

High-dose oral vitamins, minerals do not reduce recurrent cardiac events in heart attack patients

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Heart attack patients given a combination of high-dose oral vitamins and minerals do not exhibit a significant reduction in recurrent cardiac events, according to research presented today at the American College of Cardiology's 62nd Annual Scientific Session. However, the results of one component of the NIH-funded Trial to Assess Chelation Therapy (TACT) study, shows that when combined with active chelation therapy, high-dose vitamins and minerals may provide some additional benefit.

The TACT study tested the safety and effectiveness of both EDTA chelation therapy and high-dose vitamin/mineral supplements in individuals with prior heart attacks.

Previous results presented in November 2012 suggested that chelation treatment, with or without supplements, provided a modest reduction in [cardiac events](#) compared to a [placebo treatment](#). These cardiac events were combined and included recurrent [heart attack](#), stroke, coronary revascularization, hospitalization for angina and death.

The presentation today focused on the effects of the vitamin/mineral supplements, with or without chelation, compared to [placebo](#) caplets, as well as the comparative results of all four study groups (active chelation plus active oral vitamins, active chelation plus placebo oral vitamins, placebo chelation plus active oral vitamins, and placebo chelation plus placebo oral vitamins).

"We did not see a significant benefit of vitamins alone for [patients](#) who had a heart attack," said Gervasio A. (Tony) Lamas, MD, lead author of the study and chief of the Columbia University Division of Cardiology at Mount Sinai Medical Center in Miami Beach, Fla. "Interestingly, patients who received both high dose vitamins and active chelation compared to placebo of both appeared to have additional benefit, but more research is needed to understand the results."

Since 1956, alternative medicine practitioners have used EDTA chelation to treat cardiovascular disease. Chelation therapy involves multiple [intravenous infusions](#) of a synthetic amino acid called EDTA, which binds to certain minerals and metals, including calcium, lead and cadmium. The study investigators proposed studying chelation and high dose vitamins as separate and combined components to determine potential individual and synergistic effects of the two treatments.

TACT enrolled 1,708 patients with prior heart attacks who were randomly assigned to an active or placebo chelation group and an active or placebo vitamin group. This 2 x 2 factorial design allowed the investigators to clarify the independent contributions of each treatment. Patients received 40 intravenous chelation treatments (or placebo), each lasting about three hours, over about a year and a half.

They were also assigned to take three pills twice daily, which contained either high-dose vitamins and minerals or placebo. Average follow-up was over four years. About half of the patients enrolled in the trial stopped taking the vitamins during the study follow-up; researchers say patient preference was the leading reason, given the number of caplets taken daily.

The primary comparison of the study, oral vitamins and minerals versus an oral placebo, did not show a significant reduction in the primary endpoint: 27 percent in the vitamin group and 30 percent of those

receiving, placebo.

The analysis of the four study groups showed that the active/active arm had 108 (26 percent) events and the placebo/placebo arm had 139 (32 percent) events—a statistically significant difference.

The patients in the trial were 82 percent male, 94 percent Caucasian and about half were obese. All had experienced a previous heart attack. Thirty-two percent had diabetes, 68 percent had high blood pressure and 83 percent had previously undergone bypass surgery, stent implantation or balloon angioplasty. Patients were followed for an average of 55 months. The trial was conducted in 134 sites in the United States and Canada from 2002-2011.

Upon entering the study, many patients were already taking evidence-based medications: 84 percent took daily aspirin to reduce risk of stroke and heart attack, 72 percent were on beta-blockers to treat high blood pressure and 73 percent took statins to treat high cholesterol.

More information: Dr. Lamas will present "Randomized Comparison of High-dose Oral Vitamins vs. Placebo in the Trial to Assess Chelation Therapy" on Sunday, March 10 at 11:39 a.m., in Moscone Center, South, Esplanade Ballroom.

Provided by American College of Cardiology

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