—Original Article—

Percutaneous catheter drainage followed by endoscopic transluminal drainage/necrosectomy for treatment of infected pancreatic necrosis in early phase of illness

Surinder Singh Rana, Rajesh Gupta[1], Mandeep Kang[2], Vishal Sharma, Ravi Sharma, Ujjwal Gorsi[2], Deepak K. Bhasin

Departments of Gastroenterology, [1]Surgery and [2]Radiodiagnosis, Post Graduate Institute of Medical Education and Research, Chandigarh, India

ABSTRACT

Background and Objectives: Infected pancreatic necrosis (IPN) in the early phase is treated with "step up approach" involving initial percutaneous catheter drainage (PCD) followed by necrosectomy. There is a paucity of data on a combined approach of initial PCD followed by endoscopic drainage and necrosectomy. A retrospectively study on safety and efficacy of initial PCD followed by endoscopic transluminal drainage and necrosectomy in IPN. **Methods:** Retrospective analysis of data of 23 patients with IPN who were treated with a combined approach. Patients were divided into two groups as follows: patients with central necrosis in whom PCD and endoscopic drainage were done in the same collection ($n = 11$) and patients with combined central and peripheral necrosis where PCD was placed in peripheral necrosis, and endoscopic drainage was done for central necrosis ($n = 12$). **Results:** Endoscopic drainage could be done successfully in all 23 patients with mean time for the resolution being 4.0 ± 0.9 weeks. Fifteen (65.2%) patients were successfully treated using multiple plastic stents while direct endoscopic necrosectomy (DEN) was needed in 8 (34.8%) patients and fully covered self-expanding metal stent was inserted in 6 (26%) patients. The number of endoscopic sessions needed were 3 in 3 (13%), 4 in 9 (39%) patients, 5 in 5 (22%), 6 in 3 (13%), and 7 in 3 (13%) patients, respectively. Patients of central walled-off pancreatic necrosis (WOPN) with PCD catheter *in situ* needed more endoscopic sessions for resolution as well as more frequently needed DEN in comparison to patients with central WOPN with no PCD catheter. **Conclusion:** The combined approach of initial PCD followed by endoscopic drainage and necrosectomy is safe and effective treatment alternative for patients with IPN.

Key words: Acute pancreatitis, gallstones, self-expanding metallic stents, transmural drainage, walled-off pancreatic necrosis

INTRODUCTION

Acute pancreatitis (AP) is an acute inflammatory disease of the pancreas which is usually mild and recovers

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Address for correspondence

Dr. Surinder Singh Rana, Department of Gastroenterology, Post Graduate Institute of Medical Education and Research, Sector 12, Chandigarh - 160 012, India. E-mail: drsurinderrana@gmail.com

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without any sequelae in the majority of patients.[1,2] However, in 15%–20% of patients the disease has a complicated, severe and protracted course that is characterized by pancreatic/peri-pancreatic necrosis, organ failure, local complications, prolonged hospital stay, and higher morbidity as well as mortality.[1-3] The development of pancreatic necrosis is a sinister event in the natural history of AP as its occurrence increases the morbidity and mortality. In two-thirds of patients with necrotizing pancreatitis, the pancreatic necrosis remains sterile, and no intervention is usually needed.[4,5] However, in one-third of patients, the pancreatic necrosis gets infected, and this usually occurs during the 3rd or 4th week of illness.[4,5] The development of infected pancreatic necrosis (IPN) almost doubles the mortality in necrotizing pancreatitis and requires intervention that usually involves removal of infected necrotic material.

Conventionally, patients with IPN or patients with necrotizing pancreatitis having progressive clinical deterioration were treated surgically with complete removal of necrotic tissue. However, this invasive approach was associated with high morbidity and mortality rates.[6,7] Minimally invasive treatment options such as percutaneous catheter drainage (PCD), endoscopic transluminal drainage/necrosectomy and minimally invasive surgical necrosectomy have shown to improve the outcome of intervention in acute necrotizing pancreatitis.[4,8-10] Currently, the accepted invasive treatment for patients with necrotizing pancreatitis is the so-called "stepup" approach that involves an initial PCD followed by endoscopic or surgical or laparoscopic necrosectomy, if required.[4,11] The choice of necrosectomy procedure is determined by the clinical condition of the patient, local expertise, anatomical position/content of necrosis, and the presence or absence of wall of the collection.[4,12] To improve the results, it is usually recommended to delay the PCD or necrosectomy till the necrosis gets walled-off and more liquefied, a procedure that usually takes about 4 weeks.[3,4,13]

However, patients with IPN presenting in the 2nd or 3rd week of illness are a therapeutic challenge as the necrotic collection is not organized. In this situation, various treatment approaches like delaying intervention by giving antibiotics and supportive treatment or immediate PCD drainage followed by minimally invasive surgical necrosectomy or sinus tract necrosectomy or percutaneous endoscopic necrosectomy (PEN) have been reported.[14-16] Insertion of PCD helps in draining infected fluid and decreases pressure in the collection as well as controls sepsis and also helps in doing delayed necrosectomy. Along with these advantages, insertion of PCD could also give time for the collection to get encapsulated, and once a well-formed wall has developed, endoscopic transluminal drainage and necrosectomy could also be done for this walled-off pancreatic necrosis (WOPN). There is a paucity of data on this combined therapeutic approach of initial insertion of PCD in nonorganized IPN followed by endoscopic transluminal drainage and necrosectomy when the necrotic collection subsequently gets organized. In this study, we retrospectively analyzed the safety and efficacy of this combined approach of initial PCD in week 2–4 of illness in IPN followed by endoscopic transluminal drainage and necrosectomy.

PATIENTS AND METHODS

A retrospective analysis of database of patients with acute necrotic collections (ANC) who underwent PCD followed by endoscopic transmural drainage/necrosectomy during last 5 years was done. All enrolled patients had been earlier diagnosed with acute necrotizing pancreatitis (ANP) based on revised Atlanta classification.[3] Informed consent was obtained from all the patients before the procedure.

All patients of ANP were initially managed medically with fluid resuscitation followed by nutritional support, and the co-existing organ failures were managed according to the standard treatment guidelines. The patients with suspected infected necrotic collections were initially treated with empirical intravenous antibiotics. Patients not responding in the form of persisting fever, leukocytosis, and worsening or new-onset organ failure or patients having gas in the collection on imaging were treated with image-guided PCD insertion into the collection. Further treatment was guided by clinical response and imaging findings. The percutaneous drainage was continued in patients showing clinical response and improvement.

Patients not responding in the form of persistence or recurrence of fever, elevated white blood cell counts, worsening, or new-onset organ failure along with inadequate drainage of the collection on imaging underwent the placement of additional catheters, repositioning, replacement, and upsizing of catheters or surgical necrosectomy after an interdisciplinary

consultation with the pancreatic surgeon. Patients not responding beyond the 3rd week of illness underwent critical evaluation of the cross-sectional imaging to determine the formation of the wall around the necrotic collection. The patients with walled-off necrotic collection underwent further evaluation by EUS to confirm the formation of WOPN. These patients were further treated by endoscopic transluminal drainage and necrosectomy. The patients were divided into two groups: patients with central necrosis in whom PCD and endoscopic drainage were done in same collection and patients with combined central and peripheral necrosis where PCD was placed in peripheral necrosis, and endoscopic drainage was done in central necrosis.

The EUS examination was conducted with a linear scanning echoendoscope (EG-3870 UTK linear echoendoscope, Pentax Inc., Tokyo, Japan or UCT180 linear echoendoscope, Olympus Optical Co., Ltd., Tokyo, Japan). The optimal site for transluminal drainage was chosen under EUS and color Doppler guidance ensuring a minimal distance between WOPN and gastroduodenal lumen and avoiding intervening blood vessels. EUS-guided drainage was done as described by us previously.[16] In brief, WOPN was punctured with a 19 G needle (Echotip; Cook Endoscopy, Winston-Salem, NC, USA) and after confirming the position of the tip of the needle in the WOPN on EUS, the stylet was removed. Thereafter, WOPN content was aspirated, and material was sent for bacterial culture. Following this, a 0.035-inch guidewire was coiled into collection under EUS guidance, and access site was dilated using an ERCP cannula or 4 mm biliary balloon dilator. If it was not possible to dilate tract with noncautery methods, tract was dilated using electrocautery with wire-guided needle knife.

The tract was further dilated up to 12–15 mm with wire-guided hydrostatic balloon (CRE-balloon; Boston Scientific, Natick, MA, USA). One to three 7-Fr double-pigtail stents, between 3 and 7 cm in length, along with a 7 Fr nasocystic catheter drain (NCC) were inserted into WOPN. The NCC was flushed and aspirated with 200 mL normal saline every 4–6 h. Following successful placement of transluminal stents, PCD catheter was removed if it was present in the same collection where transluminal stents had been placed. In patients where endoscopic drainage was done in a different collection, the percutaneous drain irrigation with saline using a Y connector and frequent flushing was also performed as described by us earlier.[11]

The patients underwent a computed tomography (CT) of the abdomen 72 h after endoscopic drainage, and the NCC was removed in patients who had symptomatic improvement and >50% reduction in the size of WOPN. Patients with new-onset fever or worsening of existing symptoms with persistent WOPN on CT underwent repeat endoscopic transmural drainage under endoscopic and fluoroscopic guidance. The tract was further dilated (up to 18 mm in the stomach and up to 12 mm in duodenum) and multiple 10 Fr stents were inserted. If after second or subsequent session of drainage the WOPN persisted with persisting symptoms, a decision for additional transmural stents, fully covered self-expanding metal stent (FCSEMS) insertion, direct endoscopic necrosectomy (DEN) or surgery was taken after reviewing repeat imaging findings, consultation with patient and his/her family, and interdisciplinary consultation with pancreatic surgeons.

The flushing from PCD catheter present in the different necrotic collection was continued till the PCD was removed. The PCD was removed when the drain output was <10 mL/day of nonpurulent fluid for two consecutive days along with resolution of the collection on imaging as well as clinical recovery with no fever, pain, and adequate oral intake.

In patients with successful resolution, ERCP was done to document pancreatic duct disruption. In patients with the normal pancreatic duct, all stents were removed, whereas in patients with partial duct disruption, the transpapillary bridging stent was placed that was subsequently removed along with transmural stents after healing of disruption. In patients with the disconnected pancreatic duct, one or more transmural plastic stents were left indefinitely. In patients with disconnected pancreatic duct and FCSEMS, the metallic stent was replaced with a 7 or 10Fr double-pigtail plastic stent. Treatment success was defined as resolution of symptoms with resolution of WOPN on follow-up CT with no need for surgery.

RESULTS

During the study , 126 patients of ANP were managed with PCD catheter. Fifty-two (41.2%) of these

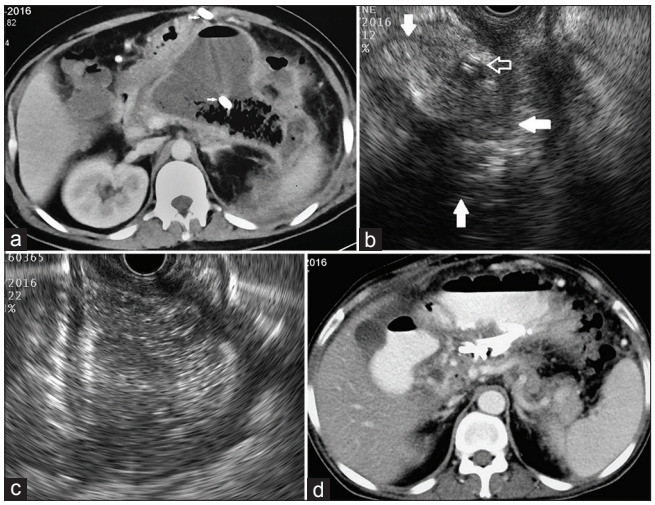

Figure 1. Patient with predominantly central necrosis with percutaneous catheter drainage catheter. (a) Computed tomography abdomen: Patient with percutaneous catheter drainage catheter in central necrotic collection (arrows). The collection has got walled off. (b) EUS shows a walled off necrotic collection with predominantly solid content (white filled arrows). The percutaneous catheter drainage catheter is seen inside the collection (open arrow). (c) Balloon dilatation of the transmural tract under EUS guidance. (d) Computed tomography shows resolution of walled off pancreatic necrosis with transmural stents *in situ*

patients were managed with PCD insertion alone. Of these, 52 patients managed with PCD alone, 3 (5.7%) patients succumbed to the illness whereas remaining 49 (94.3%) patients had a successful outcome. Forty-six patients (36.5%) patients required surgical necrosectomy following PCD and 19/46 (41.3%) of these patients died. Five patients were managed with PEN and four patients had successful outcome whereas one patient required surgical necrosectomy. Twenty-three (18.2%) patients developed WOPN and were managed endoscopically, and these patients formed the study cohort.

Demographic profile of study cohort

Twenty-three patients (21 M; mean age: 37.7 ± 8.9 years) were treated with an initial PCD followed by endoscopic transluminal drainage/necrosectomy. All patients had ANP and the underlying etiology of ANP was alcohol in 16 (69.6%), gallstones in 4 (17.4%), and idiopathic in 3 (13.0%) patients, respectively. On presentation, 16 (69.6%) patients had single organ failure (respiratory failure) whereas 2 (8.6%) patients had multiorgan failure (respiratory and renal failure). The indications for PCD insertion in these patients were as follows: persisting fever with leukocytosis (n = 16), worsening, or new onset organ failure with ANC (n = 6), and gas in the collection on CT (n = 1). One, two, and three PCD were inserted in 11, 9, and 3, patients, respectively.

Endoscopic transluminal drainage

EUS-guided transmural drainage could be done successfully in all 23 patients after a mean of 26.8 ± 8.1 days (range: 25–52 days) after the onset of an attack of ANP. The transmural drainage was done through the stomach in 21 patients and through the duodenum in 2 patients. Multiple site transluminal drainage was not done in any patient. The transluminal drainage was done in the same collection where PCD was earlier placed in 11 patients [Figure 1] and was done for a different collection in 12 patients [Figure 2]. The mean size of the collection at the time of transluminal drainage was 8.8 ± 2.8 cm. Fifteen (65.2%) patients were successfully treated using multiple 7/10 Fr plastic stents alone while DEN was needed in 8 (34.8%) patients. FCSEMS was inserted in 6 (26%) patients. Among 23 patients who underwent endoscopic drainage, the number of endoscopic sessions needed were 3 in 3 (13%), 4 in 9 (39%) patients, 5 in 5 (22%), 6 in 3 (13%), and 7 in 3 (13%) patients, respectively.

Comparison of patients undergoing endoscopic drainage of walled-off pancreatic necrosis with percutaneous catheter drainage catheter in situ versus walled-off pancreatic necrosis with no percutaneous catheter drainage catheter [Table 1]

The transluminal drainage was done in the same collection where PCD was earlier placed in 11 patients (central pancreatic necrosis) and was done for a different collection in 12 patients (peripheral pancreatic necrosis). Patients with central necrosis having PCD catheter *in situ* required endoscopic intervention earlier than patients who had PCD catheter in peripheral necrosis and no PCD catheter in the central necrosis (31.2 ± 3.5 days *vs.* 42.0 ± 7.6 days; P = 0.0004). Furthermore, patients with PCD catheter *in situ* needed more endoscopic sessions for resolution as well as more frequently needed DEN in comparison with patients of central WOPN with no PCD catheter [Table 1].

Complications and outcome

All 23 patients had a successful outcome after endoscopic transluminal drainage, and none of the patients required surgery. Two patients had self-limiting gastrointestinal bleed necessitating blood transfusion, and both these patients had undergone endoscopic drainage of WOPN that had PCD catheter *in situ*. No

other major complication of endoscopic drainage was observed.

The mean time for resolution was 4.0 ± 0.9 weeks (median 4 weeks). The mean time for resolution was significantly shorter in patients with WOPN with no PCD catheter in comparison to patients of WOPN with PCD catheter *in situ* (3.6 ± 0.5 weeks *vs.* 4.4 ± 1.0 weeks; $P = 0.017$). The PCD catheter was removed in all 11 patients who underwent endoscopic drainage of the same collection within 72 h of endoscopic drainage. In patients undergoing endoscopic drainage of a different collection, the PCD catheter was removed after 27.5 ± 15.3 days of endoscopic drainage. None of the patients developed external pancreatic fistula necessitating surgery. On ERCP, 17/23 (74%) patients had complete disruption of the main pancreatic duct, and therefore, transmural stents were left indefinitely. There has been recurrence of symptoms or collection in any of these successfully treated patients over a follow-up period of 2–60 months. During follow-up, 6 (26.3%) patients developed diabetes.

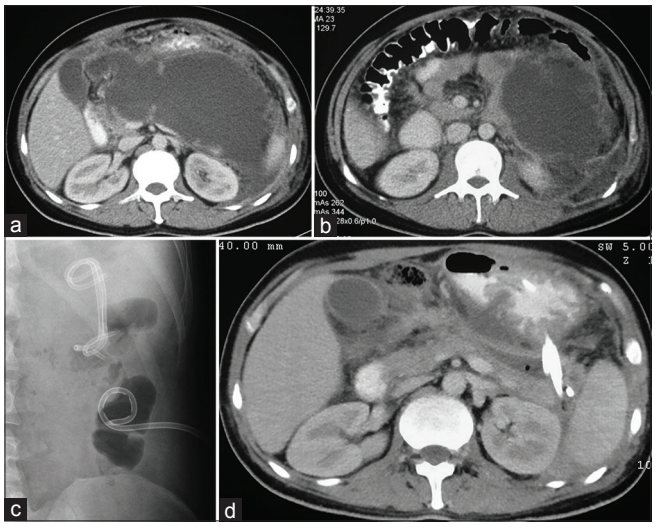

Figure 2. Patient with both central and peripheral necrosis with percutaneous catheter drainage catheter in peripheral necrosis. (a) Computed tomography abdomen: Large central necrotic collection that has not got walled off. (b) Computed tomography abdomen: A large peripheral necrotic collection. (c) AxR after percutaneous followed by endoscopic transmural drainage. Both transmural stents as well as percutaneous catheter is seen. (d) Computed tomography shows resolution of walled off pancreatic necrosis with transmural stents *in situ*. The percutaneous catheter has been removed

DISCUSSION

Patients with IPN presenting in the 2nd or 3rd week of illness are a therapeutic challenge as there are no definite treatment guidelines. Earlier, these patients were treated surgically. However, as this approach was associated with high mortality and morbidity because of difficulty in debridement of nonwalled off necrosis, it has been abandoned.[6,7] Currently, treatment approach is to delay intervention by giving antibiotics and supportive treatment or PCD so that there is the better demarcation of necrotic tissue that is walled off.[14-16] Once the collections get organized, it can be effectively treated by endoscopic, minimally invasive surgical, or percutaneous necrosectomy. In the current study, we have shown that the combined therapeutic approach of initial insertion of PCD in nonorganized IPN followed by endoscopic transluminal drainage/necrosectomy when the necrotic collection subsequently gets organized is safe and effective treatment modality in the management of patients with ANP.

The process of formation of the wall around the necrotic collection is a slow process, and there is no published study that has looked at the exact time taken for the formation of the wall around the necrotic collection. Most of the treatment guidelines on AP

Table 1. Comparison of patients undergoing drainage endoscopic drainage of walled-off pancreatic necrosis with percutaneous catheter drainage catheter *in situ versus* walled-off pancreatic necrosis with no percutaneous catheter drainage catheter

Parameter	WOPN with PCD catheter *in situ* (*n*=11)	Central WOPN with no PCD catheter (*n*=12)	*P*
Mean age (years)	39.0±7.3	42.0±7.5	0.34
Males	10	11	1.00
Etiology: Alcohol	8	8	1.00
Etiology: Gall stones	1	3	0.59
Timing of endoscopic intervention after attack of acute pancreatitis (days)	31.2±3.5	42.0±7.6	0.0004
Size of WOPN (cm)	6.5±1.2	10.9±2.3	0.00
Number of endoscopic sessions	5.4±1.3	4.1±0.8	0.01
Number of patients needing direct endoscopic necrosectomy	7	1	0.009
Time for resolution (weeks)	4.4±1.0	3.6±0.5	0.017

WOPN: Walled-off pancreatic necrosis, PCD: Percutaneous catheter drainage

suggest that it usually takes 3–4 weeks from the onset of the disease for the collection to get walled off.[3,17] We did not directly look at the process of formation of wall around the necrotic collection but critically evaluated the patients of ANC with PCD catheter not responding beyond the 3rd week of illness for the formation of wall around the necrotic collection. In these patients, we found that the wall was not formed in all patients within 4 weeks and in some patients, it took more than 4 weeks for the wall to form (range: 25–36 days).

All 23 patients included in this study had a successful outcome after endoscopic transluminal drainage, and none of the patients required surgery. Eleven of 23 patients underwent endoscopic drainage of the same collection where initially a PCD catheter was placed whereas in 12 patients' endoscopic drainage of a different collection was done. The current treatment approach for infected necrotizing pancreatitis is a "stepup" approach where initially a percutaneous drain is placed and in nonresponders, this followed by endoscopic or surgical or laparoscopic or percutaneous necrosectomy depending on the location, extent, and morphology of necrotic collections.[3,4,11] Initial drainage with PCD is used to control sepsis and delay or even avoid necrosectomy. This period provided by PCD allows the necrotic collection to become more mature, more liquefied, and organized thereby allowing easier necrosectomy/drainage.[4,13] However, placement of PCD could also lead on to drainage of liquid material leaving behind solid necrotic material that may get secondarily infected necessitating earlier necrosectomy. In our study also, patients in whom the PCD catheter was placed in the perigastric or periduodenal collection required endoscopic intervention earlier than the patients in whom the PCD catheter was placed in peripheral pancreatic necrotic collections. The patients with central necrosis having PCD catheter *in situ* required earlier endoscopic intervention because of worsening induced by undrained infected solid necrotic debris. On the other hand, patients with combined central and peripheral pancreatic necrosis and PCD catheter in peripheral necrosis required endoscopic intervention later as we could wait for the central necrosis to get organized and liquefied.

In addition, patients with PCD catheter *in situ* needed more endoscopic sessions for resolution with the more frequent requirement of DEN in comparison with patients of central WOPN with no PCD catheter. This is probably due to earlier intervention in these patients, and at this stage, the collection contains more solid necrotic debris. We have earlier shown that the morphological features of WOPN on EUS have important therapeutic implications with collections having more solid debris needing more number of endoscopic procedures as well as more aggressive intervention including DEN for a successful outcome in contrast to WOPN having <40% solid necrotic debris.[18,19]

Endoscopic treatment of WOPN involves more aggressive endoscopic drainage techniques such as larger tract dilation, placement of multiple stents, insertion of NCC along with aggressive irrigation with saline or hydrogen peroxide, use of FCSEMS/lumen apposing metal stents (LAMS), and direct debridement of necrotic tissue by endoscopic necrosectomy (DEN).[16,19,20] FCSEMS/LAMS have led on to the improvement in results of pancreatic endotherapy of WOPN as the larger diameter (10 mm or 15 mm) provided by metal stents leads on to better drainage as well as decrease the number of endoscopic procedures.[21] However, they are expensive, and few studies have shown that there is no significant difference in treatment success and adverse events between patients treated with metal *versus* plastic stents and the majority of patients can be successfully treated with plastic stents.[16,19,22]

Previous percutaneous drainage can make EUS-guided drainage of the same collection difficult because of the presence of air as well as drainage of liquid material making the leftover solid necrotic material difficult to be visualized on EUS. However, we could identify the WOPN correctly in all the 11 patients on EUS. Moreover, the percutaneous catheter could also be located inside the collection on EUS. Furthermore, we confirmed the presence of the needle in WOPN by aspirating the necrotic material. A retrospective study design with a small sample size is important limitations of our study. Furthermore, all these procedures were done at a highly specialized tertiary care center with extensive experience in pancreatic endotherapy.

CONCLUSION

The combined approach of initial PCD in week 2–4 of illness followed by endoscopic transluminal drainage/necrosectomy when the collection gets organized is a safe and effective treatment alternative for patients with IPN.

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Conflicts of interest
There are no conflicts of interest.

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