For coronary artery disease patients, B vitamins may not reduce cardiovascular events

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In a large clinical trial involving patients with coronary artery disease, use of B vitamins was not effective for preventing death or cardiovascular events, according to a study published in the August 20 issue of *JAMA*.

"Observational studies have demonstrated that the concentration of total homocysteine in blood is associated with risk of coronary artery disease and stroke," the authors provide as background information. Plasma total homocysteine levels can be lowered by oral administration of folic acid and vitamin B12. In this study, the authors' objective was "to evaluate the effects of homocysteine-lowering treatment with folic acid plus vitamin B12 on mortality and cardiovascular events."

Marta Ebbing, M.D. of Haukeland University Hospital, Bergen, Norway and colleagues, conducted a randomized controlled study with 3,096 patients in two Norwegian hospitals between 1999 – 2006. Patients were randomly assigned to one of four groups receiving a daily oral dose of one of the following treatments: folic acid, 0.8mg, plus vitamin B12 , 0.4mg, plus vitamin B6 , 40mg (n= 772); folic acid plus vitamin B12 (n = 772); vitamin B6 alone (n = 772); or placebo (n = 780).

Patients were scheduled for follow-up visits with an interview, clinical examination, and blood sampling at one month, one year, and at a final study visit. The main outcome measure (primary end point) was a

composite of all-cause death, nonfatal acute myocardial infarction (heart attack), acute hospitalization for unstable angina pectoris, and nonfatal thromboembolic stroke.

The study was stopped early because of concerns among the participants about preliminary results from another similar Norwegian study suggesting no benefits from the treatment and an increased risk of cancer from the B vitamins.

"Mean (average) plasma total homocysteine concentration was reduced by 30 percent after 1 year of treatment in the groups receiving folic acid and vitamin B12," the authors report. "During a median (midpoint) 38 months of follow-up, the primary end point was experienced by a total of 422 participants (13.7 percent): 219 participants (14.2 percent) receiving folic acid/vitamin B12 vs. 203 (13.1 percent) not receiving such treatment and 200 participants (13.0 percent) receiving vitamin B6 vs. 222 (14.3 percent) not receiving vitamin B6."

Source: JAMA and Archives Journals