Predictive factors of pancreatic necrosectomy following percutaneous catheter drainage as a primary treatment of patients with infected necrotizing pancreatitis

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Abstract. Pancreatic necrosectomy (PN) following percutaneous catheter drainage (PCD) is an effective method of treating patients with necrotizing pancreatitis, however, the predictive factors for PN after PCD have not yet been identified. A total of 74 patients with suspected infected necrotizing pancreatitis (INP) and peripancreatic fluid collection were enrolled in the current study between October 2010 and October 2015. These patients received ultrasound or computer topography guided PCD followed by PN. Patients were divided into two groups: i) A PCD-alone group (n=32) and ii) a PCD+necrosectomy group (n=42). Multivariate analysis revealed that reduction of fluid collection after PCD (P=0.021), maximum extent of peripancreatic necrosis (P=0.019) and multiple organ failure (P=0.017) were predictors of PN following PCD. A prediction model was produced to evaluate the aforementioned factors and indicated that the area under the receiver operating characteristic curve was 0.827. The probability of successful PCD was determined using a prognostic nomogram. Thus, the results of the current study demonstrated that a reduction of fluid collection by <50% following PCD, a maximum extent of peripancreatic necrosis of >50% and multiple organ failure are effective predictors of necrosectomy in patients with INP following PCD failure.

Introduction

Acute pancreatitis is usually mild and exhibits a wide range of clinical manifestations. The mortality rate of patients with infected necrotizing pancreatitis (INP) is 8-39% and ~20% of patients with acute pancreatitis succumb (1). INP is a severe condition (2) and is a major cause of mortality as its symptoms include early organ failure and infection of pancreatic or peripancreatic necrotic tissue, leading to sepsis and multiple organ failure (3).

The traditional method of treating patients with INP by laparotomy remains the 'gold standard'. However, this surgical approach is associated with post-operative mortality and morbidity, as well as organ dysfunction (4-6); therefore, laparotomy should be delayed as long as possible to decrease mortality and morbidity rates (7). Besselink *et al* (8) conducted a PANTER study to compare the efficacy of PN with the step-up approach in patients with INP. The step-up approach reduced the rate of major morbidity in patients with suspected INP compared with those undergoing maximal necrosectomy via laparotomy (8). The minimally invasive step-up approach, which involves percutaneous catheter drainage (PCD), followed by minimally invasive PN if necessary, has many advantages including damage control, fewer complications, and a decreased likelihood of multiple organ failure (9). In 2010, Van Santvoort *et al* (10) demonstrated that the minimally invasive step-up approach was the least invasive of all techniques, and is the optimal method of treating patients with INP and secondary infection.

PCD is the primary strategy in the step-up approach and a method of controlling sepsis (10). It has been applied to treat patients with acute pancreatitis and decreases the risk of morbidity and mortality (11). Furthermore, it is a well-regarded first minimal access technique, which is used to treat acute pancreatitis and avoid the use of PN. Guo *et al* (12) has suggested that acute necrotic collection and computed tomography (CT) mean density of necrotic fluid collection may affect the success rate of PCD. Indeed, previous studies have demonstrated that a high proportion of patients fail to improve following the use of PCD (11,13). If PCD does not improve clinical symptoms, PN should be performed following PCD (10). Although a number of recent studies have investigated the predictive factors of PCD (12,14), few studies have identified methods of predicting whether PN is required following PCD failure. Therefore, the current study aimed to identify predictors of PN following the use of PCD as primary treatment in patients with INP.

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Patients and methods

Patients. Patients with suspected INP and peripancreatic fluid collection in the Department of General Surgery, Capital Medical University (Beijing, China) were enrolled in the present study between October 2010 and October 2015. A series of consecutive patients were diagnosed with acute suspected INP and peripancreatic fluid collection.

The inclusion criteria were a maximum extent of fluid collection of ≥100 ml and fluid collections taken within 2 weeks of disease onset. Patients were excluded if they had mild pancreatitis, did not receive PCD as primary treatment or had a pancreatic pseudocyst.

The process of patient screening and treatment management in the current study is illustrated in Fig 1. All experiments performed in the current study were approved by the Ethics Committee of Xuanwu Hospital, Capital Medical University. Written informed consent was obtained from all participants for their clinical data to be applied in the present study.

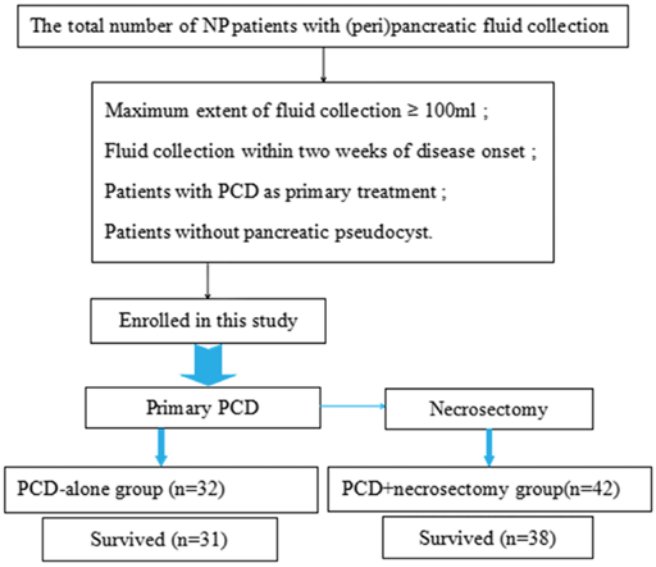

Figure 1. Enrollment, randomization, and follow-up of the study patients. PCD, percutaneous catheter drainage.

PCD procedure. All 74 patients (female, 27; male, 47) initially received resuscitative measures, gastrointestinal decompression, antibiotic prophylaxis and conservative medical care. The needle aspiration procedure and pus culture were performed under guidance with ultrasound or CT, and a pigtail catheter was put in place. Percutaneous catheters ranged in size from 8-32 French gauge (Fr) and the mean number of ultrasound or CT guidance procedures performed per patient was 1.5 (range, 1-5 per patient). Drains were routinely flushed with 0.9% saline solution every 6 h to avoid tubes becoming blocked and thicker drainage tubes were used if this could not be avoided. If patients exhibited clinical improvements and reduced peripancreatic fluid collection was confirmed by CT reassessment 72 h later, primary PCD was considered a success. Under reassessed CT guidance, multiple drainage treatments were performed in areas including the retorperitineal or transperitoneal regions. However, if peripancreatic fluid collection was only reduced in the drainage area, with no reduction of peripancreatic fluid collection away from the drainage sites, multi-points puncture and drainage should be performed under multiple CT or ultrasound guidance to reduce peripancreatic fluid collection. If there was continued clinical deterioration following ≥1 drainage, the PCD procedure was considered to be a failure.

PN after PCD. Following PCD, 42/74 of the patients (57%) were treated with further PN. Videoscopic assisted retroperitoneal debridement (VARD) or video-assisted laparoscopic debridement were primarily used to debride necrotic tissues of the peripancreas. The CT scans of patients who received PN following PCD are presented in Fig 2.

Patient data recorded included age, etiology, referral following INP onset, days spent in hospital, the span time from onset to PCD, number of PCD catheters, catheter size, the number of PCDs performed, duration of drainage, site of PCD, severity score [Modified computerized tomography severity index (MCTSI) (15) and Modified Marshall] (16), maximum extent of necrosis, maximum extent of fluid collection, reduction of fluid collection following PCD, multiple organ failure, mortality rates and laboratory parameters [C-reactive protein (CPR), procalcitonin (PTC) and white blood cell (WBC) count].

Peripancreatic fluid collection and the extent of peripancreatic necrosis was measured using a GE ADW4.5 workstation (GE Healthcare, Chicago, USA) and is pre sented in Fig. 3. The nonnecrotic and necrotic tissues of the pancreas were selected following the technique provided by *Quick Paint* of *Segment* (a setting in the GE ADW4.5 workstation) and the volume of necrotic and non-necrotic tissue in the pancreas was determined following the technique provided by *Measure Volume* of *Display* (a setting of the GE ADW4.5 workstation; Brush Diameter was set as 1.0 mm).

Statistical analysis. Patients were divided into two groups: A PCD-alone group (n=32) and a PCD+necrosectomy group (n=42). The clinical data of patients in these groups are presented in Table I. Statistical analyses were performed using SPSS Statistics 20.0 (IBM Corp, Armonk, NY, USA) and measurement data were evaluated using a independent-sample t-test to compare between two groups. Frequency counts and percentages were applied to describe categorical data, which were assessed using a χ^2 test. For grade data, a Mann-Whitney test was applied. Multivariable logistic regression analysis was applied to assess the odds ratio and 95% confidence intervals were used to identify the independent predictors of PN following PCD. P<0.05 was considered to indicate a statistically significant difference. The model with the identified predictors was further confirmed by bootstrapping, which was performed internally by a calibration plot with bootstrap sampling (n=200). The calibration plot of an accurate model may fall along the 45˚ line. A nomogram was performed using R software version 3.13 (http://www.r-project.org). The nomogram was validated internally in the training set and externally in the validation set. The internal validation was performed using the calibration method. The external validation was performed by calculating the area under the receiver operating characteristic (ROC) curve (AUC). The calibration plot with

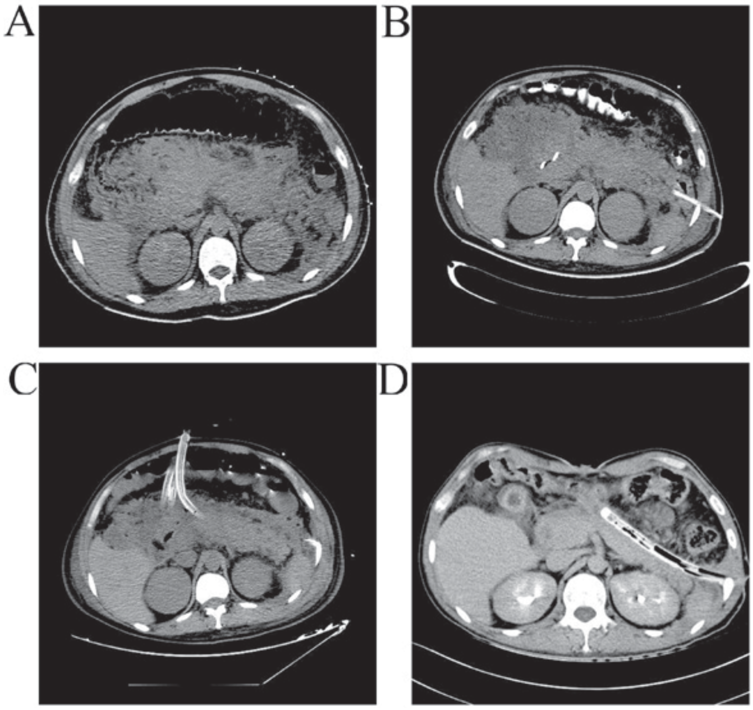

Figure 2. Representative CT of patients receiving PCD followed by PN. (A) The pancreas exhibited marked edematous and heterogeneous enhancement with indistinct margins due to a large number of acute peripancreatic fluid collection. (B) CT-guided percutaneous transperitoneal drainage was performed and a 16 Fr pigtail catheter was placed in the left lower abdomen. (C) The first minimal incision and video-assisted laparoscopic debridement. A 30-32 Fr three-cavity drainage tube was placed in the head, body and tail of the pancreas. (D) Multiple drainage and debridement resulting in a marked reduction with distinct margins of peripancreatic fluid collection. CT, computed tomography; Fr, French gauge; PCD, percutaneous catheter drainage; NP, necrotizing pancreatitis.

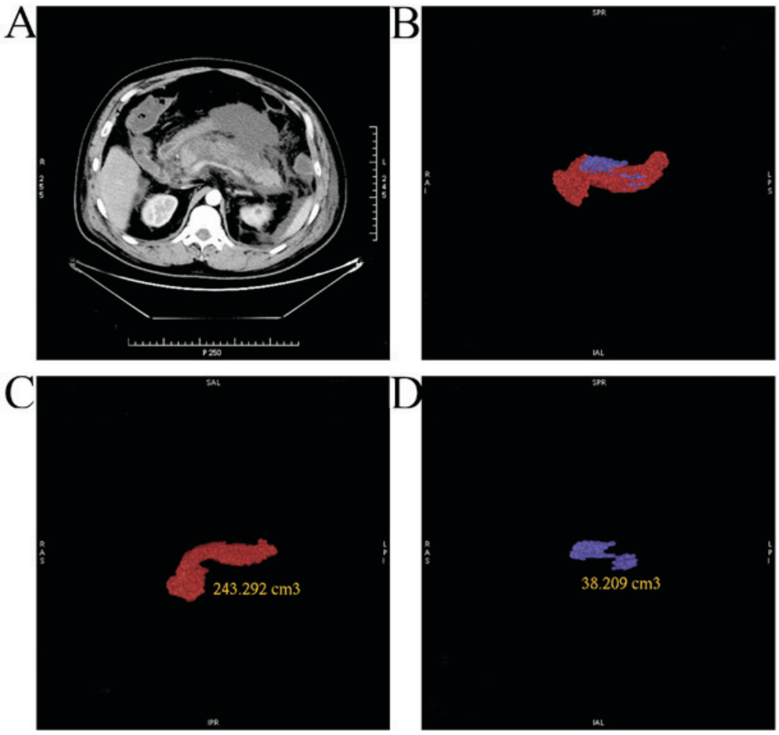

Figure 3. Peripancreatic fluid collection and extent of peripancreatic necrosis were obtained from computed tomography scanning with GE ADW4.5 workstation. (A) Axial imaging of arterial phase. (B) The entire pancreas is presented. (C) nonecrotic tissues of the pancreas were colored red, (D) necrotic tissues of pancreas were colored blue.

bootstrapping was used to illustrate the association between the actual probability and predicted probability. The AUC ranged from 0 to 1, with 1 indicating prefect concordance, 0.5 indicating no better than chance, and 0 indicating discordance.

Table I. Baseline Characteristics of the patients with INP enrolled in this study.

Characteristic	PCD-alone group	PCD+ necrosectomy group	P-values
Number of patients	32	42	
Demographic data (years)			
Age	49±14.6	50±15.9	0.921
Etiology			0.755
Gallstone	13	18	
Hyperlipemia	8	14	
Alcohol abuse	7	6	
Other	4	4	
Indexes of medical economics (days)			
Referral following INP onset	12±3.8	11±3.4	0.820
Days in hospital	42.8±16.15	69.6±23.88	0.014[a]
Days in intensive care unit	12.4±6.56	22.7±4.12	0.019[a]

[a]P<0.05. PCD-alone group, patients treated with PCD alone; PCD+necrosectomy group, patients treated with PCD prior to necrosectomy; INP, infected necrotizing pancreatitis; PCD, percutaneous catheter drainage.

Table II. Technical details of PCD and outcomes.

Variable	PCD-alone group	PCD+ necrosectomy group	P-values
Number of patients	32	42	
Onset to PCD (days)	28.1±6.11	32.0±7.19	0.384
Number of PCD catheters	1.5±0.77	1.5±0.63	0.948
Median (range)	2 (1-5)	2 (1-5)	
Catheter size, Fr (range)	16 (8-32)	16 (8-32)	0.980
No. of PCDs performed			0.974
1	26	34	
2-5	6	8	
Duration of drainage (days)	31.9±24.59	28.9±25.73	0.510
Median (range)	25 (3-98)	20 (1-95)	

PCD, percutaneous catheter drainage; PCD-alone group, patients in this group treated with PCD alone; PCD+ necrosectomy group, patients treated with PCD prior to necrosectomy.

Results

Clinicopathological characteristics. There were no significant differences in age, etiology or referral after INP onset between the two groups. The primary etiology of INP was gallstone disease (13 in the PCD-alone group and 18 in the PCD+necrosectomy group), followed by hyperlipemia (8 in the PCD-alone group and 14 in the PCD+necrosectomy group). The number of days spent in hospital or the intensive care unit by patients in the PCD+necrosectomy group was significantly higher than patients in the PCD-alone group (both P<0.05; Table I).

Parameters and outcomes of the PCD procedure. All 74 patients with INP underwent primary PCD under ultrasound or CT guidance and if necessary this was followed by PN. There were no significant differences in the technical details of PCD between the two groups (Table II). The mean interval between the onset of acute INP to PCD in the PCD-alone group (28 days) was slightly shorter than that of the PCD+necrosectomy group (32 days). However, this difference was not significant. The mean number of PCD catheters was 1.5 per patient (range, 1-5 per patient) in each group. The median catheter size was 16 Fr (range, 8-32 Fr) in each group and the most common size of the initial PCD catheter was 16 Fr in the two groups. The median duration of drainage was relatively longer in the PCD-alone group than that in the PCD+necrosectomy group (25 vs. 20 days), although this difference was not significant. A total of 26 cases in the PCD-alone success group underwent one PCD procedure. To avoid further PN, an additional 6 cases underwent the PCD procedure 2-5 times and did not require PN. In the PCD+necrosectomy group, 8/42 cases (19%) underwent the PCD procedure 2-5 times, but still underwent PN.

Differences in parameters between the PCD-alone group and the PCD+necrosectomy group. Initial MCTSI and Modified Marshall scores were significantly higher in the PCD+necrosectomy group than in the PCD-alone group (both P<0.05; Table III). The PCD+necrosectomy group also had a significantly greater amount of maximum extent of necrosis, maximum extent of fluid collection and reduction of fluid collection following PCD compared with those in the PCD-alone group (P<0.05).

The frequency of multiple organ failure was significantly higher in the PCD+necrosectomy group than that in PCD alone group (P<0.05; Table III). Only 1 patient in the PCD-alone group succumbed to multiple organ failure. By contrast, in the PCD+necrosectomy group 3 patients suffered from multiple organ failure and 1 patient succumbed following multiple organ failure with uncontrolled sepsis (Table III).

There were significant differences in the initial serum CRP and PTC levels between the two groups (P<0.05), however, there was no significant difference in the initial WBC levels between groups (Table III).

Multivariable logistic regression analysis of the predictors of PN following PCD intervention. A total of nine parameters were used in the univariate analysis (initial MCTSI scores, initial Modified Marshall scores, maximum extent of necrosis, maximum extent of peripancreatic fluid collection, reduction of fluid collection by <50% following PCD, organ failure,

Table III. The laboratory and clinical related parameters between the two groups.

Variable	PCD-alone group	PCD+ necrosectomy group	P-values
Number of patients	32	42	
Severity score			
MCTSI	6.0±1.48	7.3±1.87	0.020[a]
Modified Marshall	3.0±1.11	3.67±0.87	0.011[a]
Maximum extent of necrosis			0.011[a]
<30%	11	4	
30-50%	9	12	
>50%	12	26	
Maximum extent of fluid collection			0.008[a]
100-300 ml	4	0	
300-500 ml	23	25	
>500 ml	5	17	
Reduction of fluid collection following PCD			0.003[a]
<50%	10	28	
>50%	22	14	
Proportion of reduction fluid collection (%)	69.5 (30-90)	35.0 (15-80)	0.001[a]
Multiple organ failure, n (%)	6 (18.7)	24 (57.1)	0.001[a]
Mortality, n (%)	1 (3.1%)	4 (9.5%)	0.277
Laboratory parameters, initial			
CPR (mg/l)	63.0±13.47	67.9±17.98	0.048[a]
PTC (ng/ml)	1.43±0.58	1.72±0.51	0.027[a]
WBC (x10^9)	16.4±7.48	13.9±5.67	0.103

[a]P<0.05. PCD-alone group, patients in this group treated with PCD alone; PCD+necrosectomy group, patients treated with PCD prior to necrosectomy; PCD, percutaneous catheter drainage; INP, infected necrotizing pancreatitis; MCTSI, Modified computerized tomography severity index; CPR, C-reactive protein; PTC, procalcitonin; WBC, white blood Cell.

initial serum CRP level, PTC level and WBC count), which were assessed by multivariable logistic regression analysis. It was identified that the reduction of fluid collection following PCD (P=0.021), maximum extent of peripancreatic necrosis (P=0.019) and multiple organ failure (P=0.017) were predictors of PN following PCD (Table IV).

In addition, the number of patients experiencing a reduction of fluid collection following PCD in the PCD+necrosectomy group (14/42) was significantly lower (P<0.05) than that of the PCD-alone group (22/32). More patients in the PCD+necrosectomy group (26/42) had peripancreatic tissue necrosis of >50% compared with those in the PCD-alone group (12/32; P<0.05). Furthermore, significantly more patients in the PCD+necrosectomy group (24/42) had multiple organ failure than those in the PCD-alone group (6/32; P<0.05; Table III).

Table IV. Predictors of PN following PCD.

Variable	95% CI (lower OR-upper OR)	P-values
Reduction of fluid collection after PCD	0.269 (0.088-0.818)	0.021[a]
Maximum extent of necrosis	2.397 (1.158-4.962)	0.019[a]
Multiple organ failure	4.256 (1.295-13.985)	0.017[a]

[a]P<0.05. OR, odds ratio; PCD, percutaneous catheter drainage; PN, pancreatic necrosetomy; CI, confidence interval; Odds ratio values are presented as the OR (lower-upper).

Final prediction model. The results of the bootstrap analysis of 200 resamples (Fig. 4) indicated that final multivariable analysis confirmed three predictors of PN following PCD as a primary treatment of patients with INP: Reduction of fluid collection following PCD, maximum extent of peripancreatic necrosis and multiple organ failure. The receiver operating characteristic curve (Fig. 5) of the ROC model had an area under of 0.827 (95% CI, 0.728-0.925). Then, the nomogram was performed. The three factors were independently associated with success of catheter drainage. A nomogram was designed (Fig. 6) to determine the association of these three factors with the success of catheter drainage. This indicated that patients with a reduction in fluid collection after PCD of <50%, a maximum extent of peripancreatic necrosis of <30% and no multiple organ failure had a ~93% chance of success of experiencing primary catheter drainage. However, unfavorable scores (≥240 points) resulted in ~7% chance of success of primary catheter drainage.

Discussion

In 1998, Freeny *et al* (17) primarily treated patients with INP using imaging-guided PCD. Over the past two decades, PCD has been applied to treat patients with uncomplicated INP and the use of PCD to treat patients with INP has been assessed (18). PCD is able to treat patients with INP and stabilize sepsis, thereby avoiding the use of PN. Van Baal *et al* (19) reviewed the outcomes of PCD in a mixed group of patients with PN. Out of all the patients assessed, 55.7% recovered following PCD alone. Baudin *et al* (20) suggested that PCD was a safe and effective method of treating acute INP, although 35.4% of patients treated in this manner required further surgery. Additionally, it was suggested that CT or ultrasound guided PCD could be used to drain fluid collection around necrotic lesions and avoid the use of surgical necrosectomy. However, Van Santvoort *et al* (10) indicated that PCD failed in 32.7%

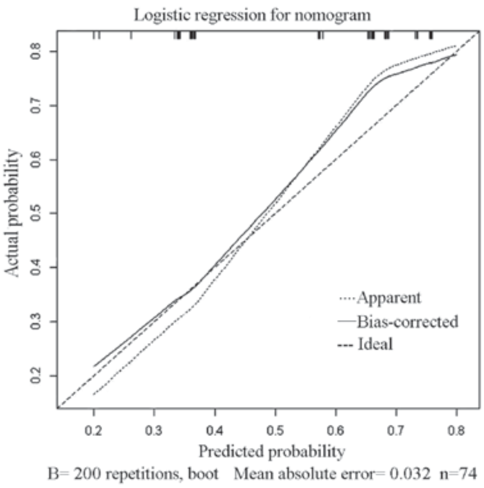

Figure 4. The model with the identified predictors was further confirmed by bootstrapping based on 200 bootstrap resamples. These predictors include a reduction of fluid collection by <50%, maximum extent of peripancreatic necrosis of >50% and multiple organ failure. Data from these predictors were applied for the calibration. The bias-corrected curve was close to the ideal curve, which indicated that the nomogram was well calibrated.

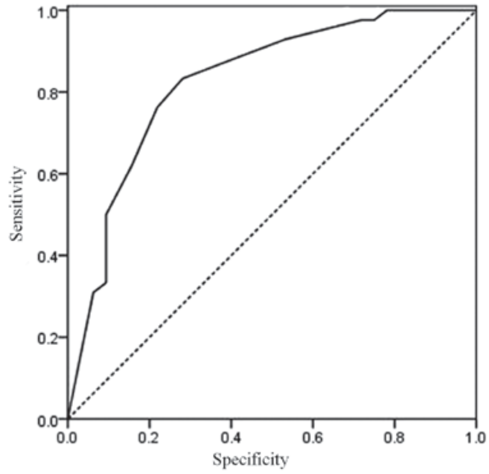

Figure 5. Receiver operating characteristic curve of the multivariable regression model of pancreatic necrosectomy following PCD as a primary treatment of patients with infected necrotizing pancreatitis. It includes predictors of reduction of fluid collection following PCD, maximum extent of peripancreatic necrosis and multiple organ failure. Area under the curve; 0.827. PCD, percutaneous catheter drainage.

(17/52) patients and that 14 of these patients subsequently required PN. This combinatorial treatment of PN following PCD significantly increased the success rate in patients with INP compared with patients undergoing open necrosectomy and consequently contributed to improved long-term patient prognosis (10).

Fluid collection may disperse following initial PCD and the reduction of fluid collection influences the success rate of PCD. Guo *et al* (12) indicated that the CT mean density of necrotic fluid collection and acute necrotic collection may influence the success rate of PCD. Patients in the PCD-alone group had a lower CT mean density of necrotic fluid collection compared with the failed PCD group (20/35 vs. 5/16, P=0.04). Following multivariate analysis of the possible predictors of surgery, only CT mean density of necrotic fluid collection (OR, 1.63; 95% CI 1.04-2.94; P=0.006) was identified as a significant factor. The potential explanation for this is that a higher CT density signifies a greater proportion of solid form in the necrotic fluid collection, leading to obstruction of the drainage tube. Therefore, in such cases, PCD will fail to reduce necrotic fluid collection. This indicates that reduction of fluid collection by PCD may influence its success rate and multiple PCD or alteration of the drainage tube could reduce the collection of fluid caused by obstruction. It was also demonstrated that 69% (22/32) of patients in the PCD-alone group achieved >50% reduction in fluid collection, which was significantly greater than those in the PCD+necrosectomy group (14/42; 33%). Therefore, patients with reduction of fluid collection of <50% following PCD have a higher chance of requiring PN than those experiencing a reduction of >50%.

Minimally invasive PN was identified as an important intervention following the failure of PCD in the step-up approach, which included retroperitoneal necrosectomy and endoscopic transgastric necrosectomy (7). Van Santvoort *et al* (10) confirmed that minimally invasive PN following PCD reduced the risk of major complications or mortality occurring in patients with INP compared with those undergoing open necrosectomy. However, there are no definitive criteria able to predict which subset of patients with INP require minimally invasive PN following initial PCD among those managed using the step-up approach. The aim of the present study was to investigate the circumstances under which PN benefits patients with INP that have undergone PCD and to identify predictors for PN.

Babu *et al* (21) conducted a prospective study investigating 70 patients with severe acute pancreatitis and suggested that a maximum extent of necrosis of >50% in the pancreas may not be a predictor of surgery in the early course of severe acute pancreatitis. However, Liu *et al* (14) indicated that the maximum extent of necrosis is an important indicator in a step-up approach, which suggests that PN should be performed. The present study also indicated that a maximum extent of peripancreatic necrosis of >50% increased the likelihood of PN. Babu *et al* (21) identified that organ failure within 1 week of disease onset was a predictor of surgery in the early course of severe acute pancreatitis. In the present study, necrosectomy was performed 4 weeks after disease onset in the majority of patients. A total of 31/74 (41.8%) patients were treated by PCD alone and one patient in the PCD-alone group succumbed to multiple organ failure. A necrosectomy was performed in 42/74 (56.8%) cases. A total of 4 patients in the PCD+necrosectomy group succumbed due to multiple organ failure and uncontrolled sepsis. Multiple organ failure is a key factor leading to mortality in patients with acute INP (3). It has been reported that the incidence of organ failure in patients with acute INP is 54% (1). Patients with no organ failure have a 0% mortality rate, those with single organ failure have a median mortality of 3% and those with multiple organ failure have a median mortality rate of 47% (1). Van Baal *et al* (19) performed a systematic literature search investigating the mortality rates of patients undergoing PCD treatment for INP and determined that the overall mortality rate was 17.4% (67/384). However, Rocha *et al* (22) suggested that the mortality rate in patients with INP and multiple organ failure treated with PCD alone

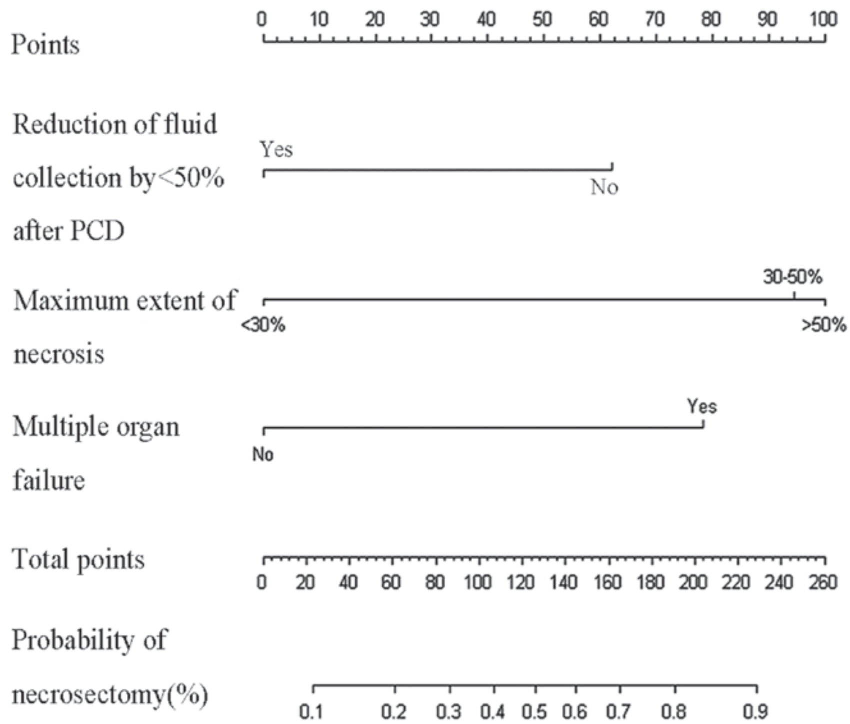

Figure 6. Nomogram for the predictors of pancreatic necrosectomy following PCD as primary treatment in patients with infected necrotizing pancreatitis. The sum of the 3 results can be found on the 'Total points' line. The line 'Probability of Necrosectomy (%)' was synchronized with the 'Total points' line, which determines the probability of pancreatic necrosectomy following PCD as primary treatment in patients with infected necrotizing pancreatitis. PCD, percutaneous catheter drainage.

was 6/11 (55%) and Mortelé *et al* (23) identified that 5/11 (45%) patients treated with PCD alone succumbed from multiple organ failure. Although PCD may successfully treat ~50% of patients with INP, it does not appear to reduce mortality rates following multiple organ failure. In the current study, multiple organ failure occurred in 4/32 (12.5%) patients who underwent PCD-alone, during which 1/4 patients (25%) succumbed. Multiple organ failure occurred in 24/42 (57.1%) patients who underwent PCD+necrosectomy, during which 4/24 patients (16.7%) succumbed. For patients experiencing multiple organ failure, the mortality rate in the PCD+necrosectomy group was significantly lower than that of the PCD-alone group. PN may therefore reduce mortality rates among patients with multiple organ failure and multiple organ failure may also be an effective predictor of necrosectomy in patients with INP.

There were a number of limitations in the current study. Although it provides the evidence for the predictors of PN following PCD, further studies with larger sample sizes are required, including a multicenter randomized controlled trial. Furthermore, the step-up approach requires unique expertise, thus the treatment received by patients may have been influenced by the variability of experience among radiologists and surgeons. This is inherent in any retrospective study and difficult to control. These novel predictors identified in the current study require further investigation if they are to be developed for clinical treatment.

In conclusion, a reduction of fluid collection by <50% following PCD, maximum extent of peripancreatic necrosis of >50% and multiple organ failure may be effective predictors of necrosectomy in patients with INP following PCD failure.

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