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ORIGINAL ARTICLE

Effects of Two Types of Protein Supplementation in Patients on Peritoneal Dialysis

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Abstract

Introduction: Protein-energy malnutrition is one of the main problems and presents a multifactorial cause in peritoneal dialysis patients.

Objective: To evaluate the effects of two types of protein supplementation in patients with peritoneal dialysis, in order to reduce the nutritional risk of these individuals.

Methods: This was a longitudinal clinical study of 26 patients who underwent peritoneal dialysis and presented nutritional risk according to serum albumin values, considering a reference of 3.6 g/dL. Before starting the intervention, the subjects were submitted to nutritional assessment, which was composed of albumin dosage, the application of the 7-point Subjective Global Assessment (AGS-7 points) and the anthropometric measurements of height, post-dialysis weight and Waist Circumference (WC), to calculate the Body Mass Index (BMI) and Waist-to-Length Relation (WL). Patients were randomly divided into 2 groups, one of which received 10 g of whey protein supplement and the other group received 10 g of albumin supplementation during 30 days.

Results: The initial protein intake data showed that the mean daily intake and the standard deviation were equivalent to 0.8 ± 0.3 grams per kilo of body weight. Initial serum albumin values were not associated with protein consumption. There was a significant increase in the mean value of albumin after supplementation ($p = 0.0344$). The albumin supplement was superior to whey protein. Initial values of albumin showed a statistically significant negative association with WC and WL ($r = -0.47$, $p = 0.0254$ for albumin and WC, ($r = -0.49$, $p = 0.02$) for albumin and WL).

Conclusion: Protein supplementation promoted an increase in serum albumin levels and this marker was inversely associated with age and abdominal adiposity. The absence of correlation between energy and protein intake with the initial values of albumin generates the need for investigations to clarify if the adequacy of food consumption is able to normalize the concentrations of this protein, or if supplementation is still necessary.

Keywords

Dialysis, Serum albumin, Protein malnutrition, Supplementation

Introduction

Chronic Kidney Disease (CKD) is characterized by the incontrovertible and gradual loss of endocrine, tubular, and glomerular kidney function, which impairs the removal of toxic metabolites from the body [1,2].

When the disease progresses to the terminal stage, the kidneys are unable to maintain the body's homeostasis and the intensification of symptoms generates the need for renal replacement therapy, such as Hemodialysis (HD) and Peritoneal Dialysis (PD) [3].

PD is a blood filtration through the peritoneal membrane, which covers the main organs of the abdomen, which has porous and semipermeable characteristics. To be performed surgery is required for insertion of a catheter into the peritoneal cavity, and through it, a

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dialysis fluid is infused. This solution after a period is drained by removing surplus substances in the blood, such as: potassium, urea and creatinine, along with excess liquid no longer eliminated by urine [4].

The DRC has an increasing prevalence. According to the Dialysis Census for the year 2016, it was estimated that 50,807 patients were on dialysis treatment, data that increase each year and is increasingly worrying the health area, due to complications and decrease in life expectancy of this population [5].

Due to the loss of internal medium homeostasis caused by renal injury, chronic renal patients usually develop various metabolic and nutritional imbalances. Protein-energy malnutrition is one of the main problems and presents a multifactorial cause in these individuals, such as: anorexia, uremic toxicity, gastrointestinal symptoms, metabolic acidosis, inflammatory cytokines increase, endocrine alterations, drug use, dietary restrictions and nutritional losses in the dialysis [6-8].

PD specifically causes losses of water soluble vitamins, amino acids and proteins, which intensify in episodes of membrane inflammation known as peritonitis [9]. The loss of proteins can lead to hypoalbuminemia, which is directly linked to nutritional risk and worse prognosis in this population [10]. For these reasons, there is great concern about the nutritional status of individuals in PD, since most are at nutritional risk, which implies a deterioration in quality of life and a significant increase in morbidity and mortality rates [11,12]. In addition, the dialysis population often presents an insufficient or inadequate food intake, due to socioeconomic reasons or because of low adherence to the recommendations, causing deterioration in the nutritional status and the need for follow-up by a nutritionist [13]. Thus, it becomes evident the importance of guiding an adequate energy-protein intake, which is often only achieved through supplementation, since adequate nutrition improves the quality of life and also decreases the metabolic changes mentioned above [14].

Based on the above findings, the present study is justified in evaluating the effects of two types of protein supplementation on serum albumin concentration in patients with peritoneal dialysis and whether they are influenced by clinical and nutritional data.

Methods

This research was performed with patients on peritoneal dialysis of a nephrology clinic located in a city in the interior of the state of São Paulo. It's a longitudinal clinical study that was approved in its ethical and methodological aspects by the Ethics and Research Committee of the University of Franca (UNIFRAN). Patients who underwent peritoneal dialysis treatment and who presented nutritional risk according to serum albumin values, considering a reference of 3.6 g/dL, were included in the study [15]. After selecting 26 patients, they signed the Free and Informed Consent Term, making clear their intention to participate in the study. Patients' personal and clinical information, such as: age, sex, CKD etiology and peritoneal dialysis time were collected or confirmed in medical records.

Before starting the intervention, the subjects were submitted to nutritional assessment, which was composed of the application of the 7-point Subjective Global Assessment (AGS-7 points) and the anthropometric measurements of height, post-dialysis weight and Waist Circumference (WC), to calculate the Body Mass Index (BMI) and Waist-to-Length Relation (WL).

The equipment used in the anthropometric evaluation was: platform weight machine (Técnica®), vertical staging (Welmy®) and inelastic measuring tape.

The measurements were performed by the nutritionist of the nephrology clinic during the consultations and followed up by the researchers, and all patients had the peritoneal cavity without dialysate fluid at this time.

For the BMI classification, the values proposed by the World Health Organization [16] and by Lipschitz [17] were used for adult and elderly individuals, respectively.

Regarding the evaluation of WL, the cutoff points were 0.80 to 0.84 [18]. In order to complement the nutritional data and to aid in the investigation of dietary intake, the patients were instructed were instructed to complete a 3-day food registry during the study to estimate energy and protein intake. Subsequently, the data was calculated using Dietpro 5i software to estimate energy and protein intake values.

Table 1: Nutritional information of the supplements portions used in the study.

	Albumax® (10 g)	100% Whey® (10 g)
Energy (kcal)	32	40
Protein (g)	7.56	6.25
Carbohydrates (g)	0.53	2.5
Fat (g)	0	0.58
Alanine (g)	0.4	1.2
Arginine (g)	0.4	1
Aspartic acid (g)	0.8	2.5
Cysteine (g)	0.2	0.6
Glutamic acid (g)	1	3.9
Glycine (g)	0.3	0.5
Histidine (g)	0.2	0.9
Isoleucine (g)	0.4	1.5
Leucine (g)	0.7	2.4
Lysine (g)	0.5	2.1
Methionine (g)	0.3	0.4
Phenylalanine (g)	0.4	0.7
Proline (g)	0.3	1.6
Serine (g)	0.4	1.5
Threonine (g)	0.4	1.6
Tryptophan (g)	0.1	0.7
Tyrosine (g)	0.3	0.9
Valine (g)	0.5	1

After the initial nutritional evaluation of the patients, they were randomly divided into 2 groups, one of which received a whey protein supplement and the other group received albumin supplementation (Table 1).

For each patient in both groups, 30 small packs containing 10 g of protein supplement were delivered, so that during 30 days the patients ingested the contents of each diluted package in 100 mL of water. It is noteworthy that the 30 packs of each portion of the supplement were delivered inside another package, which showed the product usage guidelines, as shown in Figure 1.

During the study, a telephone follow-up was conducted with the patients, totaling four calls in a month, in order to encourage the use of the supplement and question about their intake.

Figure 1: Single packs containing 30 minor packets with 10 g of protein supplement with the preparation and dilution information.

Table 2: Demographic and clinical characteristics of the population (n = 18). Franca (SP), 2017.

Variable	N	%
Sex		
Female	11	61.1
Male	7	38.9
Age (years)		
< 60 years	10	55.5
60 years or more	8	44.5
Etiology da CKD		
DM	9	50
SAH	2	11.1
Others	7	38.9
Dialysis time (months)		
12 to 24 months	11	61.1
25 to 48 months	6	33.4
49 to 60 months	1	5.5
BMI classification		
Under weight	1	5.5
Normal	5	27.8
Over	12	66.7

CKD: Chronic Kidney Disease; DM: Diabetes Mellitus; SAH: Systemic Arterial Hypertension.

After 30 days of intervention, referring to the period of consumption of the protein supplement, the albumin values were again collected in medical records to compare the initial and final values of the plasma protein.

About the statistical analysis, the numerical variables were characterized by the descriptive parameters: arithmetic mean, standard deviation, median and coefficient of variation. The Student t test was used and the linear correlation coefficient r was calculated. In all statistical tests the level of significance was set at 5.0% (α = 0.05) and the calculations were performed by Graph Pad Prism 5.0 software.

Results

Of the 26 participants selected for the study, 6 did not continue due to death, 2 refused to ingest the supplementation along the study and therefore only 18 patients participated in all stages of the research, even those who presented some resistance at the beginning.

Table 2 presents the descriptive data of the study population and Table 3 summarizes the nutritional information of anthropometry and food consumption.

The median time for dialysis treatment was 2 years, and the minimum and maximum times corresponded to 1 and 5 years, respectively. Initial values of albumin and peritoneal dialysis time had no statistically significant association. However, the peritoneal dialysis time showed an inverse association with the variables indicative of food consumption, suggesting an inverse proportionality ratio between them: r = -0.43; p = 0.0396 for energy mean and r = -0.53; p = 0.0122 for protein mean.

The mean and standard deviation of the age of participants who completed the study were 53.6 ± 15.5 years. When comparing the initial serum values of albumin according to the age classification, it was observed a statistically significant negative association between them, suggesting an inverse proportionality relationship between these two variables: (r = -0.52; p = 0.015).

Protein intake data showed that the mean daily intake and the standard deviation were equivalent to 0.8 ± 0.3 grams per kilo of body weight. There was no difference in protein intake between the whey or albumin supplement group. Initial values of albumin and mean

Table 3: Mean, minimum and maximum values of anthropometric and energy-protein intake data by serum albumin concentration (n = 18).

Variable	Serum albumin concentration	
	< 3.6 g/dL (n = 13)	= ou > 3.6 g/Dl (n = 5)
BMI (kg/m²)	26.08 (19.65-29.1)	26.21 (20.09-32.55)
WC (cm)	97.33 (73-126)	85.83 (75-97)
WL	0.58 (0.48-0.68)	0.51 (0.47-0.56)
Energy (kcal)	1163.8 (814.1-1629.2)	1205.3 (874.5-1523.1)
Protein (g/kg peso)	0.9 (0.5-1.3)	0.9 (0.5-1.2)

protein intake did not present a statistically significant association, as there was no association between energy-protein intake and patient age.

Regarding the anthropometric data, initial values of albumin showed a statistically significant negative association with WC and WL, suggesting an inverse proportionality ratio (r = -0.47, p = 0.0254 for albumin and WC, (r = -0.49, p = 0.02 for albumin and WL).

Food intake indicators were not significantly associated with WL; however, there was a statistically significant negative association between protein consumption and WC, suggesting an inverse proportionality relation between them (r = -0.39, p = 0.031).

The Table 4 summarizes the correlations presented in the study. Regarding the effects of protein supplementation, the serum concentrations of albumin enhanced in 67% of the patients, however, 33% still showed values below the cut-off point of 3.6 g/dL. There was a significant increase in the mean value of albumin after supplementation (p = 0.0344), and the albumin supplement was superior to whey protein (Table 5).

Discussion

Regarding the variables related to food consumption, there was a low energy intake in the present study. Vaz, et al. Individuals studying dialysis subjects suggested that sub-reporting may be one of the factors that justify the low energy consumption values found [19]. In addition, authors point that Brazilian patients with CKD often face socioeconomic difficulties that may impact food consumption [20].

The protein intake was also below the recommended values. Campos, et al. people evaluated the dietary profile of patients with PD with hypoalbuminemia and also observed an insufficient protein intake. The authors also pointed out that the greatest contribution of calories came from carbohydrates [21].

Table 4: Correlations between the main study variables.

Correlations	**r**	**p**
Albumin - Dialysis time	-0.09	0.3607
Albumin - Age	-0.52	0.015
Albumin - Protein intake	0.3	0.1108
Albumin - Waist circumference	-0.47	0.0254
Albumin - Waist-to-length relation	-0.49	0.02
Dialysis time - Energy intake	-0.43	0.0396
Dialysis time - Protein intake	-0.53	0.0122
Energy intake - Age	-0.27	0.2459
Energy intake - Waist circumference	-0.22	0.189
Protein intake - Age	-0.25	0.1626
Protein intake - Waist circumference	0.19	0.2155

According to the present study, as the peritoneal dialysis time increases, energy-protein consumption decreases. This is justified by the fact that the treatment promotes organic alterations that can compromise feeding, as shown in the Mekki, et al. study. The authors also point out that prolonged dialysis time and low food intake are associated with hypoalbuminemia and inadequate nutritional status [22].

Interestingly, the energy-protein intake values did not correlate with the age of study participants. That is, the older age did not imply a decrease in energy and protein consumption. However, older age was associated with a decrease in serum albumin concentrations. Kim, et al. when comparing patients of different stages of life and dialysis mode, found that older individuals and on PD treatment had the lowest values of serum albumin [23].

Initial serum albumin values were not associated with protein consumption. It is known that not only the food consumption is able to influence the blood concentrations of this protein. States of inflammation and swelling, commonly present in patients with CKD, as well as protein losses in dialysis, are strongly associated with hypoalbuminemia [24].

Considering the anthropometric data, there was a correlation between the low serum albumin values and the waist circumference. It is known that abdominal adiposity may be associated with inflammation and consequent decrease of visceral plasma proteins [25].

There was also a negative association between waist circumference and protein consumption, indicating that a low intake of this nutrient is related to the accumulation of fatty tissue in the abdominal region. Freitas, et al. also found an association between a low protein intake and abdominal adiposity when studying hemodialysis subjects [26].

After protein supplementation there was improvement in serum albumin levels in the population of the present study. This result is in line with the findings of Moscardini, Finzetto e Maniglia, in which hemodialysis patients received the same supplements used in the present study [27]. Other researchers who investigated the effects of protein supplementation on hemodialysis and peritoneal dialysis patients also found an increase in serum albumin levels. The authors still found that after discontinuation of supplement use blood protein values declined [14].

The present study made it possible to observe that some patients did not adhere to the use of protein supplements, arguing that they were afraid to use them because they were diabetic or because their taste was

Table 5: Mean values and standard deviation of serum albumin concentrations assessed before (T0) and after Intervention (T1), according to the supplementation groups: albumin and whey protein (n = 18). Franca (SP), 2017.

Variable	**Albumin (n = 10)**		***Whey protein* (n = 08)**		**Total (n = 18)**	
	T0	T1	T0	T1	T0	T1
Albumin (g/dL)	2.8 ± 0.5	3.10 ± 0.5	3.45 ± 0.3	3.33 ± 0.3	3.21 ± 0.5	3.41 ± 0.6

not pleasant and because they felt gastrointestinal discomfort. Researchers say that gastrointestinal discomfort really hinders patient adherence and may lead to impaired supplementation effectiveness [28].

Thus, for protein supplementation to be effective in order to increase blood albumin and improve nutritional indicators, is necessary monitoring the supplementation by the team involved in the patient's treatment, who should make them aware of the benefits promoted by this nutritional recovery strategy [29].

Conclusion

It was concluded that protein supplementation promoted an increase in serum albumin levels and this marker was inversely associated with age and abdominal adiposity.

The absence of correlation between energy and protein intake with the initial values of albumin generates the need for investigations to clarify if the adequacy of food consumption is able to normalize the concentrations of this protein, or if supplementation is still necessary.

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