Predictive factors of failure and mortality after CT-Guided percutaneous drainage of infected pancreatic necrosis.

Facteurs prédictifs d'échec et de mortalité après drainage percutané de la nécrose pancréatique infectée

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RÉSUMÉ

Prérequis L'approche traditionnelle du drainage des coulées de nécrose pancéatiques infectés est la necrosectomie par voie chirurgicale. Comme altérnative à la necrosectomie par voie chirurgicale, le drainage percutané scannoguidé est actuellement considéré comme le traitement de première intention des pancréatites infectées. Cette étude a pour objectif de déterminer les facteurs prédictifs d'échec du drainage percutané (DPC) des coulées de nécrose pancréatique infectées.

Méthodes: Vingt-six patients avec une pancréatite aigue infectées ont été traités entre le 1er Juin 1988 et le 31 Octobre 2011 par un drainage percutané scannoguidé. Les critères de jugements étaient l'échec du drainage percutané et/ou le décès. Une étude descriptive a été réalisée suivie d'une étude comparative des vivants versus décédés et du groupe succès versus échec. Une analyse univariée et multivariée ont été réalisées pour déterminer les facteurs prédictifs d'échec et de mortalité après drainage percutané des pancréatites aigues infectées.

Résultats: Les taux d'échec et de mortalité étaient respectivement de 38% et 34%. Le calibre des drains inférieur à 10 French était la seule variable associée à l'échec du drainage percutané (OR=27, IC95% [2.5-284.6], p=0.006]. Le nombre de collection sur la tomodensitométrie était associé au décès (OR=2.2, IC95% [1-5.1], p=0.050).

Conclusion: Le drainage percutané avec des drains de calibres ? 10 French est un moyen éfficace pour le traitement des nécroses pancréatiques infectées. Le nombre des coulées de nécrose est un facteur indépendant de mortalité.

Mots-clés

Pancréatite aigue, infection, Nécrose, drainage percutané

SUMMARY

Background: The traditional approach to the drainage of IPN is open necrosectomy. As an alternative to open necrosectomy, percutaneous drainage is the first-line treatment of IPN.

This study is aimed to identify predictive factor of failure after CT-guided percutaneous catheter drainage (PCD) of IPN.

Methods: Between June 1st 1988 and October 31th 2011, 26 patients with IPN were treated by PCD. The outcome measures were the failure of the PCD and/or death. A descriptive analysis was performed followed by a comparative analysis of alive versus deceased patients and success group versus failure group. Univariate and multivariate analysis were performed to determine predictive factors of failure after percutaneous drainage or death.

Results: The failure and mortality rates were respectively 38% and 34%. The size of catheter inferior to 10 French was the only variable associated with the percutaneous drainage failure (OR=27, CI95% [2.5-284.6], p=0.006]. The collection number on CT scan was associated with mortality (OR=2.2, IC95% [1-5.1], p=0.050).

Conclusion: PCD with catheter size equal or greater than 10 French is efficient tool for the treatment of IPN. Collection number on CT scan is an independent predictive factor of mortality.

Key-words

Acute pancreatitis, Infection, Necrosis, Percutaneous drainage.

Acute pancreatitis is a common disease with annual incidence ranging from 5 to 80 per 100 000 inhabitants / year[1]. Twenty-five percent of acute pancreatitis are severe [2]. Severe acute pancreatitis (SAP) is associated with organ failure and / or local complications, such as necrosis, abscess or pseudo cyst [3], its death rate is around 20% [4, 5]. The major cause of death is the infection of pancreatic or peripancreatic necrotic tissue, **leading to multiple** organ failure. Infection of the pancreatic necrosis (IPN) is the most feared complication of the SAP. It appears in 24,6% of patients with SAP [4]. The IPN worsens the prognostic of patients with SAP; Eighty percent of deaths for patients with SAP are due to local septic complications [6]. IPN is an indication of drainage for patients with necrotizing pancreatitis.

The traditional approach to the drainage of IPN is open necrosectomy in order to completely remove the infected necrotic tissue. This invasive approach is associated with high rates of complications (34 to 95%) and death (11 to 39%) [7]. As an alternative to open necrosectomy, less invasive techniques, including percutaneous drainage, endoscopic (transgastric) drainage and minimally invasive retroperitoneal necrosectomy, are increasingly being used [7]. Currently, percutaneous drainage is the first-line treatment of IPN for patients with SAP [7-10].

This alternative, which consisted to treat patients with IPN by CT-guided percutaneous drainage, has been adopted in department B of general surgery since 1988.

The purpose of this retrospective study was to identify the predictive factors of percutaneous drainage failure in patients with infected pancreatic necrosis.

METHODS

Study design - selection criteria:

Between June 1st 1988 and October 31th 2011, 26 consecutive patients (**eight** men and 18 women) with IPN were treated by percutaneous catheter drainage (median age= 55 years, ranging from 27 to 80 years) at the general surgical department B of Charles Nicolle Hospital, Tunis, Tunisia. Patients who were treated for IPN exclusively by open necrosectomy, were excluded from this study. We culled variables related to clinical status, laboratory data and Ranson criteria [11]. Causes of acute pancreatitis were biliary tract disease in 13 cases (50%); idiopathic in seven (27%); post-operative in three (11%); post Endoscopic retrograde cholangiopancreatography (ERCP) in two (8%) and hypertriglyceridemia in one case (4%). All patients underwent contrast-enhanced CT 24-48 hours after admission. The CT scans were scored using the Balthazar classification [12]. The IPN was suspected on clinical criteria (persistent fever, deterioration of general health status or uncontrolled one or multiple organ failure as defined by the Atlanta classification [3, 13]); biologic criteria (hyperleukocytosis, increased C-reactive-protein [CRP] level and elevation of creatinine values) and radiologic criteria (increase of the peripancreatic collection or presence of free gas in the retro peritoneum spaces). Each patient had an initial CT-guided percutaneous needle aspiration to determine the presence of infection before drainage catheter was placed. The IPN was confirmed by fine needle aspiration, showing turbid fluid and positive culture. The percutaneous catheter drainage performed under local anesthesia upon necrosis infection was confirmed in the department of radiology. The applied drainage technique was the Seldinger method using an 8F to 14F multisidehole pigtail catheter. The route for drainage depended on the location and available trajectory for an optimal access to IPN [14]. The catheter was then secured to the skin with suture and left in situ until it stopped producing any content. All patients had parenteral antibiotics and were assessed on clinical, biological and radiological criteria until they were discharged from the hospital.

Endpoints:

Primary endpoints were percutaneous drainage failure and in hospital mortality. Percutaneous drainage failure was defined by the conversion to surgery and/or death. Patients were followed up after discharge from hospital (median follow-up= 3.5 months, ranging from 0 to186 months). Clinical examination, laboratory tests and abdominal CT scan were performed on each follow-up visit.

Statistical analysis:

Continuous variables were expressed as mean (± SD) and range values. Univariate analysis was performed with the Mann-Whitney *U* test for continuous variables and with the Fisher exact test or chi-square test for categorical variables. Logistic regression analysis was used to identify independent predictive factors of percutaneous drainage failure and death by calculation of odds ratios and its 95% CI. A $p \leq 0.05$ was considered statistically significant. Statistical analysis was performed with SPSS® software (version 17.0, Statistical Package for the Social Science).

RESULTS

Infected pancreatic or peripancreatic necrosis was detected and non-surgical management was initially attempted in 26 patients. The demographic, clinical, radiological and laboratory data of the 26 patients are shown in **table1**. The median hospital stay was 55 days (ranging from 27 to 80 days) (table 1). Patients who had percutaneous drainage success were hospitalized for an average of 71.5 ± 26.5 days. The Ranson score mean was 3.27 ± 1.34. On the initial contrast-enhanced CT, 22 patients (85%) had Balthazar score= E and four had Balthazar score=D.

Table 1: Baseline characteristics of patients

Patients, n= 26	N (%) or median (range)
Demographics	
Age*	55 (27-80)
Sex, female	18 (69%)
Days of hospitalization*	51 (10-127)
Etiology	
Biliary	13 (50%)
Post-operative	3 (11%)
Post ERCP	2 (8%)
Hypertriglyceridemia	1 (4%)
Unknown/ Idiopathic	7 (27%)
Clinical variables	
Abdominal pain	25 (96%)
Fever	12 (46%)
Vomiting	19 (73)
Occlusion	5 (19)
Jaundice	0 (0%)
Temperature (mean ± SD)*	37.8 (± 0.8)
Pulse (mean ± SD)*	94.8 (± 19.7)
SBP*	13 (9-21)
Laboratory variables	
WBC* (units/mm3)	15788 (8200-27100)
CRP* (mg/l)	123 (3-420)
Lipase* (U/l)	976 (148-4130)
Creatinine* (µmol/l)	79 (52-175)
Glycemia* (mmol/l)	10.7 (6.2-18.5)
RANSON score*(mean ± SD)	3.27 (± 1,34)
Radiological variables	
BALTHAZAR score	
D	4 (15%)
E	22 (85%)
Collection number on CT scan	3 (1-5)
Collection location	
Lesser sac	19 (73%)
Left anterior pararenal space	21 (80%)
Right anterior pararenal space	149 (34%)
Left paracolic gutter	4 (15%)
Right paracolic gutter	2 (8%)
Positive culture	26 (100%)
Percutaneous drainage procedure	
Delay*	17.1 (0-54)
Catheters number*	1.12 (1-2)
Catheters sizes	
8 French	13 (50%)
10 French	8 (30%)
12-14 French	5 (20%)
Drainage duration	24.4 (1-119)
Endpoints	
Failure	10 (38%)
Living operated patients	1 (4%)
Deceased patients	9 (34%)
Mortality	9 (34%)

The mean number of necrotic collection per patient was 3 collections (ranging from 1 to 5). The necrosis was located for 19 patients (73%) in the lesser sac. Fine needle aspiration was performed for all patients based on suspicion of pancreatic necrosis infection.

Positive results from the microbial culture were obtained in all patients. The most common isolated microorganism was Escherichia Coli in ten patients (38%), followed by Pseudomonas Aeruginosa in four patients (15%), Morganella Morgani in two patients (4%), Klebsiella Pneumoniae in two patients (8%) and Staphylococcus Aureus in one patient (4%). The culture was polymicrobial in seven patients (27%). All patients received antibiotic therapy according to the results of drug sensitivity test.

The median percutaneous catheter drainage delay after hospital admission for IPN was 17 days (ranging from 0 to 54 days). The average number of catheters per patient was one ranging from one to two catheters. Catheters had variable sizes (8 French to 14 French). Catheters were placed via the most direct trans peritoneal route, avoiding intervening bowel and solid organs. Catheters were exchanged with an average of 1.77 times per patients with a range of one to five times. The median duration of catheter drainage was 24.4 days ranging from one to 119 days. Catheters were removed after clinical improvement and when drainage was less than 10 ml per day. Before removal, contrast-enhanced CT was performed to ensure that the collection disappeared and that there was no fistulas.

Table 2 : Percutaneous drainage failure: Univariate analysis

Patients, n= 26	Success group (n=16)	Failure group (n= 10)	p
Demographics			
Age (years)	52.9 ±13.09	58.3 ± 13.6	0.452
Sex (ratio)	0.45	0.42	1.000
Clinical variables			
Fever	7	5	0.756
Vomiting	12	7	0.780
Occlusion	3	2	0.937
Temperature	37.93 ± 0.94	37.56 ± 0.53	0.452
Pulse	95.19 ±20.1	94.3 ± 20.06	1.000
SBP*	18.4 ± 6.1	12.6 ± 0.56	0.660
Circulatory failure	2	4	0.105
Pulmonary insufficiency	2	4	0.105
Renal failure	2	2	0.606
Neurologic signs	1	3	0.102
Laboratory variables			
WBC* (units/mm3)	14550 ± 5763	17770± 4939	0.077
CRP* (mg/l)	129.3 ± 40.2	108± 63.2	0.503
Glycemia (mmol/l)	9.64 ± 3.1	12.5 ± 4.1	0.077
RANSON score	3.06 ± 1.3	3.60 ± 126	0.286
Radiological variables			
BALTHAZAR score E	14	10	0.245
Collection number on CT scan	2.69 ± 1.19	3.5 ± 1.08	0.097
Collection location			
Lesser sac	11	8	0.529
Left anterior pararenal space	12	9	0.345
Right anterior pararenal space	4	5	0.192
Left paracolic gutter	2	2	0.606
Right paracolic gutter	1	1	0.727
Percutaneous drainage modalities			
Catheters number	1.13 ± 0.342	1.1 ± 0.316	0.938
8 French drain	4	9	<0.001

SBP: Systolic Blood Pressure; WBC: White Blood Cells; CRP: C-reactive Protein.

Percutaneous drainage failure was recorded for ten patients (38%). Surgery was required in eight patients for ineffectiveness of percutaneous drainage with median of 10 days (ranging from 1 to 36 days) to surgery. Univariate analysis (table 2) showed that failure was significantly associated to the use of 8 French drains (*p*< 0.001). Logistic regression identified "size of catheter inferior to 10 French" as the only variable related to percutaneous drainage failure (*OR*= 27, CI95% [2.5-284.6], *p*= 0.006) **(Table 3)**.

Table 3: Endpoints: Logistic regression.

	PCD failure			Mortality		
Collection number on CT scan	OR*	CI 95%	p	OR*	CI 95%	p
8 French drain	27	2.5-284	0.006	2.2	1-5.1	0.050

Table 4 : Mortality: Univariate analysis

Patients, n= 26	**Alive (n=17)**	**Deceased (n=9)**	**p**
Demographics			
Age (years)§	53.7 ± 13.1	57.3 ± 14.1	0.711
Sex (women)	12	6	0.837
Clinical variables			
Fever	7	5	0.484
Vomiting	13	3	0.031
Occlusion	3	2	0.778
Temperature (C°)§	37.9 ± 0.91	37.6 ± 0.56	0.426
Pulse§	94.2 ± 19.8	95.8 ± 20.6	0.597
SBP* §	18.1 ± 5.7	12.4 ± 0.63	0.916
Circulatory failure	2	4	0.060
Pulmonary insufficiency	2	4	0.060
Renal failure	2	2	0.482
Neurologic signs	1	3	0.065
Laboratory variables			
WBC* (units/mm3) §	14894 ± 5758	17477 ± 5146	0.164
CRP* (mg/l)§	129.3 ± 40.2	108.9 ± 63.2	0.503
Glycemia (mmol/l)§	9.57 ± 3.07	13 ± 4.1	0.051
RANSON score§	3 ± 1.38	3.78 ± 1.2	0.133
Radiological variables			
BALTHAZAR score E	15	9	0.284
Collection number on CT scan§	2.65 ± 1.16	3.47 ± 1	0.034
Collection location			
Lesser sac	12	7	0.694
Left anterior pararenal space	13	8	0.445
Right anterior pararenal space	4	5	0.102
Left paracolic gutter	2	2	0.482
Right paracolic gutter	1	1	0.634
Percutaneous drainage modalities			
Catheters number §	1.12 ± 0.331	1.11 ± 0.333	1.000
8 French drain	4	9	<0.001
Conversion to open surgery			
Yes	1	7	<0.001
No	16	2	

*SBP: Systolic Blood Pressure, *WBC: White blood cells, *CRP: C-reactive protein, §: expressed with means ± Standard deviation.

The mortality rate was 34%. Among the nine deceased patients, eight were operated. All deaths occurred as a result of septic shock with a median delay of 17 days ranging from two to 42 days. Univariate analysis **(table 4)** demonstrated that Vomiting (p= 0.031), hyperglycemia (p= 0.05), peripancreatic collections number (*p*= 0.034), use of 8 French drain (*p*< 0.001) and conversion to open surgery (*p*< 0.001) were the variables significantly influencing mortality. Multivariate analysis identified that the collection number on CT scan was the only variable associated to mortality (OR=2.2, CI95% [1-5.1], p=0.050) **(Table 3)**.

DISCUSSION

This study, reporting 26 patients who had percutaneous drainage, showed successful outcome in 16 patients (62%). The conversion to surgery and the mortality rates were respectively 30% and 34%. The use of small drainage size (< 10 French) was a predictive factor of percutaneous drainage failure. The collection number on CT scan was a predictive factor of mortality.

Percutaneous drainage of IPN is a well-recognized minimally invasive alternative treatment to primary open necrosectomy [7]. However, only a few surveys are available [7]. Critics mainly based their skepticism on the low level of evidence as a result of a limited number of patients sampled. The populations' studies and the percutaneous drainage procedures are heterogeneous, according to the different operators, with wide failure and mortality rates [7].

The percutaneous drainage failure rate in the study (38%) was in the range of many studies [4, 7, 15-18]. Many authors recorded lower failure rate ranged from 0 to 24% [8-10, 19-21]. Higher failure rates were reported ranging from 51 to 88% [14, 22-25]. In the only reported randomized trial, the failure rate was 65% [26].

Freeny et al [14], was the first to describe a sample of 34 patients with IPN exclusively treated by percutaneous drainage. They noted a clinical success rate of 47% and identified two variables: multiorgan failure and central necrosis on CT (necrosis of the body and Wirsung canal disruption) predictive of failure. Lee et al [30] mentioned that necrosis in pancreas body was predictive of percutaneous drainage failure. Baudin et al [17] identified high Ranson score > 4.3 and early drainage (< 18 days) as correlated to percutaneous drainage failure. No significant correlation between drainage catheter size and patients outcomes was found in Breunnler's study [22].

Overall the mortality rate in the study (32%) is higher than reported mortality in the literature [7-10, 14-16, 19, 20, 24, 26-28, 32, 33]. This difference is probably caused by the overall severity of disease in our population and the exclusive presence of IPN. Similar results were reported in several studies [4, 17, 22, 23, 30].

Collection number on CT scan was predictive of mortality

for patients treated with percutaneous drainage in the study. No authors had identified the collection number on CT scan as a predictive factor of mortality. In addition to renal failure, Breunnler [22], Rocha [23] and Mortele [24] had found a significant correlation between circulatory failure/pulmonary insufficiency and mortality. Ranson score> 4.3 and early drainage (< 18 days) was identified by Baudin et al [17] as predictive factors of mortality for patients treated with percutaneous drainage for IPN.

There are some limitations to the study. It was a retrospective study without control group and with series of patients who were treated over a long period of time. Percutaneous drainage should be considered in the treatment of patients with IPN and we need prospective clinical trial to evaluate exactly the impact of percutaneous drainage. However, this type of study is not always feasible because large groups are necessary.

Currently, many authors [8, 25, 26, 32] advocate the use of percutaneous drainage for IPN as part of a step-up approach for minimally invasive necrosectomy.

This technique has become increasingly used over the last decade [7]. Studies reporting on step-up approach [2, 25, 26, 32] suggested that this technique was safer with a mortality rate ranging from 2 to 9% and failure rate ranging from 12 to 40%. As concern the randomized controlled trial, comparing the “step-up approach” to open necrosectomy [26], we calculated the number needed to treat (NNT) which was 3.4 (CI95% [2-11]). These data encourage us, in the future, to include percutaneous drainage in a step-up approach strategy to decrease the mortality and the failure rates.

CONCLUSION

Percutaneous drainage with catheter size equal or greater than 10 French has proved to be an efficient tool for treatment of infected pancreatic necrosis. Collection number on CT scan is an independent predictive factor of mortality.

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