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Impact Of Nutritional Supplements On Albumin Levels Of Dialysis Patients: Nutrition Supplement Grant Program National Kidney Foundation Of South Carolina

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Introduction

Based on the 2003 Annual Data Report (1), there are over 325,000 patients with end stage renal disease (ESRD) on dialysis in the United States (1). Mortality in ESRD patients remains high despite advancements in all aspects of medicine. Cardiovascular diseases cause the bulk of morbidity and mortality in dialysis patients (2,3). There is an increase in mortality and morbidity for ESRD patients who have an albumin below 4 mg/dl (4). Kalantar-Zadeh et al studied longitudinally a 2-year cohort of 58,058 maintenance hemodialysis (HD) patients and found that hypoalbuminemia predicts all-cause and cardiovascular death (5). He also found that increased serum albumin is associated with better survival over time, independent of baseline serum albumin or other strong predictors of cardiovascular surrogates (5). Other studies have confirmed the relationship between malnutrition and mortality in dialysis patients (6-8).

Many dialysis patients have co-morbid conditions that can impact their albumin through different mechanisms (9-14). Hakim and Levin divide the factors that affect nutritional status into different categories:

- Dialysis factors
- Biochemical factors
- Gastrointestinal factors
- Miscellaneous factors:
  - depression
  - multiple medications
  - recurrent hospitalizations
  - underlying illness
- low socioeconomic status (10).

Peritoneal dialysis (PD) may cause anorexia through different mechanisms as part of the effects of this modality. The presence of the dialysate fluid in the abdominal cavity can cause abdominal discomfort which may interfere with gastric emptying and intestinal motility. The absorption of the glucose can inhibit feelings of hunger. Peritonitis as a result of the infection and inflammation can cause anorexia (11).

Bossola et al showed that advancing age was significantly associated with lower energy and protein intakes in HD patients. They also noted that there is a well established decline in food intake with increasing age in populations of healthy persons (9).

The addition of nutritional supplements to patients' current intake could help improve their nutritional status. Previous studies have been conducted to determine the effectiveness of oral supplementation in the treatment of malnutrition (5, 15-21). In a meta-analysis of 18 trials evaluat-

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ing feeding in dialysis patients, Stratton et al reported that enteral nutritional support increased total protein intake, and serum albumin concentration improved by 0.23 g/dl (21). Steiber et al concluded that intervention with nutritional supplements of the patients' choice decreased the risk of hospitalization (20). Sharma et al showed a significant increase in albumin level in the short term with intervention of nutritional supplements (18).

Many dialysis patients are unable to afford nutritional supplements to help increase their oral intake when various factors and conditions limit their consumption of foods. Samples of supplements have become difficult to obtain and are not sufficient to make an impact on one patient, let alone several patients.

In South Carolina, dialysis clinics are responsible for the distribution of prescribed nutritional supplements for ESRD patients as part of the participation of care in the Medicaid program. Clinics are reimbursed at a set fee for the supplements. The National Kidney Foundation of South Carolina (NKF of SC) Nutrition Supplement Grant Program was designed for patients who did not have Medicaid, but had an income to expense ratio that did not allow for the flexibility to purchase supplements. This nutritional supplement grant program from the NKF of SC was designed to provide a 90 day supply of specific liquid nutritional supplements or a powdered protein supplement at no cost to the patient.

Methods

Program description

The NKF of SC provided funds from the Patient Services budget to purchase supplements and have them delivered to the approved patient's clinic. The patient signed a form giving permission for NKF of SC to access specific medical and financial information to be used for screening purposes and follow-up data collection. In addition, dialysis companies had patients sign release of information forms, giving permission to release information to the NKF of SC.

The application form had two parts. One was completed by the social worker to obtain information about household income, monthly expenses, and number of persons in the household. The second part of the form was to be completed by the dietitian and requested information as to why the patient needed the supplements, co-morbid conditions, relevant laboratory data supporting the request, body weights for the past 3 months, usual body weight, age, modality of dialysis (either HD or PD), albumin levels for the past 3 months, and recent hospitalizations or infections.

Dietitians were also asked to complete and send in a tracking form to the NKF of SC at the end of Phase B (3 months of supplementation) and Phase C (3 months following cessation of supplementation). This tracking form included information about monthly dry weights, phosphorus levels, albumin levels, and whether the patient had an infection or was hospitalized. Even though phosphorus levels and dry weights were tracked, the data analysis has not been completed for these factors. A sub group analysis is underway to evaluate the impact of supplementation on dry weight.

For clarification, the total observational period of the study was 9 months. Three months of data (Phase A) was requested on the initial application and 6 months of data was obtained and recorded on the tracking forms. The 6 month time frame was divided into two different phases: the 3 month supplementation period (Phase B) and the 3 month observational period (Phase C) following the cessation of supplements.

Due to the large response of patient applications and the limited funds available for this program, patients approved were those who had albumins <3.5 for at least 2 of the 3 months, or who had lost >5% in body weight in one month or >10 % in 6 months. A committee comprising the patient services coordinator and 1-2 dietitians reviewed the supplement requests and determined which requests met the criteria for approval.

Inclusion Criteria

Patients qualified who did not have insurance coverage for nutritional supplements. Their annual incomes were < $24,000, albumin levels <3.5 mg/dl for two consecutive months and/or experienced significant weight loss (>5% in one month, >7.5% in three months or >10 % in six months). Patients were not excluded for age or any co-morbid medical conditions.

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Impact of Nutritional... *continued from page 4*

Study Design

Three months prior to applying for supplements, dietitians observed patient body weights and albumins (stage A). Patients received a 3 month supply of the liquid supplements allowing 2 cans daily or powdered protein equivalent to 6 scoops daily. The 3 month supply was sent directly to the home of each patient participating in the study. Adherence was assessed by dietitians at least monthly. Body weights and albumin levels were tracked during the three month supplementation phase (stage B). For an additional three months, body weights and albumins were tracked after nutritional supplements were discontinued (stage C).

Supplements used

The supplements were chosen based on the product cost and funds available.

Oral Nutrition Supplements:
Boost®, Boost Plus®, Boost HP®, Boost® Diabetic (Novartis Nutrition)
Powdered Protein Supplement:
Procel ® (Global Health Products, Inc.)

Results

One hundred and thirty dialysis patients in South Carolina qualified and received supplements in 36 dialysis clinics. There were 65 males and 65 females. Mean age was 62.3 years. There were 99 HD and 31 PD patients. Eighty seven dialysis patients qualified using criteria of low albumin, 14 patients for criteria of weight loss, and 29 for criteria of low albumin and weight loss.

Etiologies and factors contributing to malnutrition in dialysis patients were studied. Table 1 illustrates the breakdown of the contributing factors to malnutrition in the patients participating in the study. Hypertension (85%) and diabetes mellitus (61%) and diabetic complications were the most common factors associated with malnutrition. Table 2 stratifies patients based on their number of risk factors (RF) for malnutrition, with most patients having two to four risk factors. There was a significant difference in the number of risk factors associated patients over 70 years old (4.3 RF) compared to those patients less than 70 years old with 4.3 RF and 2.8 RF, respectively (p value < 0.001).

Table 1

Risk factors contributing to malnutrition for 130 study participants (expressed as # of pts & % of pts)

Hypertension	110	84.6%
Diabetes	79	60.8%
Gastrointestinal Conditions	43	33.0%
Age >=70	41	31.5%
Infections	31	23.8%
Leg Amputation	15	11.5%
Stroke	14	10.8%
Cancer	13	10.0%
Psychiatric Disorder	6	4.6%
Dementia	6	4.6%
Alcohol and Substance Abuse	5	3.8%
Neurological Disorders	4	3.0%
Severe Lung Diseases	3	2.0%
Sickle Cell Disease	2	1.5%

Table 2

Number of risk factors (RF) for malnutrition

Risk Factors (RF) from Table 1 for the 130 study participants broken down with number of RF per person

# of RF	0	1	2	3	4	>=5
# pts and % pts	3 2.0%	17 13.0%	23 17.7%	37 28.5%	33 25.4%	17 13.0%

Table 3

Comparison of albumin levels during the 3 study phases

Observation for Albumin n=130 patients

	Mean Albumin
Stage A *Months 1,2,3*	2.9 + .4 mg/dl
Stage B *Months 4,6,5*	3.45 + .42 mg/dl
Stage C *Months 7,8,9*	3.49 + .4 mg/dl
P value A vs. B or C	<.004

There was a statistically significant increase in albumin level starting in the first month of supplement use that persisted throughout the three months the supplement was given. In-

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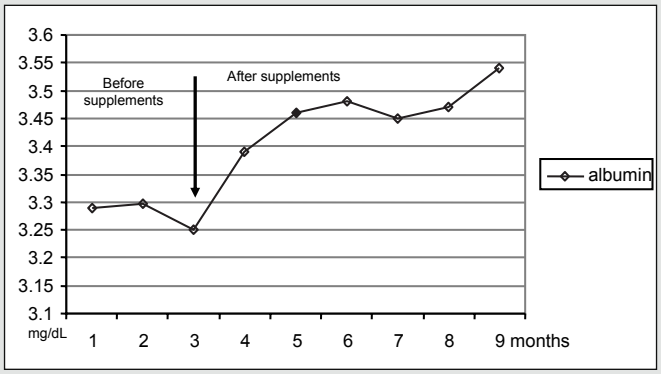
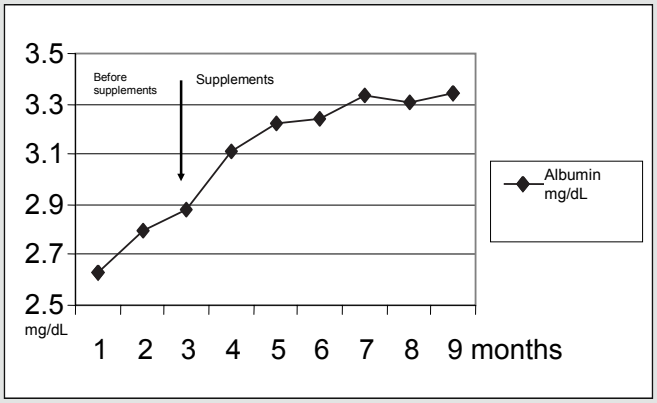
Graph 1

Mean Albumin levels for all patients



Graph 2

Mean Albumin levels for patients with initial albumin below 3.0 mg/dl



terestingly, improvement of albumin levels persisted even after the supplement was stopped during the three month observation period. The improvement continued to be statistically significant. Table 3 summarizes this data and graph (1) illustrates the improvement in albumin levels.

Patients with albumin levels less than 3.0 mg/dl received the most benefit from the supplement with albumin levels improving over 0.5 mg/dl on average (2.67 mg/dl to 3.3

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mg/dl). Although this sample size was small (n=19), the improvement was statistically significant (p value < 0.0005). Graph (2) illustrates the improvement in albumin levels in this group.

Discussion

Malnutrition is a common problem in dialysis patients and has many contributing factors. Malnutrition is correlated with increased morbidity and mortality. Many interventions have been used to treat or improve this condition with varying success (9). Intradialytic parenteral nutrition showed variable results (22-24). Approval for IDPN requires extensive documentation, may take several weeks for approval, and is expensive. Oral supplements are a more affordable option that have shown promising results in many studies (15-17). Our study illustrates a successful intervention in trying to address this common problem.

Dialysis patients are characterized by having multiple medical problems. Factors that contribute to decreased albumin and weight loss in dialysis patients are numerous and include recurrent infections, depressed immune function, loss of protein during dialysis (especially PD), frequent hospitalizations, and gastroparesis. Other factors include inability to consume enough protein and calories, living alone, dental problems, poor appetite, dementia or depression, decreased activities of daily living and poor dietary choices.

Our study differed from many previous studies in that we did not exclude any patient based on their health situation or co-morbidities. We found several studies in the literature that excluded patients with recent surgeries or sepsis, hospitalizations longer than one week, unintentional weight loss greater than 10% over 6 months, HIV, and active malignancy (16). There are valid reasons for these exclusions which are primarily to limit the number of confounding factors.

Supplements were provided without cost to the patients in our study. The improvement in serum albumin levels that resulted from nutritional supplement intervention in other studies was proven to be associated with a decreased morbidity and mortality (25, 26). We feel there may be a significant savings in the management of CKD Stage 5 by providing such a program on a large scale through decreased hospitalizations, decreased medication usage, and ultimately by improving the incidence of mortality.

Patients with the lowest albumin had the greatest improvement in albumin level. Although there were only 19 patients in this group, the great improvement in albumin was statistically significant, confirming the need to target these patients.

Intensive nutritional counseling impacts general nutritional status and albumin levels. In a study that combined nutritional counseling with supplementation, Wilson et. al. showed that nutritional counseling alone could not sustain the short-term improvement in albumin that was initially obtained (16). Apkele and Bailey suggested that for patients with protein-calorie malnutrition, intensive dietary counseling was of greater benefit than the use of nutritional supplements alone (27). It is difficult to isolate the positive effects of the counseling while providing the supplements. The dietitians in our study kept track of the patient's usage and tolerance of the supplements and as a result may have spent more counseling time with the patients. Additionally, the fact that patients were aware that they were participating in the study may have increased their adherence.

Our study showed that malnutrition in dialysis patients is multifactorial. Two or more contributing factors were found in most patients. Most of these factors are non-modifiable. Programs to provide nutritional and social support to this population should be encouraged.

Although our study did not look at morbidity and mortality outcomes, the study demonstrated a clinically and statistically significant improvement in serum albumin levels which is strongly linked and related to improved morbidity and mortality. Based on our study, providing 3 months of nutritional supplementation improved albumin levels. This improvement was sustained for the additional three month observational period.

Monitoring results was important for validating the effectiveness of the program. Initially, $10,000 was requested from the NKF of SC as a one-time request for the nutrition supplement grant program. Reports were provided quarterly to the board of directors on the positive impact the program was making in the quality of life for the patients as well as

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improved conditions substantiated by data from the tracking forms. The following year, this program became a part of the regular budget under Patient Services with an allotment of $18,000. The next year, the amount was increased to $20,000, and the last 2 years, $30,000 has been budgeted for the program. Monitoring data, ongoing tracking of the patients utilizing the program and regular communication to the board, helped validate the need for this program. It has been recognized as a valuable service for the patients and helped to justify the need for increased funding in subsequent years.

The NKF of SC Nutrition Supplement Grant Program has characteristics that can be easily adapted by others. The overhead costs were low since existing personnel and clinical data were used. The lab data and information on the tracking forms were part of the patient's medical records and no extra lab work was required. The levels of albumin, body weights, and hospitalizations were variables that were easy to measure. Grant programs that provide nutrition supplements to patients who have limited resources to purchase them could have a major impact in improving the overall treatment and outcomes of CKD Stage 5 patients throughout the country.

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FNCE 2006 Honolulu Meeting
DPG SHOWCASE

RPG Board Members gather in front of the Booth. (Left to Right) Pat Weber, Marianne Hutton, Connie Cranford, Cathy M. Goeddeke-Merickel and Leslie Wujastyk

More RPG Board Members (Left to Right) Pam Kent, Pattie Barba, Cathi Martin