Therapeutic Effects of Oral Nutritional Supplements during Haemodialysis: Physician’s Experience

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Abstract

Objectives: To evaluate the effects of predialytic oral nutritional supplementation in chronic kidney disease (CKD) patients on maintenance haemodialysis (MHD)

Methods: NEPRO HP® was provided to 77 CKD patients on maintenance haemodialysis (MHD) over 3 months. Efficacy parameters were improvement in albumin levels, weight and haemoglobin levels; safety parameters were serum potassium and phosphorus values; other parameters were SGA and MIS scores.

Results: Mean serum albumin values showed a statistically significant increase. There was a statistically significant improvement in the mean body weight and haemoglobin of the patients in the second and third months of treatment. Serum phosphorus and potassium levels did not change in a statistically significant manner. There was improvement in nourishment status as detected by MIS and SGA scores. Two patients expired during the course of the study.

Conclusion: Predialytic oral supplementation with NEPRO HP® improves nutritional status of CKD patients on MHD.

Introduction

Poor nutritional status is a well-documented consequence of chronic kidney disease (CKD). It is an important prognostic predictor for patients starting dialysis. In fact, the so-called uraemic malnutrition is recognised to be the strongest risk factor for adverse outcomes and death in patients suffering from CKD. Further, protein energy malnutrition (PEM) is also commonly observed in CKD patients undergoing haemodialysis and has been associated with increased morbidity and mortality among these patients. Life-threatening undernutrition was detected in 20-36% of French patients undergoing dialysis in a study reported in 1999. The major determinants of nutritional status in this population were reported as protein intake and dialysis efficacy.

We report the physician’s experience concerning the effects of predialytic oral supplements on nutritional markers and nutritional status in patients receiving maintenance haemodialysis (MHD).

Material and Methods

Data was collected over a period of 3 months from patients of outpatient haemodialysis unit located in Mumbai, India. All consenting patients with CKD, above 18 years of age, and receiving twice or thrice-weekly maintenance haemodialysis at the outpatient haemodialysis centre were included, and those with intercurrent acute illnesses, body weight less than 40 kg, documented history of dialysis noncompliance, documented malabsorption syndromes, and contraindications to any of the ingredients of the nutritional supplement were excluded.
All the included patients were provided with 89 grams of nutritional supplement in 167 ml of water constituted to form 237 ml of total serving for a total duration of 3 months.

The supplement given was NEPRO HP® (ABBOTT NUTRITION INTERNATIONAL INDIA), which

Table 1 : Baseline characteristics of patients enrolled in study

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>18-25</td>
</tr>
<tr>
<td></td>
<td>25-45</td>
</tr>
<tr>
<td></td>
<td>45-65</td>
</tr>
<tr>
<td></td>
<td>&gt;65</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>38</td>
</tr>
<tr>
<td>Serum Albumin (g/dl; Mean ± SD)</td>
<td>3.01 ± 0.44</td>
</tr>
<tr>
<td>Body Weight (kg; Mean ± SD)</td>
<td>58.78 ± 11.20</td>
</tr>
<tr>
<td>Serum Hemoglobin (g/dl; Mean ± SD)</td>
<td>9.23 ± 1.88</td>
</tr>
<tr>
<td>Serum Potassium (mg/dl; Mean ± SD)</td>
<td>5.22 ± 0.79</td>
</tr>
<tr>
<td>Serum Phosphorus (mg/dl; Mean ± SD)</td>
<td>6.65 ± 1.86</td>
</tr>
</tbody>
</table>

Table 2 : Efficacy and safety parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum Albumin (g/dl)</td>
<td>3.01 ± 0.44</td>
<td>3.24 ± 0.42***</td>
<td>3.58 ± 0.37***</td>
<td>3.85 ± 0.32***</td>
</tr>
<tr>
<td>Body Weight (kg)</td>
<td>58.78 ± 11.20</td>
<td>59.07 ± 10.94</td>
<td>59.19 ± 10.83*</td>
<td>59.41 ± 10.60***</td>
</tr>
<tr>
<td>Serum Hemoglobin (g/dl)</td>
<td>9.23 ± 1.88</td>
<td>9.46 ± 1.96</td>
<td>9.96 ± 1.64***</td>
<td>10.16 ± 1.82***</td>
</tr>
<tr>
<td>Serum Potassium (mg/dl)</td>
<td>5.22 ± 0.79</td>
<td>5.08 ± 1.07</td>
<td>5.12 ± 0.79</td>
<td>5.10 ± 0.46</td>
</tr>
<tr>
<td>Serum Phosphorus (mg/dl)</td>
<td>6.65 ± 1.86</td>
<td>6.65 ± 1.64</td>
<td>6.39 ± 1.76</td>
<td>6.66 ± 1.25</td>
</tr>
</tbody>
</table>

All values are mean ± SD; *p < 0.05; ***p < 0.0001; comparisons are versus baseline.

Fig. 1 : Serum albumin and haemoglobin values over time

Results

A total of 77 eligible patients were enrolled for the study. During the three months of the study, two patients expired, both at the time of the second follow-up visit (at month 2). The baseline demographic data is summarised in Table 1.

a. Efficacy parameters: Mean serum
albumin values recorded over the period of 3 months showed a statistically significant increase (Table 2, Figure 1). There was a gradual improvement in the mean body weight and haemoglobin of the patients, which was statistically significant in the second and third months (Table 2).

b. Safety parameters: There were no statistically significant changes in the serum values of potassium and phosphorus over the duration of the study, as depicted in Table 2.

c. Nourishment: As interpreted by the SGA scores, there was a gradual increase in the proportion of well-nourished patients, and a corresponding reduction in the proportion of malnourished patients. None of the patients were severely malnourished; two patients expired during the study period (Figure 2). Similar findings were obtained when nourishment status was calculated using MIS scores.

**Discussion**

Patients undergoing dialysis frequently suffer from both malnutrition (characterised by insufficient protein intake) and cachexia (characterised by defective food assimilation or utilisation in the presence of hypercatabolism and systemic inflammation) from the very early stages of the initiation of dialysis. Various factors contribute to the development of these altered nutritional states in dialysis patients: uraemia causing loss of appetite; dialysis treatment leading to loss of amino acids and proteins; premature ageing of dialysis patients; and presence of co-morbid factors that would have led to the causation of CKD. Various other factors also frequently operate together: emotional distress, impaired ability to procure, unpalatable prescribed diets, the catabolic response, loss of blood due to gastrointestinal bleeding, frequent blood sampling, blood sequestered in haemodialyser and tubing, and endocrine disorders of uraemia. Such an altered nutritional status has been shown to increase mortality and morbidity in these patients.

It is therefore imperative that patients on MHD receive adequate nutrition. Studies show that active nutritional support improve outcomes and reduce cost of treatment in severely malnourished patients.

Nutritional supplements are often prescribed to dialysis patients in order to maintain or improve the nutritional status. A wide variety of products are currently available with high biological value proteins. The recommended daily energy intake (DEI) for patients undergoing haemodialysis and peritoneal dialysis is 30 – 35 kcal / kg per day. The suggested mean dietary protein intake (DPI) is 1.2 g / kg per day in patients on haemodialysis, and 1.3 g / kg per day in patients on peritoneal dialysis. Most patients on dialysis, however, have a lower DEI and DPI than the recommended intake.

In the present physician’s experience, there was a statistically significant increase in serum albumin levels in all the patients over a period of 3 months. This is a significant finding since it is known that serum albumin is a valid and clinically useful measure of protein-energy nutritional status in MHD patients. Further, hypoalbuminaemia is a highly predictive marker of mortality risk. Finally, measurement of serum albumin is inexpensive, easy to perform and widely available. There was also a statistically significant increase in body weight and haemoglobin which further point towards an improvement in the nutritional status of the patients.

For evaluating the safety of the nutritional
supplement, we analysed the serum levels of phosphorus and potassium in the patients over the treatment duration. There were no significant changes in these values, suggesting that the nutritional supplement is not associated with any biochemical abnormality. Also, there was no history suggestive of any adverse reaction associated with the nutritional supplement. Two of the 77 patients expired during the study period, however, this death was not associated with intake of the nutritional supplement. Thus, we can conclude that the nutritional supplement is safe.

The SGA is a well-validated tool for screening for malnutrition. SGA is the only screening tool recommended by the american society for parenteral and enteral nutrition (ASPEN). The modified subjective global assessment score, which is a fully quantitative scoring system consisting of 7 components with total score ranging between 7 (normal) and 35 (severely malnourished) has been developed using components of conventional SGA. This modified SGA has other advantages as well: it can be performed in few minutes, is free of cost, and determines definitely the nutritional status of haemodialysis patients. Another study in India reported similar findings: 15 subjects who were on MHD received a multi-nutrient formulation for a period of 3 months. There were statistically significant increments in anthropometric measurements, biochemical parameters including albumin levels, and decrease in MIS at the end of the study (all \( p \leq 0.01 \)).

The major limitation of the present study is that it is not a controlled clinical trial but a documentation of physician’s experience. Also, we had not included the presence of other comorbid conditions and concomitant medications in our study. Based on the results of this study, well-designed clinical trials involving patients not only on MHD but also on peritoneal dialysis are warranted and are expected to throw light on the benefits of oral nutritional supplementation in Indian patients undergoing haemodialysis.

To conclude, we found that predialytic oral supplementation of CKD patients on MHD with NEPRO HP for a duration of 3 months resulted in statistically significant improvements in serum albumin, body weight, haemoglobin, and nourishment status as depicted by SGA and MIS scoring systems, and was not associated with any significant adverse events or biochemical derangements in phosphorus and potassium levels. Controlled clinical trials are warranted to validate the present findings.

**Conflicts of interest**

None declared

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**References**


