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Multivariate analysis of the factors affecting the prognosis of walled-off pancreatic necrosis after endoscopic ultrasound-guided drainage

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Abstract

Background and aims Endoscopic ultrasound (EUS)-guided drainage has become the treatment of choice for walled-off pancreatic necrosis (WOPN). However, no consensus exists on the most significant patient- and procedure-related factors that affect prognosis. The aim of the study is to investigate the correlation between patient- and procedure-related factors and post-procedure complications after EUS-guided drainage.

Methods A retrospective analysis of the clinical characteristics of patients with WOPN who underwent EUS-guided drainage at our endoscopy center between November 2011 and August 2017 was performed. Chi-square analysis and binary logistic regression statistical methods were used to analyze the correlation between influencing factors and prognosis.

Results A total of 85 patients (male/female, 50/35) with WOPN were included in the study. The average age was 44.95 years. The cyst diameter was 10.58 ± 4.78 cm. Multivariate analysis showed that WOPN with higher solid content (> 30%) increased the probability of endoscopic necrosectomy (OR 6.798; 95% CI 1.423, 32.470; $p = 0.016$). The use of a metal stent increased the probability of endoscopic necrosectomy (OR 3.503; 95% CI 1.251, 9.810; $p = 0.017$) and the length of hospitalization (OR 3.315; 95% CI 1.192, 9.215; $p = 0.022$). Female patients had a higher probability of requiring endoscopic necrosectomy (OR 2.683; 95% CI 1.027, 7.007; $p = 0.044$) and prolonged hospitalization (OR 2.675; 95% CI 1.065, 6.721; $p = 0.036$).

Conclusion The solid content of WOPN, type of stent, and sex of patients were associated with increased probability of endoscopic necrosectomy.

Keywords Walled-off pancreatic necrosis · Prognosis · Endoscopic necrosectomy · Multifactor analysis

Peri-pancreatic fluid collection (PFC) is a common complication secondary to acute pancreatitis and is especially common in hemorrhagic necrotizing pancreatitis. It can also be secondary to chronic pancreatitis, pancreatic trauma, and pancreatic cancer [1]. Based on the 2012 Atlanta Classification of acute pancreatitis, PFC lasting longer than 4 weeks is classified as either walled-off pancreatic necrosis (WOPN) or pancreatic pseudocyst (PC), depending on whether the

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accumulated fluid contains solid debris. In other words, even if there is only a small amount of solid debris in the PFC, it is still defined as WOPN.

Most cases of PFC resolve spontaneously, but treatment is needed if abdominal pain, abdominal swelling, gastrointestinal obstruction, jaundice, cyst infection, or other symptoms appear [2]. Endoscopic ultrasound (EUS)-guided drainage has become the treatment of choice for PFC. However, clinical studies have shown that it is significantly more effective in PC than WOPN [3–5]. Whether necrotic debris affects the prognosis of EUS-guided drainage is unclear. Furthermore, other factors that may influence the prognosis of EUS-guided drainage have yet to be elucidated.

This study focused on WOPN and analyzed the influence of patient sex and age, solid debris in WOPN, stent type, and cyst formation time on prognosis following EUS-guided drainage.

Materials and methods

Patients

A total of 273 patients were diagnosed with WOPN at the Shengjing Hospital of China Medical University between November 2011 and August 2017. Of these, 164 were followed up for lack of treatment indications, 17 chose surgery, and 7 chose percutaneous external drainage. The remaining 85 patients (50 males and 35 females) who underwent EUS-guided drainage of WOPN were selected for this study. The age, sex, type of stent placed, imaging data, and prognosis-related data of the patients were recorded.

All patients underwent abdominal computed tomography (CT), magnetic resonance imaging (MRI), or abdominal ultrasonography examination before the endoscopic procedure. In combination with their medical history, the patients were diagnosed with WOPN in accordance with the Atlanta Classification.

The indications for EUS-guided drainage were as follows: (1) WOPN diameter greater than 6 cm, (2) WOPN associated with infection or fever, (3) symptomatic gastrointestinal or biliary obstruction, or (4) persistent upper abdominal discomfort.

The exclusion criteria were as follows: (1) coagulopathy or thrombocytopenia and (2) generally poor patient condition precluding endoscopic treatment.

Ethics

This study was approved by the Institutional Review Board and Ethics Committee of China Medical University. All patients voluntarily chose their therapeutic course and provided written informed consent for participation in this study. Written informed consent was obtained from the parents or guardians of minors (age < 18 years).

Procedure

Conventional examination by electrocardiography, chest X-ray, and pulmonary function tests were performed prior to the endoscopic procedure. All procedures were conducted by an experienced therapeutic endoscopist. A linear array echoendoscope (EG3870UT; Pentax, Tokyo, Japan) in combination with an ultrasound scanner (EUB 6500; Hitachi, Tokyo, Japan) was used to scan the WOPN from the stomach or duodenum and determine the location, size, and number of cysts. The contents of the cysts were also noted. Power Doppler imaging was used to confirm that there were no interposed vessels at the puncture site.

EUS-guided drainage with plastic stents

For plastic stent delivery, a 19-G needle (EUS N-19-T; Wilson-Cook Medical, Winston-Salem, NC) was used for puncture. After withdrawing the inner needle stylet, some fluid was aspirated for routine cytological, biochemical, and microbiological analysis and culture. A 0.035-inch guidewire (Jagwire; Boston-Scientific, Natick, MA) was inserted through the needle lumen into the cyst. Subsequently, a cystotome (10 Fr; Wilson-Cook Medical) was used to dilate the tract and create a large fistula. An expanding balloon catheter (8–10 mm in diameter) was occasionally used to expand the fistula. We inserted 1–3 double-pigtail (DP) plastic stents, 7–10 Fr in diameter and 3–9 cm in length (7, 8.5 or 10 Fr; Endo-Flex GmbH, Voerde, Germany), along the guidewire. In some patients, a nasocystic drainage tube (7 Fr; Wilson-Cook Medical) was used for postoperative washing of the cyst cavity (Fig. 1).

EUS-guided drainage with metal stents

For metal stent delivery, a 19-G needle (EUS N-19-T; Wilson-Cook Medical) was used for puncture, a small amount of cyst fluid was withdrawn for examination, and an indwelling guidewire was placed. A 10-Fr cystotome (Wilson-Cook Medical) was inserted along the guidewire, a stomach/duodenum-cyst fistula was created, and a metal stent (10–16 mm in diameter) was introduced over the guidewire, which included a fully covered self-expanding metal stent (Boston-Scientific, Natick, MA) or a lumen-apposing covered self-expanding metal stent (10 mm in diameter; Micro Technique, Nanjing, China) (Fig. 2A–C).

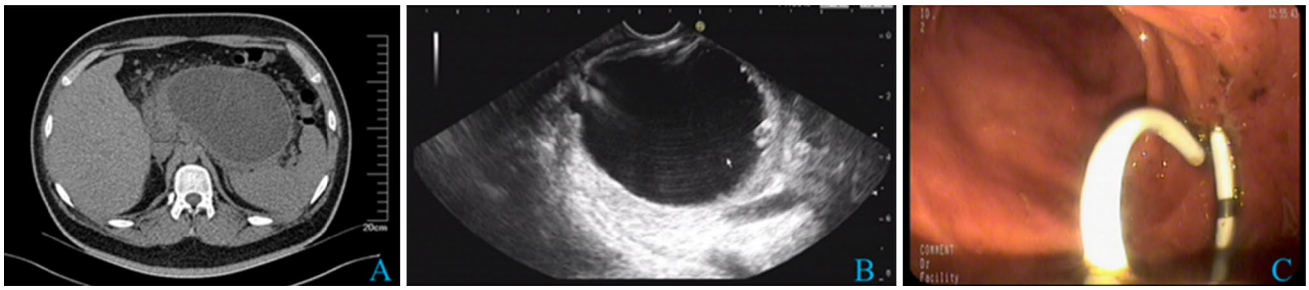

Fig. 1 **A** and **B** Walled-off pancreatic necrosis was observed by CT and EUS. **C** EUS-guided drainage were performed transgastrically. A 10-Fr, 7-cm double-pigtail plastic stent was used for drainage

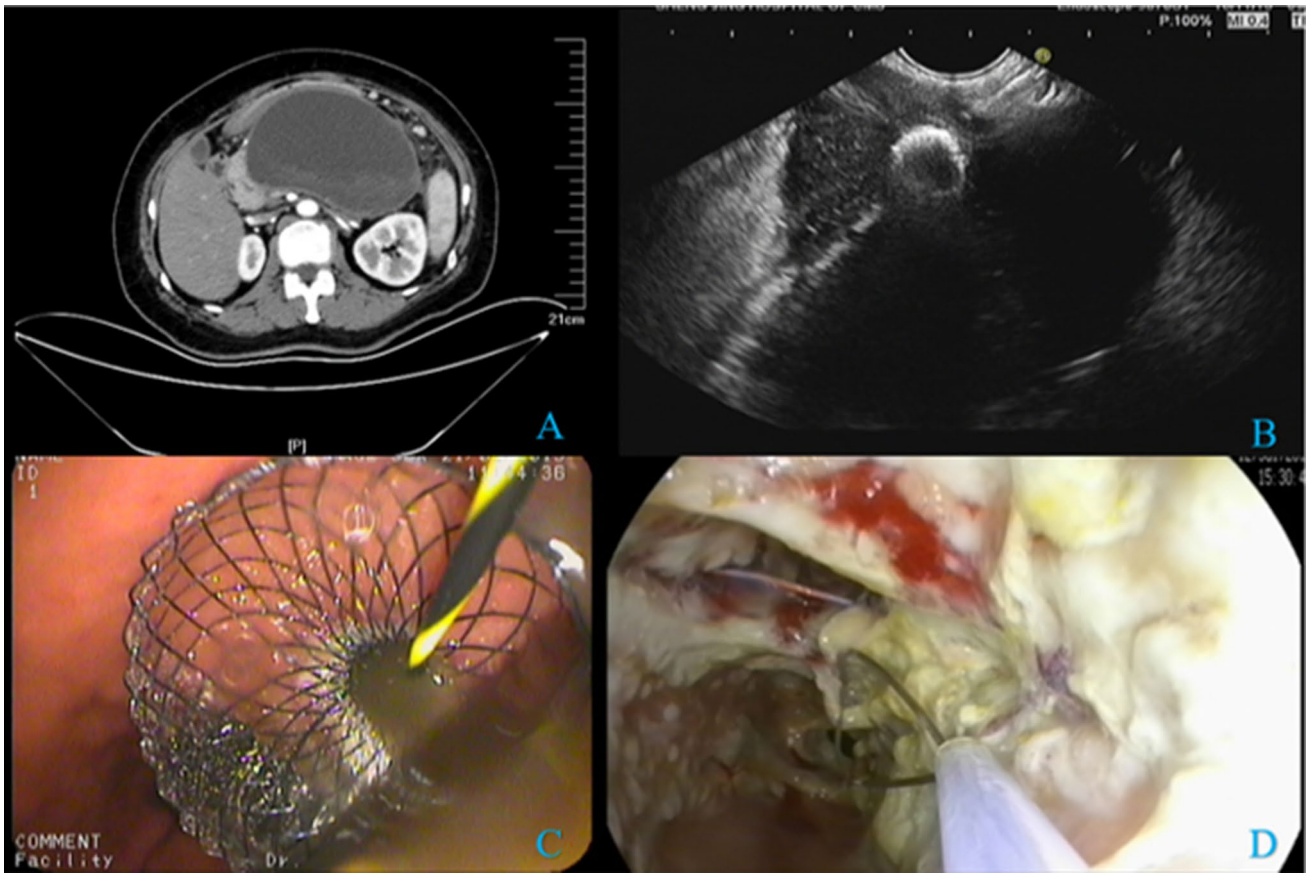

Fig. 2 **A** Walled-off pancreatic necrosis was observed by CT. **B** and **C** For EUS imaging, a double-flanged metal stent was placed transmurally between the walled-off pancreatic necrosis and gastric wall. **D** There was much debris in the cyst. Direct endoscopic necrosectomy was performed

EUS-guided drainage with a double-flanged fully covered metal stent with electrocautery

Before the delivery of a double-flanged fully covered metal stent with electrocautery (10 mm in diameter; Micro Technique, Nanjing, China), a linear array echoendoscope was used to examine the WOPN. The color Doppler function was utilized to determine whether the puncture site contained blood vessels. A double-flanged fully covered metal stent with electrocautery was used to construct a fistula and insert the stent. A nasocystic drainage tube (7 Fr; Wilson-Cook Medical) was sometimes used for PFC cavity lavage.

Patient management after the EUS-guided procedure

Post procedure, the patients were observed for a period of at least 7 days. Prophylactic antibiotics (ceftriaxone, 1 g intravenously) were given twice daily for at least 2 days after the procedure. Standard blood biochemistry, liver functions, urine amylase, and other tests were performed. Abdominal CT was performed immediately in case of post-procedure upper abdominal discomfort or severe fever (body temperature over 38.5 °C). If cyst shrinkage was not obvious, endoscopic necrosectomy was performed immediately.

The endoscopic necrosectomy procedure

The endoscope was advanced into the stomach, and a plastic or metal stent was grasped with forceps. After withdrawing the endoscope, a linear array echoendoscope was advanced into the stomach. Under EUS guidance, a contrast tube was advanced through the original fistula into the WOPN and a guidewire was placed. Subsequently, a 14-mm-diameter expanding balloon catheter was inserted along the guidewire to dilate the fistula. After dilatation, the endoscope was advanced into the WOPN. A basket was used to fully clean the necrotic tissue in the cavity, and normal saline was used for repeated lavage. After the procedure, an indwelling 10-Fr DP stent was inserted (Fig. 2D).

Follow-up

Patients were directed to undergo abdominal CT re-examinations at regular intervals (at 1 week, 1 month, 2 months, and 3 months post procedure) and immediately if upper abdominal pain, fever, or other symptoms developed.

Metal stents were left in patients for 15 days to 2 months after drainage and were removed when the WOPN disappeared. Plastic stents were left in patients for 2–3 months and were removed when the WOPN disappeared.

Assessment of post-procedure complications

Procedure-related complications

Procedure-related complications include cyst re-enlargement due to post-procedure short-term stent migration, massive intraoperative hemorrhage, intervention for post-procedure bleeding (including transfusion, interventional treatment, and surgery), and ascites due to seepage of cystic fluid into the abdominal cavity.

Endoscopic necrosectomy

In patients with upper abdominal discomfort, infection, fever, and other related symptoms after initial drainage, endoscopic necrosectomy of the cyst was recorded as a re-intervention.

Length of hospitalization

The length of hospitalization was counted from the day of the initial drainage of the WOPN to the day the patient was discharged and includes days hospitalized due to readmission.

Classification of WOPN content

Based on the 2012 Atlanta Classification of acute pancreatitis, cysts devoid of any solid components were classified as PP and those containing any solid components as WOPN.

Clinical experience suggests that solid content in cysts may be significant for prognosis. The amount of solid debris was classified as small (accounting for $\leq 30\%$) or large ($> 30\%$) based on preoperative abdominal CT and intraoperative ultrasonography.

Statistical analysis

SPSS 20.0 statistical software (IBM, Armonk, NY) was used for analysis. Continuous variables are denoted as mean ± standard deviation ($x \pm s$). Count data is shown as percentage (%). The χ^2 test was used for analyzing single factors affecting prognosis. For multivariate studies of individual outcomes, stepwise binary logistic regression was used to identify independent influencing factors (significance level $\alpha = 0.05$).

Results

Overall condition

A total of 85 patients with WOPN based on the Atlanta Classification criteria were included. The patients were classified according to the amount of solid debris content ($\leq 30\%, > 30\%$), with 39 patients classified as having a small amount and 46 as having a large amount. The average cyst diameter was 10.58 ± 4.78 cm (range 3.8–24.6 cm). The location of the WOPN was in the head of the pancreas in 10 patients (11.8%), the body in 8 (9.4%), the tail in 19 (22.4%), the body and tail in 36 (42.4%), and the entire pancreas in 11 (12.9%). The etiology was acute pancreatitis in 50 patients (58.8%), chronic pancreatitis in 15 (17.6%), pancreatitis secondary to trauma in 4 (4.7%), postoperative pancreatitis

in 9 (10.6%), and unknown in 7 (8.2%). Plastic stents were used in 61 patients (71.8%), of whom 14 received 2 or more stents, and a metal stent was used in 24 patients (28.2%), including double-flared stents in 18, straight stents in 3, and double-flared stents with plastic stents in 3. Complications associated with EUS-guided drainage developed in a total of 18 patients (21.2%), including stent dislocation and cyst recurrence in 6, intra-or post-procedure-related bleeding in 7, pneumoperitoneum or ascites in 4, and other complications in 1. A total of 27 patients required endoscopic necrosectomy after EUS-guided drainage, of whom 17 required re-hospitalization due to endoscopic necrosectomy. Post-procedure hospital stay was 13.4 ± 15.7 days (2–82 days) with a median of 7.0 days. A total of 39 patients were hospitalized for over 7 days. The cost of the hospitalization was 4589.3 ± 3757.0 USD (616.3–22606.5 USD), with a median of 3188.5 USD. The costs exceeded 3000 USD in 49 patients. Details are shown in Table 1.

Table 1 Overall results

Item	Proportion (%)
Solid material: small amount versus particularly large amount	39 (45.9%) versus 46 (54.1%)
Stent type: plastic versus metal	61 (71.8%) versus 24 (28.2%)
Complications	18 (21.2%)
Re-hospitalization	17 (20.0%)
Interventional treatment	30 (35.3%)
Endoscopic necrosectomy	27 (31.8%)
Prolonged hospitalization (> 7 days)	39 (45.9%)
Hospitalization cost (> 3000 USD)	49 (57.6%)

Univariate analysis of prognosis

Prognostic indices (whether procedure-associated complications developed, whether interventional treatment was given, whether endoscopic necrosectomy was performed, days hospitalized, hospitalization costs) were used as dependent variables, and sex, age, stent type, amount of solid content, and the time period with WOPN (the time from the first discovery of WOPN to the present) were used as independent variables in univariate analysis. The analysis showed that there were differences in interventional treatment, length of hospitalization, and hospitalization cost between the sexes ($p < 0.05$). There were differences in endoscopic necrosectomy and hospitalization cost according to the amount of solid content ($p < 0.05$) and differences in endoscopic necrosectomy and length of hospitalization according to the type of stent ($p < 0.05$). There was no significant difference in any of the prognostic factors according to age or the period with WOPN ($p > 0.05$) (Tables 2, 3).

Multivariable analysis of prognosis

Analysis of each prognostic index showed that the amount of solid content in cysts was an independent factor associated with re-interventional treatment, endoscopic necrosectomy, and hospitalization cost ($p < 0.05$). Sex was an independent factor associated with re-interventional treatment, length of hospitalization, and hospitalization cost ($p < 0.05$). Similarly, stent type was independently associated with endoscopic necrosectomy and length of hospitalization ($p < 0.05$). There were no factors independently associated

Table 2 Univariate analysis of complications and interventional treatment

Item	Complications	Endoscopic necrosectomy		
	Present	p (χ^2)	Given	p (χ^2)
Age				
≤ 45 years	8 (19.5%)	0.717 (0.131)	14 (34.1%)	0.831 (0.046)
> 45 years	10 (22.7%)		16 (36.4%)	
Sex				
Male	7 (14.0%)	0.053 (3.747)	13 (26.0%)	0.032 (4.593)*
Female	11 (31.4%)		17 (48.6%)	
Content				
Small amount	9 (23.1%)	0.693 (0.156)	10 (25.6%)	0.086 (2.940)
Large amount	9 (19.6%)		20 (43.5%)	
Stent type				
Plastic	13 (21.3%)	0.961 (0.002)	19 (31.1%)	0.202 (1.627)
Metal	5 (20.8%)		11 (45.8%)	
Cyst formation time				
≤ 2 weeks	13 (19.7%)	0.534 (0.387)	24 (36.4%)	0.701 (0.148)
More than 2 weeks	5 (26.3%)		6 (31.6%)	

*Statistically significant

Table 3 Univariate analysis of endoscopic necrosectomy, length of hospitalization, and hospitalization cost

Item	Endoscopic necrosectomy		Days hospitalized		Hospitalization cost (USD)	
	Performed	p (χ^2)	>7	p (χ^2)	>3000	p (χ^2)
Age						
≤45 years	11 (26.8%)	0.345 (0.890)	17 (41.5%)	0.430 (0.623)	26 (63.4%)	0.299 (1.079)
>45 years	16 (36.4%)		22 (50.0%)		23 (52.3%)	
Sex						
Male	12 (24.0%)	0.066 (3.378)	18 (36.0%)	0.029* (4.776)	24 (48.0%)	0.031* (4.629)
Female	15 (42.9%)		21 (60.0%)		25 (71.4%)	
Content						
Small amount	7 (17.9%)	0.012* (6.347)	14 (35.9%)	0.089 (2.894)	16 (41.0%)	0.004* (8.155)
Large amount	20 (43.5%)		25 (54.3%)		33 (71.7%)	
Stent type						
Plastic	14 (23.0%)	0.005* (7.743)	23 (37.7%)	0.016* (5.818)	33 (54.1%)	0.291 (1.114)
Metal	13 (54.2%)		16 (66.7%)		16 (66.7%)	
Cyst formation time						
≤2 weeks	21 (31.8%)	0.984 (0.000)	32 (48.5%)	0.369 *(0.805)	40 (60.6%)	0.303* (1.059)
More than 2 weeks	6 (31.6%)		7 (36.8%)		9 (47.4%)	

*Statistically significant

Table 4 Multivariable analysis of the effect of complications on prognosis

Item	p value
45 years of age	0.717
Sex	0.053*
Stent type	0.961
Small or large amount on imaging	0.439
Cyst formation time of 2 weeks	0.534

*Statistically significant

Table 5 Multivariable analysis of the effect of interventional treatment on prognosis

Item	*B*	*p*-value	OR	95% CI
Sex (male/female)	0.987	0.044*	2.683	(1.027, 7.007)
Solids	1.917	0.016*	6.798	(1.423, 32.470)
45 years of age		0.749		
Stent type		0.445*		
Cyst formation time of 2 weeks		0.578		

OR odds ratio, *CI* confidence interval

*Statistically significant

with procedure-related complications. Patient age and the period with WOPN did not have a significant association with prognosis ($p > 0.05$). Details are shown in Tables 4, 5, 6, 7 and 8.

Table 6 Multivariable analysis of the effect of debridement on prognosis

Item	*B*	*p*-value	OR	95% CI
Stent type (plastic/metal)	1.254	0.017*	3.503	(1.251, 9.810)
Solids		0.050		
45 years of age		0.433		
Sex		0.097*		
Cyst formation time of 2 weeks		0.772		

OR odds ratio, *CI* confidence interval

*Statistically significant

Table 7 Multivariable analysis of the effect of hospitalization duration on prognosis

Item	*B*	*p*-value	OR	95% CI
Sex (male/female)	0.984	0.036*	2.675	(1.065, 6.721)
Stent type (plastic/metal)	1.198	0.022*	3.315	(1.192, 9.215)
45 years of age		0.847		
Small or large amount on imaging		0.230		
Cyst formation time of 2 weeks		0.536		

OR odds ratio, *CI* confidence interval

*Statistically significant

Table 8 Multivariable analysis of the effect of hospitalization cost on prognosis

Item	*B*	*p*-value	OR	95% CI
Sex (male/female)	1.028	0.043*	2.795	(1.035, 7.547)
Content (small/large amount)	1.862	0.002*	6.436	(1.990, 20.811)
45 years of age		0.309		
Stent type		0.646		
Cyst formation time of 2 weeks		0.200		

OR odds ratio, *CI* confidence interval

*Statistically significant

Discussion

EUS-guided drainage has gradually become the treatment of choice for WOPN. It is minimally invasive, allows for rapid recovery, and can be used for endoscopic necrosectomy. To a certain extent, EUS-guided drainage is more effective and less liable to complications than surgical drainage [6–11]. It has been reported that the clinical success rate after drainage of WOPN is lower than that after drainage of PC (50–65% vs. 90%) [3, 4]. Some patients develop recurrent fevers and require multiple endoscopic necrosectomies or even develop serious complications such as ascites or bleeding. The present study conducted a multivariable analysis of several factors that may influence the prognosis of EUS-guided drainage of WOPN.

The 2012 revision of the Atlanta Classification roughly categorized chronic PFC into WOPN or PC based on whether the accumulated fluid contains solid components. In fact, the amount of solid debris inside the cyst determines the selection of EUS-guided methods and the prognosis. Currently, there are few studies on the effects of solid debris in WOPN on prognosis. One study reported that a solid debris content of > 50% was an independent risk factor for drainage failure [12]. Another study divided solid debris into three categories according to proportion (< 10%, 10–40%, and > 40%) and showed that as debris content increased, the number of endoscopic interventions required increased, and patients with > 40% debris also required treatment by endoscopic necrosectomy [13]. With continued developments in imaging technology, the discovery of solid debris in WOPN has increased. Although it has been reported that MRI is most accurate for imaging and quantifying solid debris [14, 15], it can be prohibitively expensive and clinics tend to use CT and EUS instead. The present study used 30% solid debris in the cyst as the threshold for defining debris amounts as large or small. We performed multivariable analysis which showed that WOPN with over 30% solid debris was associated with an increased need for post-procedure endoscopic necrosectomy and increased hospitalization cost. Large amounts of solid debris in the cyst require longer resorption and organization times and result in a greater chance of stent blockage and infection. Among all prognostic factors, solid debris content had the largest effect on the outcomes of drainage, making it clear that pre-procedure evaluation of the contents of WOPN is critical.

Initially, endoscopic drainage of PFC was only performed using DP stents. Later, self-expanding metal stents were gradually used in the treatment of WOPN [16–18]. Numerous reports consider metal stents to be superior to plastic stents because of their larger diameters, which facilitate drainage, and their clinical efficacy and fewer complications [19–22], a conclusion also supported by a recent meta-analysis [23]. However, some believe that metal and plastic stents have similar rates of complications [17] and that metal stents may have even more delayed-onset complications [24]. Currently, metal stents are primarily categorized into fully covered self-expanding metal stents and fully covered metal stents with flared ends. Studies have reported superior success rates and lower complication rates using metal stents for drainage of WOPN due to their generally larger diameter (10–15 mm) [25]. In a study by Rinninella et al., a stent with an even larger diameter (15 mm) was used, which increased the clinical response rate [26]. In contrast, the present study showed that compared to plastic stents, metal stents were associated with an increased probability of subsequent endoscopic necrosectomy and length of hospitalization. This may be because metal stents with large diameters achieve significant initial drainage, shrinking the cyst in a short period of time, demonstrating that the necrotic tissue in the cavity is not directly organized and instead obstructs the stent opening. In addition, metal stents with double-flared shapes undergo a decrease in diameter after insertion due to the effects of the cyst wall on the central segment, and fragmented debris can easily lead to gradual obstruction of the stent during drainage. In contrast, plastic stents have smaller diameters, have longer drainage times, and are not as easily obstructed by solid debris. Reports have shown that stent choice is neither associated with hospitalization length nor cost, supporting the conclusions of the present study [27–29].

In addition, the present study found that female patients were more likely to require re-intervention, prolonged hospitalization, and more likely to have increased hospitalization cost. Similar results have not been reported domestically or internationally; however, some studies have indicated that male pancreatitis patients are more likely to develop PFC [30], which may indicate that males have a superior ability to organize and resorb necrotic tissue. Very little necrotic tissue in the contents of WOPN drains directly into the gastrointestinal tract, and treatment primarily depends on its organization and resorption. This capacity may be diminished in

female patients, slowing recovery and affecting prognosis, but the specific reasons for this require further studies.

Formation of the cystic wall is crucial for drainage, and delaying intervention for asymptomatic cysts improves post-procedure outcomes [31]. Most cases of PFC resorb spontaneously and do not require interventional treatment. However, drainage is recommended for cysts that have formed for over 4–8 weeks [2]. In the clinic, many patients do not have clear medical histories demonstrating the development of pancreatitis, and cysts are often discovered on abdominal CT images after symptoms develop. The exact time at which the cyst forms is difficult to determine accurately. In the present study, the time was calculated from when the cyst was first discovered. However, it is likely that more cysts would have formed during that time than the number indicated by the results. Using 2 weeks as the threshold for our analysis, the conclusions still do not support the cyst formation time as a prognostic factor.

Most studies have analyzed the development of drainage-associated complications. With respect to the selection of stent type, some studies have shown that metal stents have lower post-procedure complication rates [25], while others have shown conflicting results [24]. With the widespread adoption of EUS-guided drainage techniques, accumulation of EUS experience, and prevention of drainage-associated complications, the present study showed that there was no significant association between complications and the factors included in our analysis.

In summary, solid debris content ($\leq 30\%$ or $> 30\%$) was significantly associated with prognosis (endoscopic necrosectomy, hospitalization cost). If there is excessive debris but no clear symptoms, the contents can be allowed to organize, mature, and shrink before treatment to achieve optimal results. The use of metal stents extends hospital stay and increases the possibility of endoscopic necrosectomy. Female sex may be a factor influencing the outcomes of post-procedure intervention, and it may increase hospitalization cost and the possibility of endoscopic necrosectomy. In addition to the factors involved in the present study, body mass index, age, and other factors have been reported as prognostic factors [17, 32], and further analyses are still needed in order to enhance our understanding of the prognosis after WOPN drainage.

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Compliance with ethical standards

Disclosures Jintao Guo, Bowen Duan, Siyu Sun, Sheng Wang, Xiang Liu, Nan Ge, Wen Liu, Shupeng Wang, and Jinlong Hu declare that they have no conflicts of interest or financial ties to disclose.

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