

Folic acid, B vitamins not linked to reduced risk of cardiovascular events in high-risk women

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Women at high-risk of cardiovascular disease who took a daily supplement of folic acid and vitamin B6 and B12 for seven years did not have an overall reduced rate of cardiovascular events, despite a significant lowering of homocysteine levels, according to a study in the May 7 issue of JAMA.

“Homocysteine [an amino acid produced by the body] levels have been directly associated with cardiovascular risk in observational studies; and daily supplementation with folic acid, vitamin B6, vitamin B12, or a combination have been shown to reduce homocysteine levels to varying degrees in intervention studies,” the authors write.

Observational data suggest cardiovascular benefits from B-vitamin supplementation may be greater among women, yet women have been underrepresented in published randomized trials. “Given the paucity of data on women and the known influences of estrogen on homocysteine levels, adequately powered randomized trials of homocysteine lowering in women are still needed.”

Christine M. Albert, M.D., M.P.H., of Brigham and Women’s Hospital and Harvard Medical School, Boston, and colleagues tested whether a combination of folic acid, vitamin B6 and vitamin B12 would reduce total cardiovascular events among women at high risk for the development of cardiovascular disease (CVD) over 7 years of follow-up.

Within an ongoing randomized trial of antioxidant vitamins, 5,442 women who were U.S. health professionals age 42 years or older, with either a history of CVD or three or more coronary risk factors, were enrolled in a randomized trial to receive a combination pill containing folic acid (2.5 mg), vitamin B6 (50 mg), and vitamin B12 (1 mg) or a matching placebo.

During the 7.3 years of follow-up, 796 participants (14.6 percent) experienced a confirmed CVD event included in the primary end point (heart attack, stroke, coronary revascularization, or CVD death), with some individuals experiencing more than one event. There was no difference in the cumulative incidence of the primary combined end point in the active vs. placebo treatment groups at any time during study follow-up. A total of 406 women (14.9 percent) in the active treatment group and 390 (14.3 percent) in the placebo group experienced at least one cardiovascular event included in the primary end point.

When analyzed separately, there were no significant differences for each of the components of the primary outcome including heart attack, stroke, and CVD death, between the active treatment and placebo groups. Also, the risk of death from any cause was similar between the active and placebo treatment groups.

The researchers also found that the average plasma homocysteine level was 18.5 percent lower in the active group than that observed in the placebo group.

“Our results are consistent with prior randomized trials performed primarily among men with established vascular disease and do not support the use of folic acid and B vitamin supplements as preventive interventions for CVD in these high-risk fortified populations,” the authors write.

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