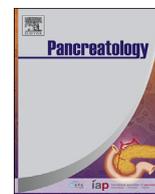




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Original Article

Timing of surgical intervention in patients of infected necrotizing pancreatitis not responding to percutaneous catheter drainage

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ABSTRACT

Background: The timing of surgery in patients not responding to percutaneous catheter drainage (PCD) in infected pancreatic necrosis remains challenging.

Materials and methods: A randomized controlled trial was designed to establish the optimal timings of surgery following PCD in patients with infected pancreatic necrosis (IPN). Patients who did not improve by day 10 after PCD insertion were included in the present study and were randomized to group A (**step-up approach as a bridge to surgery**) or group B (**step-up approach with intention to avoid surgery**). Weekly inflammatory and nutritional markers were monitored in both groups (clinical trials. gov identifier NCT-01527084).

Results: From July 2011 to December 2012, 40 patients underwent treatment with PCD. The first 8 patients were randomized into two groups. The trial was stopped prematurely because of difficulty in accrual and poor progress. All subsequent patients were managed with step-up approach with the intention to avoid surgery. Of 35 patients, 24 patients were managed by PCD alone while 11 patients required surgery. In patients who did not require surgery; levels of serum high sensitivity C-reactive protein (hsCRP), interleukin-6(IL6) and prealbumin showed a falling trend. This group also had higher baseline albumin and higher albumin at 4 weeks.

Conclusion: During the present study, randomization into surgery at a predetermined time in step-up approach was discontinued due to poor progress. Step-up approach with the intention to avoid surgery led to a success rate of 68.5%. The present study failed to predict the optimal timing of surgery after PCD. Patients who needed surgery were sicker at the time of admission, had higher incidence of organ failure, and spent more time in the ICU compared to patients who did not need surgery. In future, inflammatory and nutritional markers may be useful to identify patients who are unlikely to respond to PCD and may help determine the timing of surgery.

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1. Introduction

In the scientific literature, there are no reports on the timing of

Abbreviations: PCD, Percutaneous catheter drainage; IPN, Infected pancreatic necrosis; VARD, Videoscopic assisted retroperitoneal debridement; hsCRP, High sensitivity C-reactive protein; IL-6, Interleukin 6; MDA, Malondialdehyde.

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surgery in patients not responding to percutaneous catheter drainage (PCD). Recently published IAP/APA evidence-based guidelines for the management of acute pancreatitis recommended that the timing of repeat interventions (e.g. repeat percutaneous drainage, repeat endoscopic necrosectomy, or crossover to surgery) should be based on clinical and imaging criteria [1].

The “Step-up approach” is rapidly being adopted as the standard of care in infected pancreatic necrosis (IPN). However, two methods are currently emerging depending on use of different timings for

surgical intervention: a “**Step-up approach as a bridge to surgery**” and a “**Step-up approach with intention of avoiding surgery**”. In the PANTER trial ‘Step-up approach’ was used as a “bridge to surgery” which consisted of PCD as a first step followed by videoscopic assisted retroperitoneal debridement (VARD), if necessary. In that study, more than a third of patients with infected necrotizing pancreatitis did not require surgery and were successfully managed with PCD alone.²In our previous study of 56 patients managed initially with PCD, surgery could be avoided in 48% of patients, with reversal of organ failure in 62% of patients [3]. We used step-up approach with “intention of avoiding surgery” with extended use of PCD. This study involved aggressive use of percutaneous catheters along with large-volume saline irrigation, which helped in the evacuation of the infected fluid, debris, necrotic tissue from the cavities; while surgery was performed on demand [3].

We designed the present study to address the issue of timing of surgical intervention after step-up approach in patients managed initially by PCD catheter and saline irrigation. These patients were randomized into two groups. In one group, surgical intervention was planned at 10–15 days after PCD insertion where step up approach was used as a “bridge to surgery”. In the other group step up approach was used with the “intention to avoid necrosectomy” and to offer surgery only on demand.

In the present study levels of inflammatory and nutritional markers were measured weekly in both groups. The usefulness of these markers in deciding the timing of surgery has not been previously studied.

2. Materials and methods

In this prospective study, all patients of Infected Pancreatic Necrosis (IPN) managed with PCD and saline irrigation in the Division of Surgical Gastroenterology, and the Department of Gastroenterology, Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh from July 2011 to December 2012 were included. The diagnosis of IPN was based on clinical findings, biochemical and microbiological parameters, and CT severity index (UK GUIDELINES) [4]. All patients provided written informed consent before enrollment. This study was conducted according to the guidelines set up by the Helsinki Declaration (modified 2000). The institutional ethics committee approved the protocol. The study is registered with clinical [trials.gov](http://www.trials.gov) with the identifier NCT-01527084.

2.1. Inclusion criteria

All patients with the diagnosis of IPN (UK GUIDELINES [4]) managed with PCD for 10–15 days and those who did not show significant improvement on PCD.

2.2. Exclusion criteria

1. Patients who showed significant improvement on PCD within 10 days of its insertion. (Criteria for significant improvement on PCD included one or more of the following: defervescence, acceptance of enteral nutrition, decrease in total leukocyte count, reversal of organ system failure [3]).
2. Sterile pancreatic necrosis.
3. An acute intra-abdominal event (perforation of hollow viscus, bleeding, or abdominal compartment syndrome) during or within 10 days, after PCD insertion.
4. Previous drainage or surgical necrosectomy for infected pancreatic necrosis (ERCP, with or without papillotomy was allowed).
5. Previous exploratory laparotomy for acute abdomen and diagnosis of pancreatitis during laparotomy.

2.3. Treatment protocol

All patients with severe acute pancreatitis (Revised Atlanta criteria [5]) underwent blood investigations, which included complete haemogram, coagulogram, serum calcium levels, renal and liver function tests and blood gas analysis within 48 h of admission. In presence of fever, blood cultures for bacterial and fungal growth were taken. All the patients referred to the unit were on antibiotics at the time of referral. Subsequently antibiotics were changed according to culture sensitivity. A modified Marshall's score (for organ failure), APACHE II score and modified CTSI score were calculated for each patient at the time of admission and also serially calculated both before and after intervention. All patients were fed orally or through a naso-jejunal tube after initial medical management and fluid resuscitation. Parenteral nutrition (PN) was instituted if the enteral route was not available due to persistent ileus or if the daily requirement of the patient was not being met by enteral feeding alone.

2.4. Inflammatory markers and nutritional markers

Serial measurement of inflammatory markers (C-reactive protein, IL-6 and Malondialdehyde) and nutritional markers (Albumin and pre-albumin) were done once a week every week. Serum high sensitivity C-reactive protein (hsCRP) levels were estimated using an ELISA based kit, as per the manufacturer's protocol (Diagnostic Biochem Canada Inc, Canada). Serum Interleukin 6 (IL-6) levels were also estimated using an ELISA based kit as per the manufacturer's protocol (Diaclone, France). Malondialdehyde (MDA) was estimated using Stocks and Dormandy method [6]. Serum albumin was estimated using a Hitachi module P800 automated clinical chemistry analyzer (Roche Diagnostics, Germany). Serum pre-albumin levels were estimated using an ELISA based kit as per the manufacturer's protocol (Assaypro, St. Charles).

2.5. Step-up approach [2,3].

All patients underwent step up approach as described in our previous study [3]. Patients who had been on PCDs for 10 days without improvement and had been referred to us for surgery were recruited in the present study. These patients were then randomized to group A (**Step-up approach as a bridge to surgery**) or group B (**Step-up approach with intention to avoid surgery**). The surgical procedures for both groups were open necrosectomy and closed lesser sac drainage or retroperitoneal necrosectomy. Feeding jejunostomy was performed routinely unless it was not possible due to dense bowel adhesions. Accordingly, patients in group A underwent surgery between day 10–15 after PCD while patients in group B were continued with PCD and saline irrigation beyond 15 days. The following criteria were used to determine whether surgery was necessary in patients in group B:

- 1 Persistent sepsis or symptoms
- 2 Worsening of clinical condition
- 3 Failure to thrive
- 4 Complications of SAP or PCD

All patients were clinically assessed twice a day and the decision for surgery was made by the senior attending (RG).

Assessment was based on the following primary and secondary end points:

2.6. Primary end points

1. Mortality or complete recovery in two groups

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