

Chelation therapy reduces cardiovascular events for older patients with diabetes

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Chelation treatments reduced cardiovascular events, such as heart attacks, and death in patients with diabetes but not in those who did not have diabetes, according to analyses of data from the National Institutes of Health-funded Trial to Assess Chelation Therapy (TACT). However, researchers say more studies are needed before it's known whether this promising finding leads to a treatment option.

Chelation is a chemical process in which a substance is delivered intravenously (through the veins) to bind atoms of metals or minerals, and hold them tightly so that they can be removed from the body. Chelation is conventionally used as a treatment for heavy metal (like lead) poisoning, although some people use chelation as an unapproved and unproven treatment for conditions like heart disease.

Chelation therapy is not approved by the U.S. Food and Drug Administration to treat heart disease. However, use of chelation therapy to treat heart disease and other health problems grew in the United States between 2002 and 2007 by nearly 68 percent to 111,000 people, according to the 2008 National Health Statistics Report.

The <u>diabetes</u> subgroup analysis of TACT was published today in *Circulation: Cardiovascular Quality and Outcomes* and presented at the American Heart Association's Scientific Sessions 2013. TACT is a study supported by NIH's National Center for Complementary and Alternative Medicine (NCCAM) and National Heart, Lung, and Blood Institute (NHLBI).



TACT's initial report was published in the March 27, 2013, issue of The *Journal of the American Medical Association*. This previous report showed that infusions of a form of chelation therapy using disodium ethylene diamine tetra-acetic acid (EDTA) produced a modest but statistically significant reduction in <u>cardiovascular events</u> in all EDTA-treated participants. However, further examination of the data showed that patients with diabetes were significantly impacted by chelation therapy while patients without diabetes were not.

The patients with diabetes, which made up approximately one third of 1,708 participants, demonstrated a 41 percent overall reduction in the risk of any cardiovascular event; a 40 percent reduction in the risk of death from heart disease nonfatal stroke, or nonfatal heart attack; a 52 percent reduction in recurrent heart attacks; and a 43 percent reduction in death from any cause. In contrast, there was no significant benefit of EDTA treatment in the subgroup of 1,045 participants who did not have diabetes.

"These are striking results that, if supported by future research, could point the way towards new treatments to prevent complications of diabetes," said Gervasio A. Lamas, M.D., the study's principal investigator and chairman of medicine and chief of the Columbia University Division of Cardiology at Mount Sinai Medical Center in Miami Beach.

From 2003 to 2010, 1,708 adults aged 50 and older were enrolled in TACT, of whom 633 had diabetes. Study participants had suffered a heart attack 6 weeks or more before enrollment (on average, the heart attack occurred about 4.5 years earlier). The participants were assigned randomly to receive 40 infusions of disodium EDTA chelation solution or a placebo solution. Patients also were randomly assigned to receive high doses of oral vitamins and minerals or an identical oral placebo. Most participants also took standard medicines for heart attack



survivors, such as aspirin, beta blockers, and statins. They were followed for a minimum of 1 year and up to 5 years, with followup ending in October 2011.

TACT was not designed to discover how or why chelation might benefit patients with diabetes.

"Although subgroup analyses of clinical trials do not provide definitive answers, they are very useful in identifying future research questions," said Josephine Briggs, M.D., Director of NCCAM. "The effects seen in this population are large and very intriguing. This analysis suggests strongly that more research is needed to examine possible benefits of chelation in diabetics and the potential mechanisms."

"We share Dr. Briggs's interest in these compelling findings," said Michael Lauer, M.D., Director of the NHLBI's Division of Cardiovascular Sciences. "Additional studies are needed before we can determine the potential place of EDTA <u>chelation therapy</u>, if any, in the treatment of patients with coronary artery disease and diabetes."

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