Effect of Peridialytic Protein Bar Supplementation Among Malnourished Hemodialysis Patients

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Note from editor: While the results of this particular study are not clinically significant due to a small sample size, this original trial does highlight an area in need of continued research to optimize patient care.

Key Words: malnourished, protein supplementation, nutritional status, albumin trends in dialysis patients

Abstract

Background: Malnutrition is a common problem in hemodialysis (HD) patients. Though there are several causes in ESRD patients for protein calorie malnutrition; compromised intake is an important cause. Nutritional care and support cannot be obtained at the right time if there is a delayed diagnosis of malnutrition in HD patients. Thus in order to meet their daily protein requirements and losses seen during dialysis, peridialytic protein supplements are recommended to blunt the catabolic effect. The goal of this study was to evaluate the efficacy of peridialytic protein bar supplementation among HD patients. Method: This study involves 20 subjects (10 in each experimental and control group) by a random sampling method who were evaluated for anthropometric, biochemical and dietary parameters with and without supplementation at baseline and after eight weeks. The tools used for data collection included subjective global assessment (SGA), an interview schedule and a seven day food record. The duration of the study was three months and supplementation was given thrice a week for two months on HD days. Results: The serum albumin at baseline and eight weeks showed a significant improvement (p<0.05) in the experimental group. On HD days the energy intake from baseline (688.0 ± 76.18) to eight weeks (1325.5 ± 182.2) is significant statistically (p<0.01) for the experimental group and protein intake from baseline (28.20 ± 7.67) to eight weeks (66.60 ± 1.955) showed a one percent significance compared to non-HD days. There was an improvement in the SGA score in the experimental group from 15.80 ± 5.116 at baseline to 19.20 ± 4.638 after eight weeks of supplementation (p<0.01). Conclusion: Our findings suggest that peridialytic protein bars are an acceptable protein and energy supplement for patients on HD and have an advantage over fluid – based supplements in patients with fluid restrictions. Protein bar supplementation thereby, resulted in the improvement of serum albumin, total protein and an increase in SGA score as well. Renal dietitians should monitor closely for patients with poor appetite and intervene accordingly.

Introduction

Chronic glomerulonephritis is the major reason of end stage renal disease (ESRD) which accounts for more than one-third of patients in the world. In India, diabetic nephropathy is also a leading cause which accounts for about one-fourth of the patients (1). Hemodialysis is a procedure with a protein catabolic nature (2). However, loss of amino acid in dialysate and decreased protein synthesis but not proteolysis, is the cause of catabolic state in HD patients. Nutritional care and support cannot be obtained at the right time if there is a delayed diagnosis of malnutrition in HD patients. Though there are several causes for malnutrition, a major reason of protein calorie malnutrition is reduced intake during dialysis (3). During dialysis a high protein snack or easily consumable protein bar, low in sodium, potassium and phosphorus would be a reasonable choice.

This particular study aimed to find the efficacy of peridialytic protein bar supplementation among malnourished HD patients. Several studies have been done to compare the nutrient intake of patients on HD and non – HD days. Findings show a decrease in intake, especially during HD days. Thus, there is an impact of protein supplementation on the nutritional status of those patients, as it compensates the deficit during dialysis.

Methods and Materials

Study population - The present study is a comparative, prospective experimental design conducted on human subjects. In the present study the impact of peridialytic protein bar supplementation on the HD patient was analyzed with a control group. The sampling method used in this study was randomized/convenience sampling. Participants of the
study were selected from the Outpatient Dialysis unit, Nephrology department situated at Sri Ramachandra Medical College. The samples were recruited based on the inclusion criteria – malnourished patients undergoing HD and >25 and <60 years of age. Twenty subjects were split into an experimental and control group, with each group containing an equal number of individuals who were malnourished according to SGA and who had hypoaalbuminemia. Patients willing to participate in the study were asked to complete the informed consent form which has been accepted by the Ethical committee for student proposals of Sri Ramachandra University (CSP/10/DEC/13/43). Duration of the study was for three months and the supplementation period is thrice a week for two months.

Data Collection Tools

The tools used for data collection included subjective global assessment (SGA) to assess patients as (A) well nourished, (B) mild/moderately malnourished and (C) severe malnourishment. An interview schedule for collecting the demographic data, past medical history, duration of dialysis, appetite level and seven day food record for assessing the nutritional intake was used.

Subjective Global Assessment

The original SGA form as reported by Detsky et al. score five components of a medical history (weight change, dietary intake, gastrointestinal symptoms, functional capacity, disease and its relation to nutritional requirements) and three components of a brief physical examination (signs of fat and muscle wasting, nutrition-associated alternations in fluid balance) (4). The patient is then assigned a rating of well nourished (A), moderately undernourished (B), or severely undernourished (C) by subjective consideration of the data collected in the eight areas, without adhering to a rigid scoring system. The patients could be assigned a B rank if there was at least a 5% weight loss in the few weeks prior to admission, definite reduction in dietary intake, and mild subcutaneous tissue loss. If the patient had a recent weight gain unrelated to fluid retention, they were instructed to assign an A rank, even if the net loss was between 5% and 10%, the patient had mild loss of subcutaneous tissue, and especially if the patient noted an improvement in the other historical features of the SGA (e.g., improvement in appetite). In order to receive a C rank, the patient had to demonstrate obvious physical signs of malnutrition (severe loss of subcutaneous tissue, muscle wasting, and often some edema) in the presence of a clear and convincing pattern of ongoing weight loss. In this study the SGA tool was used for assessing the nutritional status of the HD patients.

Scoring of the SGA tool is given below:

► A = Well nourished
► B = Mild/moderately malnourished
► C = Severely malnourished

Table 1: Experimental Participant Groups and SGA category after 8 weeks

<table>
<thead>
<tr>
<th></th>
<th>Experimental group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=10</td>
<td>N=10</td>
</tr>
<tr>
<td></td>
<td>Baseline</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Well nourished</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Mild / moderately malnourished</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Severely malnourished</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

The above table describes the nutritional status of subjects in both the groups at baseline and after eight weeks according to SGA category. The increase in the SGA score after eight weeks is the result of supplementation in the experimental group.

Nutritional Assessment

Nutritional assessment of all the patients was done using anthropometric data, biochemical data (serum albumin) and dietary history. The dietary history of all the selected subjects was collected using a seven day food diary method. The study has been approved by the Ethical committee for student proposal of Sri Ramachandra University.

Experimental Procedure

Initial Assessment - Analysis of nutritional status was completed using the subjective global assessment tool, history of past and present illness, review of dietary intake using the seven day food diary, physical examination, biochemical evaluation and anthropometric measurements. The procedure involved in the present study is classified into four phases in Figure 1.

Recipe Formulation, Analysis and Sensory Evaluation

A recipe was formulated using ground nuts, oats and honey by the investigator. In order to make the supplement calorie and protein dense, groundnuts and oats have been selected as a low sodium and potassium cereal-pulse combination. Since it is given during dialysis, a dry snack is preferred, therefore the bar has been formulated and named as a ‘PROTEIN BAR’. Two protein bars were provided per HD session/day for an individual. The investigator prepared the protein bars hygienically and silver foil paper was used for packaging. It can be stored at refrigerator temperature for a period of one month. The protein bars were analyzed for shelf life of about fifteen days at room temperature without any microbial growth. Feedback about the formulation was also obtained from subjects using a score card and was found to be positive.
The results were tabulated and interpreted using percentages, mean, standard deviation and t-tests. Independent t-tests were done between the experimental and control group. Paired t-tests were performed within the experimental and control group. SPSS version 10 was employed for the statistical data analysis with p<0.01 fixed as the significant level throughout the study.

Results

A majority (70%) of the participants were male in the experimental group. In the experimental group, half (50%) of the subjects, both male and female, were 56 to 60 years of age. When compared between the groups, it was found that a majority (80%) of participants were between 56 to 60 years of age.

Group Nutritional Status: Before and After Supplementation

Weight did not show an effect on supplementation between the two groups. Within the experimental group the initial weight values from 57.80 ± 7.068 at baseline increased to 60.00 ± 8.589 after eight weeks of supplementation (p<0.01). Mean albumin levels at baseline were not significant. After eight weeks, the values were 3.740 ± .2119 (experimental group) and 2.880 ± .2251 (control group) with p<0.01.

The mean caloric intake of the subjects at baseline using a seven day food record for dialysis days was 688 kcals or 16 kcals/kg/day and 826 kcals or 19 kcals/kg/day for the experimental and control groups. Caloric intake on non-dialysis days was 871 kcal or 20 kcals/kg/day and 936 kcal or 21 kcal/kg/day for experimental and control group subjects. The energy intake increased to 1174.0 ± 171.8 or 23 kcal/kg/day at eight weeks for the experimental group on non-HD days, whereas a decrease in energy intake was observed in the control group. Energy intake increased to 1325.5 ± 182.2 or 23 kcal/kg/day after eight weeks of supplementation with a difference of 347 kcal in the experimental group whereas a decline was seen in the control group.

Mean protein intake for non-HD days at baseline was 35 grams or 0.6 gm/kg/day for the experimental group and 40 grams or 0.7 gm/kg/day for the control group respectively. On HD days, there was a reduction in protein intake, 28 grams or 0.6 gm/kg/day in the experimental group and 33 grams or 0.6 gm/kg/day in the control group. This trial highlights that protein intake increased to 58.20 ± 1.751 or 1 g/kg/day after eight weeks during non-HD days and 66.60 ± 1.955 or 1.2 g/kg/day.
at eight weeks during HD days in the experimental group. Decreased protein intake values were noted in the control group on both days.

### Nutritional Status: Experimental Group After Supplementation

The serum albumin values within the experimental group improved from 3.12 ± .235 at baseline to 3.740 ± .2119 after eight weeks of supplementation with a difference of 0.62 grams (p<0.01). (See Figure 3).

**Figure 3: Serum Albumin at Baseline versus 8 weeks in Experimental Group**

Mean energy and protein intake during non-HD days for the experimental group subjects showed that the energy intake from a baseline of 871.40 ± 215.814 to eight weeks, 1174 ± 171.818, with a p<0.01 and a difference of 303 kcal. Protein intake on non-HD days from baseline 34.50 ± 11.108, to eight weeks 58.20 ± 1.751, showed a greater difference of 24 grams for the experimental group (p<0.01).

### Table 3: Mean, Standard Deviation and Level of Significance of the Experimental Group on Energy and Protein Intake on HD Days

<table>
<thead>
<tr>
<th>Nutrients</th>
<th>Experimental Group</th>
<th>Mean ± Sd</th>
<th>‘P’ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>Baseline</td>
<td>688.0 ± 76.18</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>After 8 Weeks</td>
<td>1325.5 ± 182.2</td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>Baseline</td>
<td>28.20 ± 7.671</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>After 8 Weeks</td>
<td>66.60 ± 1.955</td>
<td></td>
</tr>
</tbody>
</table>

Table 3 represents the energy and protein intake during HD days for the experimental group subjects. The energy intake from baseline to eight weeks showed a difference of 637 kcal (p<0.01). Protein intake from baseline to eight weeks also showed a greater difference of 38 grams (p<0.01). SGA score in the experimental group increased from 15.80 ± 5.116 at baseline to 19.20 ± 4.638 after eight weeks of supplementation (p<0.01).

### Nutritional Status: Control Group

Serum albumin values showed a decline from 3.05 ± .310 at baseline to 2.880 ± .2251 after eight weeks (p<0.05). The energy and protein intake during the non-HD days also decreased from a baseline of 936.3 ±142.2 to 844.7 ± 54.84 at eight weeks (p<0.01). Protein intake declined from a baseline of 40.50 ± 3.923 to 38.4 ± 3.204 at eight weeks (p<0.01). The energy intake on HD days declined from a baseline of 826.1± 101.6 to 670.7 ± 50.91 after eight weeks with a difference of 156 kcals (p<0.01). Protein intake on HD days at baseline was 33.50 ± 2.677 and after eight weeks, 29.80 ± 2.394, showing a decline of 3.7 grams (p<0.01).

### Discussion

In India malnutrition and chronic energy deficiency is common. The major hypothesis on biomarkers, nutrient intake and the assessment tool for malnutrition in the experimental group was rejected. In the present study there is an increase in the male subjects due to the convenience sampling technique. The results suggest that inflammation is closely linked to the development of anorexia in kidney patients and is more common in men than women. Nonetheless, based on the frequency of dialysis and the uremic malnutrition, high biological value protein (non vegetarian foods) can be suggested (5).

Supplementation of protein bars (22 gm/HD session) for a period of eight weeks could have brought in a change in albumin levels at eight weeks as well as meeting the 1.2 grams of protein requirement respectively (6). Scott et al. reported that main established causes for increased protein catabolism and decreased protein synthesis in HD patients are insufficient energy-protein intakes, which could be corrected by calorie and protein supplements (7). Thus, the effect of protein bar supplementation had a greater impact on the protein intake of the experimental group subjects at the end of eight weeks. Limited published data on peridialytic protein bar supplementation is available in India which is again the strength of the study.

### Study Limitations

Lack of control on the confounding factors by the investigator was observed. Albumin is not a reliable marker when compared with CRP, which was not measured in this experiment and could be considered another limitation.

### Conclusion

Calorie rather than protein deficiency is commonly observed in HD patients, which can lead to malnutrition. Patients should be counseled to consume adequate amounts of energy and protein daily, especially on dialysis days. Oral nutrition supplements,
as part of structured, directly observed peridialytic therapy in chronic HD patients, was well-accepted. Peridialytic protein bars are an acceptable protein and energy supplement for patients on HD. It is well accepted by patients except when dentures limit chewing ability. It has advantages over fluid-based supplements in patients with fluid restrictions. Protein bar supplementation thereby, resulted in the improvement of nutritional markers, serum albumin, total protein and SGA assessment score. Renal dietitians should monitor closely for patients with poor appetite and should intervene accordingly.

References