A study of impact of cost-effective nutritional supplement in patients on maintenance hemodialysis

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ABSTRACT

Nutritional status in patients on hemodialysis is always of concern as malnutrition predisposes to excess morbidity and mortality. Most of the nutritional supplements available in the market are expensive. We explored the possibility of improving nutrition of the patients on maintenance hemodialysis by supplementation of calories and proteins that can be given in the form of a palatable and economical gruel in this prospectively designed, open labeled study. Patients who were on maintenance hemodialysis (twice a week) for a period of at least 6 months were divided into two groups. The study group was given the gruel supplement and the control group was not given the gruel supplement. Nutritional status was assessed in the study group and controls at 0 and 3 months by the following parameters: percentage body fat, mid arm muscle circumference and serum albumin. Analysis of results revealed that there was a significant decline in the protein intake at the end of the 3rd month in the control group (P = 0.01). Other parameters did not show significant change at the end of the study period in both groups. The nutritional supplement can be assumed to have helped at least in the maintenance of protein intake over this short period and could possibly in the long run contribute to improvement of nutritional parameters.

Key words: Cost-effective nutritional supplement, hemodialysis, nutritional status, parameters comparison

Introduction

Nutritional status in patients on hemodialysis is always of concern as malnutrition predisposes to excess morbidity and mortality. Most of the nutritional supplements available in the market are expensive. Against this background, we explored the possibility of improving nutrition by supplementation of calories and proteins that can be given in the form of a palatable and economical gruel in this prospectively designed, open labeled study. The aim of this study is to analyze the effect of this supplement on the nutritional status of the patients on maintenance hemodialysis patients.

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Materials and Methods

Patients who were on maintenance hemodialysis (twice a week) for a period of at least 6 months and who agreed to take the gruel supplement and were compliant were included as the study group; Patients who were on maintenance hemodialysis (twice a week) for a period of at least 6 months not taking this gruel supplement were considered as controls.

Patients who had nutritional supplementation other than this supplement within the previous 3 months were excluded from the study. Those who could not complete the study period of 3 months (because of non-compliance or death) were not considered for analysis.

The constituents of the nutritional supplement (Sai Protein 10) were cereals (wheat, boiled rice, ragi, jowar and sago), pulses (soya bean, green gram and fried gram), nuts (ground nut) and flavor (elaichi). 20 g of this powder was mixed in 150 ml milk to provide approximately 180 kcal, 20 g of carbohydrate and 10 g of proteins and 7 g of fat. Phosphorus content of 25 g of this powder is 99.6 mg (corresponding phosphorus content of commercial supplements is 110-140 mg). The cost of each feed worked out to be less than 5 rupees. Cost of

equivalent commercially available nutritional supplement is between 35 and 40 rupees. The supplement (20 g of the powder) was taken daily by the study group in addition to their usual food intake.

A total of 18 patients took the gruel for the study period (study group $n = 18$). Eighteen patients who did not take the gruel were the controls; three of them died during this period and therefore, only 15 of them were considered for analysis (control group $n = 15$).

Nutritional status was assessed in the study group and controls at 0 and 3 months by the following parameters: percentage body fat, mid arm muscle circumference and serum albumin.

Skin-fold thickness was assessed using Lange skin-fold calipers post dialysis in the non-access arm. Three measurements were recorded consecutively at four skin fold sites (over triceps, biceps, sub-scapular and supra iliac areas). Average percentage of body fat was computed using a nomogram.

Using a measuring tape, mid arm circumference was measured. Mid arm muscle circumference was calculated using the formula mid arm muscle circumference = mid arm circumference - ($\pi \times$ triceps skin fold thickness).

Diet recall for caloric and protein intake was done by the dietician while the patient was on dialysis. Compliance with the nutritional supplement was ensured with the empty pouch of the gruel powder and the purchase voucher.

Statistical analysis was performed using Graph Pad Prism 5.1 software, (GraphPad software, Inc.). Categorical variables such as sex and number of patients with diabetes mellitus were analyzed using Fisher exact test. The means and standard deviations of the parameters (age, weight, height, caloric intake, protein intake and serum albumin) in control and case groups at entry were calculated and analyzed with unpaired *t*-test; Following the study period, 0 and 3 months results of weight, calorie intake, protein intake, serum albumin, mid arm muscle circumference and percentage body fat were compared using paired *t*-test. All tests of significance were two-sided and differences were considered as statistically significant when the $P < 0.05$.

Results

There were 15 patients in the control group and 18 patients in the study group. As indicated in Tables 1and 2, the profile of patients were similar in both the groups and baseline characters were comparable in both the groups.

As shown in Table 3, at the end of 3 months there was no statistically significant change in weight, caloric intake, serum albumin levels, mid arm muscle circumference and percentage of body fat between the two groups. However there was significant drop in protein intake in the control group at the end of 3 months whereas in the study group the protein intake was maintained.

The profile of patients, baseline parameters in the control and study group and the means of nutritional parameters at different points of study period are shown in Tables 1,2 and 3 respectively.

Discussion

Malnutrition is common in patients on maintenance hemodialysis, affecting 40-70% patients.[1] Uremic toxins lower appetite and contribute to decline in nutrition once the patient is on maintenance hemodialysis (HD).[2] Malnutrition leads to increased morbidity and mortality with increased hospitalization rates, increased susceptibility to infections, wound healing impairment, fatigue and poor rehabilitation.[3] It is known that enteral multinutrient support significantly increases serum albumin and improves total dietary intake which may improve clinical outcome[4] Oral nutritional supplementation given during hemodialysis improves nutritional markers in malnourished chronic hemodialysis patients.[5] Maintenance hemodialysis patients with albumin levels ≤3.5 g/dl who received

Table 1: Profile of patients

Parameters	Control group (%)	Study group (%)	*P*
No. of patients	15	18	
Males	11 (73.3)	10 (55.5)	0.16
Diabetes mellitus	7 (46.6)	9 (50)	0.56
Positive CRP	1 (6.6)	0 (0)	0.44

CRP: C-reactive protein

Table 2: Comparison of baseline parameters in control and study group

Baseline parameters	Control group *n*=15		Study group *n*=18		*P*
	Mean	SD	Mean	SD	
Age (year)	53.16	11.42	49	15.30	0.37
Weight (kg)	56.43	12.02	56.51	8.68	0.98
Height (cm)	159.88	9.99	163.62	8.08	0.25
Duration on HD (months)	17.26	10.79	20.22	14.17	0.51
Caloric intake (kcal/day)	1306.13	391.93	1282	356	0.85
Protein intake (g/day)	41.05	5.87	42.26	4.80	0.52
Serum albumin (g/dl)	3.49	0.32	3.37	0.47	0.39
URR (%)	65.58	6.12	68.42	10.28	0.35

SD: Standard deviation, HD: Hemodialysis, URR: Urea reduction ratio

Table 3: Comparison of means of the nutritional parameters at 0 and 3 months

Nutritional parameters	Control group					Study group				
	At 0 months		At 3 months		*P*	At 0 months		At 3 months		*P*
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Weight (kg)	56.51	8.68	56.17	7.98	0.54	56.43	12.02	55.87	11.81	0.36
Caloric intake (kcal/day)	1282	356	1411	188	0.25	1306	391	1357	198	0.82
Calorie/kg	24.96	3.28	25.08	2.83	0.76	24.65	3.78	25.18	5.34	0.55
Protein intake (g/day)	42.26	4.8	39.78	4.81	0.01	41.05	5.87	41.05	6.09	1
Serum albumin (g/dl)	3.37	0.47	3.41	0.39	0.69	3.49	0.32	3.53	0.35	0.57
Mid-arm muscle circumference (cm)	20.63	3.74	20.23	4.52	0.43	25.01	5.31	24.36	5.62	0.35
Percentage body fat	31.31	3.51	30.86	3.62	0.16	35.36	6.76	35.57	5.86	0.57

SD: Standard deviation

monitored intradialytic oral nutritional supplements showed survival significantly better than similar matched patient controls.[6] Nutritional supplementation designed for hemodialysis, improved their nutritional status in the short term study.[7]

With this background the present study was devised to study the impact of oral nutritional supplement on patients on maintenance hemodialysis. In this study, the nutritional parameters were studied from recall of caloric and protein intake, serum albumin, mid arm muscle circumference and percentage of body fat.

The overall caloric intake and protein intake of patients on hemodialysis was found to be deficient. This has been found in Indian study previously also where malnutrition was found in 58% of patients on HD.[8]

Regarding weight change, caloric intake count, mid arm muscle circumference, percentage of body fat and serum albumin-there were no statistically significant changes noted between the study group and control group. Protein intake over a 3 month period significantly dropped in the control group whereas in the study group the protein intake appeared well-maintained over a 3 month period. This pattern of decreasing quality in protein intake in HD patients has been observed in previous Indian study also.[9] If taken over a sufficiently longer period it is possible that the nutritional parameters might show improvement in the group taking additional oral supplements. In our group, the intake of the supplement was verified with the purchase vouchers. The drop in protein intake observed was due to overall poor food intake in both groups but in the group with supplementation protein intake was maintained due to the supplement. We also would like to consider the following pitfalls in this study: It is possible that compliance with the supplement could have been less than 100% though we tried to ensure compliance by checking the empty gruel pouch and the purchase voucher; the study period might have been too short to observe the effects of the supplement; exclusion of patients on thrice a week HD (for want of sufficient number) could also have contributed to the predominantly negative study result. The inflammatory status of patients also needs to be analyzed in detail in the forthcoming studies to project the effect of nutritional supplements. Probably more quantities of the gruel are required daily to effect an impact.

Conclusions

Cost-effective oral nutritional supplement maintained the protein intake of hemodialysis patients over a 3 month period. Anthropometric measurements and serum albumin did not show significant improvement over this period. Long-term supplementation is probably required to make a definitive impact.

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