

Original Research Article

A randomized controlled trial of acute pancreatitis in Thanjavur medical college: an institutional experience

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ABSTRACT

Background: Acute pancreatitis is a prevalent gastrointestinal illness leading to hospitalizations in India, treated with rest, fluids, and analgesia. This study aimed to compare minimalistic and standard treatments for mild and moderate acute pancreatitis at Government Thanjavur Medical College. The outcome of patients with these conditions was assessed.

Methods: Conducted from July 2020 to July 2022, the randomized controlled trial enrolled acute pancreatitis patients, classified as mild, moderate, or severe based on the Revised Atlanta criteria. All mild and moderate cases were included and randomly assigned to two groups. Group one received early oral diet, hydration, and analgesia, omitting somatostatin analogues and antibiotics. Group two underwent comprehensive management. The outcomes of 130 patients, including those during the COVID-19 peak, were analyzed.

Results: No significant difference was found in the outcomes of patients with mild and moderate pancreatitis between the two treatments. All patients showed improvement during their hospital stay. Evaluation included hospital stay duration, sepsis development, and occurrence of local/systemic complications. Among them, three patients progressed to severe pancreatitis, with one fatality.

Conclusions: For mild and moderate pancreatitis, a minimalistic approach yielded comparable outcomes to active management. However, severe pancreatitis should follow existing guidelines, emphasizing prompt management of complications and systemic organ support.

Keywords: Acute pancreatitis, Oral hydration, Antibiotics, Somatostatin analogues

INTRODUCTION

One of the most frequent gastrointestinal illness-related hospitalizations in India is for Acute pancreatitis. Every year, it causes about 250,000 hospital admissions in India, resulting in direct expenses of more than \$2 billion.¹ Although great progress has been achieved in our understanding of the pathogenesis of this disease and the management of its consequences, the standard management of acute pancreatitis has made very limited strides.² The current approach to treating acute pancreatitis

emphasizes intestinal rest, intravenous fluid resuscitation, and analgesia. It is possible, nevertheless, that some elements of this method of treating patients with acute pancreatitis can actually operate as obstacles to recovery.³ Opioid use may cause delay in gut motility, which can result in side effects such as ileus and opioid-induced bowel dysfunction. Due to the decreased integrity of the gut mucosa, prolonged bowel rest may delay the restoration of gut function and increase intestinal permeability to microbes. Additionally, it has been demonstrated that opiates greatly exacerbate gastrointestinal dysmotility in

people with Acute pancreatitis when combined with intravenous fluids.⁴ Patients recovering from major intra-abdominal surgery also have similar demands for parenteral analgesia and intravenous fluids. Over the past few decades, techniques for enhanced recovery after surgery (ERAS) have been developed to assist postsurgical patients in overcoming these obstacles.⁵ A multidisciplinary, multimodal treatment route for improved postoperative recovery is based on evidence-based techniques that has revolutionized perioperative surgical care.⁶ The use of non-opioid supplementary analgesia, early mobilization, and early oral food beginning are all encouraged by enhanced recovery after surgery measures to speed up recovery.⁷ It has been demonstrated that using ERAS care bundles can cut care time and complications in patients having colorectal surgery by up to 50%. Data from systematic evaluations evaluating the effectiveness of ERAS in pancreatic surgery have similarly demonstrated positive results in terms of reducing length of stay and complications without compromising patient safety.⁸ Due to the hypercatabolic state, fat and protein are metabolized quickly. Nutritional support: a sufficient caloric intake, control of oxidative stress, and prevention of catabolic consequences can determine the outcome of the patient.⁹ It has been demonstrated that somatostatin and its analogues suppress this organ's endo- and exocrine secretion, which lowers mortality. In patients with mild acute pancreatitis, many studies have found that the use of ERAS methods could hasten recovery.¹⁰ The purpose and the goal of the current study is to use compare the effects of an improved recovery strategy as the standard of care and basic strategy to assess the outcomes of individuals who had mild and moderate acute pancreatitis.

Aims and objectives

The objective of this study was to compare the minimalistic treatment and standard treatment in patients with mild and moderate acute pancreatitis in Government Thanjavur Medical College and to assess the outcome of patients with mild and moderate acute pancreatitis. Dong et al conducted a double-blind, randomized controlled trial of individuals admitted to a tertiary medical facility with moderate acute pancreatitis from July 2016 to April 2017. Sixty-six people signed up. 54.3% of the population was female, with a median age of 53.1. The time to successful oral refeeding was significantly shorter in the accelerated recovery group compared to the standard therapy group (median, 13.8 vs. 124.8 hours, P 0.001). Patients allocated to improved recovery had pancreatitis activity levels that were trending lower at 48 to 96 hours (mean, 43.6 vs. 58.9, $p=0.32$). There were no changes in 30-day readmission rates or length of stay. He came to the conclusion that earlier time to refeeding in AP patients who were hospitalised was promoted by enhanced recovery was safe and successful.¹ In 2008, Baig et al conducted a hospital-based study with 45 patients (33 men, 12 women) with an average age of 30. Out of these, 34 had moderate and 11 had severe pancreatitis.¹ Causes of mild pancreatitis

included drunkenness (41.1%), gallstones, trauma, idiopathic, and post-endoscopic retrograde cholangiopancreatography. Severe pancreatitis cases were attributed to trauma, idiopathic, gallstones, alcoholism, and post-endoscopic retrograde cholangiopancreatography. Mild pancreatitis led to 10 patients returning to the hospital within six months for various reasons, while the others had uneventful recoveries. There were no deaths in the group. Severe pancreatitis resulted in complications like symptomatic sterile necrosis, infectious necrosis, pancreatic abscess, and colonic stricture. Two patients passed away due to multiple organ failure. Baig et al concluded that, despite the frequent mention of gallstones as a cause, drunkenness and blunt abdominal trauma were predominant factors in their investigation. While mild pancreatitis had a decent prognosis, severe acute pancreatitis was more dangerous and lethal, requiring careful medical and surgical treatment.² Sharma et al conducted a randomized control trial with 50 patients with AP, divided into a placebo group and a probiotic group. Gut permeability did not change after the intervention, but the probiotic group showed reduced levels of C-reactive protein and immunoglobulins. However, there were no significant differences in prealbumin levels, hospital/intensive care unit stay time, or death between the two groups. Sharma et al concluded that probiotics had no noticeable impact on gut permeability or endotoxemia in AP due to the study's early termination, which may have affected the statistical power.³ Khurram et al conducted a randomized control trial.³ The objective of the study was to evaluate how octreotide affected acute pancreatitis in the research region. Twenty-six patients ($n=26$) with an acute pancreatitis diagnosis were randomly assigned to one of two groups. Group II got 200 pg of subcutaneous octreotide three times per day for the first 10 days after admission, while Group I served as the control group. On octreotide treatment in Group II, positive treatment values and lower complication rates were seen. He came to the conclusion that adding octreotide to the otherwise conservative treatment of acute pancreatitis would be beneficial.⁴ Chowdury et al conducted a systematic review to compare the impact of a full solid diet (FSD) versus a stepwise diet (AP) on patients with mild acute pancreatitis. They analyzed seven randomized controlled trials (RCTs) and found that starting FSD resulted in significantly lower overall length of hospital stay (LOHS) compared to stepwise advancement. There was no difference in post-refeeding stomach pain, diet tolerance, or the need to stop eating between the two groups. The study concluded that initiating FSD reduced post-refeeding abdominal pain and did not increase overall LOHS in patients with mild AP, supporting the use of a solid meal and early feeding within the first 24 hours.⁵ Sateesh et al conducted a trial with 53 patients, comparing a placebo group (SMT) to a group receiving antioxidants (vitamin C and N-acetyl cysteine) with SMT. While the antioxidant group showed reduced oxidative stress and improved antioxidant status, there was no significant difference in hospital stay or complications between the two groups. The study hinted that antioxidant supplements might result in shorter hospital stays and

fewer complications in acute pancreatitis patients, but more research is required to verify these findings.⁶ Chauhan et al conducted a prospective study on 54 patients with acute pancreatitis, with alcoholism and gallstones being the most frequent causes. The study found that an increase in pancreatic and extra-pancreatic problems correlated with higher total leukocyte count, serum amylase level, and low calcium levels, resulting in increased morbidity and longer hospital stays. The Balthazar CT Severity Index (CTSI) severe group had the longest hospital stay. Gallstones (32%) and alcohol intake (50%) were identified as the most common causes of acute pancreatitis.⁷ Ramu et al studied 436 cases of acute pancreatitis over 10 years. Alcohol (42.4%) was the main cause, followed by idiopathic (36.9%) and gallstone/biliary (14.5%) pancreatitis. The most common symptom was epigastric discomfort. Idiopathic cases (36.7%) slightly exceeded alcoholic cases (42.4%), prompting investigation into new causes. The study aids policy development for similar regions.⁸ Rajkumar et al studied 60 patients with moderate acute pancreatitis. They divided them into two groups: one received a clear liquid diet (CLD), and the other a soft diet (SD) as their first meal. Both groups tolerated their diets well, with only one SD patient experiencing mild vomiting and diarrhea. The SD group had significantly shorter hospital stays (6.91 vs. 4.10 days) and post-meal hospital stays (4.23 vs. 1.96 days) compared to the CLD group. The study concluded that a soft diet as the first meal is well-tolerated and reduces hospitalization time for moderate acute pancreatitis patients.⁹ Chandana et al conducted a retrospective study on men and women with acute pancreatitis in a rural tertiary care hospital in South India. Out of all acute abdomen cases, 40% were due to acute pancreatitis. The highest prevalence of acute pancreatitis was observed in men who were heavy drinkers (62.5%). Abdominal ultrasonography (USG) showed the most frequent finding to be an enlarged pancreas (97.5%). Serum lipase levels were elevated in all acute pancreatitis patients, especially in the alcoholic group. The median lipase levels were higher in severe acute pancreatitis compared to moderate cases, but amylase values did not differ significantly. The study concluded that acute pancreatitis, particularly among male chronic alcoholics, is a common emergency condition in this rural area of India. The enlarged pancreas observed on USG can serve as a cost-effective marker for acute pancreatitis, and serum lipase can help determine the severity of the condition.¹⁰

METHODS

A randomized controlled trial was conducted at Thanjavur Medical College and Hospital, lasting from July 2020 to July 2022. The study included 130 patients with acute pancreatitis, aged 12 years and older. Ethical permission was obtained from the institutional ethical committee.

Patients were diagnosed with acute pancreatitis based on specific criteria, including epigastric abdominal pain, elevated serum lipase and/or amylase levels, and

confirmatory findings on cross-sectional imaging. Exclusion criteria included severe cardiovascular, respiratory, renal, gastrointestinal/hepatic diseases, chronic kidney disease, cirrhosis, malignancy, chronic pancreatitis, chronic pain syndrome requiring narcotic analgesics, or recent opioid use.

Participants were randomly assigned to a test group or a control group in a 1:1 fashion. The test group received moderate fluid resuscitation, early removal of NG tube, and early enteral nutrition without short starvation. No antibiotics or somatostatin analogues were used. The control group received comprehensive treatment with aggressive fluid resuscitation, IV antibiotics, somatostatin analogues, and delayed onset of enteral nutrition. The study did not involve blinding.

The patients underwent thorough history taking, clinical evaluation, and various laboratory tests including LFTs, coagulation profile, KFTs, CBC, serum calcium level, serum amylase, and serum lipase. Abdominal ultrasound and computed tomography (CT) were performed for each patient, and demographic data, comorbidities, medications, laboratory results, and imaging results were recorded. The study analyzed the outcomes of the patients, including length of hospital stay, development of sepsis, and occurrence of local/systemic complications. Data analysis was performed using MS Excel and SPSS version 24. Descriptive statistics such as mean and standard deviation were used, and inferential statistics like independent sample t test were applied, with a significance level of $p < 0.05$. The findings were presented using graphs, tables, and charts where appropriate.

RESULTS

Among 130 study participants with acute pancreatitis, the mean age was 45.96 ± 9.71 years. 85% were males and 15% were females. Diabetes mellitus was the most common comorbidity (17%) followed by smoking (12%) and hypertension (11%). Multiple comorbidities were in 10% of participants (Table 1).

Table 1: Demographic and clinical characteristics of study participants (n=130).

Characteristics	N (%)
Mean age (years)	45.96±9.71
Gender	
Male	110 (85)
Female	20 (15)
Comorbidities	
Diabetes mellitus	22 (17)
Hypertension	14 (11)
Ischemic heart disease	3 (2)
Chronic kidney disease	3 (2)
Bronchial asthma	1 (1)
Multiple comorbidities	13 (10)
Smoking	15 (12)

Ethanol intake was the most common cause for acute pancreatitis in 85% followed by idiopathic (7%), gall stone disease (6%) and hypertriglyceridemia in 2% (Figure 1).

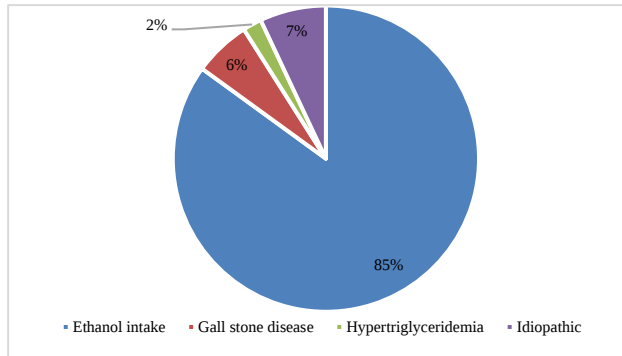


Figure 1: Etiology of acute pancreatitis among the study participants.

Table 2: Hematological characteristics of study participants (n=130).

Characteristics	Mean±SD
Complete Blood count	
Hemoglobin (g/dl)	12.36±1.45
Platelets (10 ⁹ /l)	256.30±43.34
Leucocytic count: (10 ⁹ /l)	9.87±3.67
Liver function test	
Bilirubin (mg/dl)	2.79±1.01
Direct bilirubin (mg/dl)	0.98±0.23
Aspartate transaminase (U/l)	26.92±10.78
Alanine transaminase (U/l)	33.97±4.46
Alkaline phosphatase (U/l)	155.49±39.38
Albumin (g/dl)	4.23±1.94
Renal function test	
Urea (mg/dl)	20.89±12.78
Creatinine (mg/dl)	1.98±0.09
Serum electrolytes	
Calcium (mg/dl)	8.99±1.89
Sodium (μmol/l)	137.87±3.98
Potassium (μmol/l)	4.44±1.01
Random blood sugar (mg/dl)	137.09±19.87
Serum amylase (U/l)	789.98±333.01
Serum lipase (U/l)	687.01±230.54

Among the study participants, mean hemoglobin levels was 12.36±1.45, platelets were 256.30±43.34 and leucocytic count was 9.87±3.67. LFT among the participants showed, mean bilirubin as 2.79±1.01, Direct bilirubin as 0.98±0.23, Aspartate transaminase (U/l) as 26.92±10.78, Alanine transaminase (U/l) as 33.97±4.46, Alkaline phosphatase (U/l) as 155.49±39.38 and Albumin (g/dl) as 4.23±1.94. Renal function test showed mean Urea (mg/dl) as 20.89±12.78 and Creatinine (mg/dl) as 1.98±0.09. Serum electrolytes measured showed mean Calcium (mg/dl) as 8.99 ± 1.89, mean Sodium (μmol/l) as 137.87±3.98 and mean Potassium (μmol/l) as 4.44±1.01. The mean Random blood sugar (mg/dl) was 137.09±19.87,

mean Serum amylase (U/l) was 789.98±333.01 and mean Serum lipase (U/l) was 687.01±230.54 (Table 2).

Table 3: Comparison of outcome in both the groups.

Characteristics	Group A Test group N (%)	Group B Control group N (%)	P value
Mean hospital stay (days)	6.89±1.98	6.92±1.88	0.56
Discharged	64 (98.5)	63 (97)	0.73
Complications	1 (1.5)	2 (3)	
Death	0	1	

The mean duration of hospital stay in test group was 6.89 ±1.98 days and in control group was 6.92±1.88. The difference was not statistically significant by independent sample t test (p>0.05). 98.5% were discharged in test group and 97% were discharged in control group. 1 patient developed renal failure in test group. 1 patient developed respiratory failure and 1 developed pancreatic abscess in control group. The patient who developed respiratory failure in control group died. The difference in complications and mortality was not statistically significant by Fischer exact test (p>0.05) (Table 3).

DISCUSSION

This study highlighted acute pancreatitis as a common surgical emergency, mainly caused by ethanol consumption in the rural area around our hospital. We focused on supportive management, goal-directed fluid therapy, and early enteral nutrition to improve outcomes and reduce complications. Prophylactic antibiotics didn't show significant benefits. Overall, a minimalistic conservative approach yielded comparable results to aggressive strategies. There is currently not enough data to support recommendations for people with acute pancreatitis for the best supportive care. Pain treatment, diet, and activity were the three main aspects of care.¹ The results of the current study imply that outcome of the patients are similar when compared to those who were actively managed. This discovery is in line with earlier research.^{11,12}

A Cochrane systematic review of five randomised controlled trials on pain management in acute pancreatitis reported no differences in complications or unfavourable outcomes between individuals receiving opiates versus nonopiate analgesia.¹³ In a short randomised controlled trial that contrasted metamizole and morphine as analgesics in 2008, metamizole was found to have a nonsignificant correlation with pain relief in the metamizole-treated subjects. In addition, patients taking metamizole experienced pain alleviation more quickly on average than patients taking morphine.¹⁴ The effects of nutritional assistance have mostly been researched in cases of severe acute pancreatitis.² For patients with mild episodes of acute pancreatitis, the best timing and kind of

diet are yet unknown.¹⁵ In contrast to delayed feeding, early feeding (within 48 hours of hospitalisation) did not increase adverse events and was linked with a shorter hospital stay.⁷ This was revealed by a 2017 meta-analysis of 11 randomised controlled studies on the timing of feeding in acute pancreatitis. Randomized controlled trials have demonstrated that starting oral intake with a low-fat solid food is safe and is linked to a shorter duration of stay.¹⁶

Retrospective investigation of patients with acute pancreatitis revealed that early readmission was at risk when patients were discharged before they could tolerate a substantial diet.¹⁷ By exploring the role of patient-directed dietary restart, particularly among patients with milder kinds of disease, the current study builds on these findings.^{1,3} Patients with acute pancreatitis have not received enough research on their activity level.⁵ There are currently no recommendations for the amount of activity and mobilisation that patients with acute pancreatitis should engage in while hospitalised.¹⁸ Many of the same problems that patients with acute pancreatitis face are addressed by ERAS's cornerstones.¹ Patients who have recently undergone surgery particularly require help with pain control, nourishment, and movement.¹⁹ All perioperative care issues are covered by the guidelines created for these patients in the ERAS route. By reevaluating earlier procedures and putting new evidence-based standards into place, the ERAS marks a paradigm change.²⁰ Early oral intake, stopping IV fluids, prompt movement of patients, and the use of supplemental nonopioid analgesics have all been found to decrease complication rates and overall time of hospitalisation during postsurgical care.²¹ This is similar to the treatment of patients with acute pancreatitis, which may resemble patients recovering from intra-abdominal surgery because of the local inflammation caused by the wounded pancreas. This has knock-on effects include delayed gut function, which can be made worse by opiate usage and extended bed rest.^{22,23} Patient-based moderate fluid resuscitation is superior to blindly aggressive fluid resuscitation. IV antibiotics should be avoided, and prophylactic antibiotics do not significantly reduce infective complications in pancreatic necrosis. Somatostatin analogues are unnecessary in mild and moderate cases. However, this study had limitations. The sample size was limited to 130 individuals as it was a pilot study to assess the trial's feasibility. Our findings couldn't be extended to populations with severe disease and organ failure as we didn't include such patients. Further multicentric trials are needed to confirm the effectiveness of these treatments.

CONCLUSION

Patients with mild and moderate pancreatitis can be treated with a minimalistic approach. The outcome of the patients is similar when compared to those who were actively managed. However, the treatment of severe pancreatitis should be based on existing guidelines. Prompt

management of local complications and systemic organ support should be given. Early feeding is better than short term starvation. In a setting with limited resources, the cost-effective treatment with good patient outcome is ideal. Along the course of the illness, if the disease progresses towards a severe form/ complications, a more radical approach may be started. Tailor the treatment individually according to the patient.

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