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ORIGINAL ARTICLE

Safety and efficacy of early image-guided percutaneous interventions in acute severe necrotizing pancreatitis: A single-center retrospective study

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Abstract

Background Acute necrotizing pancreatitis is managed conservatively in early phase of the disease. Even minimally invasive procedure is preferred after 21 days of onset and there is a paucity of data on decision and outcomes of early radiological interventions. This study aimed to evaluate efficacy and safety of early image-guided percutaneous interventions in management of acute severe necrotizing pancreatitis.

Methods A single-center retrospective study was performed after obtaining Institutional review board approval for analyzing hospital records of patients with acute necrotizing pancreatitis from January 2012 to July 2017. Seventy-eight consecutive patients with necrotizing pancreatitis and acute necrotic collections (ANC) were managed with percutaneous catheter drainage (PCD) and catheter-directed necrosectomy, in early phase of the disease (< 21 days). Clinical data and laboratory parameters of the included patients were evaluated until discharge from hospital, or mortality.

Results Overall survival rate was 73.1%. Forty-two (53.8%) patients survived with PCD alone, while the remaining 15 (19.2%) survivors needed additional necrosectomy. The timing of intervention from the start of the hospitalization to drainage was 14.3 ± 2.4 days. Significant risk factors for mortality were the presence of organ system failure, need for mechanical ventilation, renal replacement therapy, and the acute physiology and chronic health evaluation II (APACHE II) score. An APACHE II score cutoff value of 15 was a significant discriminant for predicting survival with catheter-directed necrosectomy.

Conclusion An early PCD of ANC in clinically deteriorating patients with acute necrotizing pancreatitis, along with aggressive catheter-directed necrosectomy can avoid surgical interventions, and improve outcome in a significant proportion of patients with acute necrotizing pancreatitis.

Keywords Necrosectomy · Pancreatitis · Percutaneous drainage

Introduction

Acute necrotizing pancreatitis is a fulminant stage of pancreatitis characterized by parenchymal necrosis, peripancreatic collections, and organ system failure and is a catastrophic disease with high morbidity and mortality. Systemic inflammatory response syndrome (SIRS), and acute peripancreatic collections in early phase, and secondary infection of the necrosis in the later phase of the disease, remain the predominant risk factor for multi-organ dysfunction and death with 8% to 39% mortality rate [1, 2].

Surgical debridement has been the mainstay of treatment for infected pancreatic necrosis [3–5], but has been associated with very high morbidity and significant mortality [6–9]. Hence, conservative/minimally invasive management is

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Bullet points of the study highlights

What is already known?

- Acute necrotizing pancreatitis is associated with extremely high mortality and morbidity with prolonged hospital stay.
- A few retrospective and prospective studies have shown the beneficial effect of percutaneous drainage of pancreatic necrosis with improved patient survival as compared to surgical necrosectomy.
- Only one study has attempted to evaluate the efficacy of early percutaneous drainage (<21days) and in that study the earliest attempt to drain was at 14 days.

What is new in this study?

- This is perhaps the first study in which early (as early as day 8) percutaneous drainage for pancreatic collections (both infected and non-infected) has been evaluated.

What are the future clinical and research implications of the study findings?

- The findings of this study suggest that the subset of patients with acute necrotizing pancreatitis (APACHE II <15) can be managed solely with percutaneous drainage without the need for surgical necrosectomy.
- It opens a new paradigm in research and suggests the need for more prospective cohort studies on larger number of patients with long-term follow up to know the exact efficacy of such an intervention and its head to head comparison with surgical necrosectomy.

favored over open surgical debridement. Minimally invasive strategies are being adopted and developed like percutaneous catheter drainage (PCD), or retroperitoneal pancreatic necrosectomy (MIRP), either alone or in a "step-up" fashion to manage infected necrotizing pancreatitis [10–12].

However, the patient selection criterion and outcome predictors for percutaneous minimally invasive catheter-directed necrosectomy are still undefined. It is unclear whether intervention in sterile peripancreatic collections with an aim of abrogating inflammatory cytokines like tumor necrosis factor-α (TNF-α) would be of benefit in sick patients [13–15]. In addition, the timing of PCD is also controversial, with a few studies advocating an early intervention at less than 21 days [13] while others advocating a later intervention [12].

The purpose of this study is to report the safety and efficacy of early (< 21 days) image-guided percutaneous interventions in acute severe necrotizing pancreatitis (computed tomography severity index, [CTSI 8-10] in patients showing clinical deterioration, despite optimal medical management.

Methods

Patient recruitment and review of data

In this single-center retrospective study, radiological, surgical, and medical data of all patients with acute necrotizing pancreatitis treated with PCD between January 2012 and July 2017 was evaluated. The diagnostic criteria for acute severe necrotizing pancreatitis were presence of pancreatic parenchymal necrosis and concomitant organ system failure.

Organ failures were classified according to Atlanta criteria [16] as follows: shock, systolic blood pressure < 90 mmHg; respiratory failure, PaO_2 < 60 mmHg; renal failure, serum creatinine > 177 μmol/L or > 2 mg/dL after rehydration; gastrointestinal (GI) bleeding, > 500 mL in 24 h; disseminated intravascular coagulation, platelets < 100,000/mm3, fibrinogen < 1·0 g/L, and fibrin-split products > 80 μg/L; severe metabolic disturbances, calcium < 1.87 mmol/L or < 7.5 mg/dL; and central nervous system failure (Glasgow coma score < 13).

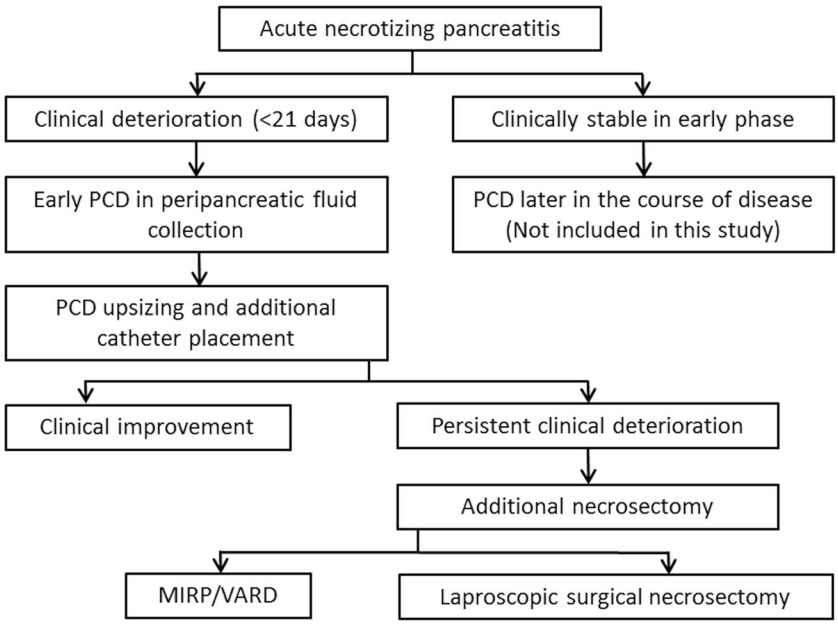

Fig. 1 Algorithm showing patient selection criteria for early drainage in this study. *MIRP* minimally invasive retroperitoneal pancreatic necrosectomy, *PCD* percutaneous catheter drainage, *VARD* video-assisted retroperitoneal debridement

Inclusion criteria

All consecutive patients with severe necrotizing pancreatitis (CTSI 8-10) treated with PCD at an early stage (< 21 days from onset of symptoms) of the disease with < 3 organ system failures were included in this study.

Exclusion criteria

Patient with pancreatitis caused by abdominal surgery, acute exacerbation of underlying chronic pancreatitis, previous exploratory laparotomy, and other co-existing major complications of acute pancreatitis, including perforation of a visceral organ, or intra-abdominal or GI tract bleeding, and those requiring drainage after 21 days of onset were excluded from the study.

Data on patient demographic details and clinical data, including APACHE II score, presence or absence of SIRS, and organ failure(s), etiology of pancreatitis, laboratory parameters, computed tomography severity index (CTSI) score, treatment modalities including medical and any surgical procedures carried out, length of hospital stay, admission to intensive care unit, were collected.

Details of PCD treatment which were collected included number and size of drainage catheters in each patient, number of catheter exchanges, timing of catheter placement, and the duration of catheter drainage.

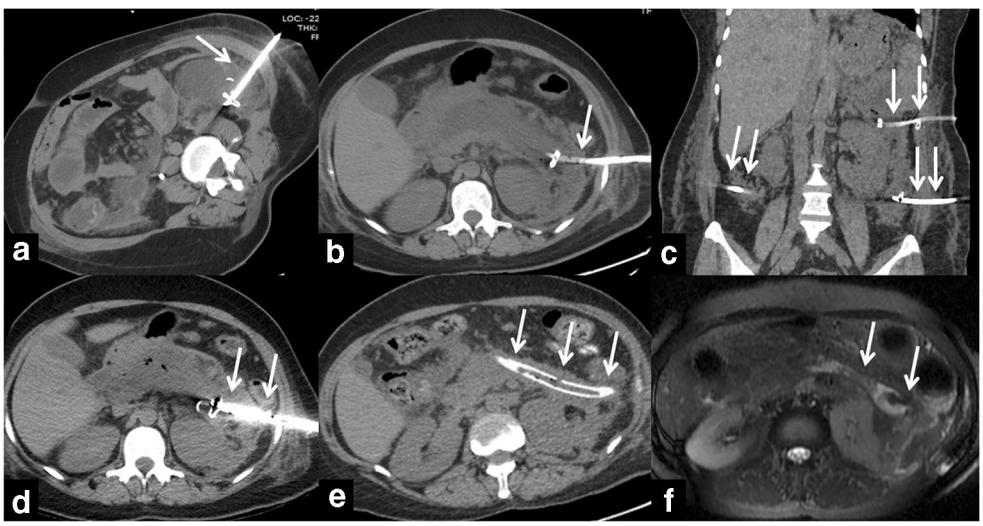

Fig. 2 Serial computerized tomography/magnetic resonance (CT/MR) images of a patient at varying stages: **a** showing 1st catheter placed in left lower quadrant collection on day 16 of pancreatitis. **b** Shows 2nd catheter placed on day 21, **c** shows 3rd catheter placed on day 28, and **d**, **e** shows serial upsizing of drainage catheter up to 28-French caliber at 5th and 6th week. Final MR image after removal of all the catheters, **f** shows resolution of necrotic debris and collection in peripancreatic region

Our protocol was to drain all the accessible intra-abdominal collections in patients showing clinical deterioration, despite optimal medical management. Acute necrotizing collection (ANC) was defined as any pancreatic/peripancreatic fluid collection developing in a patient with necrotizing pancreatitis. ANC of more than 4-week duration is termed as walled-off necrosis (WON).The drainage algorithm is illustrated in Fig. 1. Drain output was measured twice daily, and catheter malfunction was defined as decline in drain output < 10 mL for 24 h with documented residual intra-abdominal collection. Catheter malfunction was managed by catheter exchanges and upsizing.

For patients with unresolved sepsis and residual solid tissue within the collections after PCD, active necrosectomy was performed with MIRP. Once there was reduction in the drain output, imaging was done to look for residual collection. The catheter was removed if there was no collection seen. Patients with duct disruption and continuous output were treated with endoscopic retrograde cholangiopancreatography (ERCP)-guided pancreatic duct stenting or pancreatic resection.

Drainage procedure

Percutaneous drains were placed in all the patients having drainable collections, who had medically uncontrolled multiorgan failure (< 3 organ system failures), and persistent fever with elevated white blood cell (WBC) counts and/or raised C-reactive protein (CRP) levels. Drainable fluid collection in a clinically deteriorating patient was drained as early as day 8 since symptom onset.

Initial PCD was performed with ultrasound (US) or computed tomography (CT) guidance (Fig. 2a), using either local or general anesthesia. The most direct retroperitoneal/transperitoneal route was used, avoiding intervening bowel and solid organs (Fig. 2b). One or more Malecot catheter of size 12- to 16-French caliber was used as initial drainage tubes (Fig. 2c). These catheters were upsized under fluoroscopy guidance, as indicated, to facilitate necrosis evacuation or following catheter malfunction (Fig. 2d, e).

"Catheter-directed necrosectomy" was performed in patients showing clinical improvement after initial drainage in the form of reversal of organ failure, but with residual necrotic intra-abdominal collections [17]. In this technique, two or more large bore catheters (28 F or 30 F) were placed in a single necrotic cavity and vigorous saline flushing was performed twice daily. CT or US was performed after 72 h, to ascertain the amount of residual collection and guide further management.

Complications—PCD-related complications were recorded and classified as minor or major according to the Society of Interventional Radiology (SIR) classification [18].

Outcome assessment

Technical success—Technical success was defined as optimal placement of one or more drainage catheters into the target necrotic cavities, with confirmation by means of aspiration of cavity fluid and position check on CT scan.

Clinical success—Clinical success was defined as stabilization and reversal of organ system failure with reduction in inotrope requirement following minimally invasive percutaneous interventions (PCD only), resolution of the necrotic cavities on imaging (Fig. 2f), and no requirement for surgical necrosectomy (Fig. 2f). No quantifiable improvement in patients clinical and laboratory parameters, or new onset organ failure within 72 h of PCD insertion was considered as failure of percutaneous drainage procedure, needing prompt surgical intervention.

Microbiological analysis

Routine aerobic, anaerobic, and fungal cultures were performed on the aspirated necrotic material. No microbial growth over a period of 72 h was considered as "sterile necrosum."

Mortality—The occurrence of a death was recorded to allow an analysis of the factor influencing the overall and early mortality rates.

Statistical analysis

The continuous data were presented as mean ± standard deviation (SD) and in median (range). The statistical techniques applied were Student's *t* test/Mann-Whitney U test as required in case of continuous data. The association for categorical data was seen using Chi-square test or Fisher's exact test as appropriate. To find out the odds ratio and 95% CI of the predictors, univariate and multivariate logistic regression were applied. Statistical analysis was done using the SPSS 22.0 software package (SPSS for windows, version 22.0. Chicago: SPSS Inc.). A p-value ≤ 0.05 was considered statistically significant.

Results

Out of 452 patients admitted with acute pancreatitis, 126 (27.8%) had necrotizing pancreatitis. Of them, 78 (17.2%) patients were managed by PCD in the early phase of disease (< 21 days). Of the remaining 48 (10.6%) patients, 41 (9.1%) had non drainable collections and were managed conservatively. The remaining 7 patients took discharge against medical advice.

The mean age of patients with necrotizing pancreatitis was 40.9 ± 13 years (range, 12–70 years), and 57 were males. The most common cause of pancreatitis was alcohol (51.3%) and

Table 1 Demographic and clinical characteristics of the patients with acute pancreatitis included in this study and the parameters of catheter drainage in them

Age	40.9 ± 13 years (range, 12–70 years)
Sex	Male, 57; female, 21
Grade of necrosis	> 30%, 61 (78.3%); < 30%, 17 (21.8%)
Number of collections drained	2 (range, 1–4)
Diameter of drainage tubes	21.9 ± 5.7 Fr (range, 12–32 Fr)
Timing of intervention	14.3 ± 2.4 days (range, 8–18 days; median, 14 days)
APACHE II score	Survivors, 15.2 ± 6.5; non-survivors, 24.4 ± 4.9 ($p < 0.001$)
Presence of SIRS	74 (95%) patients
Organ failure(s)	45 (57.7%) patients
Computed tomography severity index (CTSI)	Survivors, 8.7 ± 1.3; non-survivors, 9.3 ± 1.0; ($p = 0.052$)
Duration of catheter drainage	Mean, 63 days; range, 13–143 days
Catheter exchanges	Mean, 3.5/patient; range, 1–8 catheter changes/patient
Culture of necrosum	Infected, 52 (66.7); sterile, 26 (33.3%)
Duration of hospital stay	48.1 ± 29.4 days (range, 6–118 days)
ICU stay	22.43 ± 15.8 days (range, 2–68 days)
Hospital re-admission rates	1.86 ± 0.6 (range, 1–10)

APACHE acute physiology and chronic health evaluation, *SIRS* systemic inflammatory response syndrome, *ICU* intensive care unit

cholelithiasis (41%). Patients' demographics and clinical features are illustrated in Table 1.

Technical and clinical success

Technical success (optimal catheter placement) was achieved in 100% of patients (78/78).

Overall survival was 73.1% (57 of 78). Of 78 patients requiring interventional management of necrotizing pancreatitis, 42 (53.8%) survived with PCD and catheter-directed necrosectomy alone, 11 survivors required MIRP in addition to the PCD. Four survivors underwent laparotomy, secondary to enterocutaneous fistula ($n = 3$) and colonic perforation ($n = 1$).

Clinical success rate was 76.3% (42 of 55) and 23 (29.5%) of 78 patients were considered clinical failures requiring surgical intervention despite PCD (Fig. 3).

Of the 55 patients managed solely with PCD and catheter-directed necrosectomy, 13 (23%) died. These non-survivors had a high mean baseline APACHE II score of 24.3 and high incidence (98%) of multi-organ system failure (MOF), as compared with the survivors who had a mean baseline APACHE II score of 15.3% and 38% incidence of MOF, ($p < 0.05$).

Of 23 patients who required necrosectomy, 8 (34.8%) died. This group of operated patients had an APACHE II score of 26.1 and high frequency of MOF (98%), which was similar to the deceased group managed with PCD alone.

Fifty-two (66.7%) patients, who underwent PCD insertion, had culture positive necrosum and the most common organisms identified were *Klebsiella* and *E. coli*.

Cultures of the drained material were sterile in 26 (33.3%) cases. Twenty (77%) of these patients with sterile necrosis survived. Fifteen were treated only with PCD, and the remaining 5 required additional MIRP. Only one patient with sterile necrosis having bowel perforation underwent laparotomy and did not survive. The non-survivors in this group with sterile necrosis had a high mean baseline APACHE II score of 27.3 and high incidence (100%) of multi-organ system failure (MOF) as compared with the survivors who had a mean baseline APACHE II score of 18.2 and 40% incidence of MOF, ($p < 0.05$).

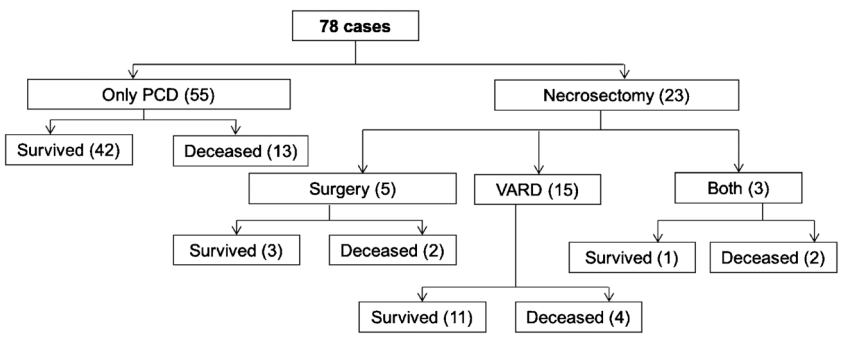

Fig. 3 Flowchart showing distribution of various procedures performed for acute necrotic collections and overall outcome. *VARD* video-assisted retroperitoneal debridement, *PCD* percutaneous catheter drainage

Table 2 Values of the continuous data for the variables evaluated in the study

Variables	Successful management by PCD + MIRP/surgical necrosectomy ($n = 57$)—overall survival	Succumbed to the disease ($n = 21$)	p value	Mean difference	95% CI of the difference
Age	39.61 ± 13.22 years	43.3 ± 12.37 years	0.27	3.672	− 2.94–10.28
CTSI	8.70 ± 1.34	9.33 ± .97	0.051	.632	− .004–1.27
APACHE II	15.18 ± 6.48	24.43 ± 4.96	0.001	9.253	6.15–12.36
Timing of PCD	19.75 ± 4.85 days	24.43 ± 4.97 days	0.0003	4.68	2.198–7.162
Maximum drain size	21.9 ± 6.5 French	21.9 ± 7.69 French	0.99	.010	− 3.21–3.23
Duration of drainage	80.86 ± 73.86 days	25.67 ± 27.39 days	0.001	− 55.193	88.21–22.17
Number of catheter exchanges	3.23 ± 1.55	3.62 ± 1.53	0.32	.391	− .39–1.18
Number of compartments drained	1.72 ± 0.75	2.05 ± 0.92	0.11	.328	− .078–.734
Duration of ICU stay	11.07 ± 9.86 days	22.43 ± 15.83 days	.001	11.358	5.39–17.32
Duration of hospital stay	48.11 ± 29.39 days	37.0 ± 29.77 days	0.14	− 11.105	− 26.10–3.89

CTSI computerized tomography scan severity index, *APACHE* acute physiology chronic health evaluation, *PCD* percutaneous catheter drainage, *ICU* intensive care unit, *MIRP* minimally invasive retroperitoneal pancreatic necrosectomy

Percutaneous catheter drainage

A total of 260 catheters were placed in 141 collections in 78 patients, averaging 3 ± 0.8 catheters per patient (range, 1–8 catheters/patient). The drain diameter ranged from 12 to 32 French. The mean time for initiation of drainage was 14.3 ± 2.4 days after onset of symptom (range, 8–18 days, median 14 days) (Table 2).

Multiple (at least 2) catheters were placed in large collections and catheter-directed necrosectomy was performed (Fig. 3). Once there was reduction in drain output of < 10 mL/day with resolution of the collection/cavity, the catheter was removed.

Clinical and laboratory data

All the patients required initial ICU care. SIRS was observed in 74 (95%), while one or more organ failure was noted in 45 (57.7%) patients. Most common organ failures were respiratory and renal, with 47 (60.2%) and 38 (48.7%) patients requiring mechanical ventilation and renal replacement therapies, respectively. The mean APACHE II score of survivors was 15.2 ± 6.5, and for the non-survivors was 24.4 ± 4.9 ($p < 0.001$). There was borderline difference in the CTSI between the survivors and non-survivors (8.7 ± 1.3 vs. 9.3 ± 1.0; $p = 0.051$). Other variables analyzed are mentioned in Tables 2 and 3.

There was a significant decline in the APACHE II score, 48 h after PCD insertion from pre-procedure score of 20.3 + 3.2 to 13.6 + 2.8 ($p < 0.001$). In addition, there was reversal in organ failure, reduction in WBC level, and decline in ventilatory support consisting of reduction in fraction of inspired oxygen (FiO_2) and positive end-expiratory pressure (PEEP) along with reduction in the requirement of noradrenaline infusion.

Significant risk factors for mortality in univariate analysis were the presence of organ system failure, need for mechanical ventilation, renal replacement therapy, and the APACHE II score (Tables 2 and 3). APACHE II score with a cutoff value of 15 for predicting survival with catheter-directed

Table 3 Various risk factors associated with success/failure of percutaneous drainage ± necrosectomy in pancreatitis

Risk factors	Successful management by PCD + MIRP/surgical necrosectomy ($n = 57$)—overall survival	Unsuccessful ($n = 21$)	p-value	Odds ratio (95% CI)
SIRS	53 (93%)	21 (100%)	0.569	1.396 (1.21–1.61)
Extent of necrosis:				
< 30%	12	5	0.766	1.172 (0.36–3.85)
> 30%	45	16		
Infected necrosis	37	15	0.588	1.351 (0.45–4.03)
Organ failure	27 (47.4%)	18 (85.7%)	0.002	0.150 (0.04–0.57)

PCD percutaneous cathteter drainage, *MIRP* minimally invasive retroperitoneal pancreatic necrosectomy, *SIRS* systemic inflammatory response syndrome, *CI* confidence interval

necrosectomy alone proved to be a statistically significant discriminant, with a sensitivity, specificity, and negative predictive value of 84%, 67%, and 71%, respectively.

Complications

Only two promptly manageable catheter-related complications were observed in the study population, being hydropneumothorax secondary to pleural puncture while draining subdiaphragmatic collections. These were managed by intercostal drain insertion and were classified as major type C complication according to SIR classification system. The drains were removed within 48 h, after near complete resolution of hydropneumothorax.

Discussion

The first study evaluating the efficacy of PCD in infected pancreatic necrosis (IPN) was published in 1998 by Freeny et al. [19] which described a clinical success rate of 47%, with multi-organ failure and central necrosis on CT as two predicting factors of poor response to catheter drainage. Since then multiple similar studies have been conducted, the most widely accepted studies being the "Step-up approach PANTER trial" [1] and a systematic review of all the studies from 1998 to 2010 [11]. These studies quoted clinical success rates of 35% (PCD only) and 55.7% (PCD along with MIRP), respectively. The overall success rates in our study were 53.8%; 42 out of 78 patients (PCD with catheter-directed necrosectomy alone) and 67.9%; 53 out of 78 patients (PCD along with MIRP), with the overall survival being 73.1%, is fairly superior to the results of major studies on this topic [11–13, 19–26]. Recently, the results of "TENSION trial" [27] conducted by the Dutch Pancreatitis Study Group were published. In this trial, 98 patients were enrolled and randomly assigned to the endoscopic step-up approach ($n = 51$) or the surgical step-up approach ($n = 47$). They found that the endoscopic step-up approach was not superior to the surgical step-up approach in reducing major complications or death. However, the endoscopic approach did reduce the rate of pancreatic fistulas and hospital stay.

In this study, percutaneous drainage was performed in all clinically deteriorating patients (CTSI 8-10) with accessible collections on imaging, at a mean duration of 14.3 ± 2.4 days, from start of symptoms, irrespective of nature of the collection. Mortality rate of 26.9% in our study is significantly better than the expected mortality rate in patients with severe necrotizing pancreatitis, of 33% to 85% [28, 29]. The mean baseline APACHE II score and incidence of MOF were similar in the deceased population of both the groups (PCD with catheter-directed necrosectomy alone and PCD with surgical necrosectomy), pointing towards the possibility that the outcome of patients with PCD alone was comparable with surgery, and these results were not influenced by allocation of less sick patients to drainage.

Clinical success rates of 71% (for IPN) and 77% (for sterile collections) demonstrate the added advantage of PCD in sterile collections. The rationale behind clinical improvement after early PCD in sterile collections may be the reduction in the source of inflammatory cytokines and vasoactive mediators.

Most of the studies published on minimally invasive interventions for pancreatitis advocate a delayed threshold for intervention of 28 days [13] in a step-up approach, and drainage for only infected pancreatic necrosis [13]. However, there is no effective treatment protocol for managing patients who continue to deteriorate in the early phase of the disease (less than 2 weeks), secondary to either SIRS or sepsis. Thus, in this study, an earlier threshold (median 14 days) for drainage was opted in clinically deteriorating patients with success rates of 53.8% (PCD with catheter-directed necrosectomy alone) and 67.9% (PCD along with MIRP).

The collections containing large amounts of non-liquefied debris were managed aggressively by "catheter-directed necrosectomy." This approach obviated the need for surgical necrosectomy in most patients.

As a last resort, surgical laparotomy was limited to only 8 patients with indications being multiple inaccessible collections (central mesentery and pancreatic head region), perforated bowel, and/or enterocutaneous fistula. An overall mortality rate of 26.9% in our study was comparable with the other major studies on this topic [11–13, 19–26] and was attributed to the overall severity of disease process and presence of multi-organ dysfunction.

The statistically significant predictors of mortality in our study were severity scores like APACHE II, presence of organ system failure, need for mechanical ventilation, and renal replacement therapies. A cutoff value of 15 for APACHE II score was obtained for predicting survival with catheter-directed necrosectomy alone.

Data regarding the size of the drainage catheter, number of collections, and catheter exchanges could not statistically predict the outcome of the disease process.

Only two promptly manageable PCD-related complications were noted during the study period while no life-threatening complications was noted.

The limitations in this study were its single-center, retrospective nature and lack of comparative group being solely managed without any type of invasive management. Bias regarding the timing of first intervention and subsequent surgical interventions could not be eliminated as these decisions were governed by the clinical experience of each team rather than by strong bibliographic evidences.

In summary, image-guided percutaneous interventions for patients with acute (< 21 days) severe necrotizing pancreatitis can avoid surgical interventions in patients with APACHE II

score of < 15 points and are associated with improved outcomes (major adverse event rate of 21.8% and overall mortality rate of approximately 30%). Patients with APACHE II scores > 15 may require additional surgical necrosectomy.

Compliance with ethical standards

Conflict of interest AM, NS, VB, AA, YP, and SKS declare that they have no conflict of interest.

Ethics statement The study was performed in amanner to conform with the Helsinki Declaration of 1975, as revised in 2000 and 2008 concerning human and animal rights, and the authors followed the policy concerning informed consent as shown on Springer.com. The study was conducted after obtaining proper ethical clearance from the institutional ethics committee.

IRB statement Approval for the study was obtained from institutional review board.

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