

Abstract

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Effect of homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 on clinical outcome after percutaneous coronary intervention: the Swiss Heart study: a randomized controlled trial.

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CONTEXT: Plasma homocysteine level has been recognized as an important cardiovascular risk factor that predicts adverse cardiac events in patients with established coronary atherosclerosis and influences restenosis rate after percutaneous coronary intervention.

OBJECTIVE: To evaluate the effect of homocysteine-lowering therapy on clinical outcome after percutaneous coronary intervention.

DESIGN, SETTING, AND PARTICIPANTS: Randomized, double-blind placebo-controlled trial involving 553 patients referred to the University Hospital in Bern, Switzerland, from May 1998 to April 1999 and enrolled after successful angioplasty of at least 1 significant coronary stenosis (> or = 50%).

INTERVENTION: Participants were randomly assigned to receive a combination of folic acid (1 mg/d), vitamin B12 (cyanocobalamin, 400 micro g/d), and vitamin B6 (pyridoxine hydrochloride, 10 mg/d) (n = 272) or placebo (n = 281) for 6 months.

MAIN OUTCOME MEASURE: Composite end point of major adverse events defined as death, nonfatal myocardial infarction, and need for repeat revascularization, evaluated at 6 months and 1 year.

RESULTS: After a mean (SD) follow-up of 11 (3) months, the composite end point was significantly lower at 1 year in patients treated with homocysteine-lowering therapy (15.4% vs 22.8%; relative risk [RR], 0.68; 95% confidence interval [CI], 0.48-0.96; P = .03), primarily due to a reduced rate of target lesion revascularization (9.9% vs 16.0%; RR, 0.62; 95% CI, 0.40-0.97; P = .03). A nonsignificant trend was seen toward fewer deaths (1.5% vs 2.8%; RR, 0.54; 95% CI, 0.16-1.70; P = .27) and nonfatal myocardial infarctions (2.6% vs 4.3%; RR, 0.60; 95% CI, 0.24-1.51; P = .27) with homocysteine-lowering therapy. These findings remained unchanged after adjustment for potential confounders.

CONCLUSION: Homocysteine-lowering therapy with folic acid, vitamin B12, and vitamin B6 significantly decreases the incidence of major adverse events after percutaneous coronary intervention.

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