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Lavage through percutaneous catheter drains in severe acute pancreatitis: Does it help?A randomized control trial

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ABSTRACT

Aims: There is no study comparing large volume lavage through image guided percutaneously placed drains in severe acute pancreatitis.
Methods: Of the 114 randomized patients, 60 eligible candidates were randomly allocated to – Lavage Treatment (LT) group (28 patients) and Dependent Drainage (DD) group (32 patients). Primary end point was reversal of pre-existing organ failure, development of new onset organ failure, need for surgery, mortality and hospital stay.
Results: Both the groups were comparable in terms of demographic data, onset and severity of pancreatitis. LT group had higher infected pancreatic necrosis (75% vs 50%,p = 0.047). On intention to treat analysis, lavage treatment group showed a significant reversal of persistent organ failure (84% vs 50%, p = 0.23), reduction in APACHEII scores (3.5 ± 3.405 vs 1.16 ± 3.811 p = 0.012), as measured at the time of placement of PCD to cessation of intervention. There was no difference in development of new onset organ failure in the two groups (25% vs37.5% p=.290). 75% in LT group and 69% in DD group improved with PCD alone. There was no difference in the catheter related complications and number of catheters used. The need for surgical intervention was comparable in two groups (18.8% vs 14.3% p=.737). There was a trend toward decreased mortality in group A (18.8% vs 28.8% p=.370).
Conclusion: Large volume lavage trough PCD improves organ failure and this translates into trend towards reduced mortality.

Introduction

Severe acute pancreatitis (SAP) accounts for 15% of patients with pancreatitis [1–3]. Mortality associated with SAP varies from 14 to 30% [1–3]. Early mortality accounts for 33–50% deaths occurring due to organ failure [4,5], while late deaths occur usually due to infective complications [5]. Presence of infective necrosis has been known to increase the mortality rate from 12% to 30% [6].

While the treatment is conservative in the early phase, surgery is considered in the later phase of the disease [7]. In recent years, there has been a paradigm shift in the management of severe acute pancreatitis from surgical to minimally invasive management [5]. Radiological and endoscopic interventions form an integral part of step up approach in the management [8].

Image-guided drainage has been reported to obviate not only the need for subsequent surgery but also decreases the severity of illness and improves organ dysfunction in these patients [8–10]. Percutaneous Catheter Drainage (PCD) in necrotising pancreatitis is an effective treatment and obviates the need for step up intervention [5,6,8–11]. Those who require surgical intervention, PCD acts as a bridging therapy and helps to optimize the patients for several weeks [5,10,11].

Lavage through peripancreatic drains placed after laparotomy has been the standard treatment for patients undergoing surgical necrosectomy [7,12]. However, this practice has not been widely utilized in the setting of percutaneously placed drains. So, the present study was planned to determine the impact of large volume lavage through PCD in the outcome of severe and moderately severe acute pancreatitis (MSAP).

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Methods

From July 2014 to December 2015, patients diagnosed with severe and moderately severe AP as per the revised Atlanta criteria [13], were prospectively enrolled at the Postgraduate Institute of Medical Education and Research, a tertiary care centre in India. The study was approved by the Institute ethics committee. Informed consent was taken from all the patients prior to enrolment. Patients with intervention done prior to referral, acute on chronic pancreatitis and evidence of haemorrhage on CT were excluded from the study.

Management protocol

All the patients were initially managed with fluid resuscitation, organ support, pain alleviation and prophylactic antibiotics. Nutritional support via enteral route (nasogastric or nasojejunal) was instituted as soon as feasible. Oral feeding was encouraged as soon as possible and was the preferred route. All the patients were closely monitored for development of organ failure and sepsis. Imaging (ultrasound and/or CT) were performed periodically to monitor the extent of the necrosis, spread of inflammation and fluid collection. Severity assessment was performed using Modified Marshall Score, BISAP score APACHEII at the time of admission. PCD was contemplated when there were features of infected necrosis, walled of pancreatic necrosis, and pancreatic abscess formation. In the presence of sterile necrosis, PCD was undertaken in the event of worsening organ failure or the development of new organ failure or the development of systemic sepsis. APACHE II score was calculated at periodic intervals (at admission, at the time of placement of PCD and 20 days after PCD) during the hospital stay to assess the progression of disease. Modified CT Severity Index (mCTSI) was calculated once CECT was done.

Periodic evaluation of hematological, biochemical, coagulation, radiological and microbiological parameters was done. Body fluid cultures were sent periodically. Broad spectrum antibiotics were started initially and then switched to culture specific antibiotics. The patients who had been hospitalized elsewhere and were on empirical antibiotics were continued with the same. Imaging was repeated as per the clinical condition. The patients were observed closely to evaluate local regional complications of pancreatitis.

Patients were clinically observed for the reversal of persistent organ failure. New onset organ failure during the course of management was observed.

Randomization

A total of 134 patients were evaluated and 114 randomized into two groups as per the computer generated random number at the time of admission. 56 were allocated to lavage treatment (LT) group out of which 28 underwent PCD while 58 were allocated to dependent drainage (DD) group out of which 32 underwent PCD (Fig. 1). Fifty four patients were excluded after randomization as they did not meet the criteria for drainage. Clinical profile of the patients not undergoing drainage is given in the Supplementary Table 1.

Technique of PCD placement

PCD was placed under either ultrasound or CT guidance. Optimum sized percutaneous catheters were placed in the patients under strict aseptic precautions and local anesthesia using Seldinger technique. The initial PCD size was generally 10 Fr. If the catheter drainage was inadequate, placement of additional

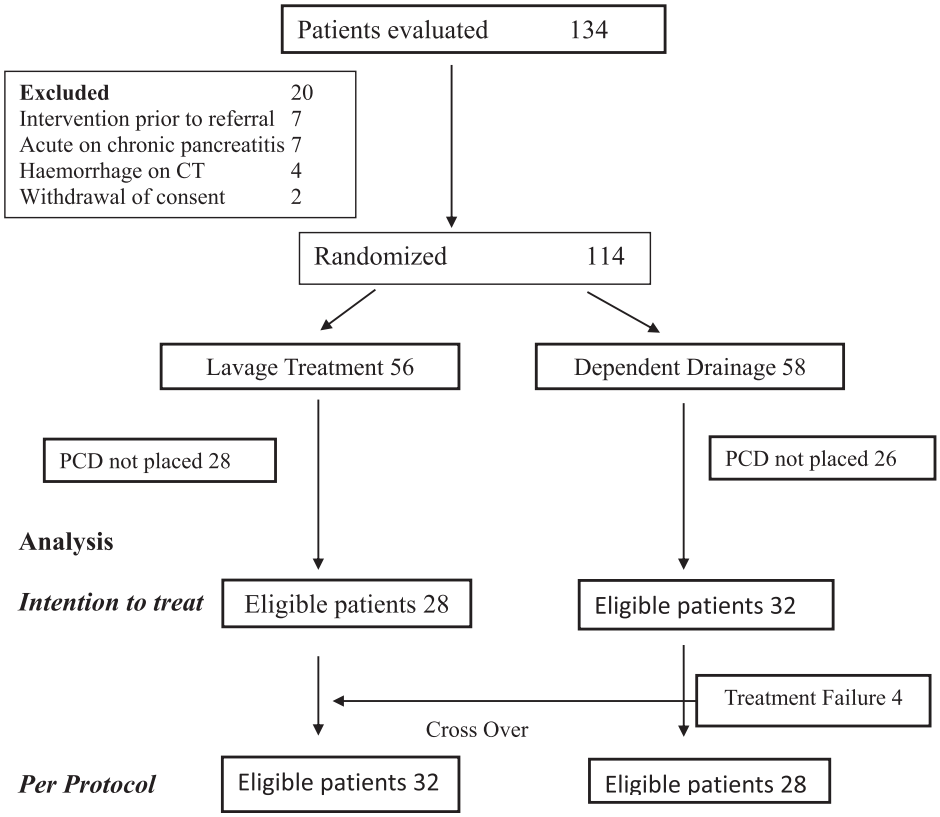

Fig. 1. Consort diagram.

catheters, repositioning, replacement, and upsizing of catheters was performed by the intervention radiologist. The number and size of the initial catheters were determined by the size and location of collections/necrosis, by the viscosity of the initially aspirated fluid, and by the amount of the aspirated particulate debris. These drains were exchanged and upgraded to a bigger size (up to 24Fr) as per the clinical need or radiological evidence suggested presence of residual or increasing collection. Additional drains were used in large collections and non communicating collections.

Dependent Drainage Group (DD): PCD was kept dependent throughout the day and daily output was recorded. Regular flushing of the catheters was done to maintain the patency.

APACHE II score was calculated at the end of 20 days of dependent drainage.

End points of dependent drainage: For improving patients, PCD was removed when there was clinical and radiological improvement with minimal volume of effluent in the drains.

For deteriorating patient, worsening clinical condition mandating surgical intervention necessitated the cessation of PCD treatment.

Lavage treatment group (LT): Large volume lavage was carried out through the PCD as per the protocol described below.

Lavage protocol

Lavage was initiated within 24 h of insertion of percutaneous catheter. Lavage was not initiated if the initial drainage was haemorrhagic or enteric in nature. Lavage was done with isotonic saline solution warmed to room temperature. Initially 250 ml of isotonic saline was given through the catheter over 1–2 h twice a day and the catheter made dependent for rest of the day. If the return of the lavage was less than 80% of instilled volume then lavage was withheld and restarted after 48 h. However in patients with lavage return $\geq$70% of the instilled volume; the lavage volume was gradually increased over a period of 3–4 days. Care was taken to give this fluid slowly. If the patient developed complains of heaviness or abdominal distention, the irrigation was stopped and titrated to a lower level. Lavage was carried out for at least 2 weeks.

APACHE II score was calculated at 20 days of PCD placement.

Lavage Volume: The target was to achieve a minimum volume of 2.5–3 L over 24 h. Higher volume of isotonic saline lavage was infused in cases of larger collections, collections extending towards the paracolic gutters and collections with necrotic material. Patients with lot of debries in the effluent also underwent high volume lavage. Large collections had additional catheters placed cavity to act as inflow and outflow for lavage.

End points of Lavage: For a deteriorating patient, lavage was stopped in the event of clinical deterioration which mandated surgical intervention or there was evidence of haemorrhage or there was development of enteric fistula. For an improving patient, clinical and radiological improvement with minimal debris in the return fluid.

Patients, in dependent drainage group, who failed to thrive without any clinical evidence of sepsis but draining purulent fluid in PCD, were managed as per the lavage protocol.

End points of the study

Primary end points were the reversal of persistent organ failure, need for surgical intervention and mortality. Secondary end points were hospital stay, ICU stay and reduction in APACHE II score after 20 days of PCD treatment.

Statistical Analysis: Data was recorded using Microsoft Office Excel 2010 and analyzed using SPSS software v17.0. For normally distributed data, continuous variables were compared using the student *t*-test. For more than two groups one way ANOVA was used. For skewed data Mann- Whitney *U* test was used. Pearson Chi [2] test and Fisher exact test were implemented for comparison of qualitative variables. A p value of <0.05 has been taken as statistically significant.

Results

Demographic Data: The mean age of the study population was 39.72 ± 14.035 (16–68) years with a sex ratio of 2:1. The mean interval between onset of symptoms and presentation to our hospital was 10.73 ± 9.579 days.

Severity Assessment: Moderately severe AP was seen in 19 (32%) and SAP in 41 (68%) patients.

At admission, the mean BISAP, APACHE II, Modified Marshall score was $2.05 \pm .699$, 10.98 ± 3.934 and 2.60 ± 1.543 respectively. The mean modified CTSI was 8.23 ± 1.691. At admission, respiratory failure was seen in 55(92%) patients –17 transient and 38 persistent. Renal failure was seen in 43 (72%) – 29 transient and 14 persistent. Cardiac failure was seen in 6 (10%) – 4 transient and 2 persistent.

Complications: Acute necrotic collection was seen in 41 (68.3%), walled of pancreatic necrosis (WOPN) in 14(23.3%) and infected pseudocyst in 5 (8.3%) patients. Infected pancreatic necrosis was observed in 37 (62%) patients.

Peripancreatic venous thrombosis was observed in 15(25%) patients. Arterial pseudoaneurysms were seen in 3 (5%) patients – one from superior pancreatic duodenal artery and two from splenic artery.

Blood stream infections were seen in 23 patients – bacterial in 12 (20%) fungal in 11 (18%) and both bacterial and fungal in 4 (7%) patients.

*PCD characteristics:*The mean interval between the onset of symptoms and PCD placement was 17.68 ± 9.043 (4–57) days. The mean size of the PCD used was 18.14 ± 3.758Fr (10-24Fr). The mean number of PCD required per patient was $1.54 \pm .703$ (1–4). One PCD was required in 34 (57%), two in 18 (30%), three in 7 (12%) and four in one (1%) patient. PCD was kept for a mean of 30.07 ± 10.52 days.

Catheter related complications were seen in 16 (27%) with catheter dislodgement occurring in 8, haemorrhage in 5 and GI fistula in 3.

Deviation from protocol

LT could not be initiated in one patient with haemorrhage and two with GI fistula.

LT related abdominal discomfort was seen in 2 and retention of fluid in 2. However, LT could be re-instituted in all albeit after a few days.

Clinical Outcome: Reversal occurred in 26 (67%) of 39 patients who had persistent organ failure. New onset organ failure after placement of PCDs developed in 19(32%) patients. A total of 43 (72%) patient improved with PCD alone.

Ten patients (16.67%) underwent surgical intervention. The mean duration of hospital stay was 33.67 ± 16.731 (7–94) days. The mean duration of ICU stay was 10.38 ± 10.757 (0–46) days. Fourteen (23.3%) patients died. Eight (13.33%) patients developed external pancreatic fistula.

Intention to treat analysis (Tables 1 and 2)

Both lavage treatment (LT) and dependent drainage (DD) groups were comparable with regards to age, sex, etiology, severity scores and organ failure. Incidence of local complications, vascular complications and blood stream infections was comparable between

the two groups. However, LT group had a higher incidence of infected pancreatic necrosis (75% vs 50%, p = 0.047). Timing of PCD insertion and PCD related complications were comparable between the groups.

Reversal of organ failure was significantly higher in patients undergoing lavage treatment (84% vs 50%, p = 0.023), however, new onset organ failure was comparable. There was no difference in the APACHE II scores between the groups measured at admission, at the time of PCD placement and two weeks of PCD treatment. However, the mean reduction of APACHE II score from admission and from the time of PCD placement to two weeks of PCD treatment was significantly higher in LT group. The number of PCDs used per patient was higher in LT group.

There was no difference in the need for surgery, hospital stay, ICU stay and mortality.

Per protocol analysis (Tables 1 and 2)

Four patients in DD group were crossed over to LT group as per the protocol described above. Out of these 4, one needed surgery, one died and the other two recovered. So the LT group had 32 and DD group had 28 patients for analysis.

Both lavage treatment (LT) and dependent drainage (DD) groups were comparable with regards to age, sex, etiology, severity scores and organ failure. Incidence of local complications and blood stream infections was comparable between the two groups. However, LT group had a higher incidence of infected pancreatic necrosis (75% vs 46%, p = 0.023) and vascular complications. Timing of PCD insertion and PCD related complications were comparable between the groups.

Reversal of organ failure was significantly higher in patients undergoing lavage treatment (82% vs 44%, p = 0.011), however, new onset organ failure was comparable. There was no difference in the APACHE II scores between the groups measured at admission, at the time of PCD placement and two weeks of PCD treatment. However, the mean reduction of APACHE II score from admission and from the time of PCD placement to two weeks of PCD treatment was significantly higher in LT group. The number of PCDs used per patient and the duration of PCD was higher in LT group.

There was no difference in the need for surgery, hospital stay and ICU stay. There was no difference in mortality.

Outcome in infected pancreatic necrosis (Table 3)

The mean reduction of APACHE II score and reversal of organ failure was significantly better in patients with lavage treatment. However, it did not translated to reduced need for surgical intervention and reduced mortality.

Discussion

The present study has shown effectiveness of large volume lavage in improving the clinical condition by reversing the organ failure. We found a lower mortality, though statistically not significant, in patients undergoing lavage treatment, despite the fact that there was a significantly higher incidence of infective necrosis in LT group. This study is first of its kind to evaluate the role of large volume lavage through percutaneously placed drains in a randomized control setting.

Ever since the first description by Freeny et al. [11], the role of PCD in the management of severe and moderately severe acute pancreatitis is established. PCD not only treats a subset of patients but also helps to postpone the surgical intervention [5,6,8–11,14]. In addition PCD helps to optimize the patient by decreasing intra-abdominal pressure and improving the organ dysfunction [15,16]. A systematic review comprising 384 patients reported a success in 214 (56%) with PCD alone. Although the most of the studies in the review were retrospective, none the less it showed that PCD could avoid surgery in considerable number of cases [17]. A randomized controlled trial showed that 35% (15 out of 43) could be successfully treated with PCD alone in the step up approach when compared to open necrosectomy [18]. A recent study from China reported only 33% success rate with PCD alone [19].

There are no guidelines regarding the optimum PCD strategy to be followed in step up approach [20]. A recent study has shown 48% success with standard PCD strategy which included a maximum of 1–2 drainage procedures without routine upsizing of drains, but an early “step-up” with minimally invasive necrosectomy. On the contrary, when proactive strategy was initiated the success rate improved to 71%. Proactive strategy included frequent and early drain revision and upsizing of drains in case of lack of clinical improvement [21]. In the present series, we reported 75% success with PCD using a lavage treatment, despite three fourth of the

Table 1
Comparison of baseline characteristics between Lavage Treatment and Dependent Drainage group on the basis of intention to treat and per protocol analysis.

Parameter	Intention To treat Analysis			Per Protocol Analysis		
Group	Lavage Treatment(N = 28)	Dependent Drainage (N = 32)	P value	Lavage Treatment (N = 32)	Dependent Drainage (N = 28)	P Value
Age (years)	37.4 ± 12.9	41.6 ± 14.8	0.25	38.4 ± 13.3	41.2 ± 14.8	0.44
Sex Ratio M:F	18:10	22:10	0.71	20:12	20:8	0.46
Interval in days (onset to admission)	10.6 ± 11.5	10.8 ± 7.6	0.37	10.4 ± 10.8	11.0 ± 8.0	0.80
Etiology			0.61			0.53
Gall stone	12	14		13	13	
Alcohol	9	12		12	9	
Other	7	6		7	6	
mCTSI	8.2 ± 1.6	8.1 ± 1.7	0.83	8.3 ± 1.6	8.1 ± 1.7	0.70
Modified Marshall Score	2.6 + 1.4	2.5 + 1.6	0.87	2.7 + 1.5	2.4 + 1.5	0.25
APACHE II at admission	11.1 ± 3.4	10.8 ± 4.3	0.52	11.4 ± 3.3	10.4 ± 4.5	0.17
Organ Failure (OF) Transient/Persistent	25/26	25/28	0.85	26/32	24/22	0.46
No pf patients with persistent OF	19 (68)	20 (62.5)	0.66	23 (72)	16 (57)	0.23
Local Complications			**0.48**			**0.44**
Ac Necrotic collection	**21**	**20**		**23**	**18**	
WOPN	**6**	**8**		**8**	**6**	
Infected Pseudocyst	**1**	**4**		**1**	**4**	
Vascular Complications	11 (39)	7 (22)	0.16	13 (41)	5 (18)	**0.055**
Blood Stream Infection	15 (54)	15 (47)	0.60	17 (53)	13 (46)	0.60
Infected pancreatic necrosis	**21 (75)**	**16 (50)**	**0.047**	**24 (75)**	**13 (46)**	**0.023**

Table 2
Comparison of Outcome Parameters between Lavage Treatment and Dependent Drainage group on the basis of Intention to Treat and Per Protocol analysis.

Parameter	Intention to treat Analysis			Per Protocol Analysis		
Group	Lavage Treatment (N = 28)	Dependent Drainage (N = 32)	P value	Lavage Treatment (N = 32)	Dependent Drainage (N = 28)	P Value
APACHE II at Admission (A)	11.1 ± 3.4	10.8 ± 4.3	0.52	11.4 ± 3.3	10.4 ± 4.5	0.17
APACHE II at PCD placement (B)	11.9 ± 3.61	11.6 ± 4.5	0.65	12.2 ± 3.5	11.2 ± 4.6	0.25
APACHE II 20 days after PCD (C)	8.4 ± 4.6	10.2 ± 6.4	0.45	8.6 ± 5.0	10.2 ± 6.3	0.42
Reduction of APACHE II (from Admn) (A-C)	2.5 ± 3.4	0.5 ± 4.04	**0.029**	2.6 ± 3.9	0.14 ± 3.4	**0.011**
Reduction of APACHE II (from PCD) (B–C)	3.5 ± 3.4	2.2 ± 3.7	**0.012**	3.6 ± 3.6	0.68 ± 3.3	**0.002**
No. of patients with Reversal of persistent OF	16/19 (84)	10/20 (50)	**0.023**	19/23 (82)	7/16 (44)	**0.011**
No of patients with New onset OF	7 (25)	12 (37.5)	0.30	9 (28)	10 (36)	0.53
Interval (Onset to PCD) (days)	18.0 ± 10.8	17.8 ± 7.3	.727	17.9 ± 10.5	16.8 ± 7.7	.630
No. of PCD used	1.71 ± 0.72	1.41 ± 0.61	**0.089**	1.75 ± 0.76	1.30 ± 0.54	**0.008**
No of days PCD kept	30.1 ± 11.8	29.9 ± 8.9	0.92	32.7 ± 11.5	27.1 ± 8.6	**.069**
No of days of lavage treatment	15.7 ± 6.2	–	–	15.8 ± 5.8	–	–
Improvement with PCD alone	21 (75)	22 (69)	0.59	24 (75)	19 (68)	0.54
PCD Complications	9 (32)	5 (16)	0.13	10 (31)	4 (14)	0.12
Surgery	5 (18)	5 (16)	0.82	6 (19)	4 (14)	0.65
Interval form onset to surgery (days)	40.2 ± 9.1	44.0 ± 11.5	**0.07**	39.0 ± 8.6	46.8 ± 11.8	**0.03**
Hospital Stay	36.9 ± 17.8	30.8 ± 15.4	0.16	39.3 ± 18.6	27.2 ± 11.5	0.16
ICU stay	10.2 ± 10.9	10.5 ± 10.7	0.91	10.5 ± 10.6	10.3 ± 10.7	0.82
Mortality	5 (18)	9 (28)	0.35	6 (19)	8 (29)	0.37
External Pancreatic fistula	**4**	**4**	**0.86**	**5**	**3**	**0.84**

Table 3
Comparison of outcomes in Infected Pancreatic necrosis Subgroup.

Parameter	Lavage (N = 24)	Drainage (N = 13)	P Value
Reduction of APACHE II (from Admn)	4.17 ± 3.79	1.31 ± 3.77	0.01
Reduction of APACHE II (from PCD)	3.21 ± 3.95	2.31 ± 3.95	0.01
Reversal of Organ Failure	17	3	.014
New Onset Organ Failure	8	3	0.51
Need for Surgery	5	4	0.54
Hospital Stay	44.25 ± 18.47	33.77 ± 11.95	0.74
ICU stay	14.75 ± 12.2016	15.38 ± 7.355	0.86
Mortality	5	8	0.16

patients having infected necrosis.

Regular flushing the PCD with saline to prevent it from clogging has been the universal practice [5,9–11,17–21]. Other strategies after PCD placement have been described in the step up approach [22–24]. Some authors advocate upsizing the PCD on demand, while others upsize it routinely [21]. In a recent survey of international pancreatologists, two thirds were in agreement regarding the utility of upsizing of the PCD [25]. In the present study we also followed the strategy to upsize the PCD to up to 24F. Tong et al. [23] have described the use of negative pressure irrigation through PCD as a step up procedure. Another report has suggested instillation of streptokinase through PCD to lyse the necrosum [24]. Liu et al. [26] have described the use of abdominal paracentesis in conjunction with PCD to improve the outcome. A recent meta analysis has shown the role of abdominal paracentesis in reducing the mortality in patients who had ascites secondary to pancreatitis [27]. Most of the studies have used small volume irrigation through the PCD just to maintain its patency. In the present study we have shown the advantage of large volume lavage when compared to dependent drainage in terms of cure without surgical intervention.

There is no consensus regarding the number of PCDs to be used to establish adequate drainage [25]. However, the aim is to drain all the collections. Many reports have described the use of multiple large size catheters and as many as seven PCD have been used in some series [17,18]. In the present study we used a maximum of 4 catheters to establish drainage. However, the mean number of PCD used in LT group was higher probably to establish appropriate drainage of lavage fluid and a higher incidence of infected necrosis in that group.

The timing of PCD in the present study was around day 18 from the onset of pain in both the groups. Others have reported as early as 9 days [11] while some have reported as late as 30 days [18]. Many have reported the timing of PCD to be towards the end of third week, coinciding with the timing of onset of infective complications. PCD was kept for a longer duration in LT group probably because of higher IPN and a better response rate in that group.

The use of continuous closed lesser sac lavage after an open necrosectomy is a well described technique to clear the residual necrosum and debris has been well described previously [5,7,18]. Others have described a variety of minimally invasive techniques to establish the same [18,19,21–23,26]. The present study is novel in this aspect of describing the large volume lavage as a part of step up approach. We observed clinical improvement by lavage treatment in three of the four patients in whom dependent drainage strategy failed. These patients otherwise would have been subjected to surgical necrosectomy. Failure of PCD treatment has been shown to increase mortality in MSAP and SAP [26].

The response assessment to PCD has been assessed in terms of subjective evaluation of improvement in sepsis and reversal of organ failure or the development of new onset organ failure [10,11,13,14]. There has been no objectivity to these parameters in past at a particular discrete point of time of treatment with PCD. In the present study we observed the higher reversal of organ failure by the use of LT, with similar incidence of new onset organ failure. We have used objective criteria of decrease in the APACHE II score from admission and from PCD placement to 20 days of PCD treatment. Time period of 20 days was taken arbitrarily as initial 6 days were required to titrate the lavage volume and manage lavage

related problems and subsequently two weeks of lavage treatment was given before the assessment of any clinical benefit.

In conclusion, large volume lavage through a PCD does not cause any discomfort or increase complications. It significantly improves the organ failure associated with acute pancreatitis. This strategy does lead to a trend towards decrease in mortality. We propose to introduce lavage treatment through PCD as a part of proactive strategy in the step up approach.

Financial disclosure

None.

Conflicts of interest

None.

Author's contribution

VG, RK, SKS, TDY: concept and idea; PK: clinical data collection; AL: Radiological data, RK, SKS: Endoscopic Data; VG, PK: drafting and correction.

Ethical clearance

Obtained.

Registration no

UMIN000033798 (UMIN-CTR Clinical Trial).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pan.2019.09.003.

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