Secondary prevention with antioxidants of cardiovascular disease in endstage renal disease (SPACE): randomised placebo-controlled trial

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Summary

Background

Excess cardiovascular mortality has been documented in chronic haemodialysis patients. Oxidative stress is greater in haemodialysis patients with prevalent cardiovascular disease than in those without, suggesting a role for oxidative stress in excess cardiovascular disease in haemodialysis. We investigated the effect of high-dose vitamin E supplementation on cardiovascular disease outcomes in haemodialysis patients with pre-existing cardiovascular disease.

Methods

Haemodialysis patients with pre-existing cardiovascular disease (n=196) aged 40–75 years at baseline from six dialysis centres were enrolled and randomised to receive 800 IU/day vitamin E or matching placebo. Patients were followed for a median 519 days. The primary endpoint was a composite variable consisting of: myocardial infarction (fatal and non-fatal), ischaemic stroke, peripheral vascular disease (excluding the arteriovenous fistula), and unstable angina. Secondary outcomes included each of the component outcomes, total mortality, and cardiovascular-disease mortality.

Findings

A total of 15 (16%) of the 97 patients assigned to vitamin E and 33 (33%) of the 99 patients assigned to placebo had a primary endpoint (relative risk 0.46 [95% CI 0.27–0.78], p=0.014). Five (5.1%) patients assigned to vitamin E and 17 (17.2%) patients assigned to placebo had myocardial infarction (0.3 [0.11–0.78], p=0.016). No significant differences in other secondary endpoints, cardiovascular disease, or total mortality were detected.

Interpretation
In haemodialysis patients with prevalent cardiovascular disease, supplementation with 800 IU/day vitamin E reduces composite cardiovascular disease endpoints and myocardial infarction.

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