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Research Article

Effect of High Protein versus Normo Protein Normo Caloric Feeding in Nutritionally High Risk Critically Ill Patients: A Randomized Controlled Trial

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ABSTRACT

Background: Malnutrition in critically ill patients is associated with poor outcomes. Evidence supporting the benefit of high-protein normo-caloric nutrition over standard protein intake in nutritionally high-risk ICU patients remains limited.
Methods: This randomized, double-blind comparative study was conducted in a mixed ICU. All patients were screened using the modified Nutrition Risk in the Critically Ill (mNUTRIC) score. Patients with mNUTRIC score >5 fulfilling eligibility criteria were randomized into two groups: Group S received a normo-caloric high-protein enteral diet (25 kcal/kg/day, protein 2 g/kg/day) and Group C received a normo-caloric normo-protein diet (25 kcal/kg/day, protein 1 g/kg/day). Demographic variables, severity scores, caloric and protein intake, ICU length of stay, duration of mechanical ventilation, mortality, change in SOFA score at 96 hours, and complications were recorded.
Results: Of 644 patients screened, 328 had mNUTRIC score >5. One hundred patients were analyzed (50 in each group). Baseline demographics, severity of illness, mNUTRIC, and SOFA scores were comparable. Fourteen-day cumulative calorie deficit was similar between groups (4954±1843 vs 5239±2071 kcal; p=0.12), while cumulative protein deficit was significantly lower in Group S (142±165 vs 199±188 g; p=0.01). There was no significant difference in mortality (38% vs 42%; p=0.68) or ΔSOFA at 96 hours. ICU length of stay and duration of mechanical ventilation were shorter in Group S but did not reach statistical significance. Complication rates were comparable.
Conclusions: High-protein normo-caloric nutrition reduced protein deficit but did not significantly improve clinical outcomes in nutritionally high-risk ICU patients.

Keywords*: Nutrition , critical care, high protein, NUTRIC score.*

INTRODUCTION

Malnutrition is a common yet frequently under-recognized and undertreated problem in critically ill patients. The reported incidence of malnutrition in intensive care units (ICUs) ranges from 39% to 60%.[1,2] Critical illness induces a hypermetabolic and hypercatabolic state that predisposes patients to rapid protein depletion and loss of lean body mass. This risk is further exacerbated by inadequate nutritional delivery due to gastrointestinal intolerance, frequent interruptions for procedures, hemodynamic instability, and delayed initiation of enteral nutrition.[3,4]

Malnourished ICU patients experience higher mortality, prolonged ICU and hospital length of stay, increased duration of mechanical ventilation, and poorer clinical outcomes due to impaired immune function, accelerated skeletal muscle catabolism, and delayed wound healing when compared with optimally nourished patients.[5,6] Despite increasing recognition of the importance of nutritional therapy, consensus regarding the optimal balance between energy and protein delivery remains elusive.

Observational studies have demonstrated that a cumulative caloric deficit ≥6000 kcal or a protein deficit ≥300 g is associated with prolonged ICU stay, longer hospitalization, and fewer ventilator-free days.[7] Conversely, randomized trials have suggested that aggressive caloric delivery early during critical illness may be associated with harm.[8,9] Consequently, contemporary critical care nutrition has shifted focus from calorie targets toward prevention of protein debt. However, robust data evaluating the clinical impact of high-protein normo-caloric feeding compared with standard-protein normo-caloric feeding in nutritionally high-risk patients are limited. This study aimed to evaluate whether administration of a high-protein normo-caloric enteral diet improves outcomes in critically ill patients with high nutritional risk (mNUTRIC score >5).

METHODS

Study Design and Population

This prospective, randomized controlled trial was conducted in the adult ICU of Safdarjung Hospital and Vardhman Mahavir Medical College, New Delhi, over an 18-month period (February 2020 to July 2021), following approval from the Institutional Scientific and Ethics Committees. Written informed consent was obtained from patients or their legally authorized representatives.

Nutritional risk was assessed using the modified Nutrition Risk in the Critically Ill (mNUTRIC) score (table-1) . Adult patients (≥18 years) with an mNUTRIC score >5 who required ICU care for more than 48 hours and received enteral nutrition via a naso-enteric route for at least five days were eligible for inclusion.

Exclusion criteria included receipt of prior nutritional support during the same hospitalization, concomitant parenteral nutrition, gastrointestinal surgery requiring >48 hours of nil-per-oral status, transfer from another ICU or long-term care facility, enrollment in transplantation programs, chronic kidney disease with uremic encephalopathy, and morbid obesity.

Randomization and Intervention

Eligible patients were randomized using a computer-generated randomization sequence into two groups:

- **Study Group (Group S):** Normo-caloric high-protein enteral nutrition (25 kcal/kg ideal body weight [IBW]/day and protein 2 g/kg IBW/day)
- **Control Group (Group C):** Normo-caloric normo-protein enteral nutrition (25 kcal/kg IBW/day and protein 1 g/kg IBW/day)

Target feeding rates were achieved within 48–72 hours depending on clinical status and feed tolerance. Only patients who completed at least five days of follow-up and received >5 kcal/kg/day were included in the final analysis. Daily and cumulative caloric and protein deficits were calculated for up to 14 days or until ICU discharge, death, or initiation of oral feeding.

Outcomes

The primary outcome was 14-day ICU mortality. Secondary outcomes included change in Sequential Organ Failure Assessment (ΔSOFA) score at 48 and 96 hours, ICU length of stay, duration of mechanical ventilation, and complications such as hypo- and hyperglycemia, insulin requirements, acute kidney injury (AKI), and need for renal replacement therapy (RRT).

Statistical Analysis

Data were analyzed using SPSS version 21. Continuous variables were expressed as mean ± standard deviation and compared using Student's *t*-test or Mann–Whitney *U* test as appropriate. Categorical variables were analyzed using the chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

During the study period, 644 patients were admitted to the ICU, of whom 328 (50.9%) were identified as nutritionally high risk (mNUTRIC >5). One hundred patients fulfilled inclusion criteria and were randomized equally into the two groups (flowchart-1). Baseline demographic characteristics, body mass index, APACHE II score, SOFA score, and mNUTRIC score were comparable between groups (table-2).

Fourteen-day mortality was 38% in Group S and 42% in Group C (p=0.68). Mean cumulative caloric deficit did not differ significantly between groups (4954±1843 kcal vs 5239±2071 kcal; p=0.12). However, cumulative protein deficit was significantly lower in Group S (−112±165 g) compared with Group C (199±188 g; p=0.01) (table-3).

Group S demonstrated shorter ICU length of stay (9.6±13.8 vs 13.8±24.1 days) and reduced duration of mechanical ventilation, though these differences were not statistically significant. The change in SOFA score at 96 hours favored the high-protein group but did not reach statistical significance. Rates of glycemic complications, insulin use, AKI, and RRT were similar between groups.

Table 1- mNutric Score (modified NUTRIC score (without IL-6))

Variable	Range	Points

Age	<50	0
	50-75	1
	>/=75	2
SOFA	<6	0
	6-9	1
	>/=10	2
APACHE II	<15	0
	15-19	1
	20-27	2
	>/=28	3
Comorbidities	0-1	0
	>/=2	1
Days from hospital to ICU admit	0-1	0
	>1	1

Flow Chart-1- Methodology

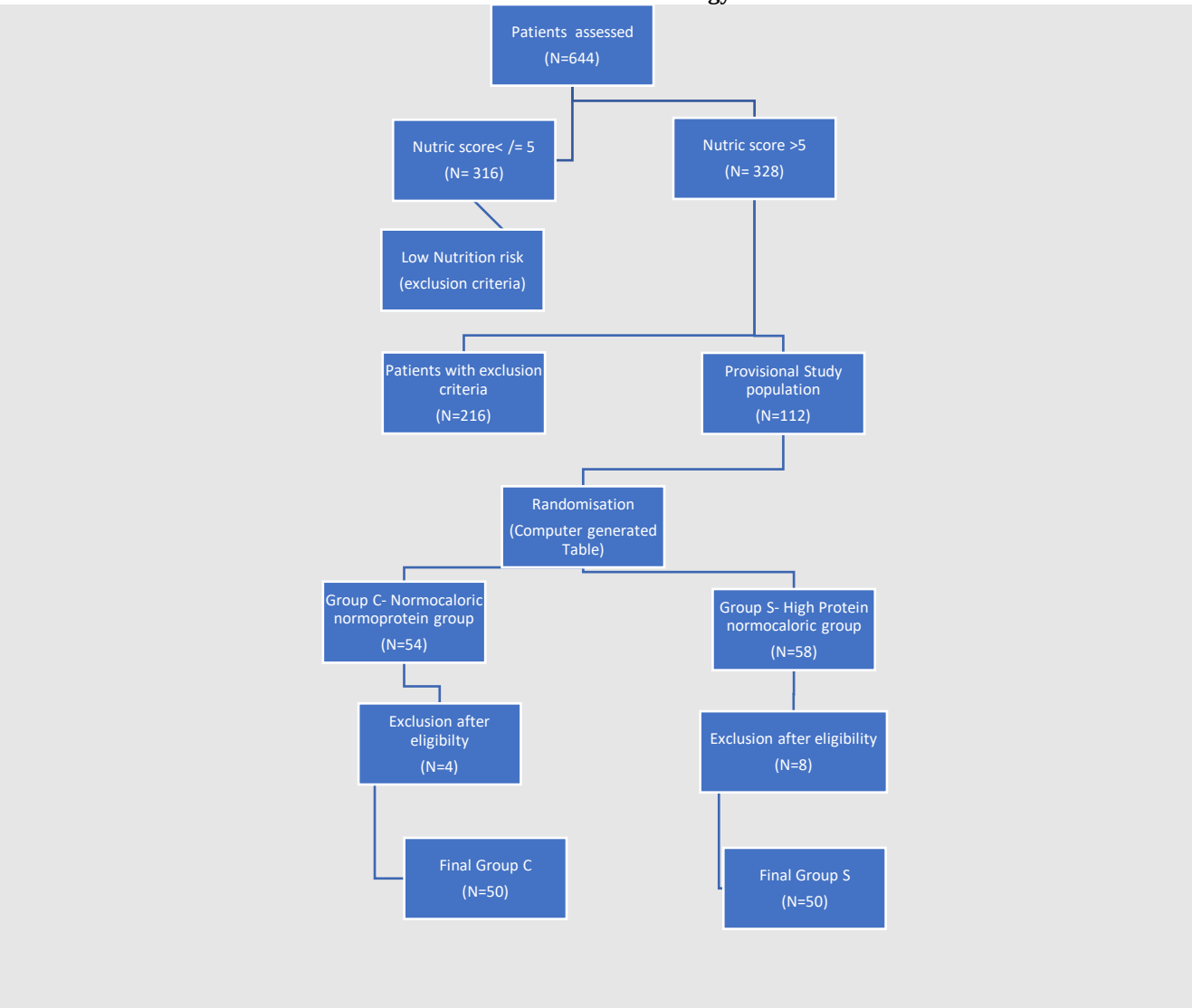

Table 2: Baseline characteristics

	Group S	Group C	Pvalue
Age (in years)	34.28±19.93	39.12±18.29	0.2
BMI (kg/m^2)	22.67±3.14	22.26±2.63	0.47
APACHE-II	17.34±2.07	17.30±1.68	0.91
SOFA Baseline	8.10±1.50	7.96±1.24	0.61
NUTRIC Score	6.34±0.59	6.46±0.64	0.28

Mean +/- SD

Table 3: Study observation between Group S and Group C

	Group S	Group C	Pvalue
Mortality (%)	38%	42%	0.68
SOFA at 96 hours	7.3±2.63	7.46±2.22	0.74
SOFA Mean change#	-1.08±2.40	-0.40±2.24	0.14
Cumulative calorie deficit up to Day 14 (in kcal)	4954.00±1843.40	5239.00±2071.11	0.12
Cumulative protein deficit up to Day 14 (in grams)	-112±165.50	199.52±187.95	0.01*
Duration of ICU stay in days	9.60±13.81	13.76±24.12	0.57
Duration of mechanical ventilator in days	7.80±10.84	11.44±19.18	0.27
patients with Hypoglycemic events	1	1	1
Patients with Hyperglycemic events	6	10	0.27
Insulin requirement (in number of patients)	6	9	0.4
AKI*(in number of patients)	9	7	0.72
RRT#(in number of patients)	3	2	

Mean +/- SD

DISCUSSION

Nutrition therapy in critically ill patients has evolved with increasing recognition that uniform and static feeding strategies fail to address the dynamic metabolic, inflammatory, and hormonal changes seen during critical illness. Contemporary guidelines emphasize individualized nutrition, particularly in patients identified as nutritionally high risk. In this context, we evaluated whether a high-protein, normo-caloric enteral diet improves outcomes in patients with mNUTRIC score >[5].[10]

During the study period, 644 patients were admitted to the ICU, of whom 328 (50.9%) were identified as nutritionally high risk using the mNUTRIC score. This prevalence is higher than that reported in earlier studies that used subjective assessment tools such as the Subjective Global Assessment (SGA), likely reflecting the greater objectivity and ICU-specific applicability of the mNUTRIC score. Similar prevalence rates have been reported from Indian tertiary care centers using the same scoring system.[10]

The primary outcome of 14-day mortality was marginally lower in the high-protein group compared to the control group; however, this difference was not statistically significant. Overall mortality remained high (~40%) across both groups, highlighting the strong association between malnutrition and adverse outcomes. Comparable mortality rates have been reported in other studies involving patients with high mNUTRIC scores.[10],[11] These findings further support the role of mNUTRIC as a predictor of mortality, as its components—advanced age, severity of illness, organ dysfunction, and comorbidities—are independently associated with poor outcomes.[12]

Despite identical calorie targets, both groups accrued significant calorie deficits, reflecting the well-recognized challenges of achieving energy goals in critically ill patients.[13] In contrast, protein delivery differed substantially. Patients receiving high-protein enteral nutrition achieved a cumulative protein surplus, whereas the control group remained in deficit, demonstrating the feasibility of meeting recommended protein targets using high-protein formulations.[14]

Although reductions in ICU length of stay, duration of mechanical ventilation, and early SOFA score improvement favored the high-protein group, these differences were not statistically significant, consistent with prior studies.[15],[16] No increase in metabolic or renal complications was observed.

Overall, while high-protein enteral nutrition improves protein adequacy and may influence morbidity, its impact on short-term mortality in nutritionally high-risk ICU patients remains inconclusive, in line with previous mixed evidence.[17–19]

LIMITATIONS

Key limitations include reliance on the mNUTRIC score for risk stratification, inability to consistently achieve target protein intake in all patients, absence of indirect calorimetry for individualized energy prescription, and lack of parenteral protein supplementation.

CONCLUSIONS

High-protein normo-caloric enteral nutrition significantly reduced protein deficit but did not translate into improved mortality or organ dysfunction in nutritionally high-risk critically ill patients. Larger, adequately powered trials with individualized nutrition strategies are warranted.

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