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Original Article

Effect of Pre-operative Nutritional Protocol Implementation on Postoperative Outcomes Following Gastrointestinal Surgeries: A Randomized Clinical Trial

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Abstract
Introduction: A significant proportion of patients undergoing major gastrointestinal operations suffer from malnutrition. Although the benefit of postoperative nutritional support is well established, the effects of energy intake during pre-operative period is less reported. The present study was designed to test the effect of structured pre-operative nutritional therapy on the postoperative recovery of patients undergoing major gastrointestinal operations.
Methods: A randomized clinical trial was conducted among 80 patients of the surgical gastroenterology department of a tertiary care center in south India. A simple random sampling method was used. The nutritional status of all participants was assessed by subjective global assessment (SGA). While control group received standard energy intake nutrition, the experimental group received calculated nutrition with an extra 50 g of soy protein for seven days pre operatively. Data were analysed using SPSS version 20.
Results: The median day of removal of abdominal drainage tube was 3 (0-5) compared to 5 (2.5-7.5) in the control group. In the intervention group, the median time for the appearance of bowel sounds and starting of enteral feeding was 1.1 (0.5) days and 2 (1-2) days, while in the control group, it was 1.6 (0.9) days, 3 (1-4) days, respectively which was significant at $P<0.05$. Similarly, the mean (SD) postoperative serum albumin on third day was 3.6 (0.4) g/dL vs 3.4 (0.4) g/dL experimental and in the control group.
Conclusion: Preoperative nutrition protocol improved the patients' clinical outcomes in terms of post-operative serum albumin, the timing of bowel sounds, and early initiation of enteral feeds.

Introduction

When illness or injury occurs, optimal nutrition is essential for healing and resisting infection and other complications. A negative nitrogen balance of 10 g/day for ten days could mean wasting 2.5 kg of muscle tissue as it is converted to glucose for energy, which results in malnutrition.[1] Malnutrition is responsible for impaired wound healing, increased complications, extended hospital stays, and prolonged confinement of patients to bed.[1,2] Large studies have found the prevalence of malnutrition in hospitalized patients is almost 40%-60%.[2] It has been seen that increased risk for healthcare-associated infections is associated with the poor nutritional status of the patients. Nutritional screening identifies patients who are at nutritional risk and will benefit from further nutritional assessment and intervention.[3,4]

Several tools and scoring procedures are used to screen for malnutrition in the community and hospitals. Most of these tools are either not validated clinically or are not operator-friendly in daily practice. Subjective global assessment (SGA) scores, evaluated by medical history on seven items and clinical findings on four items, is an established tool for screening for malnutrition.[5]

Adequate nutritional support in the perioperative setting is essential in reducing post-operative complications. Hence, personalized nutrition is recommended for each patient during the pre-operative period.[6] Studies have shown that calorie intake through oral feeding reduces stress response in the postoperative period. So if the patient can take it orally, it is always better to use the gut.[7,8] The European Society of Parenteral and Enteral Nutrition (ESPEN) guidelines on enteral nutrition have reviewed and analysed hundreds of interventional studies to create evidence-based recommendations for the use of structured enteral nutrition in different diseases. Poor Nutritional status at admission and worsening nutritional status during hospital stay were associated with a prolonged hospital stay.[9] There was a significantly higher incidence of surgical site infection among patients at nutritional risk than those who were not.[10] Many studies have shown that nutritional supplementation during the pre-operative period has been beneficial in postoperative recovery.[10-13]

The reduced nutritional status leads to increased postoperative complications and too late recovery after the surgical procedure. While well-known concepts of enhanced recovery after surgery and rehabilitation aim to improve the patient after surgery, the concept of pre-habilitation targets the phase before surgery, which includes enhancing the nutritional status of the patients. This study aimed to assess the effect of structured pre-operative nutritional protocol on the post-operative recovery pattern of the patients undergoing major gastrointestinal surgeries.

Materials and Methods

A total of 80 adults, can take orally or through enteral routes and underwent planned gastrointestinal surgeries during the data collection period were enrolled. The sample size is calculated to be 96 subjects, with 48 in each group. It was calculated by comparing the percentage of postoperative complication as 28% in the study group compared to 60% in the control group, with the power of study as 0.8 and 5% level of significance. Due to the limited data collection period, a total of 80 participants were enrolled.

The research design adopted for this study was a randomized clinical trial. Consecutive patients admitted, and meeting inclusion criteria were enrolled in the study using a simple random technique. Patients undergoing all types of gastrointestinal surgeries, who could take orally or through a nasogastric tube above 18 years, were included in the study. Patients operated on an emergency basis and who had been supported through total parenteral nutrition were excluded from the study. Structured energy intake nutritional protocol in the experimental group and conventional therapy in the control group were the independent variables. Postoperative recovery patterns in terms of duration of intensive care unit (ICU) stay, day of ET extubation, any infection, complications, day of removal of the drainage tube, first bowel sound, day of starting feeding, and postoperative albumin level on 3rd postoperative day in both groups were outcome variables. The study was conducted among the patients of the surgical gastroenterology department of a tertiary care center at Puducherry in south India. CTRI registration number is CTRI/2018/10/015882.

All the recruited patients were admitted in the hospital for 7 days pre-operatively to enhance the nutritional status of the patients. Their nutritional assessment and intervention was carried out in the surgical gastroenterology ward of the hospital. Calculated energy requirement as per SGA tool was fed through orally or enteral tubes by the research nurse with concurrent confirmation with treating physician and dietician. The study was approved by Institute Ethics committee and informed consent was obtained from study participants. The ethical risk included in the study was minimal risk as per Indian council of medical research guidelines. Confidentiality and anonymity of the data were maintained throughout the study.

All the recruited patients were assessed based on the SGA tool and categorized as mild, moderate, and severely malnourished. Patients who were mildly malnourished (SGA score 7-14) were treated with calorie requirements of 30-35-kcal/kg IBW with protein 1.2 g/kg IBW+ 50g soy protein. The moderately malnourished patients (SGA score 15-28) were treated with calories of 30-35-kcal/kg IBW, protein 1.2 g/kg IBW+ 50 g soy protein. Patients severely malnourished (SGA score of 29-35) were treated with calorie -35-40 kcal/kg IBW, protein 1.5-2 g/kg IBW+ 50 g soy protein for seven days preoperatively in the intervention group. Five gm of Jaggery were added along with feeds. Catch-up nutrition was provided when the nutrition was withheld for diagnostic purposes in the intervention group. In comparison, only energy intake nutrition based on appropriate calorie and protein requirements was provided for the patients in the control group. SGA is considered an established tool with excellent content validity (S-CVI = 0.94) and a reliability coefficient (alpha) of 0.9.

Patients were followed up during postoperative period for the duration of hospital stay, time of ICU stay, postoperative day of extubation, any infection, complications, day of removal of the drainage tube, first bowel sound, day of starting feeding, postoperative albumin level on 3rd post-operative day. The postoperative outcome parameters were assessed from records, and physical examination of the patients by the Research Nurse and confirmation by the senior resident physician during ICU stay and until discharge. The categorization of patients and intervention is shown in Figure 1.

Data were analysed using SPSS version 20. The distributions of categorical variables such as age, education, occupation, residence, diagnosis, type of surgery, comorbidities were expressed in forms of frequency/percentage. The continuous variables were expressed in terms of mean with standard deviation/median with range. The comparison between the continuous variables was done by independent *t* test or Wilcoxon rank-sum test and comparison between the categorical variables was done by chi-square test.

Results

Eighty patients were enrolled in the current study. The mean age was 48.3 years for the experimental group and 49 years for the control group. Most of the patients belonged

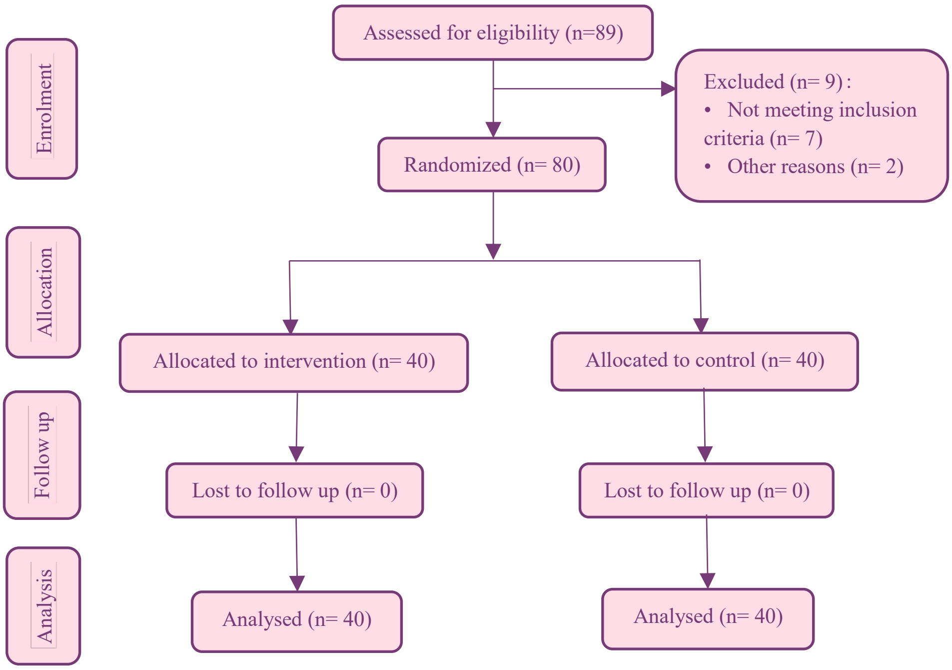

Figure 1. Consort flow diagram

to the age group of 40-60 years in the experimental group (47.5%), whereas in the control group, most of the patients were between 31-45 years (35%) and 40-60 years (35%). Male preponderance was noted in both groups (experimental 52.5%, control 60%). The groups were comparable in other demographic parameters such as educational qualification, occupational status, marital status, and locality. The majority of patients were suffering from hepatobiliary disorders in both groups. About 75% of patients in the experimental group and 70% of patients in the control group underwent laparoscopic surgeries. (Table 1)

The mean haemoglobin for experimental and control groups were 11.1 (1.8) and 12.1 (1.7) respectively. Both groups were comparable in means of other biochemical parameters and calories and protein requirement during the pre-operative period. (Table 2)

The groups were comparable in terms of all parameters of SGA and in control group observed to have a more well-nourished category as per SGA. The energy intake energy requirement in the experimental and control group were 1345 (315.0) and 1333.9 (226.1) respectively. The protein requirement for the experimental and control group were 51.1 (10.1) and 51.725 (8.9) respectively. (Table 3)

The current study showed that there was a significant difference between both groups in postoperative outcomes in terms of, time of removal of the drainage tube, the timing of first bowel sound, day of starting enteral feeding, and albumin level on 3rd postoperative day. (Table 4)

There was a drop in albumin level during the postoperative period compared to pre-operative serum albumin in the control group which was significant at $P < 0.004$. The median (IQR) difference in albumin before

Table 1. Patient's demographic and clinical characteristics (N = 80)

Variables	Experimental group (n = 40) N (%)	Control group (n = 40) N (%)	*P* value
Age[a]	48.3 (11.9)	49 (14.0)	0.07[b]
18-30 years	3 (7.5)	4 (10)	
31-45 years	12 (30)	14 (35)	
46-60 years	19 (47.5)	14 (35)	0.72
>60 years	6 (15)	8 (20)	
Gender			
Male	21 (52.5)	24 (60)	0.49
Female	19 (47.5)	16 (40)	
Diagnosis			
Esophageal disorders	7 (17.5)	10 (25)	
Gastric disorders	4 (10)	5 (12.5)	
Hepatobiliary diseases	16 (40)	12 (30)	0.62
Pancreatic disorder	4 (10)	7 (17.5)	
Lower GI disorders	9 (22.5)	6 (15)	
Type of surgery			
Laparoscopic	30 (75)	28 (70)	
Open	8 (20)	8 (20)	0.69[c]
Robotic	2 (5)	4 (10)	
Comorbidities			
Nil	27 (67.5)	25 (62.5)	
Diabetes mellitus	6 (15)	8 (20)	
Hypertension	1 (2.5)	2 (5)	0.81
DM+HTN	2 (5)	3 (7.5)	
Others	4 (10)	2 (5)	

[a] Mean (SD) was reported; [b] Student *t* test; [c] Chi-squared test.

Table 2. Comparison of preoperative biochemical parameters

Variables	Mean (SD)		T value	*P* value[a]
	Experimental group (n = 40)	Control group (n = 40)		
Bio chemical parameters				
Haemoglobin (g/dL)	11.1 (1.8)	12.1 (1.7)	-2.58	0.01*
WBC	9307.3 (2693)	12545.8 (2562)	-0.79	0.43
Platelet	2.5342 (0.9)	2.371 (0.5)	1	0.32
Albumin (g/dL)	3.457 (0.5)	3.6 (0.4)	-1.29	0.2
Sodium (mEq/L)	135.3 (3.8)	136.9 (3.4)	-2.04	0.04*
Potassium (mEq/L)	4.1 (0.6)	4.1 (0.5)	0.05	0.95
Pre-operative nutrition requirement				
Energy requirement (based on subjective global assessment)	1345.5 (315.0)	1333.9 (226.1)	0.19	0.85
Protein requirement	51.1 (10.1)	51.725 (8.9)	-0.279	0.78

[a] Student *t*-test was used; *Statistically significant.

and after the intervention in the experimental group was 0.3 (-0.1–0.5) and in the control group was -0.3 (0.7-0.2). This difference in albumin between the groups was significant ($P < 0.001$). (Table 4)

Discussion

Major gastrointestinal (GI) surgeries stimulate metabolic responses related to increased muscle proteolysis and augmented energy expenditure that places patients at increased risk of acute disease-related malnutrition, where even an excess of adipose tissue will not avert catabolism of lean tissue. This catabolic state cannot retreat only through protein and energy intake, but, strategies to slow lean body mass wasting alleviate the inflammatory response, and if it is provided through enteral route, the integrity of the gastrointestinal tract is maintained.

Malnutrition before GI surgery is caused by decreased oral food intake, pre-existing chronic disease, tumour cachexia, impaired absorption due to intestinal obstruction, and previous surgical bowel resection. Malnutrition is one of the important observations in patients with hepatobiliary disorders which had been widely recognized.[14] In the current study most of the patients in both group were well-nourished according to SGA but several studies reported most of the patients with chronic GI problems to tend to be moderately malnourshied.[15,16]

Malnutrition is linked to the length of hospital stay and plays a role in postoperative outcomes such as infection. Clear pre- and postoperative nutrition has shown improved outcomes in many studies.[17] In the current study although the duration of hospital stay was extended in the control group it was not statistically significant. During the pre-operative period, patients in the experimental group were more malnourished compared to the control group but still, the patients in the experimental group were discharged early. Energy intake nutritional status has a significant role in the postoperative duration of hospital stay and postoperative outcome parameters.[18]

In the current study, the duration of ICU stay between the two groups was not statistically significant. Similar findings reported by Lew et al., showed no significant association between malnutrition and higher ICU length of stay.[19]

The current study showed, the incidence of infection was less in experimental group compared to the control group. Despite low nutritional status during the pre-operative period, less infection is noted in the experimental group than in the control group, it could be due to the effect of pre-operative nutritional protocol implementation. Energy intake oral supplementation of a minimum of five days is reported to have beneficial effects for the patients.[19] In the current study there are no statistically significant changes between the groups in terms of the presence of complications. Son et al., reported that appropriate nutritional therapy can significantly reduce patient's postoperative complications.[20]

In the current study, there is early removal of a drainage tube in the experimental group which was statistically significant. Similar findings reported by Ljungqvist et al., which showed, there is a significant association between energy intake with optimum nutritional supports with early drainage tube removal.[13]

In the current study, there was a shorter timing of appearance of first bowel sound and early initiation of enteral feeding in the experimental group compared to the control group which was statistically significant. The results are concurrent with evidence of previous studies.[21-23]

Studies have reported that energy intake protein-rich nutrition can enhance the postoperative serum albumin which will be effective in the context of preventing postoperative stress.[24-26] Albumin is considered a universal indicator for the nutritional status of patients. The current study also showed, patients who received structured pre-operative nutritional protocol had increased post-operative albumin.

Table 3. Comparison of subjective global assessment among patients with experimental group and control group

Variables	Experimental group (n = 40) N (%)	Control group (n = 40) N (%)	*P* value[a]
Surgical history			
Nil	30 (75)	29 (72.5)	0.05
<5 years	2 (5)	3 (7.5)	
5-10 years	6 (15)	4 (10)	
>10 years	2 (5)	4 (10)	
BMI			
Under nourished	15 (37.5)	8 (20)	0.22
Normal	21 (52.5)	27 (67.5)	
Over weight	4 (10)	5 (12.5)	
Type of feeding			
Oral	34 (85)	38 (95)	0.14
Feeding jejunostomy	6 (15)	2 (5)	
Weight loss during past 3 months			
No weight change	22 (55)	24 (60)	0.40
Weight loss < 5%	14 (35)	12 (30)	
Weight loss 5- 9%	2 (5)	4 (10)	
Weight loss 10-15%	2 (5)	0 (0)	
Severe weight loss > 15%	0 (0)	0 (0)	
Any change in food intake over the past three months due to loss of appetite, digestive problem, chewing, or swallowing difficulties			
No change	21 (52.5)	23 (57.5)	0.45
Sub-optimal diet	11 (27.5)	13 (32.5)	
Full liquid of moderate decrease	8 (20)	4 (10)	
Hypo caloric liquid	0 (0)	0 (0)	
Starvation	0 (0)	0 (0)	
Gastrointestinal symptoms			
No symptoms	18 (45)	24 (60)	0.39
Nausea/decreased appetite	11 (27.5)	10 (25)	
Vomiting/moderate GI symptoms	7 (17.5)	5 (12.5)	
Diarrhoea	4 (10)	1(2.5)	
Severe anorexia	0 (0)	0 (0)	
Decreased fat stores or loss of subcutaneous fat			
No change	29 (72.5)	32 (80)	0.50
Moderate	10 (25)	8 (20)	
Severe	1 (2.5)	0 (0)	
Signs of muscle wasting			
No change	31 (77.5)	37 (92.5)	0.13
Moderate	7 (17.5)	3 (7.5)	
Severe	2 (5)	0 (0)	
Nutritional status			
Well nourished	34 (85)	39 (97.5)	0.04*
Moderately malnourished	6 (15)	1 (2.5)	
Severely malnourished	0 (0)	0 (0)	

[a]Chi square test; *Statistically significant.

Table 4. Comparison of post- operative outcome parameters among patients with experimental group and control group (N=80)

Variables	Mean (SD)		*P* value
	Experimental group (n=40)	Control group (n=40)	
Duration of hospital stay(day)	9.12 (4.64)	10.77 (3.95)	0.09[c]
Albumin level on 3rd post-operative day	3.6 (0.4)	3.3 (0.4)	0.003[c*]
Pre and post operative difference in albumin[a]	0.3 (-0.1–0.5)	-0.3 (-0.7 – 0.2)	0.001[d*]
Duration of ICU stay[a]	3 (2-4)	4 (2-5)	0.15[e]
Duration of mechanical ventilator support[a]	1 (0-1.5)	1 (0-2.5)	0.16[e]
Presence of any infection[b]			
Nil	28 (70)	23 (57.5)	
Surgical site infections	9 (22.5)	15 (37.5)	0.50[f]
Pleural effusion	2 (5)	1 (2.5)	
Others	1 (2.5)	1 (2.5)	
Presence of any complications[b]			
Nil	33 (82.5)	32(80)	0.77[f]
Current	7 (17.5)	8 (20)	
Day of removal of drainage tube[a]	3 (0-5)	5 (2.5-7.5)	0.02[e*]
Timing of first bowel sound[a]	1.1 (0.5)	1.6 (0.9)	0.01[e*]
Day of starting enteral feeding[a]	2 (1-2.5)	3 (1- 4)	0.007[e*]

[a] Median (IQR) was reported; [b] N (%) was reported; [c] Student *t* test; [d] Mann-Whitney U test; [e] Wilcoxon rank sum test; [f] Chi-square test; [*] Statistically significant.

Conclusion

This study assessed the effect of the structured pre -operative energy intake nutritional protocol over postoperative recovery in patients undergoing gastrointestinal surgeries. Although the effect of structured energy intake nutritional therapy on duration of hospital stay, duration of ICU stay, and presence of complications was not statistically significant, there was a positive trend noted on these parameters. The current study shows, early postoperative recovery has an effect of structured energy intake nutritional therapy over the existing nutritional protocol in terms of removal of the drainage tube, early bowel sound, early starting of enteral feeding, and increases in postoperative albumin level. However, the results may not be generalized due to limited sample size and diverse pre -operative diagnosis. There were various implicit factors that would have influenced the preoperative nutritional status of patients in control group and also in postoperative outcomes.

Research Highlights

What is the current knowledge?

An optimal nutritional state is a significant consideration in providing effective operative outcomes. Malnutrition and surgical stress cause the suppression of immune function. Poor pre-operative nutritional status has been associated with an increase in postoperative complications and poorer surgical outcomes.

What is new here?

Improving the nutritional status preoperatively among malnourished patients would improve functional recovery in post-operative period. Regardless of nutritional status, reducing pre-operative fasting periods and implementing structured nutritional protocol was useful in improving post-operative clinical outcomes. Nutritional support must not be ignored when considering optimal surgical care.

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Ethical Issues

None to be declared.

Conflict of Interest

The authors declare that they have no conflict of interest.

Authors' Contributions

AB, LR, BP: Conception and design, analysis and interpretation of the data, drafting of the article, final approval of the article; AB, LR: Data collection; LR, BP: Critical revision of the article for important intellectual content.

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