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### Randomized double-blind trial of oral essential amino acids for dialysis-associated hypoalbuminemia

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*Background.* Hypoalbuminemia is associated with substantial morbidity and mortality in dialysis patients.

*Methods.* Subjects with a mean three-month prestudy serum albumin of 3.8 g/dL or less and who demonstrated  $\geq 90\%$  compliance during a two-week run-in period were randomized to 3.6 g of essential amino acids (EAAs) or placebo three times daily with meals for three months. Randomization was stratified by dialysis modality and by severity of the hypoalbuminemia. The primary study outcome was change in the average of three monthly serum albumin measurements between baseline and follow-up.

*Results.* Fifty-two patients were randomized; 47 patients (29 hemodialysis and 18 peritoneal dialysis) met the predetermined primary analysis criteria. The mean compliance rates averaged 75, 70, and 50% at months 1, 2, and 3, respectively, and were similar for EAAs and placebo. Serum albumin in the hemodialysis patients, EAA versus placebo, improved [(mean  $\pm$  SE)  $0.22 \pm 0.22 \pm 0.09$  g/dL,  $P=0.02$ ]. Changes in peritoneal dialysis patients were not significant ( $0.01 \pm 0.15$  g/dL), but approached significance for the total study group ( $0.14 \pm 0.08$  g/dL,  $P=0.08$ ). Patients in the very low albumin strata ( $<3.5$  g/dL) improved more than those in the low albumin strata (3.5 to 3.8 g/dL,  $P<0.01$ ). There was a significant correlation ( $r=0.83$ ,  $P=0.001$ ) within the hemodialysis EAA group between the baseline C-reactive protein level and improvement in serum albumin. Improvements were also seen in grip strength and SF-12 mental health score, but not in serum amino acid levels, SF-12 physical health score, or anthropometric measurements.

*Conclusions.* Oral EAAs induce a significant improvement in the serum albumin concentration in hemodialysis but not peritoneal dialysis subjects. Further study of their long-term effects on morbidity and mortality is warranted.