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ORIGINAL ARTICLE

Effect of Oral Protein Supplementation on Nutritional Status and Quality of Life in Hemodialysis Patients

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Abstract:

Background: *Malnutrition and protein-energy wasting (PEW) are significant predictors of morbidity and mortality in patients undergoing maintenance hemodialysis (HD). This study evaluated the impact of oral nutritional supplementation (ONS) on nutritional status and healthrelated quality of life (HRQoL) in a real-world clinical setting.*

Methods: *A prospective quasi-experimental pre–post study was conducted at Dhaka Medical College Hospital involving 50 adult HD patients. Participants received a high-protein ONS (Fresubin HP, 42g protein/day) for one month. Nutritional status was assessed via serum albumin levels, while HRQoL was measured using a 25-item questionnaire adapted from the KDQOL-36. Statistical analysis was performed using SPSS version 26.0, employing the Wilcoxon signed-rank test to compare pre- and post-intervention biochemical markers.*

Results: *The mean age of participants was 47.62±12.40 years. Following the one-month intervention, mean serum albumin levels increased significantly from 4.16±0.40 g/dL to 4.36±0.38 g/dL ($p < 0.001$). Post-intervention HRQoL assessment revealed a mean total score of 95.98±12.19 (range: 25–125). Patients reported the highest satisfaction in the "Dialysis Care" (22.06±3.35) and "Symptoms & Problems" (20.98±3.24) domains, while "Social Functioning" (16.68±2.85) and "Emotional Well-being" (17.66±3.00) remained the lowest-scoring areas.*

Conclusion: *Short-term oral protein supplementation effectively improves serum albumin levels in maintenance hemodialysis patients, addressing critical nutritional deficits. While ONS contributes to high satisfaction regarding physical symptoms and clinical care, the persistence of lower social and emotional QoL scores suggests that nutritional interventions should be integrated into a broader multidisciplinary support framework. These findings support the routine use of highprotein ONS in resource-limited renal care settings to improve clinical outcomes.*

Keywords: *Hemodialysis, Malnutrition, Oral Nutritional Supplementation, Serum Albumin, Quality of Life.*

Introduction

Malnutrition, particularly protein–energy wasting (PEW), is highly prevalent among patients undergoing maintenance hemodialysis (HD) and represents a major clinical concern. It has been reported that up to 40–70% of HD patients suffer from some degree of malnutrition, which significantly contributes to increased morbidity, mortality, hospitalization rates, and diminished quality of life (QoL)[1,2]. PEW in HD patients results from multiple factors including inadequate dietary intake, chronic inflammation, metabolic acidosis, and

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dialysis-related nutrient losses[3]. Consequently, poor nutritional status is strongly associated with adverse clinical outcomes and reduced survival among this population[2,4].

Oral nutritional supplementation (ONS) has been widely recommended as a practical and costeffective strategy to improve dietary protein and energy intake in HD patients. Several studies have demonstrated that ONS can lead to improvements in key nutritional indicators such as serum albumin, body mass index (BMI), and subjective global assessment (SGA) scores, as well as enhance overall QoL[5,6]. High-protein oral supplements have been shown to mitigate the effects of PEW and improve patient-reported outcomes, making them an important component of nutritional management in dialysis care[6,7].

Despite the growing body of evidence supporting the benefits of ONS, most available studies are randomized controlled trials (RCTs) conducted in well-resourced settings. There is a paucity of data from low- and middle-income countries, particularly from real-world clinical settings using simpler quasi-experimental designs. Moreover, short-term interventional studies evaluating the immediate impact of protein supplementation on both nutritional status and QoL remain limited.

Therefore, this study aimed to assess the effect of oral protein supplementation on nutritional status and quality of life among hemodialysis patients using a pre–post quasi-experimental design.

Methods

Study design

The research was structured as a prospective, quasi-experimental pre–post study. This design was selected to evaluate the efficacy of nutritional intervention in a pragmatic, real-world clinical setting, which is particularly essential in low-resource environments where strict randomization might encounter significant logistical or ethical barriers. By utilizing the patients as their own controls, the study effectively accounts for stable individual confounding factors such as genetics and chronic baseline comorbidities. The study focused on measuring changes over a one-month intervention period, which represents a critical window for identifying biochemical shifts in protein markers like serum albumin.

Study setting and duration

The study was conducted at Dhaka Medical College Hospital (DMCH) in Dhaka, Bangladesh. DMCH is the largest tertiary care public health facility in the country and serves as a primary hub for renal replacement therapy for a diverse and medically complex patient population. The hemodialysis unit at DMCH operates under extreme demand, reflecting the broader national challenge where approximately 35,000 to 40,000 individuals reach ESKD annually but dialysis facilities can only accommodate a fraction of new cases.

The duration of the intervention was one month (30 days), with follow-up and data collection conducted at baseline and at the conclusion of the supplementation period. This timeframe was chosen based on evidence indicating that short-term ONS can rapidly stabilize serum albumin levels and improve patient energy levels before longer-term anthropometric changes manifest.

This study was conducted among patients undergoing maintenance hemodialysis at Dhaka Medical College Hospital. A total of 50 HD patients were enrolled in this quasi-experimental study. All participants were assigned to receive oral nutritional supplementation containing 42 g protein powder daily for a duration of 1 month. Nutritional status and quality of life were assessed before and after the intervention.

Study population

A cohort of 50 patients undergoing maintenance hemodialysis was enrolled in this quasiexperimental study. The participants were selected from the existing patient pool at the DMCH hemodialysis unit.

Inclusion criteria

- The study utilized rigorous inclusion criteria to ensure the stability of the cohort and the relevance of the nutritional intervention:
- Adult patients aged e”18 years
- Patients receiving maintenance hemodialysis for at least 3 months
- Patients willing to provide informed consent

Exclusion criteria

- Patients with acute illness or active infection , recent hospitalization (within the last month), or active malignancy, as these conditions significantly alter albumin as a negative acute-phase reactant.
- Known allergies or intolerance to milk proteins or any ingredients in the prescribed supplement
- Patients with malignancy or severe liver disease
- Known allergy or intolerance to milk proteins or any ingredients in the prescribed supplement

Terminal illness with a life expectancy of less than six months

- Patients receiving parenteral nutrition
- Patients who were unable to complete the follow-up assessment

Sample size

A total of 50 patients were included in this study based on feasibility and availability during the study period.

Intervention

All participants received oral nutritional supplementation (ONS) in the form of high-protein powder preparation, providing approximately 42 g of protein daily for 1 month. The intervention utilized a specific high-protein powder formulation (Fresubin HP®), 60 mg. Patients were instructed to consume the supplement as per standard recommendations in addition to their regular diet.

Nutrient Composition and Administration

The supplement was prescribed at a dosage of one serving (42 g) daily. Each serving was designed to deliver approximately 18.5 to 20 grams of high-quality protein (whey and casein blend) and approximately 200 kcal of energy. The supplement is calorie-dense (2 kcal/ml when reconstituted), ensuring high nutrition in a low volume, which is critical for patients on fluid restriction.

Data collection

A comprehensive assessment was performed at baseline and after 30 days of supplementation. Data collection was divided into three primary categories: biochemical laboratory results, anthropometric measurements, and quality of life surveys.

Nutritional status assessment

Nutritional status was evaluated using the following parameters:

Serum albumin (g/dL)

Body mass index (BMI, kg/m²)

These parameters are widely used and validated indicators for assessing nutritional status in HD patients[2,3].

Quality of life assessment

The Kidney Disease Quality of Life 36-item Short-Form Survey (KDQOL-36) was the primary instrument used to assess HRQOL. This survey is specifically designed for the dialysis population and includes the SF-12 as a generic core plus kidney disease-targeted scales. For this study, the Bengali (Bangladesh) version of the KDQOL-36 was used, which has been translated and utilized in previous studies within the country to ensure linguistic and cultural validity[8].

Scores for each subscale were transformed into a scale from 0 to 100, where higher scores represent a superior health-related quality of life.

Study variables

Independent variable

Oral protein supplementation

Dependent variables

Serum albumin (g/dL)

Body mass index (BMI) (kg/m²)

Quality of life scores

Statistical analysis

Data were analyzed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation (SD).

KDQOL-36 Subscales	Measurement Focus
SF-12 Physical (PCS)	General physical health, mobility, and pain management.
SF-12 Mental (MCS)	Emotional well-being, depression, and social function.
Burden of Kidney Disease	The perception of how much the illness interferes with life.
Symptoms and Problems	Frequency of specific dialysis-related physical complaints.
Effects of Kidney Disease	The impact of the disease on daily chores and social activities.

Results

Demographic Characteristics

The study included 50 maintenance hemodialysis patients. The mean age of the participants was 47.62 ± 12.40 years (range: 17–71 years). In terms of gender distribution, 62% (n=31) were male and 38% (n=19) were female. All participants completed the one-month oral nutritional supplementation (ONS) protocol.

Table-I

Distribution of sex

Sex	Frequency Percentage	Percentage	Cumulative
F	19	38	38
M	31	62	100
Total	50	100	

Table-II

Descriptive statistics of age, albumin and QOl Score

	Mean	Std. Deviation
Age (years)	47.62	12.4
Serum Albumin (Before) (g/dL)	4.156	0.395
Serum Albumin (After) (g/dL)	4.363	0.379
Total QoL Score (Post)	95.98	12.19

Impact on Nutritional Status (Serum Albumin)

Nutritional status was primarily assessed via serum albumin levels. Baseline serum albumin was 4.16 ± 0.40 g/dL. Following one month of supplementation with 42g of protein daily, the mean serum albumin increased significantly to 4.36 ± 0.38 g/dL. The Wilcoxon signed-rank test confirmed that this improvement was statistically significant ($Z = -4.43$, $p < 0.001$). Most patients exhibited a positive trend, though individual responses varied.

Table-III

Comparison of serum albumin before and after intervention

Parameter	Before (Mean ± SD)	After (Mean ± SD)	Mean Difference	p-value
Serum Albumin (g/dL)	4.16 ± 0.39	4.36 ± 0.38	0.21	<0.001

Table-IV

Tests of Normality

Variable	Shapiro-Wilk Statistic	df	Sig. (p value)
Serum Albumin (Before)	0.95	50	0.034
Serum Albumin (After)	0.958	50	0.073

Note: Albumin (Before) is non-normally distributed ($p < 0.05$); therefore, non-parametric testing (Wilcoxon Signed-Rank Test) is primarily used for comparison.

Table-V

Wilcoxon Signed-Rank Test Results

	Serum Albumin (After)	Serum Albumin (Before)
Z-Statistic	-4.434	
Asymp. Sig. (2tailed)	<0.001	

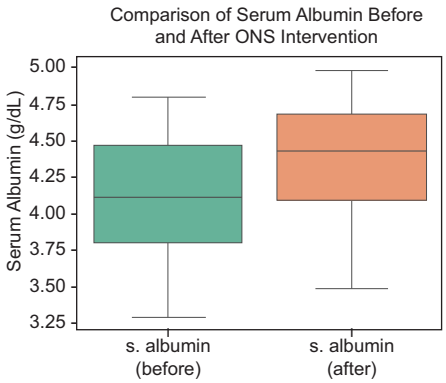

Figure 1: *Comparison of Serum Albumin before and after intervention*

Quality of Life (QoL) Assessment

The Quality of Life was assessed post-intervention using a 25-item questionnaire adapted from the KDQOL-36 and WHOQOL-BREF. The total possible score ranged from 25 to 125, where higher scores indicate better QoL.

The mean total QoL score post-intervention was 95.98± 12.19. When categorized into specific domains (each range 5-25), the scores were as follows:

- Dialysis Care Satisfaction: 22.06 ± 3.35 (Highest scoring domain)
- Symptoms & Problems: 20.98 ± 3.24

- Physical Health: 18.60 ± 1.63
- Emotional Well-being: 17.66 ± 3.00
- Social Functioning: 16.68 ± 2.85 (Lowest scoring domain)

The high scores in Dialysis Care and Symptoms suggest that while patients felt supported by the clinical setting and experienced manageable physical symptoms, the social and emotional impact of the disease remained the primary areas of concern.

Table-6

Baseline QoL score

Parameter	Mean ± SD
Overall QoL Score	2.81 ± 0.11

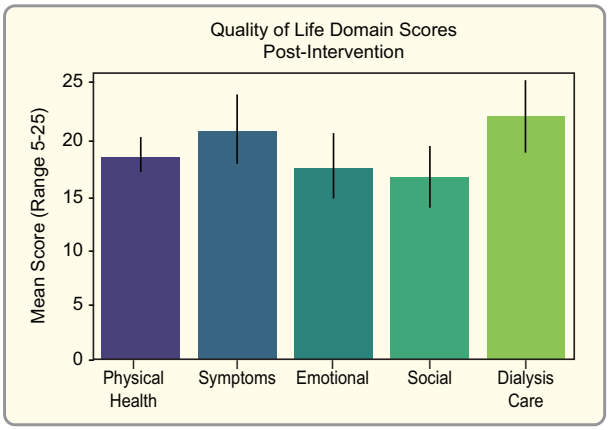

Figure2: *Quality of life domain scores after intervention*

Discussions

The findings of this study demonstrate that short-term (one month) oral protein supplementation significantly improves serum albumin levels among maintenance hemodialysis patients. This is a critical finding, as low serum albumin is one of the strongest predictors of mortality and morbidity in the ESRD population[9]. The observed increase from 4.16 g/dL to 4.36 g/dL aligns with previous literature suggesting that ONS provides the necessary nitrogen balance to counteract the protein-energy wasting (PEW) common in dialysis[10].

The significant improvement in albumin levels ($p < 0.001$) suggests that even a relatively brief intervention in a real-world setting like Dhaka Medical College Hospital can yield measurable clinical benefits. Our results are consistent with the findings of Lacson et al., who reported that patients receiving ONS showed a significant rise in albumin compared to those receiving standard care[11]. The use of a high-protein formula (42g/day) likely provided sufficient anabolic stimulus to overcome the chronic inflammatory state associated with uremia.

Regarding the Quality of Life, the post-intervention scores indicated a relatively high level of satisfaction with clinical care and symptom management. However, the lower scores in social and emotional domains (16.68 and 17.66, respectively) highlight that nutritional intervention alone may not fully address the psychosocial burden of hemodialysis. Sahathevan et al. have noted that while ONS improves physical markers, a multidisciplinary approach involving psychological support is often required to enhance the "Social Functioning" aspect of QoL[12].

The positive correlation between nutritional status and HRQoL has been well-documented in the Dialysis Outcomes and Practice Patterns Study (DOPPS), which showed that better nutrition is linked to improved physical component scores[13]. Our study reinforces this, as the "Physical Health" domain scores were relatively stable, likely supported by the improved protein intake.

Limitations of this study include the short duration of the intervention and the lack of a control group. Nevertheless, the quasi-experimental pre-post design provides valuable real-world evidence of the efficacy of ONS in resource-limited settings where malnutrition is prevalent. Future studies should aim for a longer follow-up period to assess the long-term sustainability of these nutritional gains and their impact on survival[14].

Conclusion

The study concludes that a short-term, one-month intervention with high-protein oral nutritional supplementation (42g protein/day) significantly improves serum albumin levels in maintenance hemodialysis patients, providing a practical strategy to combat protein-energy wasting in resource-limited clinical settings. While the supplementation was associated with high patient satisfaction regarding physical symptoms and the quality of dialysis care, the persistently lower scores in social and emotional domains highlight that nutritional support alone is insufficient to address the comprehensive psychosocial burden of end-stage renal disease. Consequently, while ONS should be integrated into standard renal care protocols to improve biochemical outcomes, it must be part of a broader, multidisciplinary approach that includes psychological and social support to achieve a holistic

improvement in the overall quality of life for hemodialysis patients.

Ethical considerations

The study was conducted with full adherence to ethical guidelines for human research. Institutional Review Board (IRB –) approval was secured from Dhaka Medical College Hospital. Informed consent was obtained in writing from every participant prior to their inclusion in the study. The confidentiality of participant data was maintained throughout the research, and the intervention was supervised by the attending nephrology medical officers to monitor for any adverse effects of supplementation, such as gastrointestinal intolerance or electrolyte disturbances. Participants were informed that their participation was voluntary and that withdrawal would not affect their standard dialysis care at the facility.

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