

Original Research Article

Clinical outcome in low socioeconomic patients with severe acute pancreatitis treated either with early nasogastric tube or total parenteral nutrition: a randomized controlled trial

Anil Kumar^{1*}, Shiv S. Paswan², Shiv Kishor¹, Vimal Bhandari³

¹Department of General Surgery-Trauma and Emergency, All India Institute of Medical Sciences, Patna, Bihar, India

²Department of Trauma and Emergency, All India Institute of Medical Sciences, Bhubaneswar, Odisha, India

³Department of Surgery, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, Delhi, India

Received: 28 April 2019

Revised: 18 May 2019

Accepted: 20 May 2019

*Correspondence:

Dr. Anil Kumar,

E-mail: dranil4@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Early nasogastric feeding has shown beneficial effect in the low socioeconomic group of patient with severe acute pancreatitis (SAP). The current randomized controlled study was performed to assess the effect of early nasogastric feeding as compared to total parenteral nutrition (TPN).

Methods: Fifty patients admitted with diagnosis of SAP were randomly allocated to receive enteral feeding (EF) (at the rate of 25 ml/hour and was gradually increased up to 100 ml/hr) or TPN within 24 hours of hospital admission. The nutritional regimen was aimed to be iso-caloric between the two groups. Patient's demographics, hospital stay, nutrition, total cost, complication, and mortality were observed for 1 month in follow up.

Results: All fifty patients were completed the study. Patient demographics were similar in both groups. 38/50 belonged to low socioeconomic status in the study group (Twenty in EF and eighteen in TPN group). The complications were significantly lower in EF group (pancreatic infection (11 vs. 4, $p=0.037$), central venous catheter infection (EF=0 vs. TPN=8, $p=0.002$), multiorgan failure (EF=5, TPN=12, $p=0.037$). Early recovery in EF group was significant with the mean duration of hospital stay of 6.76 days as compared to 10.4 days in the TPN group. The mean expenditure in the EF group was 1268 as compared to 13688 Indian rupees in the TPN group.

Conclusions: This study shows that early EF improves early recovery, lower complications and cost effective measure in SAP especially in low socioeconomic group of patients.

Keywords: Pancreatitis, Enteral feeding, TPN, Low-socioeconomic

INTRODUCTION

Severe acute pancreatitis (SAP) accounts for approximately three percent of all patients with abdominal pain admitted to hospital. The condition is common in northern India especially in patients of low socioeconomic status. The reported mortality from SAP ranges from 9 to 27 percent.^{1,2} The recovery depends on the nutritional reserves of the body, thus mandating the

need for adequate nutritional supplement especially in patients of low socioeconomic country. TPN had been the standard nutritional management for many years for SAP. In view of increase the cost, increased incidence of catheter induced sepsis that may also lead to electrolyte and metabolic disturbances, alteration in gut mucosal barrier and increased intestinal permeability with TPN may limit its widespread use. On the contrary, enteral nutrition has been considered safe, less expensive and

well tolerated in SAP. The present prospective study was undertaken to evaluate the role of early nasogastric feeding in patients with predicted SAP and to compare it with total parenteral nutrition in view of clinical outcome and efficacy.

METHODS

This prospective randomized study was conducted between May 2012 and March 2015 at Vardhman Mahavir Medical College and Safdarjung Hospital. Sample size calculation showed that 25 patients in each arm would be required to demonstrate a difference of 10% between two groups at the 5% level of significance with a power of 80%. A total of 50 patients out of 60 patients with clinical diagnosis of severe acute pancreatitis were enrolled in the study. 10 patients were excluded from the study. The inclusion and exclusion criteria are summarised in Table 1.

Table 1: Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Abdominal pain	History of Surgery, Trauma or Malignancy
Serum amylase \geq 3 times upper normal limit	Chronic pancreatitis with exacerbation
Onset of pain within 48 hours	High Profile patient in the term of high socio-economic condition
APACHE II score \geq 8	Patient with ileostomy or colostomy
C-reactive protein \geq 150 mg/L or/ and Peripancreatic collection shown on CT scan.	Short bowel syndrome
Age >13 years.	Inflammatory bowel disease
BPL (Below poverty line) card holder.	Not willing for follow up.

The severity of pancreatitis was assessed by Acute physiological and chronic health evaluation (APACHE II score), Ranson score and Balthazar computed tomography (CT) severity index along with measurement of serum amylase and C - reactive protein level. The case was subsequently assigned to receive either TPN or EF by randomization. The TPN or EF was started within 24 hours of hospital admission. The nutritional component in concern of energy for both groups was iso- caloric. The nutritional formula, its nutrient value with direction to use for both groups are summarized in Table 2. In both the groups no added immunomodulator nutrients were used. TPN was infused via central venous catheter while nasogastric tube was used to provide enteral nutrition. The starting dose of enteral nutrition was at the rate of 25 ml/hour and was gradually increased up to 100 ml/hour. The aim was to reach full nutritional support within 72 hours of admission. Intravenous fluids were provided

along with the nasogastric feed. The dose of TPN was given as 1000 ml of the formula on first two days and 1500 ml on day three. The amount was increased gradually as per caloric requirement of the patient and which was decided according to body weight at admission. The fluid requirement was adjusted according to daily need and TPN volume. Patients were monitored daily for nutritional status, gastrointestinal symptoms, and APACHE II scoring. Laboratory and radiological investigations were also performed. Both groups received broad spectrum antibiotics according to current recommendations. The observation period was kept for 10 days and follow up after discharge was done at 1 week and again at one month and subsequently. The study parameters included patient's demographics, duration of symptoms, duration of hospital stay, amount of nutrition given, total cost of nutritional supplement, complication, and mortality. Comparative analysis between the two groups were done in respect to development of complications (infectious, non infectious and systemic), need for surgical intervention, and mortality. Data were presented as mean, median and standard deviation. Statistical comparison between the groups was performed using the t- test and Fischer exact test for small samples. All continuous variables were compared with the Mann Whitney test and a $p < 0.05$ was considered significant. Statistical analyses were performed with SPSS version 12.0.2.

RESULTS

A total of 50 patients were randomly allocated to early nasogastric feeding and TPN groups, with each group having 25 patients. The mean age for enteral feeding (EF) group was 36.92 years while that for the TPN group was 37.48 years. Male to female ratio in the former group was 18:7 while it was 14:11 in the TPN group. The average duration of onset of symptoms varied from 8 to 48 hours with a mean of 35.12 hours in EF group and 33.28 hours in the TPN group. Alcohol consumption was the main etiological factor among males in both the groups, while gall stone induced pancreatitis was more common among female population. Thirty eight patients out of total fifty belonged to low socioeconomic status in the study. The mean APACHE II score was more in patients who were enterally fed (11.96) as compared to the patients in the TPN group (10.61). The demographic data are summarised in Table 2.

But it decreased gradually as days of feeding passed. Likewise the mean Ranson score at admission was also higher for the EF group than the TPN group (3.2 and 2.9 respectively) but its decline to normality was more rapid than in the TPN group. Serial estimation of serum amylase and lipase levels followed a steady decline in both the groups and didn't show any significant pattern. However the fall in elevated C-reactive level was more rapid in EF group. Further a total of 16 patients had infective complications in the TPN group as against 8 in EF group. The difference was statistically significant

($p=0.024$). The most significant infective complication was pancreatic infection (pancreatic necrosis and pancreatic abscess) [11 vs. 4, $p=0.037$] followed by central venous catheter infection (EF=0 vs. TPN=8, $p=0.002$). Systemic complications including multiorgan failure were also significantly lower in the EF population (EF=5, TPN=12, $p=0.037$). Early recovery was also observed in EF group with the mean duration of hospital stay of 6.76 days as compared to 10.4 days in the TPN group. The total expenditure on nutrition therapy in TPN was 11 times higher than in the EF group. The mean expenditure in the EF group was 1268 Indian rupees while it was 13688 Indian rupees in the TPN group. Only one patient required surgical exploration within the EF group while four patients underwent surgical intervention in the TPN group. In all these patients laparotomy with necrosectomy was done. Two patients within the TPN group required re-exploration while one patient required repeated lavage and drainage. Further a total of four patients expired during treatment in the TPN group while only one life was lost among patients who received enteral feeding. The outcome of both groups are summarised in Table 3.

Table 2: Demographic profile of patients.

Demographic profile	Enteral feeding group	TPN group
Mean age (years)	36.92±5.6	37.48±7.30
Sex (male/female)	18:7	14:11
Weight (kilogram)	48.2 ±5.27	50.1±5.9
Duration of onset of symptoms (hours)	8-48 (Mean-35.12)	8-48 (Mean-33.28)
Socio-economic profile (low/high)	20:7	18:5

There are no significant statistical differences in two groups.

Table 3: Results of EF and TPN.

Parameters	EF (n=25)	TPN (n=25)	P value
Infection	8	16	0.024
Pancreatic infection	4	11	0.037
Central venous catheter infection	0	08	0.002
Multi organ failure	5	12	0.037
Early recovery (mean duration in days)	6.76	10.4	0.038
Expenditure (Indian rupees)	1268	13,688	0.001
Surgical intervention	01	04	0.003
Hyperglycaemia	02	06	0.0034
Death	01	04	0.0031

DISCUSSION

The physical stress of severe acute pancreatitis leads to hyper catabolic state promoting nutritional deterioration in the setting of systemic inflammatory response. Thus nutritional support is an integral part of patient care in this setting and should be started early in the course of disease. Enteral nutrition has been advocated as the best mode of nutritional supplementation in this regard.^{3,4} EN has been shown to be safe, less expensive and well tolerated in acute pancreatitis.⁵ EN also eliminates the complications associated with TPN. The present prospective study was undertaken to assess the potential merits and demerits of early nasogastric feeding with TPN in terms of clinical outcome in patients with severe acute pancreatitis. Eatock et al reported no significant clinical or biochemical deterioration on commencement of nasogastric feeding in severe acute pancreatitis (SAP).⁶ Windsor et al also found improvement in the severity of the disease with enteral feeding (EF).⁷ They further observed attenuation of the acute phase response on initiation of Kalfarentzos et al have also documented the benefit of enteral feeding in SAP.⁸ We also in our study found that early naso gastric feed was not only feasible in SAP but was also not associated with any worsening in the clinical condition of the patient. Further we observed a gradual decline in serum amylase, serum lipase and C-reactive protein levels along with improvement in organ function for ten days observation period after commencement of EF and TPN. The normalisation of CRP was quicker in enterally fed patient than in the TPN group. In other study also the authors found a significant reduction in CRP levels in the EF group while in another series it was observed that more rapid normalisation of physiological disturbances occurred in patients who received early enteral nutrition.^{7,9} Contrary to these findings few literature showed that there is in no reduction in CRP level or amelioration of inflammatory response was observed with enteral feeding. Incidence of infective complications has also been shown to be influenced by the type of nutrition.^{10,11} In our study, infective pancreatic complications were significantly higher among the TPN group than EF patients. A significant decrease in the incidence of infective complication in the EF group consequently leads to a reduction in surgical intervention in this group. This is in accordance with the observation made in other series.^{8,12,13} The most common organism isolated on culture in our series was E coli and pseudomonas species which is similar to earlier reports.^{14,15} Non-infectious complications were also more in the TPN group in our study. This is in contrast to the data obtained by Meta-analysis in which no significant difference was found between EF and TPN group.¹⁶ Nevertheless complications associated with enteral nutrition like diarrhoea (7 vs. 1) and abdominal bloating (5 vs. 0) were less severe and did not warrant discontinuation of enteral feeding. One study showed that a strict glucose control at lower level improved the outcome with decreased

mortality and morbidity in SAP.¹¹ We found a significantly lower incidence of hyperglycaemia in the EF group (3 vs. 14) than in the TPN group. The effects of normoglycemia in SAP have not been studied but potentially this concept might further improve the outcome in patient with SAP. Patients in the EF group had a lower incidence of systemic complications including multiorgan failure. On the contrary Powell et al found that introduction of enteral nutrition did not affect Marshall multiple organ dysfunction score in patients with SAP within the first four days after admission.¹⁷ The overall mortality of 10 percent in present series is also quite relevant to the estimated severity of the disease. Considering the fact that majority (38) of our patient belonged to low socioeconomic status with poor nutritional reserve and other associated co-morbidities the severity of disease process and expected final outcome can well be assumed. Despite this, the mortality rate was lower in the enterally fed group as compared to TPN group. In the present study the expenditure in the EF group 11 times less than that for TPN group which is similar to other study.^{8,10} The immunonutrition has no beneficial effect on complications, mortality or length of hospital stay in acute pancreatitis.¹⁸ Several guideline including European Society of Parenteral and Enteral Nutrition (ESPEN) recommended the early enteral feed in SAP.^{19,20}

CONCLUSION

This prospective study likely confirms that early enteral nutrition may be safely administered to patient with severe acute pancreatitis and is associated with lesser incidence of infectious as well as non infectious complications and better control of blood glucose with the added advantage of early recovery, shorter hospital stay and high cost effectiveness.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Popa CC, Badiu DC, Rusu OC, Grigorean VT, Neagu SI, Strugaru CR. Mortality prognostic factors in acute pancreatitis. *J Med Life*. 2016;9(4):413-8.
2. Kotán R, Pószán J, Sápy P, Damjanovich L, Szentkereszty Z. Analysis of clinical course of severe acute biliary and non biliary pancreatitis: a comparative study. *Orv Hetil*. 2010;151(7):265-8.
3. Bhatia M. Novel therapeutic targets for acute pancreatitis and associated multiple organ dysfunction syndrome. *Current Drug Targets Inflammation Allergy*. 2002;1(4):343-51.
4. Windsor JA, Hammodat H. Metabolic management of severe acute pancreatitis. *World J Surg*. 2000;24(6):664-72.
5. Olah A, Romics L Jr. Enteral nutrition in acute pancreatitis: A review of the current evidence. *World J Gastroenterol*. 2014;20(43):16123-31.
6. Eatock FC, Chong P, Menezes N, Murray L, Mckay CJ, Carter CR, et al. A randomised study of early nasogastric versus nasojejunal feeding in severe acute pancreatitis. *AM J Gastroenterol*. 2005;100(2):432-9.
7. Windsor AC, Kanwar S, Li AG, Barnes E, Guthrie JA, Spark JJ, et al. Compared with parenteral nutrition, enteral feeding attenuates the acute phase response and improves disease severity in acute pancreatitis. *Gut*. 1998;42(3):431-5.
8. Kalfarentzos F, Kehagias J, Mead N, Kokkinis K, Gogos CA. Enteral nutrition is superior to parenteral nutrition in severe acute pancreatitis; result of a randomised prospective trial. *Br J Surg*. 1997;84(12):1665-9.
9. Swank GM, Deitch EA. Role of gut in multiple organ organ failure: bacterial translocation and permeability changes. *World J Surg*. 1996;20(4):411-7.
10. Gupta R, Patel K, Calder PC, Yaqoob P, Primerose JN, Jonhson CD. A randomised clinical trial to assess the effect of total enteral and parenteral nutrition support on pancreatitis. (APACHE II; 6). *Pancreatology*. 2003;3(5):406-13.
11. Eckerwall G.E, Axelsson J.B, Andersson R.G. Early Nasogastric Feeding in Predicted Severe Acute Pancreatitis. A Clinical Randomized Study. *Ann Surg*. 2006;244(6):959-67.
12. Bradley EL 3rd, Allen K. A prospective longitudinal study of observation versus surgical intervention in the management of necrotising pancreatitis. *Am J Surg*. 1991;161(1):19-25.
13. Olah A, Pardavi G, Belagyi T, Nagy A, Issekutz A, Mohamed GE. Early nasojejunal feeding in acute pancreatitis is associated with a lower complication rate. *Nutrition*. 2002;18(3):259-262.
14. Beger HG, Buchler M, Bittner R, Block S, Nevalainen T, Roscher R. Necrosectomy and postoperative local lavage in necrotizing pancreatitis. *Br J Surg*. 1988;75(3):207-12.
15. Isenmann R, Runzi M, Kron M, Kahl S, Kraus D, Jung N, et al. Prophylactic antibiotic treatment in patients with predicted severe acute pancreatitis: a placebo -controlled, double blind trial. *Gastroenterology*. 2004;126(4):997-1004.
16. Marik PE, Zaloga GP. Meta analysis of parenteral nutrition versus enteral nutrition in patients with acute pancreatitis. *BMJ*. 2004;328:1407-13.
17. Powell J, Murchison T, Fearon KC, Ross JA, Siriwardena AK. Randomized controlled trial of the effect of early enteral nutrition on markers of the inflammatory response in predicted severe acute pancreatitis. *Br J Surg*. 2000;87:1375-81.
18. Petrov MS, Atduev VA, Zagainov VE. Advanced enteral therapy in acute pancreatitis: Is there a room for immunonutrition? A meta-analysis. *Int J Surg*. 2008;6(2):119-24.

19. Meier R, Ockenga J, Pertkiewicz M, Pap A, Milinic N, Macfie J. ESPEN guidelines on enteral nutrition: pancreas. *Clin Nutr.* 2006;25(2):275–84.
20. Spanier BW, Bruno MJ, Mathus-Vliegen EMH. Enteral Nutrition and Acute Pancreatitis: A Review. *Gastroenterol Res Pract.* 2011;2011:857949.

Cite this article as: Kumar A, Paswan SS, Kishor S, Bhandari V. Clinical outcome in low socioeconomic patients with severe acute pancreatitis treated either with early nasogastric tube or total parenteral nutrition: a randomized controlled trial. *Int Surg J* 2019;6:1907-11.