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B vitamin therapy linked with decline in kidney function for some kidney disease patients

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Patients with diabetic nephropathy (kidney disease caused by diabetes) who received high dose B-vitamin therapy experienced a more rapid decline in kidney function and had a higher rate of heart attack and stroke than patients who received placebo, according to a study in the April 28 issue of *JAMA*.

Diabetic nephropathy typically affects the network of tiny blood vessels in the glomerulus, a key structure in the kidney composed of capillary blood vessels, which is necessary for the filtration of the blood. "In addition to the personal burden, the societal burden of diabetic nephropathy is enormous, exceeding U.S. $10 billion in annual medical expenditures. Despite effective therapies to slow disease progression, approximately 40 percent of the estimated 21 million patients with diabetes in the United States develop overt nephropathy. New treatment approaches to this problem are needed," the authors write.

According to background information in the article, several observational studies have shown a significant association between high concentrations of plasma total homocysteine and the risk of developing diabetic nephropathy, retinopathy, and vascular diseases, including myocardial infarction (MI; heart attack) and stroke. B-vitamin therapy (folic acid, vitamin B6, and vitamin B12) has been shown to lower the plasma concentration of homocysteine.

Andrew A. House, M.D., of the University of Western Ontario, and J. David Spence, M.D., of the Robarts Research Institute, London, Ontario, and colleagues conducted a study to examine whether B-vitamin therapy would slow the progression of diabetic nephropathy and prevent vascular events in 238 patients with type 1 or 2 diabetes. The randomized, placebo-controlled trial was conducted at five university medical centers in Canada between May 2001 and July 2007. Patients received single tablet of B vitamins containing folic acid (2.5 mg/d), vitamin B6 (25 mg/d), and vitamin B12 (1 mg/d), or matching placebo. The primary outcome was change in radionuclide glomerular filtration rate (GFR; a measure of kidney function) between baseline and 36 months. Other outcomes included dialysis and a composite of heart attack, stroke, revascularization and all-cause death. Plasma total homocysteine was measured. Participants were followed-up for an average of 31.9 months.

Among the results, the researchers found that participants assigned to the B-vitamin group had a greater decrease in radionuclide GFR (and subsequently poorer kidney function) compared with the placebo group. Also, participants randomized to receive B vitamins had a significantly greater number of cardiovascular and cerebrovascular events, with the 36-month risk of a composite outcome, including heart attack, stroke, revascularization, and all-cause mortality that was double in the B-vitamin group, compared to the placebo group. There was no difference in requirement of dialysis.

Regarding plasma total homocysteine levels, at 36 months, participants in the B-vitamin group had an average decrease while participants in the placebo group had an average increase.

"Given the recent large-scale clinical trials showing no treatment benefit, and our trial demonstrating harm, it would be prudent to discourage the use of high-dose B vitamins as a homocysteine-lowering strategy outside the framework of properly conducted clinical research," the authors

conclude.

More information: JAMA. 2010;303[16]:1603-1609.

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