

## **Randomized trial of folic acid for prevention of cardiovascular events in end-stage renal disease.**

[Wrone EM](#), [Hornberger JM](#), [Zehnder JL](#), [McCann LM](#), [Coplion NS](#), [Fortmann SP](#).

Satellite Research, Redwood City, California 94598, USA. [ewrone@stanfordalumni.org](mailto:ewrone@stanfordalumni.org)

### **Abstract**

High serum total homocysteine (tHcy) is gaining scrutiny as a risk factor for cardiovascular disease in the general population. The relationship between tHcy and mortality and cardiovascular events in patients with end-stage renal disease (ESRD) is unsettled. This randomized trial evaluates the efficacy of high-dose folic acid in preventing events in ESRD. A total of 510 patients on chronic dialysis were randomized to 1, 5, or 15 mg of folic acid contained in a renal multivitamin with a median follow-up of 24 mo. Mortality, cardiovascular events, and homocysteine levels were assessed. There were 189 deaths, and 121 patients experienced at least one cardiovascular event. Composite rates of mortality and cardiovascular events among the folic acid groups did not differ (at 24 mo: 43.7% in 1 mg group, 38.6% in 5 mg group, 47.1% in 15 mg group; log-rank  $P = 0.47$ ). Unexpectedly, high baseline tHcy was associated with lower event rates. From lowest to highest quartile, event rates at 24 mo were 54.5% for Q1, 41.8% for Q2, 41.2% for Q3, and 34.7% for Q4 (log-rank  $P = 0.033$ ). In contrast to some studies describing tHcy as a risk factor for mortality and cardiovascular events, this study found a reverse relationship between tHcy and events in ESRD patients. Administration of high-dose folic acid did not affect event rates.

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