

## Oral Nutrition Supplements and Outcomes in Patients on Maintenance Dialysis

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Epidemiological studies show that protein-energy malnutrition is a strong predictor of morbidity and mortality in patients with chronic kidney disease (CKD) undergoing maintenance dialysis therapy (1-3). Low serum albumin and body mass index have been identified as key contributors to increased mortality, and many patients starting dialysis have energy and protein intake below the National Kidney Foundation's Kidney Dialysis Outcome Quality Improvement guidelines (2,4).

Projections based on data from more than 77,000 maintenance hemodialysis (HD) patients suggest that nutritional interventions that increase serum albumin by  $\geq 0.2$  g/dL may lead to improved outcomes, including reduction in death rate, hospitalizations and related costs (5). Nutrition counseling, often the first step in treating malnutrition, has been used in conjunction with oral nutrition supplements in attempt to improve nutritional intake and functional outcomes (6,7). However, research published in the late 1990's found little evidence that nutrition supplements definitively improve nutritional status in patients undergoing maintenance dialysis therapy (8,9). Furthermore, few of the studies reviewed explored the impact of nutrition supplements on morbidity and mortality rates in this population.

Since reimbursement for nutrition supplementation is difficult to secure and requires that stringent criteria are met, efficacy and cost effectiveness of oral nutrition supplements deserves greater attention (10). This article will summarize findings from studies conducted since 2000 and directed to determine the effect of oral

nutrition supplements on patient outcomes.

A number of studies investigating benefits of oral nutrition supplements in patients with CKD undergoing maintenance dialysis have shown positive effects on biochemical and nutritional measures. A systematic review of 18 studies suggested that both standard and renal disease specific oral supplements increase total energy and protein intake, and serum albumin levels (11).

Research has also been conducted to investigate the impact on nutritional measures of oral supplements in combination with, or in place of, nutrition counseling. One small study compared the standard practice of providing nutrition counseling alone with therapy combining both nutrition counseling and oral supplementation, when serum albumin begins to drop ( $3.5\text{--}3.7$  g/dL) in maintenance HD patients (10). Fourteen patients in a control group were counseled to liberalize calorie and protein intake. Eighteen patients in an experimental group received nutrition counseling and one or two cans of NuBasics supplement (Nestle Clinical Nutrition, Deerfield, IL) free of charge to increase protein intake to  $1.2$  g/kg daily. During a six month treatment phase, nutritional repletion (defined as serum albumin  $\geq 3.8$  g/dL for 2 consecutive months) occurred more quickly ( $3.2 \pm 1.7$  months) and in a larger number of patients in the experimental group than in the control group ( $3.5 \pm 1.2$  months). During a three month follow-up, patients in the experimental group were more likely to maintain or improve their nutritional status than those in the control group. Findings from this study indicate that early intervention with oral nutrition supplements may allow more rapid and sustained nutritional repletion.

Another study compared rates of change in serum albumin level in 41 malnourished HD patients randomly assigned to receive either intensive dietary counseling or oral nutrition supplementation for 14 months (12). Patients in the supplementation group received 1 or 2 cans of Nepro daily (Abbott Nutrition, Abbott Park, IL) while those in the nonsupplement group received dietary counseling designed to promote daily intake of  $30\text{--}35$  kcal/kg and  $1.2$  g protein/kg ideal body weight. Patients in both groups had serum albumin  $\leq 3.5$  g/dL prior to the study. Rate of change in serum albumin was significantly greater in patients who received dietary counseling than in those receiving oral supplements, suggesting that in patients who are already malnourished, intensive dietary counseling may be of greater benefit than nutritional supplements.

Research in the non-CKD population has demonstrated variable adherence to oral nutrition supplements and several more recent studies have investigated the effects on patient outcomes of providing nutrition supplements during dialysis treatments (13-17). One such study assigned hemodialysis patients to a supplement

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or comparison group based on patient preference (13). Forty-four patients in the supplement group (mean baseline serum albumin  $3.68 \pm 0.33$  g/dL) received 8 ounces Nepro before or immediately after each hemodialysis treatment in addition to standard nutrition care. Forty-four patients in the comparison group (mean baseline serum albumin  $3.93 \pm 0.34$  g/dL) received standard care without oral nutrition supplementation. Changes in quality of life were also monitored using the Kidney Disease Quality of Life – Short Form. Nepro was well accepted by patients in the supplement group and successfully maintained serum albumin concentration and role physical domain scores in the quality of life survey. In contrast, patients in the comparison group experienced a significant drop in serum albumin to  $3.81 \pm 0.37$  g/dL and in role physical domain scores during the course of the study.

In a smaller randomized study, 26 patients received a high-calorie, high-protein milkshake (500 kcal and 15 g protein) administered under supervision post-HD for one month in addition to standard nutrition counseling (14). Ten patients in a control group received nutrition counseling only. While both groups showed significant improvements in dry weight and body mass index, the supplement group also showed a significant increase in serum albumin and functional status, as measured by the Karnofsky score. Intradialytic oral supplementation has also been associated with persistent anabolic effects for muscle protein metabolism and increase in subjective global assessment scores in maintenance HD patients (15,16).

There is little published research addressing the impact of nutrition supplements on morbidity and mortality in this population. However, a recent study evaluated the impact on hospitalizations of oral protein supplements administered during HD and peritoneal dialysis (17). Patients were randomly assigned to treatment or control groups and all patients received counseling from dietitians throughout the study to maintain dietary protein intake at goal levels. HD patients in the treatment group received 15 g Proteinex protein supplement (Llorens Pharmaceutical Corporation, Miami, FL) three times a week after dialysis. Peritoneal dialysis patients in the treatment group received 15 g protein supplement daily. The control group did not receive protein supplementation. At the end of an initial 6-month period, patients crossed over to the opposite group for 6 months. For patients receiving protein supplementation during the first 6 months, normalized protein catabolic rate (nPCR) increased significantly by month 4 of treatment; serum albumin also increased, but not significantly. For patients receiving protein supplements during the second 6 months, nPCR and serum albumin trended upward but did not increase significantly. Serum albumin and nPCR both declined when protein supplementation

was discontinued. Trends towards a decrease in both hospital admissions and length of stay were seen in both crossover treatment groups. During the first 6 months, 50% of the control group was hospitalized, versus 42% of patients receiving protein supplements. During the second 6 months, 45% of the control group versus 39% of the protein group was hospitalized.

In summary, nutrition supplements increase energy and protein intake, and maintain or improve nutritional status (10,11,13-16). According to one study, outcomes appear to be better when nutrition supplementation is initiated prior to onset of malnutrition (10). There is limited evidence that nutrition supplements reduce hospitalization in this population and larger studies are needed to confirm trends observed (17). The success of nutrition supplementation is strongly dependent on patient compliance and outcomes are improved when supplements are administered under supervision during or immediately after dialysis (13-17). Patient preferences regarding taste, texture, flavor ranges, phosphate binder requirements and fluid contribution of nutrition supplements have also been investigated (18,19). Findings from these studies indicate good acceptance rates for renal-specific liquid supplements and selected high-protein supplement bars.

The impact of nutrition supplementation on nutrition outcomes in patients undergoing maintenance dialysis therapy remains an important topic for additional research. Results from existing research need to be confirmed and extended through larger studies so that standards can be developed for effective use of nutrition supplements in this patient population. ♦

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