RESEARCH ARTICLE

Impact of an individualized hypocaloric, high-protein enteral nutrition protocol on clinical outcomes in critically Ill obese Indian patients: A pre-and post-intervention study

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ABSTRACT

Background: Current clinical nutrition guidelines for critically ill obese (CIO) patients rely on expert consensus and general ICU data, necessitating research into targeted approaches. This study evaluated the impact of an individualized hypocaloric, high-protein (HHP) enteral nutrition (EN) protocol on clinical outcomes in CIO Indian patients. *Methods:* In this study, 104 mechanically ventilated CIO Indian patients (WHO-Asian Obese BMI classification) receiving EN were divided into the HHP (n=52) and pre-intervention (n=52) groups. The HHP protocol provided 20 to 25 calories/kg actual body weight (ABW) for BMI 25 to 29.9 kg/m^2, 15 to 20 calories/kg ABW for BMI ≥30 kg/m^2 and 1.5 g protein/kg ideal body weight (IBW). The pre-intervention protocol provided 25 to 30 calories/kg adjusted body weight and 1.2 to 1.3 g protein/kg IBW. Primary endpoints were mechanical ventilation (MV) days, ICU, and hospital length of stay (LOS). The secondary endpoint was in-hospital mortality. *Results:* The HHP group received higher target calories and proteins. HHP protocol significantly reduced MV days (6.8 ± 4.3 *vs.* 9.5 ± 5.4 days; $p = 0.001$), ICU LOS (9.7 ± 3.6 *vs.* 15.5 ± 8 days; $p = <0.001$), and hospital LOS (14.9 ± 6.6 *vs.* 20.4 ± 10.8 days; $p = 0.008$). In-hospital mortality was lower in the HHP group (13 *vs.* 29%; $p = 0.056$). *Conclusion:* The HHP EN protocol improved nutrition delivery and significantly reduced MV days, ICU stay, and hospital stay, with a trend toward lower in-hospital mortality in CIO Indian patients.

Keywords: Obese, critically ill, hypocaloric, high-protein, enteral nutrition, clinical outcomes.

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INTRODUCTION

Enteral nutrition (EN) is crucial for managing critically ill patients, especially those critically ill and obese. Managing nutrition in critically ill obese (CIO) patients is particularly challenging due to their hypermetabolic state, stress-induced inflammation, and comorbidities. The hypermetabolic state that occurs due to the stress of critical illness leads to increased energy expenditure and intensified protein catabolism, which may cause insulin resistance, leading to hyperglycemia and accelerated muscle breakdown. The accompanying inflammatory response further elevates the body's energy needs and alters nutrient metabolism. These factors can severely deplete nutritional reserves and disrupt nutrient metabolism, increasing the risk of malnutrition in the intensive care unit (ICU).[1] In addition, many of the CIO patients may also have pre-existing, undiagnosed malnutrition that often worsens during their ICU stay, further exacerbating the morbidity. Adequate nutritional support is essential for managing the immune response, preserving lean muscle mass, reducing the catabolic rate, and maintaining gastrointestinal health in CIO patients.[2]

Effective management of nutrition support can significantly impact recovery and outcomes in the ICU. However, providing tailored nutritional support for critically ill obese (CIO) patients is complex due to the lack of robust evidence and clear guidelines. Estimation of the caloric and protein requirements accurately for CIO patients is challenging. While indirect calorimetry is considered the gold standard for assessing energy requirements, it is not feasible in daily clinical practice. Conventional predictive equations often fail to provide precise requirements, either underestimating or overestimating the nutritional needs.[3]

Current guidelines offer varying recommendations for CIO patients. According to the European Society for Parenteral and Enteral Nutrition (ESPEN) guidelines, CIO patients should receive 20 to 25 kcal/kg/day ('isocaloric') and 1.3 g protein/kg/day based on adjusted body weight.[4] In contrast, the American Society for Parenteral and Enteral Nutrition (ASPEN)/ Society of Critical Care Medicine (SCCM) guidelines

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suggest 11 to 14 kcal/kg/day ("hypocaloric") using actual body weight for those with a BMI between 30 to 50 kg/m^2 and 22 to 25 kcal/kg/day using ideal body weight for those with a BMI > 50 kg/m^2 and a protein target of 2 to 2.5 g/kg ideal body weight/day to preserve lean body mass, mobilize adipose stores, and reduce the metabolic complications of overfeeding.[5] ASPEN/SCCM and ESPEN emphasize the need for individualized approaches and close monitoring for the nutritional management of CIO patients.[4-6] In India, Mehta *et al*. (2018) recommended considering hypocaloric, high-protein enteral feeding for critically ill obese patients.[7]

The hypocaloric, high-protein (HHP) nutritional strategy has gained attention due to its potential benefits in improving clinical outcomes by addressing the unique metabolic needs of critically ill patients. This approach emphasizes providing adequate protein while restricting caloric intake to reduce complications associated with overfeeding in critically ill patients. Research indicates that HHP nutrition support may reduce mechanical ventilation (MV) days, ICU length of stay (LOS), and hospital LOS.[8,9]

In CIO, the hypocaloric regimen can help prevent exacerbation of hyperglycemia and overfeeding complications. Limiting caloric intake and focusing on protein aims to manage metabolic demands without contributing to excessive caloric intake. High-protein nutrition supports muscle maintenance and repair by providing essential amino acids necessary for these processes. The HHP strategy helps manage the hypermetabolic state, reduce muscle catabolism, and avoid complications of overfeeding, ultimately supporting better clinical outcomes and recovery in CIO patients.[10]

However, only a few studies have investigated HHP feeding in CIO patients, and their findings have needed to be more consistent. Research by Burge *et al*.[11] and Choban *et al*.[12] reported no differences in the hospital LOS and mortality in CIO surgical patients receiving HHP parenteral nutrition. In contrast, a retrospective study by Dickerson *et al*.[13] reported significant reductions in ICU LOS, decreased antibiotic use, and a trend towards fewer MV days in CIO trauma patients receiving HHP nutrition.

These mixed results emphasize the need for further investigation into the effects of HHP EN, especially in CIO patients. The impact of HHP feeding on CIO patients, particularly in different geographical contexts, such as India, has yet to be extensively studied. Therefore, this study aims to fill this gap by evaluating the impact of an individualized HHP EN protocol on clinical outcomes in CIO Indian patients through a pre-and post-intervention analysis, providing valuable insights into its efficacy and practical implications in this specific patient population.

METHODS

Study Design and Population

This prospective comparative cohort study aimed to evaluate the impact of an individualized, hypocaloric, high-protein (HHP) enteral nutrition (EN) protocol on critically ill obese (CIO) Indian patients in a multidisciplinary ICU. The study compared retrospective data from a pre-intervention group (July- December 2019) with prospective data from an HHP group (November 2020—March 2021). The Institutional Ethics Committee-Biomedical Research Apollo Hospitals, Chennai, approved the study. Written informed consent was obtained from patient representatives.

Inclusion Criteria

The study included consecutive adult critically ill patients admitted to the ICU who met the WHO-Asian obese BMI classification[14] criteria, were mechanically ventilated within 48 hours of ICU admission, and received enteral nutrition (EN) for at least three days.

Exclusion Criteria

Patients under 18 years, those with burns, pregnant women, patients with BMI under 25, and those receiving EN for less than three days were excluded.

Enteral nutrition (EN) Protocol

HHP EN protocol (Figure 1)

The HHP EN protocol, as outlined in Table 1, includes the following:

• *Multidisciplinary team training*

To ensure effective implementation of the HHP EN protocol, a comprehensive training session was conducted for the multidisciplinary team, including doctors, nurses, and dietitians. The training included an overview of the protocol, clinical significance and protocol specifics, and role-specific training and documentation instructions for the doctors, nurses, and dietitians. Periodic refresher sessions were conducted to ensure protocol adherence and address challenges encountered during implementation.

• *EN prescription*

The EN prescription was tailored based on WHO-Asian Obese BMI categories. The specific nutrition targets were as follows:

- For patients with an estimated BMI between 25 to 29.9 kg/m^2, the caloric prescription was set at 20 to 25 calories per kilogram of actual body weight. This range was suggested to balance nutritional needs while avoiding excessive caloric intake.
- For patients with an estimated BMI ≥30 kg/m^2, the caloric prescription was 15 to 20 calories per kilogram of actual body weight. This lower caloric range was adopted to better match the needs of patients with higher levels of obesity and to mitigate the risks of overfeeding.
- For proteins, regardless of BMI category, all patients were prescribed 1.5 g of protein per kilogram of ideal body weight. This protein target was selected to support muscle maintenance and to address the increased requirements often seen in critically ill patients.

EN Initiation

EN was initiated within 48 hours of ICU admission, unless contraindicated, in line with ESPEN 2019 and ASPEN 2016 guidelines for critically ill patients[4,5]. Any decision to delay or withhold EN was based on specific clinical contraindications, such as severe gastrointestinal dysfunction, hemodynamic instability, or other conditions where EN might be deemed unsafe or ineffective.

EN was initiated at a rate of 30 mL per hour and then gradually increased stepwise until the target rate was achieved.

Nutritional Assessment

A Clinical Dietitian evaluated the nutritional status of CIO patients using the modified Subjective Global Assessment (mSGA) tool.[15] This validated and widely recognized tool for assessing the nutritional status of critically ill patients ensured that the evaluation was both thorough and objective, supporting accurate identification of the patient's dietary needs, optimizing nutrient delivery, and enhancing recovery.

Caloric and Protein Requirements

A Clinical Dietitian calculated the caloric and protein requirements according to the new HHP EN protocol. A high-protein EN formula was used to meet the increased protein requirements. The protocol followed a stepwise incremental approach to achieve 80% of the prescribed caloric and protein targets by day three and 90% of the targets by day five.

Nursing Responsibilities

Nurses were trained to "catch up" on feeds if interruptions occurred, whenever feasible, to minimize calorie and protein deficits. Details on feed initiation, EN tolerance, reasons for interruptions, and enteral feeding details, including EN volume and timings, were documented in the patient's case record by the Nurses and monitored by the Clinical Dietitian daily.

Daily Monitoring

The Clinical Dietitian monitored the nutritional support provided to each patient daily. This involved meticulously calculating and recording the prescribed caloric and protein requirements and the amounts delivered through EN. The Clinical Dietitian tracked these details daily to ensure that the nutritional goals were being met, adjusting to match the patient's evolving needs and addressing any discrepancies between the prescribed and delivered nutrition. This thorough daily documentation allowed for precise adjustments to the nutritional plan, ensuring optimal support for the patient's recovery and overall health.

Protocol Continuation

The HHP EN protocol was maintained throughout the patient's stay in the ICU until one of the following conditions was met: the patient could start an oral diet, be discharged from the ICU, or in the event of patient mortality. The continuation of the protocol ensured that patients received consistent and appropriate nutritional support during the critically ill period. This approach provided a structured framework for managing nutritional needs, enabling timely adjustments to the protocol based on the patient's evolving condition and recovery progress.

Pre-intervention Protocol

CIO patients admitted to the ICU before November 2020 received nutritional support based on a standardized protocol. Each patient received 25-30 calories per kg of adjusted body weight and 1.2 to 1.3 g of protein per kilogram of ideal body weight.

Table 1: HHP and Pre-intervention EN protocols

Variable	*HHP group*	*Pre-intervention group*
EN initiation	Within 48 hours of admission to the ICU	No protocol
Calories	BMI 25-29.9 kg/m2 = 20 to 25 calories/kg actual body weight (ABW), BMI ≥30 kg/m2 = 15 to 20 calories/kg ABW	25-30 calories/kg adjusted body weight
Proteins	1.5g/kg ideal body weight	1.2-1.3g/kg ideal body weight
EN formula	Isocaloric formula + high protein formula	Isocaloric formula
Interruptions	Catch-up EN feeding for interruptions when not contraindicated	No protocol

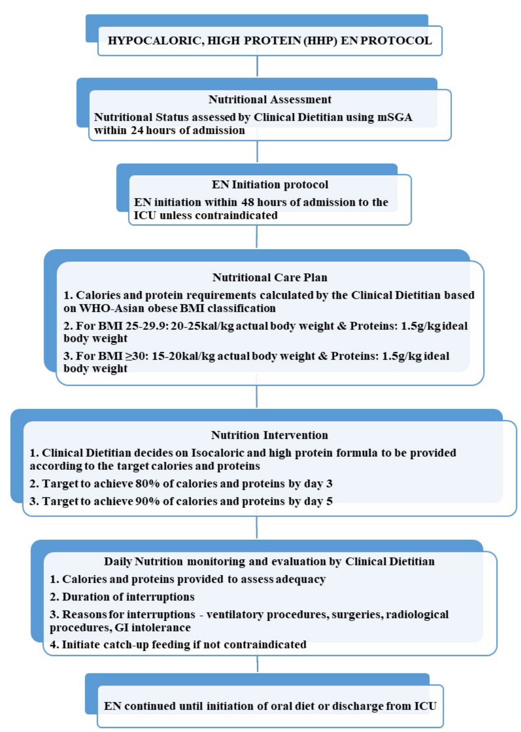

Figure 1: Hypocaloric, high protein (HHP) EN protocol

Data collection

A comprehensive data collection was performed to support the analysis and evaluation of nutritional interventions. The following basic demographic data were collected from the medical records: sex, age, reported weight, estimated BMI, comorbidities, admission diagnosis, Glasgow Coma Scale (GCS), and Acute Physiology and Chronic Health Evaluation II (APACHE II) scores. These details provided a fundamental understanding of each patient's profile and severity of illness. Specific data on nutrition support, including the EN initiation time, frequencies, reasons for interruptions, and both prescribed and achieved target calories and proteins, were meticulously recorded. These nutritional metrics were tracked on days three and five, as well as throughout the entire ICU stay, to facilitate insights about protocol adherence, the impact of nutritional support on patient outcomes, and potential areas for improvement.

Outcomes

Primary outcomes assessed were mechanical ventilator (MV) days, length of stay (LOS) in the ICU, and hospital LOS. The secondary outcome observed was all-cause hospital mortality. The Clinical Dietitian collected outcome data by reviewing patient case records, including electronic health records and other relevant documentation, to ensure accuracy in data collection.

Statistical Analysis

Various statistical methods were used to analyze the data. The mean, a measure of central tendency, provided an overall summary of the dataset, while the standard deviation quantified the variation from the mean. To compare parametric data between the two groups, independent t-tests were performed to assess whether the means of two independent samples were significantly different from each other. For non-parametric data, the Mann-Whitney U test was used to compare the medians of two independent groups, particularly when data did not meet the assumptions required for parametric testing.

Categorical variables were analyzed using Chi-square tests of independence to determine if there is a significant association between two categorical variables by comparing observed frequencies to expected frequencies under the null hypothesis of no association. Two-tailed tests were used for all analyses, as our hypotheses did not specify a direction of effect. The statistical models employed were Model I (fixed-effects models), as we focused on specific groups and categories defined in our study. A p-value of less than 0.05 was considered statistically significant. All statistical analyses were conducted using SPSS software, version 29.0.

RESULTS

This study assessed the impact of an HHP EN protocol on various clinical outcomes in a cohort of 104 CIO Indian patients, equally divided between the HHP group and the pre-intervention group. At baseline, the groups had no significant differences in age, sex, and BMI. APACHE II scores (23 ± 6.7 *vs.* 20.9 ± 4.9; $p = 0.086$) and polymorbidity rates (48 *vs.* 42%; $p = 0.556$) were similar in both groups. However, the Glasgow Coma Scale (GCS) scores were notably lower in the HHP group (Table 2). Most patients were admitted with neurological diagnoses, followed by respiratory conditions, sepsis, and trauma profiles. Table 2 summarizes the baseline characteristics of the study patients.

Nutritional assessment by the Clinical Dietitian using the mSGA tool revealed a significantly higher prevalence of malnutrition among patients in the HHP group. The HHP group had 65% of malnourished patients relative to 42% in the pre-intervention group. EN was initiated earlier in the HHP group compared to the pre-intervention group, with an average difference of 7.4 hours. However, this difference was not statistically significant.

The caloric target in the HHP group was significantly lower at 1523 ± 104.4 kcal compared to 1874 ± 294.5 kcal in the pre-intervention group. In contrast, the protein target was significantly higher in the HHP group (92.5 ± 13.5 g) versus the pre-intervention group (75 ± 11.4 g).

Implementing the HHP EN protocol led to a significantly improved delivery of both calories and proteins. On day three, patients in the HHP group received a significantly higher proportion of calories (85 vs. 55%; $p = <0.001$), and the trend continued on day five (91 *vs.* 51%; $p = <0.001$). Similarly, the target protein delivered was higher on day three (71 *vs.* 55%; $p = <0.001$) and day five (83% vs. 51%; $p = <0.001$) (Table 3) in the HHP group (Figure 2).

Throughout the ICU stay, the HHP group received a significantly higher proportion of their target calories (94 vs. 65%; $p = <0.001$) and proteins (80 vs. 63%; $p <0.001$). A higher number of patients in the HHP group met or exceeded the 75% threshold for caloric targets ($p = <0.001$) and protein targets ($p = <0.001$) during their ICU stay (see Figure 3).

Feeding interruptions occurred more frequently in the pre-intervention group, although the difference was insignificant. The primary reasons for interruptions were intubation and extubation (51%), followed by tracheostomy (38%), surgeries (19%), radiological procedures (18%), and gastrointestinal disturbances (13%).

The HHP group showed a significant 20% reduction in MV days (6.83 ± 4.33 vs. 9.58 ± 5.43 days; $p = 0.001$). Similarly, the ICU-LOS and the hospital-LOS were also significantly lesser in the HHP group (9.75 ± 3.5 days vs. 15.5 ± 8.02 days; $p = <0.001$), (14.96 ± 6.6 days vs. 20.46 ± 10.88 days; $p = 0.008$) (Table 4). All-cause hospital mortality decreased by over 50% after implementing the HHP EN protocol, although it only showed near statistical significance (13 vs. 29%; $p = 0.056$). A subset analysis indicated an inverse relationship between protein intake and mortality: mortality was lowest in patients achieving at least 1.2 g/kg IBW (14%), followed by those receiving 1 to 1.19 g/kg IBW (29%) and highest in patients who received less than 1 g/kg IBW of protein (57%).

Table 2: Baseline Characteristics of Study Cohort

Patient Characteristics	*HHP group (n=52) [mean±SD/n (%)]*	*Pre-intervention group (n=52) [mean ± SD/n (%)]*	*p-value*
Age, y	58.4±14.6	56±13.1	0.256
Sex - Male	35 (67%)	35 (67%)	1
BMI, kg/m^2	28±3.3	28.3±3.3	0.443
APACHE II	23±6.7	20.9±4.9	0.086
GCS	4.04±1.95	6.12±6.03	<0.001
Polymorbidity	25 (48%)	22 (42%)	0.556
DM	30 (58%)	33 (63%)	0.549
HTN	31 (60%)	26 (50%)	0.24
Diagnosis			
Neurology and neuro-surgery	16 (31%)	14 (27%)	
Respiratory	11 (21%)	12 (23%)	
Sepsis	8 (15%)	12 (23%)	0.836
Trauma	7 (13%)	2 (4%)	
Others	10 (19%)	12 (23%)	
Malnutrition	34 (65%)	22 (42%)	0.018

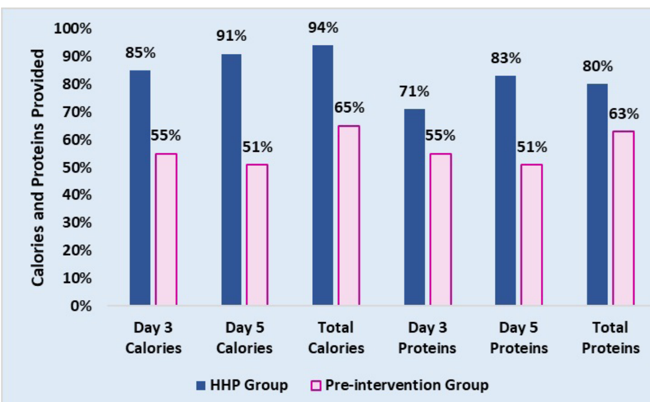

Figure 2: Enteral nutrition provided to the HHP and pre-intervention groups

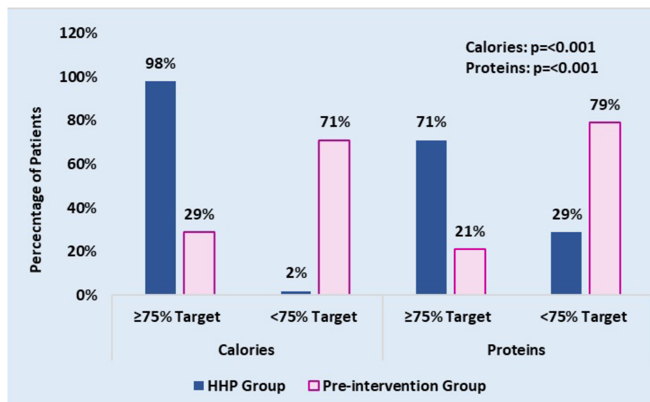

Figure 3: Percentage of Patients Achieving ≥75% Calorie and Protein Targets in the HHP and Pre-intervention groups

DISCUSSION

This study demonstrates that implementing the HHP EN protocol significantly improved the delivery of optimized nutrition and several key outcomes, including a reduction in MV days, ICU LOS, and hospital LOS. The findings also suggest a trend toward reduced mortality, though this did not reach statistical significance.

The HHP EN protocol significantly improved the delivery of calories and proteins compared to the pre-intervention group. The HHP group received more target calories and proteins on days three and five. This aligns with previous studies emphasizing the importance of meeting nutritional targets to improve patient outcomes. For instance, Weijs *et al*. (2014) found that early and adequate delivery of calories and proteins in ICU patients is associated with better clinical outcomes, including reduced infection rates and shorter ICU stays.[16] Our study shows that an HHP regimen can achieve similar benefits, potentially offering a more tailored approach to nutrition in CIO Indian patients.

The observed reduction in MV days by 20% and ICU LOS by 37% in the HHP group is consistent with findings from another research. Rugeles *et al*. (2013) demonstrated that optimizing nutritional support could reduce MV days and ICU LOS, improving recovery rates.[9] The observed decrease in mortality in the HHP group (13% versus 29% in the pre-intervention group) approached but did not reach statistical significance (p = 0.056). This result is consistent with the mixed results found in the literature regarding the impact of nutritional interventions on mortality. However, the results

Table 3: Comparison of Nutrition Delivered between HHP and Pre-intervention groups

Variables	*HHP group (n=52) (mean±SD)*	*Pre-intervention group (n=52) (mean±SD)*	*p-value*
EN Initiation (hours)	16.5 ± 14.6	23.9 ± 35.6	0.802
Total Calories prescribed (kcal)	1523 ± 104.4	1874 ± 294.5	<0.001
Total Proteins prescribed (g)	92.5 ± 13.5	75 ± 11.4	<0.001
Day 3 Calories (kcal)	1325 ± 344.7	1006 ± 282.5	0.006
Day 5 Calories (kcal)	1442 ± 358.7	947 ± 447.6	<0.001
Total Calories (kcal)	1431 ± 162	1218 ± 282	<0.001
Day 3 Proteins (g)	64.8 ± 19.8	53.3 ± 13.9	<0.001
Day 5 Proteins (g)	75.4 ± 22.5	42.5 ± 21.2	<0.001
Total Proteins (g)	74 ± 14.06	54.5 ± 13.9	<0.001
ENICU (days)	8.73 ± 3.1	11.71 ± 7.69	0.053
Interruptions (hours)	15.29 ± 18.3	24.83 ± 27.69	0.073

Table 4: Comparison of Clinical Outcomes between HHP and Pre-intervention groups

Variables	*HHP group (n = 52) (mean ± SD)*	*Pre-intervention group (n = 52) (mean ± SD)*	*p-value*
Mechanical ventilator Days	6.83 ± 4.33	9.58 ± 5.43	0.001
LOS ICU (days)	9.75 ± 3.5	15.5 ± 8.02	<0.001
LOS Hospital (days)	14.96 ± 6.6	20.46 ± 10.88	0.008
Mortality (n, %)	7 (13%)	15 (29%)	0.056

observed in our study are similar to findings by Doig *et al*. (2013), who reported that high-protein, hypocaloric feeding protocols are associated with lower mortality rates, although not all studies have consistently shown significant reductions in mortality.[17]

The inverse relationship between protein intake and mortality observed in our study highlights the importance of adequate protein provision. Previous research supports this association, noting that higher protein intake improves outcomes in critically ill patients. Suzuki *et al*. (2020) emphasized that achieving high protein targets can mitigate muscle loss and improve survival rates in critically ill patients.[18] Our findings reinforce these conclusions, suggesting that a high-protein, hypocaloric approach may significantly reduce mortality.

Achieving high protein intake within a hypocaloric regimen presents a significant challenge but is crucial for effective nutritional management. This challenge was addressed by incorporating a high-protein EN formula in the HHP EN regimen, enabling the delivery of 80% of the target protein, a critical factor in the observed clinical improvements. Careful planning and monitoring were required to balance the high protein intake with the hypocaloric approach, ensuring that patients received adequate nutrition without exceeding calorie targets. This meticulous planning highlights the complexity of managing nutritional support in CIO patients and demonstrates that such an approach is feasible and beneficial. Achieving substantial protein delivery while adhering to caloric constraints was instrumental in enhancing patient outcomes, reinforcing the importance of tailored nutritional strategies in CIO patients.

Early EN initiation appears to be a critical factor in improving clinical outcomes, given its importance in managing critically ill obese patients during the acute phase of illness. Existing research indicates timely nutritional support can mitigate muscle catabolism, enhance immune function, and improve overall clinical outcomes.[17,19,20] In the current study, although the HHP group initiated EN earlier than the pre-intervention group, this difference was not statistically significant, suggesting that while early EN is beneficial, other factors may also influence outcomes.

Feeding interruptions were more frequent in the pre-intervention group, although this difference was not statistically significant. The reasons for interruptions - such as intubation, extubation, and other procedures—are consistent with challenges reported in different studies.[9,10] Addressing these interruptions through improved management and protocol adjustments could enhance nutritional delivery and patient outcomes.

This study is one of the few prospective investigations to implement and evaluate the effect of an HHP EN protocol on clinical outcomes in CIO Indian patients. It is important to note that this pilot study, with its small sample size and single-center setting, did not fully explore the practical challenges of multicentre implementation. Future prospective, multicentre studies with larger cohorts are crucial to fully assess the benefits of an HHP EN protocol on clinical outcomes in CIO Indian patients.

CONCLUSION

When implemented with comprehensive multidisciplinary team support, an individualized hypocaloric, high-protein EN protocol substantially enhances enteral nutrition practices. This strategy results in significant reductions in mechanical ventilation days, ICU length of stay, and hospital length of stay and may contribute to a decrease in mortality rates among critically ill obese patients in India.

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CONFLICT OF INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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PEER-REVIEWED CERTIFICATION

During the review of this manuscript, a double-blind peer-review policy has been followed. The author(s) of this manuscript received review comments from a minimum of two peer-reviewers. Author(s) submitted revised manuscript as per the comments of the assigned reviewers. On the basis of revision(s) done by the author(s) and compliance to the Reviewers' comments on the manuscript, Editor(s) has approved the revised manuscript for final publication.