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Association Between Oral Nutritional Supplements and Serum Biomarkers on Hemodialysis Patients. A Retrospective Study

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Abstract
Background: The prevalence of end-stage renal disease (ESRD) is expected to increase over the next few decades. ESRD is accompanied by various complications including malnutrition, uremia, electrolyte, mineral, and bone disorders. Continuously monitoring the clinical complications of patients on maintenance hemodialysis dialysis (HD) therapy is of great concern. Patients on maintenance HD are at risk of malnutrition which could lead to hospitalization, morbidity, and mortality of these patients. Therefore, this retrospective study aims to evaluate the effects of oral nutrition supplements (ONS) provided during hemodialysis on serum biomarkers of HD patients with hypoalbuminemia. **Method**: Laboratory measurements were taken before the start of ONS intake and after two months of continuous ONS intake on 34 patients who received ONS for two months. Serum biomarkers such as albumin, creatinine (Cr), potassium (K), phosphorus (P), calcium (Ca), and sodium (Na) data was extracted from the electrical medical records (EMR). The eligible patients received 7 bottles (125ml each bottle) per week for two months. Each bottle contains 9.4 grams of whey protein instead of animal protein because whey protein has a lower content of electrolytes. Statistical analysis using SPSS software and paired-t test was used to assess changes in serum biomarkers during the provision of supplements. **Result**: The provision of ONS with the patients on HD demonstrated a significant increase (P value 0.038 < 0.05) in serum albumin level (Mean: 31.91, SD 4.10) after two months compared to before ONS provision (Mean:30.64, SD 3.54). However, no statistically significant difference was found in other serum biomarkers (Cr, K, P, Ca, and Na). **Conclusion**: ONS provision in patients with hypoalbuminemia undergoing maintenance HD showed significant improvement in serum albumin levels that could lead to enhanced nutrition status. Additionally, no abnormal electrolyte disturbance was found in the duration of ONS provision. Hence, renal-specific ONS might be considered a complementary dietary supplement for malnourished HD patients. Furthermore, more trials are required with a large sample size to confirm the long-term efficacy of other brands of renal-specific ONS particularly in patients undergoing maintenance HD with different comorbidities.
Keywords: Hemodialysis, Hypoalbuminemia, Oral nutrition supplement, Serum biomarkers.
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Introduction

The prevalence of ESRD is expected to increase over the next few decades (1). ESRD is accompanied by various complications including malnutrition, uremia, electrolyte, mineral, and bone disorders (2). Controlling clinical complications associated with ESRD in patients undergoing maintenance HD therapy is of great concern. Malnutrition is an important factor in HD patients, as it is the main reason linked to hospitalization, morbidity, and mortality (2,3).

The failure of conservative treatments in individuals with ESRD leads to the introduction of renal replacement therapy including renal peritoneal dialysis (PD), transplantation, and HD to maintain the quality of life of the patients (4). HD is a dialysis modality that permits the intermittent removal of toxic substances, fluid, and solutes (5). During this filtration process, blood is drawn from vascular access (arteriovenous fistula or catheter) into an extracorporeal circulation system, that contains a semipermeable filter (dialyzer). Inside the filter, the blood encounters the dialysis solution through a semipermeable membrane. During this circulation, the filter removes toxins, and solutes and the clean blood returns to the patient (4-6). Elevated serum calcium levels and hyper-phosphatemia could result in vascular calcification which is associated with cardiovascular diseases and increases the mortality rate in HD patients (7-8). Cardiovascular diseases are always mentioned as the main reason for morbidity and mortality in HD patients (2). Serum calcium and phosphate levels should be carefully monitored and kept within the normal range in PD, HD, and pre-dialysis patients (9).

Another electrolyte with an important role in HD patients is potassium. It is a concern that cardiac fatal outcome is correlated with any change in serum potassium level. For example, hyperkalemia might induce fatal arrhythmia in HD patients (10). Mortality due to hyperkalemia in HD patients can be reduced (11,12). Effective

HD and diet therapy can play a significant role in preventing serum potassium fluctuations or disturbances. While, maintaining optimal sodium levels in the body or serum can reduce hypertension, and fluid overload, and could diminish cardiovascular mortality in this population (13,14).

Nutritional imbalances are common in HD patients, around 10 to 70% of HD patients will present with signs of malnutrition (4,15). Morbidity and mortality rates in this population are influenced by protein malnutrition (16). The increased risk of malnutrition should be matched with a thorough medical and nutrition intervention (17). The factors associated with nutritional deficit are, the loss of proteins (1 to 3 g per HD session), poor dietary intake, increased protein catabolism due to metabolic acidosis, uremia, and hormonal disorders (18-20). Different studies suggest that the most important nutritional-related biomarkers which are highly correlated with survival in HD patients are serum creatinine concentration (10) and serum albumin level. Serum albumin concentrations between 3.51 and 4.0 g/dL were associated with a two-time higher mortality rate compared to serum albumin levels higher than 4.0 g/dL (4). A fivefold increase in mortality risk was observed in patients with serum albumin concentrations between 3.01 and 3.5 g/dL. Some researchers suggested that low albumin concentrations are a consequence of deficient calorie and protein intake (4,21,22). Other studies recommended HD patients be advised to consume their daily recommended amount of protein. The recommended dietary allowance for protein is at least 1.2 g/kg/day and calories of 30-35kcal/kg/day for most stable patients, but in case of increased metabolic and stress the requirements may be higher (23,24).

Malnutrition in maintenance HD patients is a great concern. Adherence to the daily recommended amount of protein intake and the provision of ONS could potentially improve albumin levels and recover the effects of malnutrition in this population. Whey protein is commonly used because of the low content of potassium, sodium, and phosphate, which might be safer for these patients and to control serum biomarkers concentration to improve malnutrition. Therefore, we aim in this retrospective study to evaluate the effects of the provision of ONS during hemodialysis on serum biomarkers of HD patients with hypoalbuminemia.

Methodology

For all the patients who received ONS for two months, laboratory measurements were taken before the start of ONS intake and after two months of continuous ONS intake. Serum biomarkers such as albumin, Cr, K, P, Ca, and Na data were extracted from EMR after getting approval from the Medical Research Center of Hamad Medical Corporation (HMC) for two readings. The renal-specific beverage Renilon which is an approved oral nutrition supplement by HMC is to be used as a complementary oral food source for HD patients in all HD units in HMC and is manufactured by Nutricia Company in prepackaged bottles of 125ml each. The patients with low albumin levels (<35 mmol/L) received 7 bottles (125ml each bottle) per week for two months. Each bottle contained 250kcal, 12.5 grams of fat, and 9.4 grams of whey protein instead of animal protein because whey protein has a lower content of electrolytes. The electrolyte content of Renilon per 100 ml is Na: <2.65 mmol, K: <0.87 mmol, Ca: <0.27mmol, and P: <0.29 mmol. All patients included in this study were visited and were encouraged to consume the ONS provided. Statistical analysis using SPSS software and paired-t test was used for assessing and comparing changes in serum biomarkers before and after the ONS two months. Analysis of the covariance using (ANOVA) model to assess the effect of providing ONS and the baseline parameters as covariance, a p-value of < 0.05 was considered statistically significant.

Sample size

This study was conducted on patients treated at the hemodialysis unit in Hazm Mebaireek General Hospital (HMGH), Doha, State of Qatar. During the monthly nutrition assessment of the 64 patients receiving HD, many patients were observed to be at risk of malnutrition based on serum albumin concentration. According to this assessment, the assigned physician decided to prescribe a high-protein ONS for these patients. Among the patients treated at the HMGH hemodialysis unit, 34 patients were found to be eligible to participate in this study. The inclusion criteria in this study were age older than 18 years and serum albumin levels less than 35 mmol/L, while the exclusion criteria include patients who have liver disease, active inflammation, and who are undergoing peritoneal dialysis.

Statistical analysis

Descriptive statistics were used to summarize and determine the sample characteristics and distribution of various considered parameters related to demographics, serum nutritionally related biomarkers, clinical, and other related features of the cohort of participants. The normally distributed data and results were reported with mean and standard deviation (SD) with corresponding 95% CI, and the remaining results were reported with median and interquartile range (IQR). Categorical data was summarized using frequencies and percentages. Associations between two or more qualitative variables were examined and assessed using Pearson Chi-square and Fisher Exact tests as appropriate. Quantitative outcome (serum nutritional related biomarker) measured between the two-time points was analyzed using paired t-test or Wilcoxon signed ranked test as appropriate. The relationship between

two quantitative variables were examined using Pearson's or Spearman's correlation coefficients. Linear or non-linear regression was performed to explore and assess the impact of potential factors and predictors affecting the serum nutritional-related biomarkers by adjusting potential predictors and confounders. Repeated measure analysis of variance (ANOVA) was used to analyze quantitative outcome measures recorded at various time points. Pictorial presentations of the key results (serum nutritional-related biomarker) were made using statistical graph Box plots. All P values presented were two-tailed, and P values. All Statistical analyses were done using statistical packages SPSS 27.0 (SPSS Inc. Chicago, IL) software.

Result

This study was conducted in the dialysis unit of HMGH, Doha, State of Qatar. A total of 34 patients were found to be eligible and meet the inclusion criteria of age older than 18 years and serum albumin levels less than 35 mmol/L. The exclusion criteria are patients who have liver disease, active inflammation, and who are undergoing peritoneal dialysis. The participants who were investigated and completed the study were composed of 6 (17.6%) females compared to 28 (82.4%) males. The age of the participants varied between 25 to 77 years old, 9 of them were ≤45 years old and 25 were ≥ 45 years old as shown in table no 1. All participants are undergoing maintenance HD therapy.

Gender					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	28	82.4	82.4	82.4
	Female	6	17.6	17.6	100.0
	Total	34	100.0	100.0	

Age Group					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Age <=45 years	9	26.5	26.5	26.5
	Age >45 years	25	73.5	73.5	100.0
	Total	34	100.0	100.0	

Table 1. Demographic frequency table

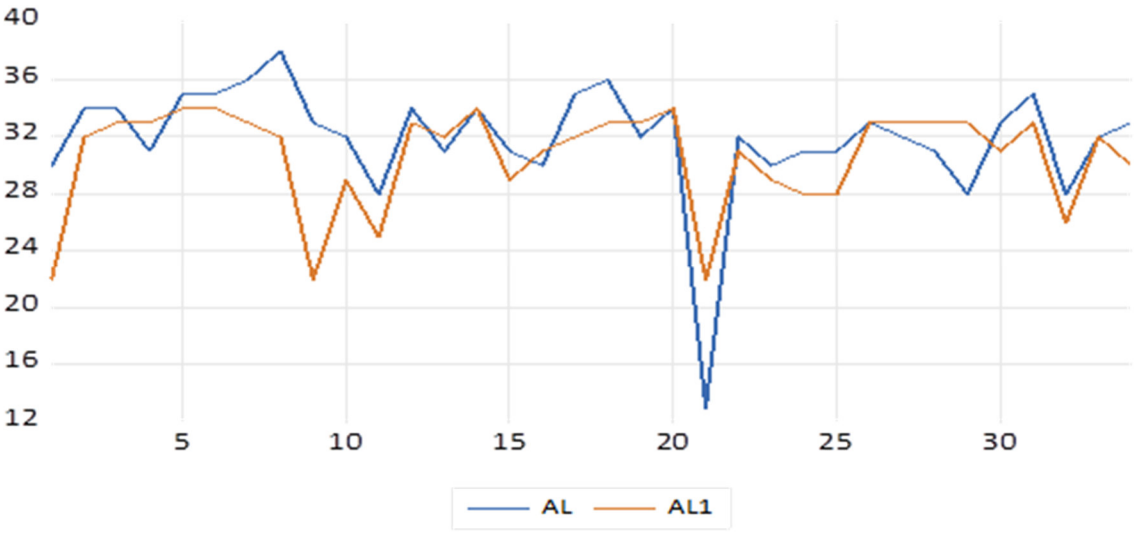

Figure 1. Albumin level before and after ONS provision

Statistics

	Age	Albumin Before	Albumin After	Cr Before	Cr After	K Before	K After	P Before	P After	Na Before	Na After	Ca Before	Ca After
N	34.00	34.00	34.00	34.00	34.00	34.00	34.00	34.00	34.00	34.00	34.00	34.00	34.00
Mean	52.74	30.65	31.91	783.15	733.53	4.68	4.56	1.66	1.59	137.82	137.79	2.29	2.26
Median	53.00	32.00	32.00	808.50	763.00	4.70	4.45	1.75	1.50	138.50	138.00	2.29	2.28
Std. Deviation	12.90	3.55	4.10	229.43	243.01	0.65	0.63	0.43	0.53	2.77	3.40	0.19	0.24
Range	52.00	12.00	25.00	1,238.00	1,060.90	3.70	2.80	1.97	1.99	10.00	16.00	1.19	1.48
Minimum	25.00	22.00	13.00	144.00	5.10	2.90	3.60	0.63	0.72	133.00	127.00	1.56	1.10
Maximum	77.00	34.00	38.00	1,382.00	1,066.00	6.60	6.40	2.60	2.71	143.00	143.00	2.75	2.58
P Value		0.038		0.150		0.354		0.407		0.951		0.430	

*p<(0.05)

Table 2. Statistical analysis: comparison between renal biomarkers before and after dietary intervention

Table 2 shows that there is a significant difference between the results before and after the ONS provision for 2 months. There was a significant increase (P value 0.038 < 0.05) observed in the albumin level after the ONS was taken (Mean: 31.91, SD 4.10) versus before the ONS provision (Mean:30.64, SD 3.54). Moreover, figure 1 shows the improved level of albumin in most of the patients before and after ONS was taken. However, 6 out of 34 patients were not able to achieve improvement in their albumin level compared to after 60 days.

Group Statistics

	gender	N	Mean	Std. Deviation	Std. Error Mean
Albumin2	f	6	31.5000	2.25832	.92195
	m	28	32.0000	4.42217	.83571

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Albumin2	Equal variances assumed	.600	.444	-.267	32	.791	-.50000	1.87098	-4.31106	3.31106
	Equal variances not assumed			-.402	14.748	.694	-.50000	1.24435	-3.15622	2.15622

Table 3: Gender comparison of albumin level after ONS provision.

Table 3 illustrate the comparison between male and female participants after ONS provision. The mean was 31.50 (SD 2.25) for females versus 32.00 (SD 4.42) for males which indicates no significant difference (P value > 0.05) in albumin level between genders.

In Table 2 a reduction was observed in the levels of Cr (Mean: 733.53, SD 243.00), K (Mean: 4.55, SD 0.62), P (Mean: 1.59, SD 0.52), Na (Mean: 137.79, SD 3.40), and Ca (Mean: 2.25, SD 0.24) after and before the provision of ONS with the levels of Cr (Mean: 783.14, SD 229.43), K (Mean: 4.68, SD 0.65), P (Mean: 1.65, SD 0.42), Na (Mean: 137.82, SD 2.76), and Ca (Mean: 2.29, SD 0.19) . However, the reductions in the levels of Cr, K, P, Na, and Ca were found to be statistically insignificant.

Discussion

This study was conducted retrospectively on eligible 34 patients who were found to meet the inclusion criteria of age older than 18 years and serum albumin levels of less than 35 mmol/L. The exclusion criteria are patients who have liver disease, active inflammation, and who are undergoing peritoneal dialysis. This retrospective study aims to evaluate the effects of ONS given during hemodialysis on serum biomarkers of HD patients with hypoalbuminemia.

The provision of ONS illustrated a significant increase (p < 0.038) in the albumin level of 31.91 mmol/L after versus before with 30.64 mmol/L. These results coincide with the outcome of the study conducted by Tuyen Van Duong et al. (21) which demonstrated that in three groups, albumin levels after the three-month intervention were

significantly higher compared to baseline levels ($p < 0.05$). Another prospective study done by Pokkrong Limwannata et al. (20) in 2020, at the hemodialysis center in Chaiyaphum, Thailand approved that there was ONS is recommended for malnourished patients with kidney failure, serum albumin concentration increased significantly in the ONCE dialyze group. Another study was conducted on patients recruited from the Hemodialysis Center of West China Hospital and Sichuan University from July 2019 to September 2019 by Aiya Qin et al. (24) illustrated a significant increase in serum albumin 39.6 (37.6–45.8) vs. 43.4 (39.1–46.7) g/L; ($p=0.018$) after 2 months of therapy. Moreover, a study conducted in Taiwan in 2019 by Tuyen Van Duong et al. (21) showed that after a three-month intervention, serum albumin was significantly increased. When comparing male and female albumin levels after ONS provision, the data in Table.3 suggests that no significant difference was found between the two genders in this study.

In our study, a statistical reduction was found in the Cr level as the mean before was 783.14 (SD 229.43) while after taking the ONS was 733.53 (SD 243.00). However, this result showed that there is no significant difference (p-value = 0.15>0.05) between the two values. The same result was observed in two studies conducted in Thailand by Pokkrong Limwannata et al (20 and Bancha Satirapoj (9) which stated that dietary intervention did not significantly change the levels of serum creatinine.

No significant decrease (p-value = 0.354>0.05) was found in the levels of K in our study. The result of K before and after using the ONS for the participant was Mean: 4.68 (SD .65) and 4.55(SD .62) respectively. The study conducted by Pokkrong Limwannata1et al. (20) found that the provision of oral renal-specific nutrition supplement (ONCE dialyze) had significantly decreased K levels for the control group (mEq/L) 4.3 ± 0.8 and for the ONCE dialyze group 4.2 ± 0.6 in patients on hemodialysis. Interestingly, a study of a systematic review of randomized controlled trials by Peng Ju Liu et al (1) investigated the effects of ONS in patients undergoing maintenance dialysis therapy (MDT). The results support the use of ONS for the improvement of nutritional status in MDT patients without significant influence on serum potassium levels, especially for patients receiving hemodialysis. The level of P illustrates no significant decrease (p-value = 0.407 > 0.05) with the before and after mean levels of 1.65 (SD .42) and 1.59 (SD .52), respectively. The study of Pokkrong Limwannata1 et al (20) shows that ONCE Dialyze and NEPRO supplements had no significant effect on serum phosphorus levels. Both renal-specific ONS with low phosphorus content did not increase the risk of electrolyte abnormalities among patients with kidney failure undergoing maintenance hemodialysis as same as with the result of our study. In contrast, the study conducted by Zahra Sohrabi et al. (2) in Shiraz, Iran demonstrated that there were significant decreases in serum phosphorus levels of the study participants.

Our study shows that no significant decrease (p-value 0.951 > 0.05) was found in Na level before (Mean:137.82 SD 2.76) and after (Mean: 137.79 SD 3.40) the provision of ONS. A similar result was observed in the study conducted by Bancha Satirapoj et al (9) that showed no significant change (Na (mEq/L) 132.9±6.1 vs 134.8±5.3) was found in the Na level of the participants in their study. Also, dietary intervention did not significantly change the levels of serum sodium. Lastly, no significant decrease (p-value 0.430 > 0.05) was found in the serum Ca level with a mean of 2.29 (SD .19) versus 2.25 (SD .24), before and after ONS supplementation. A similar result was observed in the study conducted by Bancha Satirapoj et al. (17), which found no significant changes (P value 0.718) in Ca levels after 30 days (Ca (mg/dL) before 9.4±0.5 and after 9.3±0.4). Similarly, the study conducted by Vahid Naseri-Salahshour (13) found no significant difference between the two groups in their study after intervention (p = 0.16) in Ca level.

Our study found that the provision of ONS has a significant effect on albumin levels. However, no significant effect was seen on serum creatine, calcium, potassium, phosphorus, and sodium levels. Using ONS with low electrolyte content did not increase the risk of electrolyte abnormalities among patients undergoing maintenance hemodialysis. The compliance of patients with ONS for 60 days in this study was good. Providing the appropriate medical and nutritional intervention and timely follow-up could positively affect the percentage of patient compliance with ONS provision.

Conclusion

Short-term ONS provision (Renilon) were associated with increased protein, fat, energy, and electrolyte intake. ONS significantly improved nutritional status and serum albumin levels in malnourished patients undergoing maintenance hemodialysis without abnormal electrolyte disturbance. Therefore, renal-specific dietary supplements might be considered as a complementary dietary supplement for malnourished hemodialysis patients. More trials are needed with a large sample size to confirm the long-term efficacy of other brands of renal-specific ONS particularly in patients undergoing maintenance hemodialysis with different comorbidities considering observation morbidity and mortality risk.

Limitations

- Our study is retrospective which is conducted in a single dialysis center with a small sample size leading to a lack of control group and direct interventions causing performance bias.

- The use of one type of ONS could not represent all macronutrients and micronutrients that are required which may affect the treatment outcomes among those patients.
- Our study did not consider other comorbidities which may affect serum biomarker of the participant.

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