ORIGINAL ARTICLE

The Effect of Nutritional Supplement Program on the Malnutrition and Biochemical Indicators of Patients Undergoing Hemodialysis

Ali Tayebi[1], PhD; Abbas Ebadi[2, 3], PhD; Nahid Rajai[4], MSc; Effat Afaghi[5], MSc

[1]Nephrology and Urology Research Center, Faculty of Nursing, Baqiyatallah University of Medical Sciences, Tehran, Iran
[2]Behavioral Sciences Research Center, Lifestyle Institute, Baqiyatallah University of Medical Sciences, Tehran, Iran
[3]Nursing Faculty, Baqiyatallah University of Medical Sciences, Tehran, Iran
[4]Department of Hygiene, Faculty of Nursing, Aja University of Medical Sciences, Tehran, Iran
[5]Department of Critical Care Nursing, Faculty of Nursing, Aja University of Medical Sciences, Tehran, Iran

Correspondence:
Effat Afaghi, MSc;
Department of Critical Care Nursing, Faculty of Nursing, Aja University of Medical Sciences, Kaj St., Shariati St., Tehran, Iran
Tel: +98 21 77500404
Fax: +98 21 77601533
Email: afaghi8181@gmail.com
Received: 05 July 2023
Revised: 15 August 2023
Accepted: 20 September 2023

Abstract

Background: Protein-energy malnutrition is an important problem for hemodialysis patients due to decreased quality of life, increased hospitalization, and mortality. The present study aimed to investigate the effect of nutritional supplement programs on the malnutrition and biochemical indicators of patients undergoing hemodialysis.

Methods: In this Randomized Controlled Trial study, 66 patients undergoing hemodialysis were allocated to three groups according to the random allocation methods. Groups A and B received nutritional supplements IsoWhey protein powder (one cup or 24 grams' powder) and BCAA Muscle Guard Tablet (6 tablets per day: 2 tablets every 8 hours), respectively, along with a schedule of nutrition counseling, nephrology visits, and telephone follow-up for two months. The control group (group C) received a routine diet without supplementation. Biochemical indicators (Hemoglobin, BUN before and after dialysis, creatinine, cholesterol, triglyceride, TIBC, total protein, albumin, ferritin) were measured for all three groups before, one and two months after the intervention, and nutritional status based on SGA was assessed before and after the intervention.

Results: Before the intervention, three groups were homogeneous in demographic variables, biochemical indicators, and nutritional status ($P>0.05$). But, after the intervention, there was a statistically significant difference between groups in means of TIBC, total protein, and albumin ($P<0.05$). Also, nutritional status significantly differed in groups after intervention ($P=0.02$). The two intervention groups achieved a better nutritional status after two months of taking the dietary supplement ($P=0.008$). But in the control group, there was no significant difference in nutritional status before and after the study ($P<0.05$).

Conclusion: According to the results of this study, it could be suggested that the use of nutritional supplements under the supervision of a nutritionist, along with patient education and consistent nutritional assessment, is suggested to improve the nutritional status of patients undergoing hemodialysis.

Please cite this article as: Tayebi A, Ebadi A, Rajai N, Afaghi E. The Effect of Nutritional Supplement Program on the Malnutrition and Biochemical Indicators of Patients Undergoing Hemodialysis. J Health Sci Surveillance Sys. 2023;11(4):727-735.

Keywords: Hemodialysis, Malnutrition, Patients, Supplements

Introduction

Protein-energy malnutrition (PEM) is a current and important problem of chronic hemodialysis patients, with a prevalence of more than 50-75 percent of cases.[1, 2] Malnutrition is the intake of low or inadequate nutrition regarding the individual's nutritional needs, which is associated with some undesirable clinical outcomes, including decreased functional capacity, decreased quality of life, increased hospitalization, and mortality.[3, 4] Important causes of malnutrition in these clients include reduced food and protein intake, decreased appetite due to increased uremic toxins, protein loss during dialysis, chronic inflammation, increased catabolism during dialysis, inadequate dialysis, which reduces appetite, underlying diseases, and economic problems.[5-9]

Given the high malnutrition statistics, patients need a nutritional support system, and oral nutritional supplements (ONS) are among the cases that have received a lot of attention recently for the nutritional support of dialysis patients.[10] ONS are an easy, effective, and safe method to prevent and treat PEM.[7] Weight gain, improved daily living activities, reduced hospitalization, readmission, hospital costs, depressive symptoms, and mortality, especially in older people, are the benefits of ONS.[11-13]

The nutritional status of hemodialysis patients is one of the effective factors on clinical status. It is an important treatment method for these patients.[14] In this regard, a 10-year cohort study showed that malnutrition and decreased serum albumin independently predicted mortality in hemodialysis patients. In contrast, weight gain, Body Mass Index (BMI), and obesity changes did not predict mortality in these patients.[15]

Blasco et al. showed that intake of amino acid supplements increased serum albumin, total protein, dialysis adequacy, hemoglobin, and body weight. At the same time, it reduced C C-reactive protein (CRP) in the study group.[16] However, another study indicated that a protein-rich diet increased protein intake but did not affect dialysis adequacy or status of nutrition.[17] IsoWhey protein and Branched-Chain Amino Acid (BCAA) supplementation are the two protein products. IsoWhey protein Contains 100% pure whey protein isolate and minimal carbohydrates and has an enzyme complex to help better and faster protein digestion. BCAA contains essential branched-chain amino acids (leucine, isoleucine, and valine) that the body cannot produce. These three amino acids increase the synthesis rate and reduce the breakdown of proteins.[18, 19]

Given the high rates of Protein-Energy Malnutrition in hemodialysis patients and the positive clinical outcomes of nutritional supplements, it seems necessary to evaluate the effect of different protein supplements in these patients. Therefore, the purpose of this study was to investigate the effect of ONS of IsoWhey protein and BCAA supplementation on some biochemical indicators (Hemoglobin, BUN before and after dialysis, creatinine, Cholesterol, Triglyceride, TIBC, Total Protein, Albumin, Ferritin) and malnutrition in patients undergoing hemodialysis. The researcher did not find a study on the effect of these two supplements on dialysis patients.

Methods

This study is a randomized controlled trial of three groups performed in the hemodialysis ward of Baqiyatallah Hospital in Tehran. The sample size was calculated to be 22 for each group and 66 in total, using Altman nomogram and considering error type I (α=0.05) and error type II (β=10%) along with the test power of 80% and standard deviation calculation (E=2.1) from the study of Blasco et al.[16] and 10% probability of sample loss. Albumin was used as the primary outcome for sample size calculation.

Inclusion criteria consist of age between 18 and 75 years, albumin less than 4gr/dl, performing hemodialysis at least twice a week, having a history of at least six months of hemodialysis, BMI between 18.5 and 35 kg/m^2, absence of acute infection, severe heart and respiratory failure, chronic inflammatory disease with unknown cause, liver disease, dementia, nephrotic syndrome, neurological disease, cancer, hepatitis B, hepatitis C, HIV, active infection in last four weeks, surgery during the past three months or follow-up, no use of parenteral nutrition and ONS. Exclusion criteria included allergy to oral nutritional supplements, taking another supplement while studying, and withdrawal from continuing to study.

Outcome Evaluations

Demographic variables, including age, sex, education, BMI, duration of hemodialysis treatment, the frequency of hemodialysis per week, and the duration of a hemodialysis session, were collected using a clinical and demographic information questionnaire. Patients' weight was recorded with a scale with an accuracy of 100 grams and height with meters (cm).

Biochemical indicators (Hemoglobin, BUN before and after dialysis, creatinine, Cholesterol, Triglyceride, TIBC, Total Protein, Albumin, and Ferritin) were recorded according to the laboratory results. In this study, albumin level was considered a primary outcome, and other biochemical indicators and nutritional status of patients as a secondary outcome. Baqiyatallah Hospital laboratory measured biochemical indicators and all devices were pre-calibrated.

Also, Subjective Global Assessment) SGA (was used to assess the nutritional status of patients. SGA is a gold standard for determining nutritional status in

patients undergoing hemodialysis. SGA form consists of two categories: medical history (dietary intake, gastrointestinal symptoms, weight change, functional capacity and/or body wasting, and metabolic needs or disease conditions, such as head trauma, burns, physical injuries, infection, and inflammatory diseases) and physical examination (muscle wasting, loss of subcutaneous fat, and the presence of edema). If any of these components are normal, it will be given a score of A; if it is mildly to moderately affected, it will receive a score of B; if it has been severely affected, it will receive a score of C. In the final scoring of the SGA form, if most of the components are A-rated, the individual is in a normal nutritional status; if most of the components are B-rated, the individual is in mild to moderate malnutrition and if most of the components are C-rated, the individual is in severe malnutrition.[20]

The SGA form was completed twice for 20 clients at 15-day intervals to assess the reliability. The reliability coefficient between the two measurement times was acceptable (r=0.85).

Pre Interventions Phase

Selected patients were randomly allocated into study groups according to simple random allocation with Lottery.

Nutritional status based on SGA was assessed for all three groups before intervention. Before starting the hemodialysis process, a four cc venous blood sample was taken to analyze biochemical indicators (Hemoglobin, BUN before and after dialysis, creatinine, Cholesterol, Triglyceride, TIBC, Total Protein, Albumin, Ferritin), nutritional status based on SGA and biochemical indicators results recorded in the data collection form.

Interventions Phase

Group A received IsoWhey protein powder, and Group B received BCAA Muscle Guard Tablet produced by Karen Food and Pharmaceutical Company (Tehran, IR). The daily dose of supplements (prescribed by nutritionists and nephrologists for two months) was explained to caregivers and patients. The dosage in the IsoWhey group was the daily consumption of one cup or 24 grams of powder dissolved in water and for the BCAA group, six tablets (2 tablets every 8 hours) per day. At first, according to nutritionists and nephrologists, the supplement was started with a smaller amount (half a cup or 12 grams for IsoWhey and three tablets for BCAA). Then, it gradually increased to the prescribed amount if tolerated.

Nutrition counseling was performed monthly for groups A and B, and a nephrologist visited the participants weekly. Patients were also reminded to take supplements and followed up by phone calls, text messages, and in person. The researcher was responsible for answering patients' questions during the study.

Also, the control group (group C) received a routine diet without supplementation for two months. In the intervention phase, one month after the start of the intervention, biochemical indicators were analyzed in all three groups.

Post Interventions Phase

Two months after the intervention's start, nutrition status was assessed based on SGA and biochemical indicators analyzed in all three groups like pre intervention phase.

Ethical Considerations

This study with the code IR.BMSU.REC.1393.3 was approved by the Research Ethics Committee of Baqiyatallah University of Medical Sciences, Tehran, Iran. It was conducted with full adherence to ethical standards by obtaining written informed consent, informing patients about the study objectives, keeping enrollment completely free and voluntary, observing the principles of confidentiality, upholding patients' right to leave the study, obtaining necessary permits from relevant authorities, paying attention to the Helsinki Declaration, and respecting the original authors' rights concerning the use of printed and electronic materials. (IRCT Code: IRCT201209088650N5)

Statistical Analyses

Data analysis was performed using SPSS software version 16. The test of Kolmogorov-Smirnov was employed to check the normality of the data. In addition, descriptive statistics (mean, standard deviation [SD], percentage, and frequency) and inferential statistics (One-way analysis of variance [ANOVA], repeated measures ANOVA [RMANOVA], Chi-square, independent-samples t-test) were used. $P<0.05$ was considered the level of significance.

In this study, the authors used a Modified Intention to Treat analysis (MITT) approach to account for dropout occurrences during the study. This approach is a subset of the Full Intention to Treat analysis-MITT method. This approach is commonly used to explain an analysis that excludes participants who did not adequately adhere to the protocol, specifically those who did not receive a defined minimum amount of the intervention; thus, this method was used for analysis in the present study.

Results

Sixty-one patients completed the study (Figure 1). Thirty-three patients (54.09%) were male, and their mean

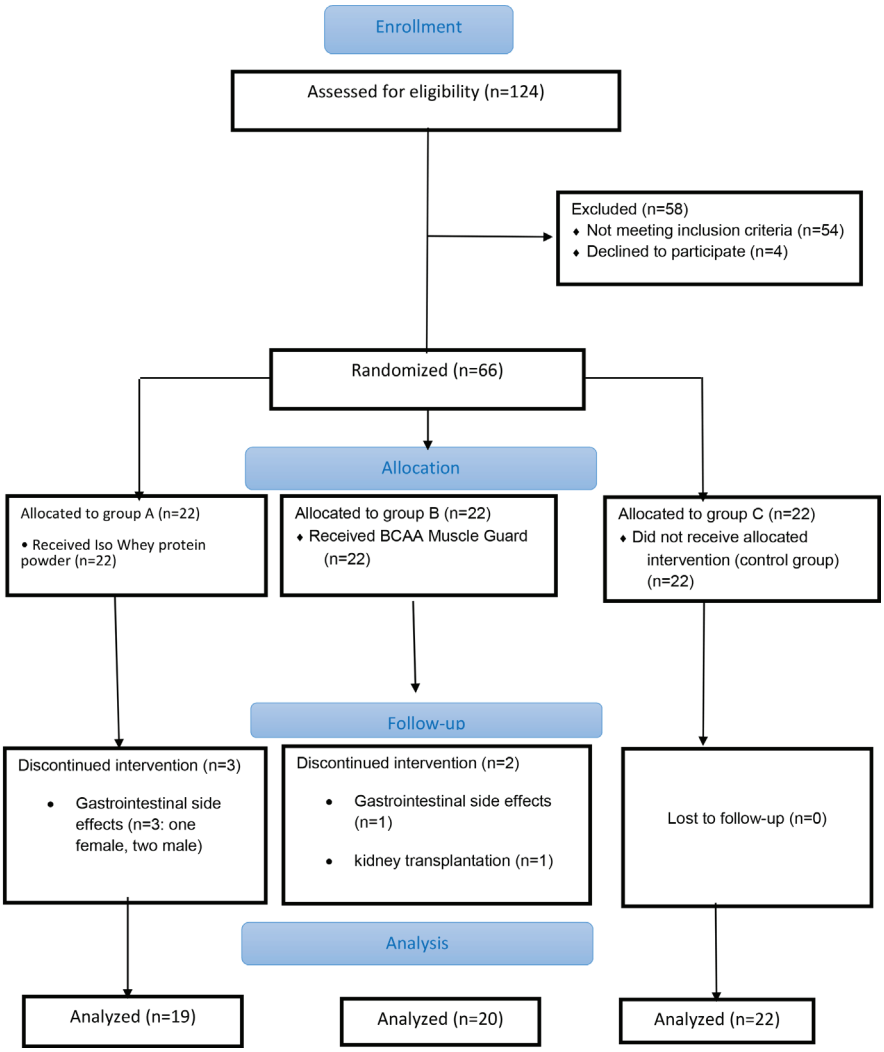

Figure 1: Data collection flowchart

Table 1: Comparison of quantitative demographic variables comparisons in ISO Whey, BCAA and control groups

Variable \ Group	ISO Whey (N=19)	BCAA[2] (N=20)	Control (N=22)	Test result^
Age (year)*	59.89 (10.75)	53.5 (10.14)	61.45 (14.1)	P=0.13
BMI[1] (m^2)*	25.67 (4.77)	23.52 (4.07)	26.1 (8.85)	P=0.38
Duration of hemodialysis treatment (year)*	4.21 (3.76)	3.05 (5.32)	2.84 (2.62)	P=0.51

*Mean (Standard Deviation), ^ANOVA test, P<0.05. [1]BMI: Body Mass Index, [2]BCAA: Branched-Chain Amino Acid

age was 58.28 years. Before the intervention, the groups were homogeneous regarding demographic variables, biochemical indicators, and nutritional status (P>0.05) (Tables 1-4)

The mean of biochemical indicators (hemoglobin, BUN before and after dialysis, creatinine, cholesterol, triglyceride, ferritin) in the two stages after the intervention in the three groups were not statistically different (P>0.05).

Regarding the TIBC index, a significant difference was shown between the three groups in the third stage of the study (P=0.002). Also, RMANOVA showed a significant difference between the three groups in the process of changes in the mean TIBC (P=0.001). Post Hoc test (Tukey HSD) showed the difference between Isoway and control groups (P=0.007, MD=50.10) and BCAA and control (P=0.006, MD=15.72) in two months after intervention.

Also, RMANOVA showed a significant difference between the three groups in the process of changes in the mean total protein (P=0.002). The post hoc test (Tukey HSD) did not show a significant difference between the groups in pairs.

Also, the results indicated a significant difference between groups in the second and third stages regarding albumin index, and the BCAA group had the highest amount of albumin compared to the other groups (P<0.001). Moreover, there was a significant difference between study groups in the process of changes in mean Albumin (P<0.001).

Table 2: Comparison of qualitative demographic variables comparisons in ISO Whey, BCAA and control groups

Variable \ Group	ISO Whey (N=19)	BCAA[1] (N=20)	Control N=22))	Test result^
Sex[ʃ]				
Male	9 (47.4)	12 (60)	12 (54.5)	x^2=0.62
Female	10 (52.6)	8 (40)	10 (45.5)	P=0.73
Education[ʃ]	5 (26.3)	6 (30)	3 (13.6)	
Elementary and less	7 (36.8)	7 (35)	14 (63.6)	x^2=4.51
Diploma and less	7 (36.8)	7 (35)	5 (22.7)	P=0.34
University				
Number of hemodialysis sessions[*]				
Twice a week	2 (10.53)	1 (5)	2 (9.09)	x^2=0.25
Three times a week	17 (89.47)	19 (95.5)	20 (90.91%)	P=0.68
Duration of one session[*]				
3 hours	2 (10.53)	3 (15)	4 (18.18)	x^2=0.63
4 hours	17 (89.47)	17 (85)	18 (81.82)	P=0.49
Total	19 (100)	20 (100)	22 (100)	

[ʃ]Mean (Standard Deviation); [*]Frequency (%); ^chi-Square test, P<0.05. [1]BCAA: Branched-Chain Amino Acid

Table 3: Comparison of mean values of biochemical indicators at different measurement stages in ISO Whey, BCAA and control groups

Biochemical indicators	Group/Times	IsoWhey (N=19) Mean (SD[3])	BCAA[4] (N=20) Mean (SD)	Control (N=22) Mean (SD)	Between group test^	Time× Group´
Hemoglobin (g/dl)	Before intervention	10.3 (1.23)	10.72 (1.51)	10.68 (1.22)	P=0.56	P=0.60
	One month later	10.5 (1.16)	10.88 (1.33)	10.55 (1.1)	P=0.55	
	Two months later	10.47 (1.29)	10.93 (1.24)	10.42 (1.19)	P=0.36	
BUN[1] before dialysis (mg/dl)	Before intervention	62.94 (23.2)	56.15 (12.46)	53.72 (13.5)	P=0.21	P=0.23
	One month later	61.78 (14.48)	62.05 (13.17)	50.68 (14.98)	P=0.02	
	Two months later	63.68 (17)	22.25 (6.85)	56 (12.56)	P=0.22	
BUN after dialysis (mg/dl)	Before intervention	21.05 (6.49)	22.25 (6.85)	21.45 (8.45)	P=0.87	P=0.56
	One month later	21.10 (6.16)	25 (8.78)	21.36 (11.9)	P=0.34	
	Two months later	22.47 (7.64)	25.90 (8.58)	21.59 (6.25)	P=0.25	
Creatinine (mg/dl)	Before intervention	7.25 (1.89)	7 (1.92)	6.23 (1.51)	P=0.25	P=0.32
	One month later	6.75 (1.88)	7.05 (1.88)	6.04 (1.55)	P=0.17	
	Two months later	6.8 (1.59)	6.8 (1.73)	6.32 (1.42)	P=0.51	
Cholesterol (mg/dl)	Before intervention	136.89 (37.85)	144.1 (35.69)	152.81 (53.78)	P=0.50	P=0.61
	One month later	135.21 (32)	131.2 (24.56)	142.4 (41.39)	P=0.55	
	Two months later	129.89 (32.19)	128.5 (24.17)	143.68 (39.26)	P=0.25	
Triglyceride (mg/dl)	Before intervention	109 (52.15)	107.2 (72.94)	144.31 (86.5)	P=0.18	P=0.63
	One month later	98.15 (37.5)	98.65 (74.57)	151.86 (94.5)	P=0.06	
	Two months later	106.89 (51.37)	99.05 (84.74)	144.95 (102.68)	P=0.17	
TIBC[2] (mcg/dl)	Before intervention	239.21 (56.37)	217.15 (39.56)	226.36 (50.75)	P=0.38	P=0.001[*]
	One month later	226.05 (38.86)	217.5 (57.41)	199.72 (58.58)	P=0.27	
	Two months later	239.73 (50.36)	220.1 (45.7)	189.63 (55.57)	P=0.002	
Protein (g/dl)	Before intervention	6.5 (0.59)	6.48 (0.45)	6.72 (0.54)	P=0.27	P=0.002[€]
	One month later	6.5 (0.72)	6.51 (0.45)	6.42 (0.47)	P=0.87	
	Two months later	6.69 (0.58)	6.71 (0.54)	6.38 (0.59)	P=0.11	
Albumin (g/dl)	Before intervention	3.64 (0.28)	3.69 (0.18)	3.51 (0.24)	P=0.06	P<0.001[©]
	One month later	3.64 (0.36)	4.06 (0.29)	3.68 (0.3)	P<0.001	
	Two months later	3.82 (0.53)	4.36 (0.31)	3.93 (0.34)	P<0.001	
Ferritin (ng/ml)	Before intervention	564.65 (241.92)	431.49 (308.57)	486.71 (265.82)	P=0.28	P=0.22
	One month later	516.45 (211.19)	459.59 (348.80)	489.52 (241.16)	P=0.79	
	Two months later	549.4 (217.63)	466.03 (367.58)	556.31 (241.1)	P=0.53	

^ANOVA test; ´RM ANOVA test; Post Hoc test (Tukey HSD), showed the difference between Isoway and control groups (P=0.007, MD=50.10) and BCAA and control (P=0.006, MD=15.72) in two months after intervention; [€]The post hoc test (Tukey HSD), did not show a significant difference between the groups in pairs; [©] Post Hoc test (Tukey HSD), showed the difference between BCAA and control groups (P<0.001, MD=-0.41) and BCAA and Isoway (P=0.002, MD=0.38) in one months after intervention also showed between BCAA and control groups (P<0.001, MD=-0.53) and BCAA and Isoway (P=0.006, MD=-0.42) in two months after intervention. [1]BUN: Blood Urea Nitrogen, [2]TIBC: Total Iron Binding Capacity; [3]SD: Standard Deviation, [4]BCAA: Branched-Chain Amino Acid.

Table 4: SGA[1]-based Nutritional Status in ISO Whey, BCAA and control groups

Time/Group	Before Intervention		After Intervention		Result test^
	Malnutrition	No malnutrition	Malnutrition	No malnutrition	
Iso Whey (N=19)	12 (63.2%)	7 (36.8%)	4 (21.1%)	15 (78.9%)	P=0.008*
BCAA[2] (N=20)	12 (60%)	8 (40%)	4 (20%)	16 (80%)	P=0.008*
Control (N=22)	11 (50%)	11 (50%)	10 (45.5%)	12 (54.5%)	P=0.95
Chi-Square	x^2=0.8 P=0.66		x^2=7.39 P=0.02*		

*P<0.05, ^McNemar Test. [1]SGA: Subjective Global Assessment, [2]BCAA: Branched-Chain Amino Acid

Post Hoc tests (Tukey HSD) revealed significant differences between the BCAA and control groups (P<0.001, MD=-0.41) and between the BCAA and Isoway groups (P=0.002, MD=0.38) one month after intervention. Similar differences were observed between the BCAA and control groups (P<0.001, MD=-0.53) and the BCAA and Isoway groups (P=0.006, MD=-0.42) two months after intervention (Table 3).

Furthermore, the nutritional status of patients was measured before and after the intervention. After the intervention, the nutritional status of patients was significantly different in groups (P=0.02). The two intervention groups achieved a better nutritional status after two months' intervention (P=0.008) (Table 4).

Discussion

This study assessed the effect of high protein ONS on several biochemical indicators and nutritional status in hemodialysis patients. Based on the results, the groups exhibited homogeneity in terms of demographic variables, biochemical indicators, and nutritional status before the intervention, enhancing the generalizability of the findings.

The results indicated that there was a significant difference between the groups in terms of albumin levels during the study stages. Specifically, the BCAA group had the highest albumin levels at one and two months after the intervention. The results of several articles were consistent with the present study. In this regard, a meta-analysis study was conducted in 2018 investigating the effect of oral supplements on hemodialysis patients. The results showed that the macronutrient blends or protein/amino acid supplements increased albumin levels.[21] Also, in a one-year cohort study, ONS in hemodialysis patients improved albumin levels and reduced patient mortality.[22] A randomized crossover design study examined the effect of protein supplementation on hemodialysis and peritoneal dialysis patients. The results showed no significant difference between the groups in the first six months of the study. However, in the fourth month, a significant decrease in albumin levels was reported in the intervention group, although the researcher pointed out a problem in calibrating the device. In the second 6 months of the study (months 3 and 6), the intervention group had significantly higher albumin levels.[23]

A decrease in serum albumin is one of the strongest predictors of mortality in chronic kidney failure.[24] The risk of mortality increases by up to seven-fold in each g/dl decrease in serum albumin. Of course, albumin is not a purely nutritional index because it is also reduced in inflammation but is well-suited to identify patients at risk of malnutrition.[25] Benner et al. stated in their study that ONS is an effective intervention for patients whose albumin is less than 3.5 mg/dl.[10] A pilot study reported that albumin concentrations below 3.8 gr/dl indicate inflammation-malnutrition syndrome, seen in half of hemodialysis patients and related to an increased mortality risk.[24]

The results showed that ONS had not affected hemoglobin, BUN before and after dialysis, creatinine, cholesterol, triglyceride, or serum ferritin. Consistent with this finding in the nonrandomized trial study, ONS containing protein, carbohydrates, and fats did not affect dialysis patients' creatinine and BUN levels.[26] Also, a study by Lacson et al. did not affect the hemoglobin of dialysis patients.[22] A Randomized Controlled Trial study showed that eight weeks of Whey protein intake in hemodialysis patients did not affect cholesterol and triglyceride levels.[27]

Regarding the nutritional status assessment, the results show that more than half of the patients had malnutrition at the beginning of the study. Based on various studies' results, insufficient daily intake of protein and energy compared to the recommended levels, restriction of certain dietary groups, anorexia, and loss of nutrients during hemodialysis, as well as abnormal nutrient metabolism, can lead to poor nutritional status.[28, 29]

The results also indicate that consumption of high protein ONS improves SGA-based nutritional status, which is consistent with the results of the study by Sohrabi et al.[27] In this study, fermented vitamin E-fortified whey beverage improved SGA score and malnutrition-inflammation score (MIS) in hemodialysis patients.[27] Moreover, Dudar et al. concluded that eating disorders affect patients' quality of life, significantly correlated with albumin and SGA levels (P<0.001).[30] This finding was consistent with the Lacson et al.[22] study. In this study, dietary supplementation led to a reduction in malnutrition in dialysis patients, and hypoalbuminemia was considered an indicator of malnutrition in patients.[22]

One of the study's strengths is the comprehensive examination of numerous available biochemical indicators. Additionally, the study's use of a nutrition counselor, nephrology visit, and telephone follow-up by the researcher during the duration of dietary supplementation contributed to its robustness. This study has several limitations that should be considered. Firstly, the small sample size could impact the generalizability of the results. Secondly, the lack of blinding among the researchers may introduce bias into the study. Additionally, the difficulty in controlling and evaluating the nutritional intake of patients both before and after the intervention was noted as a limitation. Future studies should aim to address these limitations for more robust results.

Certainly, conducting studies with larger sample sizes and longer durations is recommended to explore further the effects of interventions, such as BCAA supplementation, on hemodialysis patients. Additionally, considering a broader range of outcomes, including measures of depression, fatigue, and quality of life, can provide a more comprehensive understanding of the intervention's impact on patients' well-being.

Conclusion

The results of the study suggest that using oral nutritional supplements with high protein, in conjunction with a carefully planned diet under the guidance of a nutrition consultant, can lead to improvements in various biochemical parameters and nutritional status in hemodialysis patients. These findings underscore the importance of a comprehensive approach to patient care, focusing on nutrition, dialysis adequacy, quality of life, and overall well-being. By addressing these aspects, healthcare providers can aim to enhance patient outcomes, reduce mortality, and ultimately increase patient satisfaction.

Ethical Consideration

Ethics approval for this study was obtained from the Ethics Committee of Baqiyatallah University of Medical Sciences. Ethical Code: IR.BMSU.REC.1393.3

Financial Support

This article is an excerpt from the master's thesis and is sponsored by Baqiyatallah University of Medical Sciences.

Authors' Contribution

EA conceptualized and designed the study, prepared the manuscript and data collection; AT and AE analyzed the results and critically reviewed the manuscript; NR was involved in data analysis and editing. All authors read and approved the final manuscript.

Acknowledgment

The authors thank the Nephrology and Urology Research Center, Faculty of Nursing of Baqiyatallah University of Medical Sciences for its financial support, the guidance and advice of the Clinical Research Development Unit of Baqiyatallah Hospital, Karen Pharmaceutical and Food Supplement Company, dialysis ward staff and all those who participated in this study.

Conflict of Interest: None declared.

References

1 Afaghi E, Tayebi A, Sajadi SA, Ebadi A. The relationship between nutritional status based on subjective global assessment and dialysis adequacy. Nephro-Urol Mon 2021;13 (3):e116254. doi: 10.5812/numonthly.116254.

2 Ebadi A, Tayebi A, Afaghi E. The effect of an oral nutritional supplement on nutritional status of hemodialysis patients in a military hospital. J Mil Med 2021;22 (12):1222-30. doi: 10.30491/JMM.22.12.1222.

3 Małgorzewicz S, Gałęzowska G, Cieszyńska-Semenowicz M, Ratajczyk J, Wolska L, Rutkowski P, Jankowska M, Rutkowski B, Dębska-Ślizień A. Amino acid profile after oral nutritional supplementation in hemodialysis patients with protein-energy wasting. Nutrition. 2019 ;57:231-6. doi: 10.1016/j.nut.2018.06.013. Epub 2018 Jul 11. PMID: 30184517.

4 Afaghi E, Ebadi A, Tadrisi SD, Naghii MR. The effect of Nutrition Support Protocols on Patient Outcomes in Intensive Care Unit: A Systematic Review. Int J Med Rev 2015;2 (2):256-60.

5 Afaghi E, Tayebi A, Ebadi A, Sobhani V, Einollahi B, Tayebi M. The Effect of BCAA and ISO-WHEY Oral Nutritional Supplements on Dialysis Adequacy. Nephrourol Mon. 2016;8 (6):e34993. doi: 10.5812/numonthly.34993. PMID: 27896236; PMCID: PMC5120366.

6 As' habi A, Tabibi H, Hedayati M, Mahdavi-Mazdeh M, Nozari B. Association of energy-protein malnutrition with risk factors of cardiovascular diseases in hemodialysis patients. Iranian J Nutr Sci Food Technol 2011;6 (2):0-0. URL: http://nsft.sbmu.ac.ir/article-1-506-en.html.

7 Sabatino A, Regolisti G, Karupaiah T, Sahathevan S, Sadu Singh BK, Khor BH, Salhab N, Karavetian M, Cupisti A, Fiaccadori E. Protein-energy wasting and nutritional supplementation in patients with end-stage renal disease on hemodialysis. Clin Nutr. 2017;36 (3):663-71. doi: 10.1016/j.clnu.2016.06.007. Epub 2016 Jun 18. PMID: 27371993.

8 Steyaert S, Holvoet E, Nagler E, Malfait S, Van Biesen W. Reporting of "dialysis adequacy" as an

outcome in randomised trials conducted in adults on haemodialysis. PLoS One. 2019;14 (2):e0207045. doi: 10.1371/journal.pone.0207045. PMID: 30721242. PMCID: PMC6363141.

9 Aditia K, Palar S, Karema-Kaparang AM, Moeis ES, Sugeng C, Umboh O. POS-552 correlation of interleukin-6 levels, high sensitivity c-reactive protein, and malnutrition inflammation score with quality of life chronic kidney disease patients undergoing routine hemodialysis. Kidney International Reports. 2022;7 (2):S239. doi: 10.1016/j.ekir.2022.01.584.

10 Benner D, Brunelli SM, Brosch B, Wheeler J, Nissenson AR. Effects of oral nutritional supplements on mortality, missed dialysis treatments, and nutritional markers in hemodialysis patients. J Ren Nutr 2018;28 (3):191-6. doi: 10.1053/j.jrn.2017.10.002. Epub 2017 Dec 6. PMID: 29221626.

11 Cawood A, Elia M, Stratton R. Systematic review and meta-analysis of the effects of high protein oral nutritional supplements. Ageing Res Rev. 2012;11 (2):278-96. doi: 10.1016/j.arr.2011.12.008. Epub 2011 Dec 22. PMID: 22212388.

12 Philipson TJ, Snider JT, Lakdawalla DN, Stryckman B, Goldman DP. Impact of oral nutritional supplementation on hospital outcomes. Am J Manag Care. 2013;19 (2):121-8. PMID: 23448109.

13 Tayebi M, Tayebi A, Einollahi B, Ebadi A, Jafari A. Isometric resistance training and branched-chain amino acids supplementation can improve dialysis adequacy: A clinical trial. Nephrourol Mon 2019;11 (2) ; e91175. doi: 10.5812/numonthly.91175.

14 Taghdir M, Ashourpour M, Ghandchi Z, Pourghaderi M, Sepandi M, Alavi Naini A. Assessment of energy and protein intake and some of the related factors in hemodialysis patients referred to Imam Khomeini Hospital. Iranian Journal of Endocrinology and Metabolism 2011;13 (6):690-6. URL: http://ijem.sbmu.ac.ir/article-1-1203-en.html.

15 Chan M, Kelly J, Batterham M, Tapsell L. Malnutrition (subjective global assessment) scores and serum albumin levels, but not body mass index values, at initiation of dialysis are independent predictors of mortality: a 10-year clinical cohort study. J Ren Nutr. 2012;22 (6):547-57. doi: 10.1053/j.jrn.2011.11.002. Epub 2012 Mar 9. PMID: 22406122.

16 Bolasco P, Caria S, Cupisti A, Secci R, Saverio Dioguardi F. A novel amino acids oral supplementation in hemodialysis patients: a pilot study. Ren Fail. 2011;33 (1):1-5. doi: 10.3109/0886022X.2010.536289. PMID: 21219197.

17 Kloppenburg WD, Stegeman CA, Hovinga TK, Vastenburg G, Vos P, de Jong PE, Huisman RM. Effect of prescribing a high protein diet and increasing the dose of dialysis on nutrition in stable chronic haemodialysis patients: a randomized, controlled trial. Nephrol Dial Transplant. 2004;19 (5):1212-23. doi: 10.1093/ndt/gfh044. Epub 2004 Feb 19. PMID: 14993506.

18 Karen Pharma and Food Supplement Co. Amino acid [cited 2022 15 March]. Available from: https://en.karenpharma.com/Sport-PNC/Amino-acid.

19 Karen Pharma and Food Supplement Co. High protein [Available from: https://en.karenpharma.com/Sport-PNC/High-protein.

20 Akhlaghi Z, Sharifipour F, Nematy M, Safarian M, Malekahmadi M, Barkhidarian B, Norouzy A. Assessment of nutritional status in maintenance hemodialysis patients: A multicenter cross-sectional study in Iran. Semin Dial. 2021;34 (1):77-82. doi: 10.1111/sdi.12917. Epub 2020 Oct 14. PMID: 33058310.

21 Liu PJ, Ma F, Wang QY, He SL. The effects of oral nutritional supplements in patients with maintenance dialysis therapy: A systematic review and meta-analysis of randomized clinical trials. PLoS One. 2018;13 (9):e0203706. doi: 10.1371/journal.pone.0203706. PMID: 30212514. PMCID: PMC6136747.

22 Lacson E Jr, Wang W, Zebrowski B, Wingard R, Hakim RM. Outcomes associated with intradialytic oral nutritional supplements in patients undergoing maintenance hemodialysis: a quality improvement report. Am J Kidney Dis. 2012;60 (4):591-600. doi: 10.1053/j.ajkd.2012.04.019. Epub 2012 May 24. PMID: 22632807.

23 Moretti HD, Johnson AM, Keeling-Hathaway TJ. Effects of protein supplementation in chronic hemodialysis and peritoneal dialysis patients. J Ren Nutr. 2009;19 (4):298-303. doi: 10.1053/j.jrn.2009.01.029. PMID: 19539184.

24 Kalantar-Zadeh K, Braglia A, Chow J, Kwon O, Kuwae N, Colman S, Cockram DB, Kopple JD. An anti-inflammatory and antioxidant nutritional supplement for hypoalbuminemic hemodialysis patients: a pilot/feasibility study. J Ren Nutr. 2005;15 (3):318-31. doi: 10.1016/j.jrn.2005.04.004. PMID: 16007562.

25 Leonberg-Yoo AK, Wang W, Weiner DE, Lacson E Jr. Oral nutritional supplements and 30-day readmission rate in hypoalbuminemic maintenance hemodialysis patients. Hemodial Int. 2019;23 (1):93-100. doi: 10.1111/hdi.12694. Epub 2019 Feb 14. PMID: 30762294; PMCID: PMC7699822.

26 Scott MK, Shah NA, Vilay AM, Thomas J 3rd, Kraus MA, Mueller BA. Effects of peridialytic oral supplements on nutritional status and quality of life in chronic hemodialysis patients. J Ren Nutr. 2009;19 (2):145-52. doi: 10.1053/j.jrn.2008.08.004. PMID: 19218041.

27 Sohrabi Z, Eftekhari MH, Eskandari MH, Rezaianzadeh A, Sagheb MM. Intradialytic Oral Protein Supplementation and Nutritional and Inflammation Outcomes in Hemodialysis: A Randomized Controlled Trial. Am J Kidney Dis. 2016;68 (1):122-30. doi: 10.1053/j.ajkd.2016.02.050. Epub 2016 Apr 15. PMID: 27086768.

28 Jeloka TK, Dharmatti G, Jamdade T, Pandit M. Are oral protein supplements helpful in the management of malnutrition in dialysis patients? Indian J Nephrol. 2013 Jan;23 (1):1-4. doi: 10.4103/0971-4065.107185. PMID: 23580797. PMCID: PMC3621231.

29 Małgorzewicz S, Aleksandrowicz-Wrona E, Owczarzak A, Debska-Slizień A, Rutkowski B, Łysiak-Szydłowska W. Adipokines and nutritional status for patients on maintenance hemodialysis. J Ren Nutr. 2010;20 (5):303-8. doi: 10.1053/j.jrn.2009.10.005. Epub 2010 Jan 13. PMID: 20071195.

30 Dudar I, Shymova A, Gonchar Y, Loboda O, Krasiuk E. Quality of life in peritoneal dialysis patients and its relationship with nutrition disorders. Ukrainian Journal of Nephrology and Dialysis 2019;1 (61): 45-52. doi: 10.31450/ukrjnd.1 (61).2019.06.