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補充含大豆蛋白商業配方對於血液透析患者營養狀況的影響

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Effects of oral soy protein-containing commercial formula supplementation on nutritional status in hemodialysis patients

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Abstract Inadequate energy intake and muscle wasting often occur in patients with end-stage kidney disease, particularly in those undergoing hemodialysis (HD). Proper protein and energy intake has long been recognized to maintain the condition of patients with renal disease, especially those who undergo HD. An ongoing problem is the inadequate dietary intake of these patients, which poses them with the risk of malnutrition. However, limited research has been conducted on the effects of soy protein-containing commercial formula supplementation on the nutritional status of patients undergoing HD with hypoalbuminemia. This study investigated the effects of a commercial soy protein-con-

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taining formula on the nutritional status of hypoalbuminemic patients undergoing HD. The inclusion criteria were HD patients with a serum albumin level of ≤ 3.0 mg/dL. The interventional study included 44 eligible HD patients who received soy protein-containing commercial formulas daily for 12 weeks, providing 206 kcal and 16.8 g of soy protein. After 12 weeks of soy protein-containing commercial formula supplementation, an increase in plasma albumin concentration, mean corpuscular volume, and nutritional status-related values was observed. Our results suggested that oral supplementation with a commercial soy protein-containing formula may improve the nutritional status of malnourished patients on HD.

Key words: soy protein-containing commercial formula, hemodialysis, protein-energy malnutrition, nutritional status, kidney failure

INTRODUCTION

Protein-energy malnutrition (PEM) frequently occurs in patients with end-stage kidney disease undergoing long-term hemodialysis (HD) and constitutes a heavy burden on global health [1]. PEM can occur for several reasons, such as uremia as the common sign of end-stage kidney disease or the side effects of HD treatment. All of these factors contribute to the poor appetite of patients, accelerating protein loss [2-5]. The degree of malnutrition, as assessed by the low serum albumin level and fat and muscle wasting, is positively correlated with an increased length of hospital stay and is the strongest predictor of mortality [6, 7]. While the prevalence of PEM may range between 18-70% among HD patients [8, 9], it has been found that for those consuming insufficient calories or protein, poor nutritional status can be ameliorated by supplementing a diet with adequate protein and calories [10-12].

According to the recommendations of the Kidney Disease Outcomes Quality Initiative (KDOQI-2020) proposed by the National Kidney Foundation (NKF) for patients undergoing HD, the caloric requirement is 25-35 kcal/kg dry body weight (DBW)/day and 1.0-1.2 g/kg DBW/day for protein [13]. Ensuring adequate protein and calorie intake is critical for patients undergoing HD to prevent the catabolism of body tissues, as mentioned above. Soy protein is a protein with a high biological value, commonly used in special formulas

However, reaching the recommended intake is challenging for those with poor appetite, which is very prevalent in end-stage kidney disease patients, and more than half of the HD patients struggle to meet the recommended dietary intake goal [14]. Oral nutritional supplementation (ONS) conventionally provides an additional 7-10 kcal/kg/day of energy and 0.3-0.4 g/kg/day of protein [15]. It has been shown to reduce mortality among in-center HD patients when ONS was implemented on a daily basis and during HD on dialysis days [16], and to significantly increase plasma albumin and prealbumin concentrations [17]. However, studies on soy protein ONS in Asian hypoalbuminemic patients undergoing HD are lacking. This study investigated the effects of commercial soy protein formula on the nutritional status of malnourished patients undergoing HD, with the objective of improving the nutrition markers often altered in patients with end-stage kidney disease.

MATERIALS AND METHODS

The patients for this interventional study were recruited from the HD department of Taipei Tzu Chi Hospital between June and September 2013. The inclusion criteria were as follows: age ≥ 20 years old and not scheduled for kidney transplantation in the near future, plasma albumin concentration ≤ 3.0 mg/dL, and not on parenteral nutrition, intravenous albumin supplementation, or enteral nutrition. Patients with hemodynamic instability or poor compliance of medication use (as determined by the attending physician in the nephrology department) and those on steroids or immunosuppressive drugs were excluded. All recruited participants received a daily supplement of a commercial powder formula containing 206 kcal and 16.8 g of isolated soy protein (Table 1) as a nutritional intervention. The patients only received instructions regarding formula usage with

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Table 1. Nutrient composition of the soy protein-containing commercial formula[1,2]

Nutrients per 48 g	
Calories (kcal)	205.92
Protein (g)	16.8
Fat (g)	6.96
Saturated fat (g)	0.432
Trans fat (g)	0
Carbohydrate (g)	18.96
Dietary fiber (g)	1.68
Vitamin A (μg RE)	160.32
Vitamin D (μg)	3.264
Vitamin E (mg α-TE)	3.456
Vitamin K (μg)	5.472
Vitamin C (mg)	22.416
Vitamin B1 (mg)	0.288
Vitamin B2 (mg)	0.384
Vitamin B6 (mg)	1.392
Vitamin B12 (μg)	0.576
Niacin (mg NE)	3.264
Pantothenic acid (mg)	1.44
Folic acid (μg)	159.36
Biotin (μg)	72
Choline (μg)	64.32
Calcium (mg)	177.6
Phosphorous (mg)	211.68
Magnesium (mg)	8.64
Zinc (mg)	1.2
Iron (mg)	3.312
Manganese (mg)	0.096
Copper (mg)	0.288
Iodine (μg)	13.2
Fluorine (mg)	0.048
Sodium (mg)	214.56
Potassium (mg)	158.4
Chloride (mg)	58.08
Chromium (μg)	1.344
Molybdenum (μg)	1.296
Selenium (μg)	1.392
Taurine (mg)	27.36

[1] Nu-Reno, Nutritec Enjoy, Taipei, Taiwan

[2] Protein 31% (100% isolated soy protein); fat 30% (100% canola oil); carbohydrate 39% (100% maltodextrin).

no additional nutrition-related consulting, All participants were instructed to mix 48 g of the powder formula with 150 mL of water and consume the su pplement daily for 12 weeks.

On the days that the patients underwent HD, the dietitians prepared the supplement onsite and administered the supplement to the participants during dialysis under the supervision of the attending nurse. On non-dialysis weekdays, the participants were instructed to take the supplement at home and return empty packaging as proof of supplement intake. Pre-dialysis blood urea nitrogen (BUN), Kt/V, and normalized protein nitrogen appearance (nPNA) values were used to objectively estimate protein intake and compare it with the reported dietary protein intake, thus confirming the actual use of supplements.

After the intervention period, intervention compliance was assessed; patients consuming < 75% of the intended dosage were excluded from the final analysis. A total of 294 patients undergoing HD were screened, of whom 66 met the eligibility criteria. Of these, 50 were recruited for the study and provided written informed consent. Furthermore, 6 participants were excluded from the study because of death (n = 2), change in treatment plan (n = 2), or personal reasons (n = 2). Finally, 44 participants were included in the analysis. All 44 participants had a supplement usage rate of > 75%. This study was approved by the Institutional Review Board (IRB) of the Taipei Tzu Chi Hospital.(Protocol No.: **01-X21-069**)

Anthropometric data, such as dry body weight (DBW), along with biochemical values, were collected before and after the intervention. Body mass index (BMI) was calculated using the DBW. 3-day food records, including one HD day, one non-dialysis weekday, and one weekend, were obtained at week 0 (pre-intervention) and 12 (post-intervention) via face-to-face interviews conducted by a dietitian. The EKitchen Royal Kitchen Nutrition Analysis Software (Nutrition Steward Enhanced Labeled Version, Royal Kitchen Business Co., Ltd.) was used to calculate and analyze dietary nutritional intake, including calorie, protein, phosphorus, and potassium intake. Blood was sampled from the participants prior to HD treatment for biochemical analysis. Biochemical values related to nutritional status were obtained from the patient's medical record, including the concentrations of albumin, creatine, blood phosphorus, hemoglobin (Hb), hematocrit, blood cholesterol, triglycerides (TG), fasting blood glucose (glucose AC), low-density lipoprotein-cholesterol (LDL), BUN, Kt/V, and nPNA. An automated biochemical and immunological analyzer (Siemens Dimension RXL Chemistry Analyzer; Pennsylvania, USA) was used for blood biochemical analysis, and an automated blood cell counter (Sysmex XE-5000 Automated Hematology System; Kobe, Japan) was used for blood count analysis.

Statistical analysis: Data were presented as mean ± standard deviation (SD), whereas dietary intake analysis data were presented as mean ± standard error of the mean (SEM). Statistical Package for the Social Sciences (SPSS, version 18.0) software was used for statistical analysis. Paired t-tests were used to compare differences in blood biochemical measurements and dietary intake before and after the 12-week intervention with soy protein nutritional supplements. Statistical significance was set at $P < 0.05$.

RESULTS

The baseline characteristics of the patients are shown in Table 2.

Table 3 presents the analysis of dietary intake based on the 3-day food records collected pre-intervention (shown as 'Baseline') and during the intervention period. The intake of all participants was calculated using the values obtained from the average of the 3-day record on and off dialysis days. Compared to pre-intervention, there were significant increases in calorie (1709.4 ± 67.3 vs. 1441.9 ± 58.0 kcal/day) and protein intake (80.5 ± 3.1 vs. 57.5 ± 2.7 g/day), even after DBW normalization (30.2 ± 1.3 vs. 25.0 ± 1.0 kcal/kg DBW/day, and 1.4 ± 0.1 vs. 1.0 ± 0.1 g/kg DBW/day). A significant increase in potassium (1565.5 ± 65.7 vs. 1294.0 ± 90.4 mg/day) and phosphorus intake (907.8 ± 34.5 vs. 666.3 ± 43.9) post-intervention was also observed.

表二

Table 2. Baseline characteristics of hemodialysis patients

	All Patients[1] (n = 44)
Age (years)	69.7 ± 11.1
Gender	
Male	19 (43.2%)
Female	25 (56.8%)
DBW (kg)	58.3 ± 11.2
BMI (kg/m^2)	22.9 ± 4.1
Dialysis vintage[2]	
Mean (years)	6.4 ± 6.9
Median (years)	5.0 2.0-7.0
Cause of ESRD (%)	
Diabetic nephropathy	47.7
Hypertension nephropathy	31.8
Glomerulonephritis	13.7
Autosomal recessive polycystic kidney disease	4.5
Misuse of drugs	2.3
Albumin (mg/dL)	2.8 ± 0.3

[1] All values are shown in mean ± SD or n (%) unless marked

[2] Shown in mean and median (years)

Abbreviations: DBW, dry body weight; BMI, body mass Index; ESRD, end-stage renal disease

表三

Table 3. Differences in intake at baseline and during usage of soy protein-containing commercial formula supplementation on kidney disease-related nutrient

	Intervention period		
	Baseline	averaged 3-d food intake	averaged 3-d food intake + ONS
Total calorie (kcal/day)	1441.9 ± 58.0	1503.4 ± 67.3	1709.4 ± 67.3*
Intake per kilogram DBW (kcal/kg DBW/day)	25.0 ± 1.0	26.5 ± 1.3	30.2 ± 1.3*
Total protein (g/day)	57.5 ± 2.7	63.7 ± 3.1[a]	80.5 ± 3.1*
Intake per kilogram DBW (g/kg DBW/day)	1.0 ± 0.1	1.1 ± 0.1	1.4 ± 0.1*
Potassium (mg/day)	1294.0 ± 90.4	1407.1 ± 65.7	1565.5 ± 65.7*
Phosphorus (mg/day)	666.3 ± 43.9	696.1 ± 34.5	907.8 ± 34.5*

Averaged 3-d food intake: nutrition intake from food without soy protein-containing commercial formula supplementation, averaged 3-d food intake + ONS: nutrition intake from food with soy protein-containing commercial formula supplementation

All values are shown in mean ± SEM, * $P < 0.05$ versus baseline

Abbreviation: DBW, dry body weight

Table 4 presents the analysis results of the comparison of biochemical values between pre- and post-intervention. The average plasma albumin concentration after 12 weeks of supplementation has significantly increased (3.0 ± 0.3 mg/dL) compared to the average pre-intervention (2.8 ± 0.3 mg/dL; $P < 0.001$). A similar trend can also be observed in BUN (90.1 ± 19.9 mg/dL vs. 72.7 ± 20.6 mg/dL, $P < 0.001$), phosphorus (5.1 ± 1.0 vs. 4.5 ± 1.2 mg/dL, $P < 0.001$), sodium (135.2 ± 2.5 vs. 134.0 ± 3.4 mEq/L, $P = 0.033$), calcium (9.2 ± 1.0 vs. 8.9 ± 0.7 mg/dL; $P = 0.034$), total iron-binding capacity (TIBC; 238.1 ± 52.2 vs. 204.5 ± 48.0 μg/dL, $P < 0.001$), and normalized protein equivalent of nitrogen (nPNA; 1.4 ± 0.3 vs. 1.2 ± 0.4 mEq/L, $P < 0.001$). A decrease after oral soy protein-containing commercial formula supplementation can be seen in mean corpuscular volume (MCV; 91.0 ± 6.7 vs. 91.9 ± 6.3 fL, $P = 0.040$) and transferrin saturation (23.0% ± 11.5% vs. 25.8% ± 11.3%, $P = 0.015$). No statistically significant changes was observed for other biomarkers.

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Table 4. Effects of soy protein-containing commercial formula on biochemical values.

	Pre-intervention	Post-intervention	*P*-value
DBW (kg)	58.3 ± 11.2	57.9 ± 10.9	0.181
BMI (kg/m^2)	22.9 ± 4.1	22.8 ± 4.0	0.152
Albumin (mg/dL)	2.8 ± 0.3	3.0 ± 0.3	< 0.001*
Predialysis BUN (mg/dL)	72.7 ± 20.6	90.1 ± 19.9	< 0.001*
Predialysis creatinine (mg/dL)	9.8 ± 2.1	9.7 ± 1.9	0.785
Kt/V	1.8 ± 0.3	1.8 ± 0.3	0.881
Phosphorus (mg/dL)	4.5 ± 1.2	5.1 ± 1.0	< 0.001*
Potassium (meq/L)	4.9 ± 0.8	4.8 ± 0.8	0.482
Sodium (mEq/L)	134.0 ± 3.4	135.2 ± 2.5	0.033*
Calcium (mg/dL)	8.9 ± 0.7	9.2 ± 1.0	0.034*
Triglyceride (mg/dL)	129.4 ± 90.8	132.9 ± 79.9	0.881
Total cholesterol (mg/dL)	147.6 ± 34.1	153.5 ± 36.3	0.236
LDL-C (mg/dL)	91.0 ± 23.0	96.8 ± 50.5	0.473
Glucose AC (mg/dL)	139.0 ± 61.3	133.1 ± 55.5	0.46
Hb (mg/dL)	10.0 ± 1.6	10.3 ± 1.2	0.052
Hct (%)	30.1 ± 4.9	31.0 ± 4.0	0.068
MCV (fL)	91.9 ± 6.3	91.0 ± 6.7	0.040*
Fe (μg/dL)	50.6 ± 19.6	52.5 ± 22.8	0.441
TIBC (μg/dL)	204.5 ± 48.0	238.1 ± 52.2	< 0.001*
Ferritin (ng/dL)	702.4 ± 458.7	723.8 ± 462.7	0.461
Transferrin saturation (%)	25.8 ± 11.3	23.0 ± 11.5	0.015*
nPNA (g/kg DBW/day)	1.2 ± 0.4	1.4 ± 0.3	<0.001*

All values are shown in mean ± SD

*$P < 0.05$

Abbreviations: DBW, dry body weight; BMI, body mass index; BUN, blood urea nitrogen; LDL-C, low-density lipoprotein-cholesterol; Hb, hemoglobin; Hct, hematocrit; MCV, mean corpuscular volume; TIBC, total iron-binding capacity; nPNA, normalized protein equivalent of nitrogen.

DISCUSSION

The presence of inflammation often accompanies the occurrence of PEM in patients undergoing HD [18]. A high concentration of nitrogenous waste in the bloodstream stimulates the secretion of inflammatory cytokines [19]. Patients can experience symptoms such as anorexia, taste changes, fatigue, and delayed gastric emptying, which can affect their nutritional status, contributing to the malnutrition commonly present in end-stage kidney disease patients [20, 21]. Incorrect dietary beliefs and adherence to diets that restrict phosphorus, potassium, and sodium can also contribute to a deteriorating nutritional status caused by inadequate nutritional intake [22, 23].

According to the most recent NKF KDOQI-2020 guideline, patients on HD have a caloric requirement of 25-35 kcal/kg DBW/day [13], while the guideline used during the experiment period, NKF KDOQI-2001, suggested 30-35 kcal/kg DBW/day [24]. The intake prior to intervention was lower than NKF KDOQI-2001 suggestion and right within the recommended energy consumption range in NKF KDOQI-2020 guideline. Supplementation helped raise the calorie intake to approximately 30.2 kcal/kg DBW/day, fitting the energy requirement for both guidelines. A similar pattern can be observed for protein intake, where oral supplementation can contribute to approximately a quarter of the protein requirement per day. The intake of protein post-supplementation exceeds the recommended range of 1-1.2 g/kg/day for patients on maintenance HD, with values corresponding to the nPNA calculated [13]. In this study, patients with hypoalbuminemia were recruited, some of whom had comorbidities such as chronic inflammatory diseases or infections. These conditions are known to elevate metabolic stress and increase protein catabolism. Consequently, a protein intake of at least 1.2 g/kg DBW/day, and ideally 1.3 g/kg DBW/day, was considered more appropriate for hemodialysis patients under metabolic stress [13, 24]. Our study demonstrated that a 12-week intervention using soy protein-containing commercial formulas increased participants' average protein intake from 1.0 to 1.4 g/kg DBW/day and significantly improved their plasma albumin concentrations by the end of the study period.

Interestingly, though there was a significant increase in calorie and protein intake, no substantial changes in DBW or BMI were observed after the 12-week dietary supplementation period. After considering the significant increase in plasma albumin concentration, it can be inferred that the low albumin level prior to intervention may contribute to increased swelling in the periphery and reduce the effectivity of dialysis. After supplementation, the albumin increased significantly, allowing the excess water from the periphery to be removed effectively by dialysis. Fouque et al. observed that even with daily supplementation of 500 kcal for 12 weeks, no significant changes were observed in body weight or BMI [25], which is similar to the phenomenon we observed in this study. As body weight maintenance in patients undergoing hemodialysis is critical to prevent the decline of health status [26], supplementation can help patients achieve their caloric intake and maintain their body weight.

Oral supplementation of the formula increased the intake of potassium and phosphorus, which is related to the higher protein intake. However, phosphorus and potassium levels in the plasma were still in the normal range for HD patients [13, 27], despite the former seeing a significant increase of about 0.6 mg/dL.

Albumin is commonly used to assess nutritional status and is considered the best predictor of prognosis and survival in patients undergoing HD [28]. Studies have indicated that approximately 40% of HD patients have blood albumin concentrations below the standard range [29]. A systematic review and meta-analysis found patients undergoing HD had an average increase of 0.23 mg/dL in albumin concentration after a high-protein nutritional supplementation [30]. This is similar to our findings, where after continuous supplementation for 12 weeks, there was a significant increase of 0.2 mg/dL in plasma albumin concentration. In severely malnourished HD patients, even a small increase of 0.2 mg/dL in albumin levels can lead to significant benefits, including a 25% increase in survival rates, reduced hospitalization days, and substantial cost reduction in healthcare

expenses [31].

BUN concentration is another parameter used to monitor the buildup of nitrogenous waste [32], and the values can rise with an increased intake of proteins or during catabolic conditions. Though findings regarding high BUN and its outcomes, with some studies indicating increased mortality rate with increased BUN levels, Lee et al. found that BUN may also be indicative of adequate protein intake [32]. In this study, the participants had a pre-supplementation BUN concentration of 72.7 ± 20.6 mg/dL, significantly increasing to 90.1 ± 19.9 mg/dL post-supplementation. The increased protein intake *via* oral supplementation corresponded to the increase in albumin concentration and BUN levels. Notably, there were no differences in creatinine levels, which also increased with protein intake. A meta-analysis analyzing protein supplementation in CKD patients found a decrease in creatinine levels post-soy protein-containing commercial formula supplementation [33]. The differences between BUN and creatinine trends should be addressed in future studies.

This study found that the predialysis sodium and calcium levels saw a statistically significant increase after supplementation. The sodium level was below the normal range and entered the normal range post-supplementation [34]. Serum calcium saw a 0.3 mg/dL increase; plasma calcium level increase, even in the normal range, was found to help attenuate the progression of CKD [35].

The most commonly used tests to assess iron status in dialysis patients are transferrin saturation and serum ferritin concentration. Hematological alterations is a common phenomenon in patients with renal disease, as the kidney accounts for hematopoiesis regulation [36]. Surprisingly, there was a significant decrease in transferrin saturation among the participants after the intervention, whereas ferritin levels did not differ; the two values are still outside of the absolute iron deficiency range [37]. However, because the synthesis of erythropoietin in patients with kidney failure is altered, iron status cannot be used as a sole marker for nutrition status. This study also detected a significant decrease in MCV.

The strength of this study lies in the various biomarkers, aside from body weight changes, that were included in the study for analysis. This led to the findings of notable features of soy protein-containing commercial formula supplementation. This study had several limitations. This study had no placebo control group to compare the effects of the intervention, and the sample size was too small to generalize the findings. Additionally, participants were not explicitly advised to maintain their usual dietary intake, which may have led to a reduction in food consumption during the period of the supplementation. This study also lacked biomarkers related to diabetic nephropathy or hypertension nephropathy, which prevented us from analyzing further correlations.

CONCLUSION

In conclusion, this study showed that a 12-week intervention with oral nutritional supplementation of a soy protein-containing commercial formula significantly increased plasma albumin concentration and nutritional status-related values, including plasma sodium and calcium concentration. The high dietary compliance of participants also indicated that this approach is feasible for future nutritional intervention in clinical settings among malnourished patients undergoing HD.

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the manuscript.

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補充含大豆蛋白商業配方對於血液透析患者營養狀況的影響

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摘要 末期腎病患者，特別是接受血液透析（hemodialysis, HD）者，常見熱量攝取不足和肌肉流失問題。適當的蛋白質與熱量攝取已被證實對維持 HD 患者之營養狀況至關重要，然而這些患者的飲食攝取不足是一個持續存在的問題，使他們面臨營養不良的風險。目前關於大豆蛋白之補充對低白蛋白血症的 HD 患者之營養狀況影響之研究仍有限，所以本研究旨在探討大豆蛋白商業配方對低白蛋白血症之 HD 患者營養狀況的影響。本研究為介入性研究，納入 44 位血清白蛋白濃度低於或等於 3.0 mg/dL 的 HD 患者，患者每日口服補充大豆蛋白商業配方，為期 12 週。商業配方提供 206 大卡和 16.8 克的大豆蛋白。經過 12 週的大豆蛋白商業配方補充後，我們觀察到患者的血漿白蛋白濃度、平均紅血球體積以及與營養狀況相關的數值有明顯進步。本研究之結果顯示針對低白蛋白血症 HD 患者，補充含大豆蛋白之商業營養配方可有效提升血漿白蛋白濃度與營養相關數值，有助於改善其營養不良狀況。

關鍵字：大豆蛋白商業配方、血液透析、蛋白質能量營養不良、營養狀況、腎衰竭