	8 (50.0)	0.999
Male	55 (51.9)	8 (50.0)	
Ethnicity *n* (%)			
Caucasian	80 (75.5)	14 (87.5)	0.358
Other	26 (24.5)	2 (12.5)	
Size of pseudocyst *n* (%)			
≤80 mm	43 (40.6)	6 (37.5)	0.999
>80 mm	63 (59.4)	10 (62.5)	
Location of pseudocyst *n* (%)			
Head/uncinate	24 (22.6)	2 (12.5)	0.518
Body/tail	82 (77.4)	14 (87.5)	
Type of pseudocyst *n* (%)			
Acute	25 (23.6)	4 (25.0)	0.999
Chronic	81 (76.4)	12 (75.0)	
Stent diameter *n* (%)			
7Fr	67 (63.2)	10 (62.5)	0.999
10Fr	39 (36.8)	6 (37.5)	
No. of stents placed *n* (%)			
1	32 (30.2)	4 (25.0)	0.776
>1	74 (69.8)	12 (75.0)	
Luminal compression present on endoscopy *n* (%)			
Yes	46 (43.4)	4 (25.0)	0.185
No	60 (56.6)	12 (75.0)	
Method for pseudocyst drainage *n* (%)			
CTD	33 (31.1)	3 (18.7)	0.390
EUS	73 (68.9)	13 (81.3)	
Pancreatic duct stent placed *n* (%)			
Yes	35 (33.0)	6 (37.5)	0.779
No	71 (67.0)	10 (62.5)	
Permanent stent placed *n* (%)			
Yes	20 (18.9)	3 (18.7)	0.999
No	86 (81.1)	13 (81.3)	
Cyst contents at drainage *n* (%)			
Clear	91 (85.8)	13 (81.3)	0.705
Debris	15 (14.2)	3 (18.7)	

CTD conventional transmural drainage, *EUS* endoscopic ultrasound

(one intervention required in 32 (88.9 %) of 1 stent versus 70 (88.6 %) of >1 stent group; $p = 0.999$).

On multiple logistic regression analysis, the size and number of stents placed were not significantly associated with the number of interventions required for treatment success when adjusted for patient and pseudocyst characteristics, technical factors, the presence/absence of transpapillary pancreatic duct stents, and the presence/absence of permanent transmural stents. These factors remained non-significant on reverse stepwise multivariate logistic regression (Table 3).

Table 3 Multiple logistic regression of factors associated with the need for only one drainage procedure in patients where pseudocyst drainage was successful

Variable	OR	95 % CI	*p* value
Age: ≤50 versus >50 years	1.11	0.31–4.02	0.870
Gender: male versus female	1.09	0.28–4.25	0.900
Race: caucasian versus non-caucasian	0.59	0.10–3.32	0.546
Pseudocyst size: >80 versus ≤80 mm	0.32	0.07–1.54	0.155
Pseudocyst location: head versus body/tail	2.06	0.22–19.5	0.527
Pseudocyst type: chronic versus acute	0.76	0.16–3.70	0.735
Stent size: 7 versus 10Fr	1.54	0.23–10.4	0.656
No. of stents placed: >1 versus 1	1.15	0.25–5.25	0.853
Luminal compression: present versus not present	5.25	0.48–57.2	0.173
Drainage type: EUS-guided versus CTD	0.44	0.01–14.4	0.647
PD stent: placed versus not placed	1.13	0.26–4.82	0.870
Permanent stent: placed versus not placed	2.06	0.33–13.0	0.442

OR odds ratio, *CI* confidence interval, *CTD* conventional transmural drainage, *EUS* endoscopic ultrasound, *PD* pancreatic duct

Discussion

In this study, we did not find any association between the number of procedures performed and the size or number of stents placed in patients undergoing successful endoscopic transmural drainage of uncomplicated pancreatic pseudocysts. Unlike WOPN, the contents of a pseudocyst are less turbid and therefore are more amenable to rapid drainage when treatment is undertaken (Fig. 1A, B).

At conventional endoscopic drainage, the point of maximal "bulge" when punctured and dilated results in immediate decompression of the pseudocyst. On the other hand, when accessing a pseudocyst under EUS guidance, the puncture site chosen is based not on "bulge" but on "proximity" of the transducer to the pseudocyst. This results in creation of a tract that is not "gravity-dependent" but rather "tunneled" and hence is likely to be "more tortuous" than that created by conventional endoscopic techniques. Therefore, a delay in pseudocyst resolution may occur and some patients may even require a second intervention. In the present study, 81 % of patients who

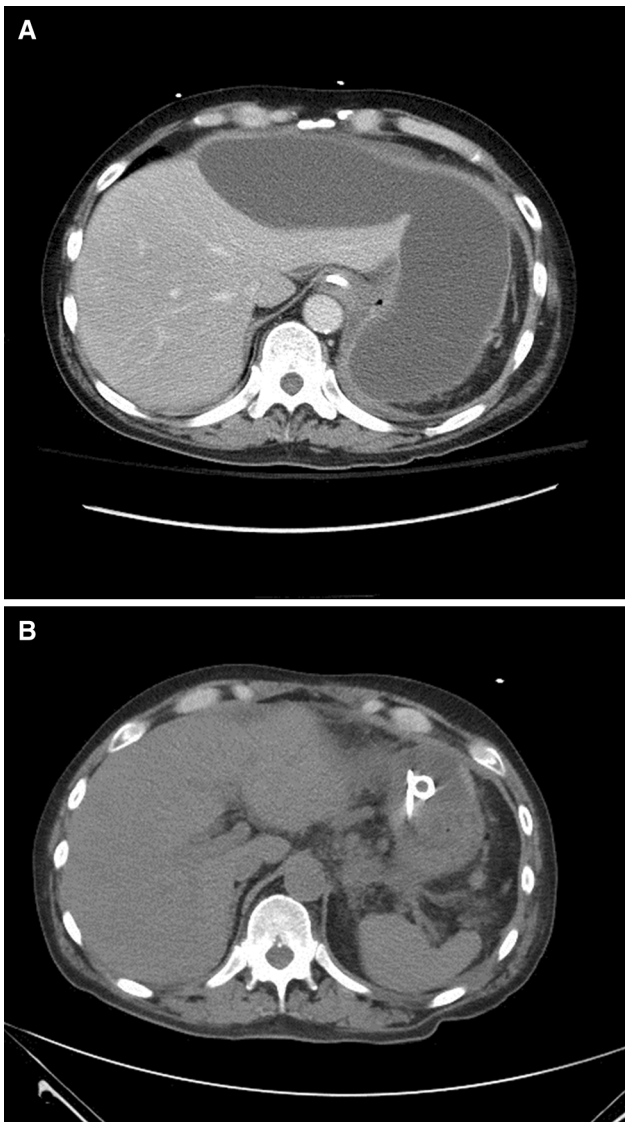

Fig. 1 **A** Computed tomography (CT) axial image of a large pseudocyst. **B** CT axial image showing complete resolution of the same pseudocyst 24 h following the placement of a single 7Fr double-pigtail plastic stent

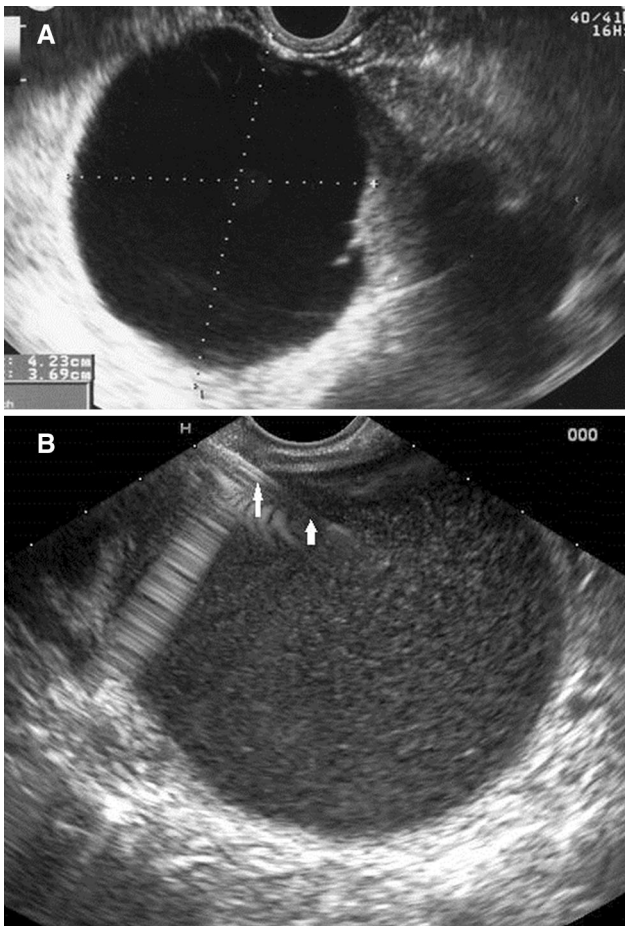

Fig. 2 **A** Uncomplicated pancreatic pseudocyst appears uniformly anechoic at endoscopic ultrasound. **B** Infected pancreatic pseudocyst appears anechoic but with floating hyperechoic debris that has no solid component within it

required a second intervention had their initial pseudocyst drainage performed under EUS guidance.

A major limitation of current imaging techniques is their inability to differentiate a WOPN from a pseudocyst. Oftentimes, the presence of a large amount of necrosis is identified only at the time of EUS-guided drainage, and a significant proportion of these collections are erroneously labeled as "pseudocysts" by cross-sectional imaging. While "true" pseudocysts appear anechoic at EUS and without the presence of debris or solid material (Fig. 2A), WOPN contains hyperechoic solid component and/or septations. An infected pseudocyst, erstwhile described as an "abscess", also appears anechoic but with hyperechoic floating debris that does not contain a solid component (Fig. 2B). To our knowledge, the morphological spectrum of PFCs has not been described in the EUS literature. In our opinion, EUS is superior to both CT and MRCP in diagnosing WOPN but is likely to be "over-sensitive". Additionally, EUS cannot evaluate large PFCs that extend beyond the reach of the transducer. Therefore, in patients with a large PFC and focal necrosis, the disease process can be incorrectly categorized as a pseudocyst based on limited range of imaging. In this study, despite the stringent selection criteria, two patients who failed endoscopic drainage were found to have necrosis at surgery. Both patients had more than one stent placed at endoscopy but still had suboptimal clinical outcomes.

Although the use of self-expandable metal stents (SEMS) has been gaining increasing popularity in the treatment of PFCs [7], its advantage over conventional plastic stents is unclear. In this study, we achieved an overall treatment success of more than 90 % using only

plastic stents. The role of SEMS in pseudocyst drainage requires further clarification, and its routine use should be discouraged unless its advantages are proven in well-designed randomized trials. The results from our study suggest that SEMS will provide no advantage when used to treat true pseudocysts.

There are several limitations in this study. Firstly, the favorable outcomes reported herein are restrictive to "true" pseudocysts as we excluded patients with WOPN. At institutions that do not have access to state-of-the-art body imaging or EUS, it may be prudent to place multiple transmural stents in order to avoid the possibility of instrumentation-related infections. In the present study, most patients had a dedicated CT at our facility that was interpreted by expert radiologists. Although there is a growing consensus that MRI is superior to CT in diagnosing necrosis, this has not yet been studied in a randomized trial. In a recent study, while MRI was found to be superior to CT in predicting clinical outcomes, the performances of both technologies were comparable in diagnosing pancreatic necrosis [11]. Most of the discrepancies in diagnosis between the two technologies were due to CT "overcalling" the extent of the necrosis. Secondly, our study design was retrospective with its inherent limitations. Finally, the data presented herein are from two tertiary referral centers and therefore may not be applicable to all institutions due to varying levels of technology and endoscopic techniques being used for pseudocyst management.

In conclusion, there appears to be no relationship between the number of interventions required for treatment success and the size and number of stents placed in patients undergoing endoscopic transmural drainage of uncomplicated pancreatic pseudocysts. However, this inference is limited only to patients with uncomplicated pancreatic pseudocysts and not to those with complex PFCs.

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