

# Pro-Stat®64 supplementation in ESRD (End Stage Renal Disease) in Patient's Receiving Hemodialysis: An Observational Program.

## ABSTRACT

### OBJECTIVE:

To increase serum albumin levels in hemodialysis patients by increasing protein intake through Pro-Stat®64, while receiving dialysis three times per week.

### MATERIALS AND METHODS:

This observational program was designed to evaluate the efficacy of a concentrated protein supplement, fortified with all Essential and Non-essential Amino Acids, Modified Amino Acids, low phosphorus (P--), low sodium (NA+), low potassium (K+), and low in fluid, (Pro-Stat®64™ Medical Nutrition USA Inc, Englewood, NJ) in the treatment of hypoalbuminemia in hemodialysis patients.

Subjects were male and female residents of a national dialysis outpatient dialysis facility in Indianapolis, Indiana. The current standard of care for treating hypoalbuminemia consists of encouraging patients to increase protein intake through foods and/or protein supplements. This observational program measured the effect on albumin with the supplementation of Pro-Stat®64 while on dialysis.

### RESULTS:

Patients who received Pro-Stat®64 (15g in 30mL) after a minimum of 15 treatments, (approximately 1 month) were seen to have improved albumin levels.

### CONCLUSION:

Patients given Pro-Stat®64 (15g in 30mL) while on treatment 3 times per week had an overall improvement in albumin levels compared to when patients did not receive Pro-Stat®64.

## INTRODUCTION

- The National Kidney Foundation reports serum albumin as a valid and clinically useful measure of protein-energy nutrition status in maintenance dialysis patients<sup>1</sup>. Malnutrition is widespread in the end-stage renal disease (ESRD) population. Further, hypoalbuminemia is a high predictive factor of the mortality and morbidity risk in the dialysis population. Nutritional interventions and an increase of serum albumin concentrations may be associated with improved long-term survival<sup>2</sup>. Serum albumin levels may fall with a decrease in dietary protein and/or may rise with an increase in protein intake. On the contrary, serum albumin levels may fall acutely with inflammation, stress, or from recovery<sup>2</sup>.
- According to the United States Renal Data System (USRDS) 2003 estimated economic Medicare costs for Maintenance Hemodialysis (MHD) patients was approximately \$18 billion<sup>3</sup>. Further, Employer Group Health Plans (EGHP) in 2003 spent \$338 million on ESRD patients<sup>3</sup>.
- Nutrition interventions include, but are not limited to, protein supplements to assist with increasing dietary protein needs<sup>2</sup>.
- Nephrology Internal Medicine Physicians group established a non-profit fund which provided Pro-Stat®64 to the patients at no extra cost.
- This observational program shows the efficacy of a concentrated protein supplement in hemodialysis patients given three times per week while on dialysis.

## MATERIALS AND METHODS

### REVIEW DESIGN:

- Randomized, observational review trial at a 38 chair patient facility in Indianapolis, Indiana.
- Key indicators in which patients could qualify to receive Pro-Stat®64 while receiving dialysis included a serum albumin of  $\leq 3.2$  on a scale of 3.8-4.5 g/dL, or an **actual** enPCR of less than 0.8 grams; unintentional weight loss of less than 10% of the patients ideal body weight (IBW); a stage II or greater wound; and/or high risk patients who have been evaluated by the Physicians, Nurse Practitioners, and/or the Registered Dietitians. Those excluded from this program included Medicaid patients, (due to their ability to have Medicaid cover the cost of nutrition supplements) those with special diet needs, and/or those with gastrointestinal disorders.

### SUBJECTS:

- 15 patients over a period of 7 months qualified for the Pro-Stat®64 program. The program included both male and female, nursing home patients, and/or patients living independently.

### INTERVENTION:

- Patients who met the qualifications for the Pro-Stat®64 program received an order in their charts to begin Pro-Stat®64 at the start of the following month. The patients would receive Pro-Stat®64, along with their medicines by the Registered Nurse (RN), while on hemodialysis. Further, the RN would indicate if patients accepted or refused the protein supplement. Monthly evaluations of Serum Albumin, enPCR, infection and/or wound healing status, as well as weight, would determine if patients would remain on the program. However, for simple outcome measures, serum albumin was the primary assessment tool used in this program.

### REFERENCES

- <sup>1</sup>National Kidney Foundation: Kidney Disease Outcomes Quality Initiative (KDOQI) Adult Guidelines. *Evaluation of Protein-Energy Nutritional Status*. 2000: Guideline 3; 1-3
- <sup>2</sup>National Kidney Foundation: Kidney Disease Outcomes Quality Initiative (KDOQI) Adult Guidelines. *Management of Protein and Energy Intake*. 2000 Guideline 3; 1-3
- <sup>3</sup>USRDS 2005 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2005. *Costs of CKD and ESRD*. 2005: 200-201

### Materials and Methods - Continued

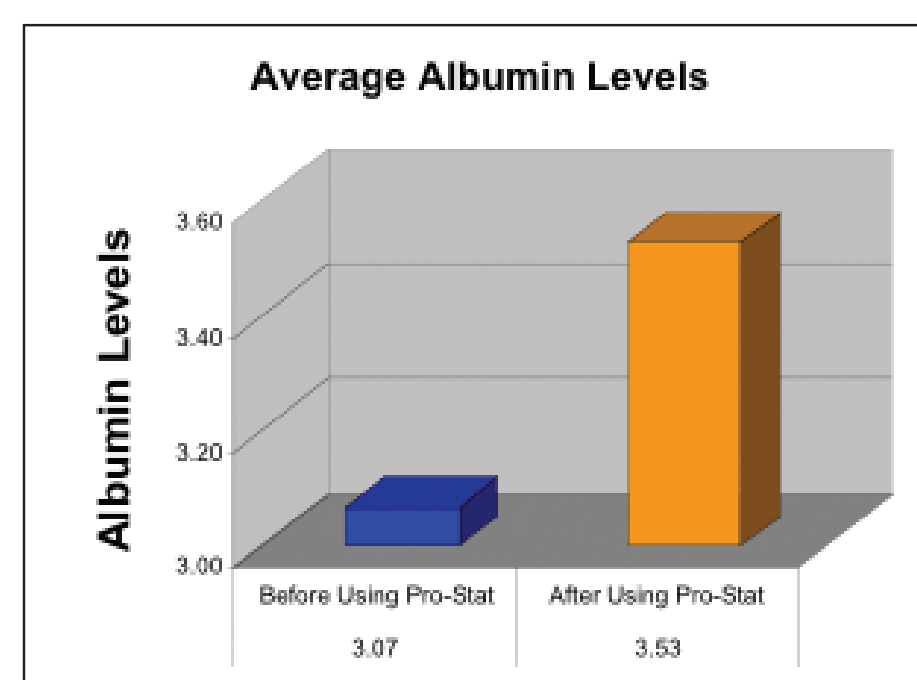
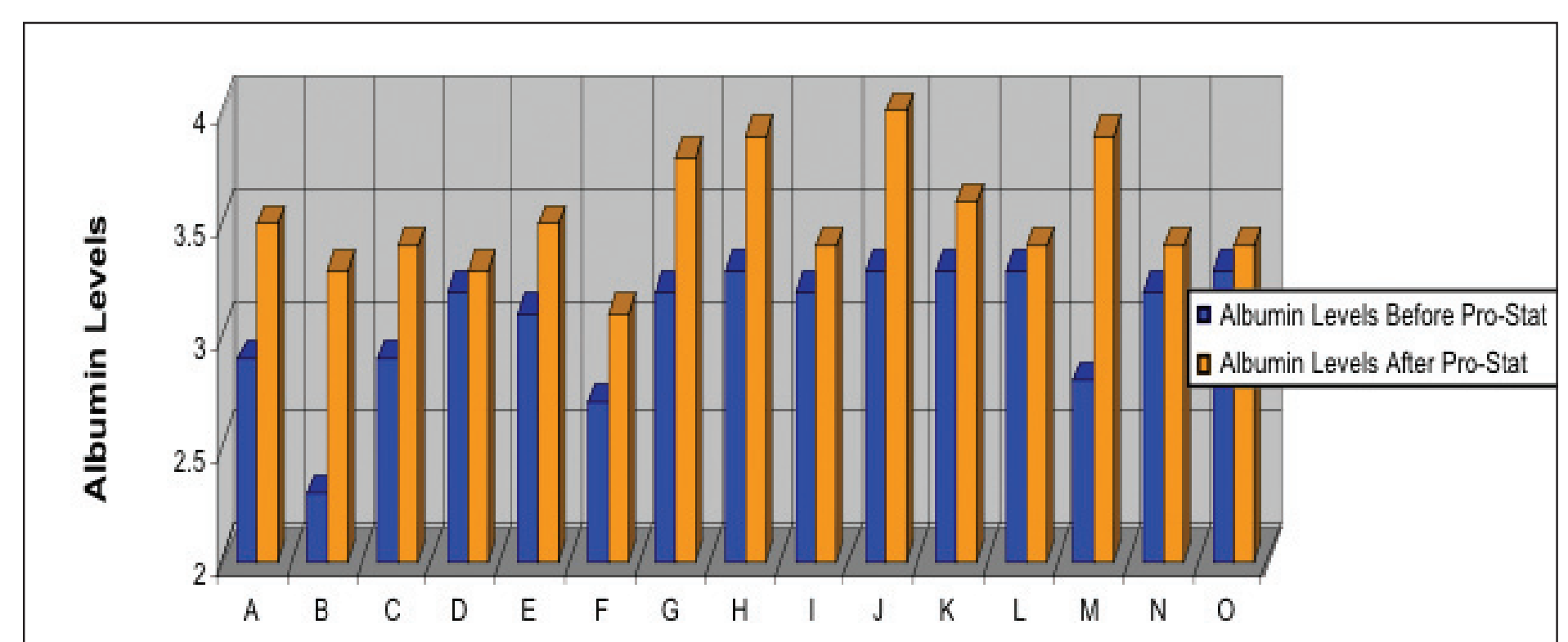
### PRIMARY OUTCOME MEASURE:

- Change in serum albumin occurred in almost all of the patients who were on the Pro-Stat®64 Program.

### ANALYSIS:

- Serum albumin levels were taken prior to initiating Pro-Stat®64 and monthly while on Pro-Stat®64 after program had been discontinued were used to evaluate the +/- change in serum albumin levels. However, other variables taken into account were hospitalizations, infections, length of protein supplement treatment, and/or compliance issues.
- On table 1, the blue areas indicate lab results reviewed for approval in order for patients to be placed on the Pro-Stat®64 program, (at this particular unit, the complete set of labs were drawn and resulted at the end of the month. Therefore, this data shown is one month behind putting patients on the program).
- On table 1, the orange areas indicate the final lab results prior to Pro-Stat®64 discontinuation.

Table 1. Pro-Stat®64 Supplementation in ESRD



Patient ID	Pre-Pro-Stat	After Pro-Stat
A	2.9	3.5
B	2.3	3.3
C	2.9	3.4
D	3.2	3.3
E	3.1	3.5
F	2.7	3.1
G	3.2	3.8
H	3.3	3.9
I	3.2	3.4
J	3.3	4
K	3.3	3.6
L	3.3	3.4
M	2.8	3.9
N	3.2	3.4
O	3.3	3.4
Mean	3.07	3.53

## RESULTS

- Between March of 2005 and September 2005, the dialysis clinic developed a protein supplement program, using Pro-Stat®64 to decrease the risk of malnutrition in hemodialysis patients.
- Patient M showed the most significant change of +1.1 overall and was able to maintain an albumin of greater than 3.5 g/dL three months after the Pro-Stat®64 program discontinued.
- On average, patients taking Pro-Stat®64 3 times per week while on dialysis achieved improved serum albumin levels of 0.5.

## DISCUSSIONS AND CONCLUSIONS

- This is an observational review and which was developed to assist patients with an increased need for protein while receiving maintenance hemodialysis.
- Pro-Stat®64 was chosen because it is a concentrated protein supplement, fortified with all Essential and Non-essential Amino Acids, Modified Amino Acids, low phosphorus (P--), low sodium (NA+), low potassium (K+), and low in fluid, (Pro-Stat®64™ Medical Nutrition USA Inc, Englewood, NJ).
- The patients who received Pro-Stat®64 three times a week while at dialysis showed overall improvements in serum albumin levels.
- This observational review shows that even an additional 15 grams of Pro-Stat®64, three times a week, for a total of 45 grams of extra protein per week, can improve serum albumin levels in maintenance hemodialysis patients.
- There is a significant responsibility for patients on maintenance hemodialysis to increase protein intake to assist in the fight against infection, and/or wound healing issues. However, many obstructions exist that can prevent patients from getting in enough protein through food. Offering Pro-Stat®64, three times per week while patients receive dialysis can aid in keeping those protective barriers in place, as well as ensure the dietitian and healthcare team that patients are taking the supplement as prescribed.
- Overall, keeping hemodialysis patients well-nourished can assist in lowering morbidity and/or mortality outcomes in ESRD.