Oral High-Dose Multivitamins and Minerals After Myocardial Infarction: A Randomized Trial

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Background: Whether high-dose multivitamins are effective for secondary prevention of atherosclerotic disease is unknown.

Objective: To assess whether oral multivitamins reduce cardiovascular events and are safe.

Design: Double-blind, placebo-controlled, 2 × 2 factorial, multicenter, randomized trial. (ClinicalTrials.gov: NCT00044213)

Setting: 134 U.S. and Canadian academic and clinical sites.

Patients: 1708 patients aged 50 years or older who had myocardial infarction (MI) at least 6 weeks earlier and had serum creatinine levels of 176.8 µmol/L (2.0 mg/dL) or less.

Intervention: Patients were randomly assigned to an oral, 28-component, high-dose multivitamin and multimineral mixture or placebo.

Measurements: The primary end point was time to total death, recurrent MI, stroke, coronary revascularization, or hospitalization for angina.

Results: The median age was 65 years, and 18% of patients were women. The qualifying MI occurred a median of 4.6 years (interquartile range [IQR], 1.6 to 9.2 years) before enrollment. Median follow-up was 55 months (IQR, 26 to 60 months). Patients received vitamins for a median of 31 months (IQR, 13 to 59 months) in the vitamin group and 35 months (IQR, 13 to 60 months) in the placebo group (P = 0.65). Totals of 645 (76%) and 646 (76%) patients in the vitamin and placebo groups, respectively, completed at
least 1 year of oral therapy ($P = 0.98$), and 400 (47%) and 426 (50%) patients, respectively, completed at least 3 years ($P = 0.23$). Totals of 394 (46%) and 390 (46%) patients in the vitamin and placebo groups, respectively, discontinued the vitamin regimen ($P = 0.67$), and 17% of patients withdrew from the study. The primary end point occurred in 230 (27%) patients in the vitamin group and 253 (30%) in the placebo group (hazard ratio, 0.89 [95% CI, 0.75 to 1.07]; $P = 0.21$). No evidence suggested harm from vitamin therapy in any category of adverse events.

**Limitation:** There was considerable nonadherence and withdrawal, limiting the ability to draw firm conclusions (particularly about safety).

**Conclusion:** High-dose oral multivitamins and multiminerals did not statistically significantly reduce cardiovascular events in patients after MI who received standard medications. However, this conclusion is tempered by the nonadherence rate.

**Primary Funding Source:** National Institutes of Health.

**Topics**

minerals; vitamins; multivitamins; myocardial infarction; follow-up; adverse event