

## The Benefits of Nutritional Supplementation in Hospitalized Older Adults

Gariballa S, Forster S, Walters S, Powers H. A randomized, double-blind, placebo-controlled trial of nutritional supplementation during acute illness. *Am J Med* 2006;119:693–9.

### Study Overview

**Objective.** To determine the impact of nutritional supplementation on clinical outcomes in older patients hospitalized with acute illness.

**Design.** Randomized, double-blind, placebo-controlled trial with an intention-to-treat analysis.

**Setting and participants.** Hospitalized patients were included if they were aged  $\geq 65$  years, were able to swallow, and were able to give informed consent. Patients were excluded if they had diagnosed malabsorption, morbid obesity, severe dementia, or malignancy; currently used nutritional supplements; had undergone gastric bypass surgery; or were institutionalized.

**Intervention.** Participants were allocated to receive oral supplements or placebo in addition to a normal hospital diet over 6 weeks. Supplements were continued after hospital discharge. Oral supplements were administered twice daily and provided 995 kcal along with 100% of the Reference Nutrient Intakes for vitamins for a healthy older person. The placebo was identical in appearance and provided 60 kcal and no vitamins. Patients were reassessed at 6 months' postrandomization.

**Main outcome measures.** Primary outcome measures were disability at 6 months, nonelective readmissions, hospital length of stay at 6 months, home versus institutional discharge, infectious complications, and mortality. Disability was measured using the Barthel score on a 20-point scale where higher numbers indicate greater functional independence. Secondary outcomes included measures of nutritional status, such as anthropometric measurements, serum albumin, transferrin, red cell folate, vitamin B<sub>12</sub>, and C-reactive protein.

**Main results.** 445 patients were randomized to the intervention ( $n = 223$ ) or placebo ( $n = 222$ ). The 2 groups had similar baseline characteristics. The most common admission diagnoses were ischemic heart disease, chronic obstructive pulmonary disease, chest infection, and congestive heart failure. Serum albumin was statistically significantly greater

in the supplement group at 6 months compared with placebo (mean 42 g/L versus 40.5 g/L, respectively;  $P = 0.04$ ). No differences were seen in body weight, skin fold thickness, or serum transferrin between the supplement and placebo groups at 6 months. The supplement group had significantly improved concentrations of red cell folate and vitamin B<sub>12</sub> at 6 weeks, which were no longer significant by 6 months. With respect to clinical outcomes, the percentage of patients readmitted to the hospital at 6 months was significantly reduced in the supplement group compared with the placebo group (29% versus 40%, respectively;  $P = 0.02$ ). There were no differences seen in infectious complications, disability scores, or deaths between the 2 groups. On Cox regression analysis, the hazard ratio for hospital readmission by 6 months in the supplement group was 0.68 (95% confidence interval, 0.49–0.94).

**Conclusion.** Nutritional supplementation for older adults with acute illness during convalescence and rehabilitation can reduce the risk of nonelective hospital readmission and improve several measures of nutritional status.

### Commentary

It has become increasingly clear that nutritional status with respect to protein and energy balance can directly impact clinical outcomes. For elderly patients, protein undernutrition can result in an increased risk of nonelective hospital admission, infectious complications, and mortality [1–3]. Despite the growing body of evidence linking protein malnutrition to clinical outcomes, little evidence exists evaluating the effectiveness of interventions to improve nutritional status. This well-designed, randomized, placebo-controlled, double-blind study by Gariballa et al suggests that routine nutritional supplementation may improve clinical outcomes for elderly patients who have been hospitalized with acute illnesses. Although disability and mortality did not appear to be impacted, the risk of nonelective hospital readmission at 6 months was reduced by more than 30%.

Surprisingly, some markers of nutritional status improved over the course of the 6-week trial despite overall poor adherence to the supplements. The maximum number of supplement drinks that a participant could have con-

sumed over the trial was 84. Only about 10% of patients allocated to the intervention group consumed even close to this number (64–84 supplemental drinks). Roughly 25% of participants consumed between 43 to 63 drinks, while about 60% of trial participants consumed 21 drinks or less. If these results are corroborated by other clinical trials, future work would need to be directed at how to increase nutritional supplementation adherence. One unexpected finding was a nonsignificant increased risk of death at 6 months in the supplement group compared with the placebo group (hazard ratio, 1.65 [95% confidence interval, 0.93–2.92];  $P = 0.09$ ). This may represent a chance finding and, as the authors point out, almost 80% of the 19 subjects who died during the trial (12 in the intervention group and 7 in the placebo group) consumed 3 or less supplement drinks over the course of the study. Regardless, future trials aimed at evaluating the effectiveness of nutritional supplementations should include mortality as an endpoint.

**Applications for Clinical Practice**

Hospitalizations for the elderly are costly and can result in significant declines in functional status. This relatively simple intervention improves the nutritional status of acutely ill older adults and may potentially result in substantial improvements in quality of life as well as economic benefits.

—Review by Harvey J. Murff, MD, MPH

**References**

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