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Featured Article

Chelation: What the Results of the Trial to Assess Chelation Therapy (TACT) Mean

Jeff Morris

When the results of the NIH-sponsored Trial to Assess Chelation Therapy (TACT) were presented to the American Heart Institute last November, there was a great deal of hedging on what the study actually showed. With publication of these results in the March 27th issue of *JAMA*, the reception has again been decidedly mixed. What is actually going on?

Here is some background: Chelation therapy is used to remove metals from the bloodstream. Calcium EDTA is approved to treat lead poisoning and other chelation drugs are used to manage iron overload following repeated blood transfusions. There has been a decades-long debate about whether chelation therapy could be effective as a treatment for patients with atherosclerosis—fatty deposits in arteries that can cause heart attacks. Until now, there have been no large, long-term clinical trials to determine if these intravenous infusions might work for patients with coronary artery disease. TACT was a double-blind efficacy trial conducted in 134 sites in the United States and Canada from 2002-2011. The purpose of the study was stated as, "to determine the safety and effectiveness of ethylene diamine tetra-acetic (EDTA) chelation therapy in individuals with coronary artery disease." Funded by the National Center for Complementary and Alternative Medicine and the National Heart, Lung, and Blood Institute, the study was led by Gervasio A. (Tony) Lamas, M.D., chief of Columbia University Division of Cardiology at Mount Sinai Medical Center in Miami Beach, FL. Patients in the trial were 82 percent male, 94 percent Caucasian and about half were obese. All had experienced a previous heart attack, 83 percent had already had bypass surgery, stent implantation or balloon angioplasty. Thirty-two percent had diabetes, 68 percent had high blood pressure and 73 percent had been prescribed cholesterol-lowering statins. Patients were followed for an average of 55 months.

"The chelation therapy was an arduous regimen," Dr. Lamas said. The study used the less common disodium EDTA and the infusion regimen contained other components including vitamin C. Each patient received 40 infusions, each lasting at least three hours. The first 30 infusions were one week apart. The last 10 were two weeks to two months apart depending on the patient's schedule. All told, researchers delivered 55,222 infusions. A stringent safety infrastructure made sure patients experienced no undue risk. In addition, the research team worked with a central pharmacy to ensure the safety and purity of the infused products and had in place a computerized system that calculated doses based on the patient's kidney function and the system sent an alert if an infusion was completed faster than usual. "Although not approved by the Food and Drug Administration for treating heart disease, chelation therapy has been used for over 50 years and has generally been believed by conventional medical practitioners and cardiologists to be without value," Dr. Lamas stated. "A definitive answer on chelation therapy will take much additional research. The most exciting part of this study is that there may be an unexpected signal of benefit. We need to understand whether the signal is true, or whether it occurred by chance."

If that less than enthusiastic endorsement by the study's author makes you wonder what kind of results were found, consider it in light of this summary:

- Overall improvement in heart health 18%
- Death reduced 7%
- Heart Attacks reduced 23%
- Hospitalizations reduced 28%
- Diabetic heart complications reduced 39%
- Heart Surgeries reduced 19%
- Strokes reduced 23%

Those certainly look like positive outcomes. Why, then, did the authors say their findings were "unexpected and additional research will be needed to confirm or refute our results and explore possible mechanisms of therapy" and that TACT "does not constitute evidence to recommend the clinical application of chelation therapy"? Why, then, did the American Heart Association send out a press release that stated:

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Alternative therapy produces intriguing results in some heart patients but many questions remain

Study Highlights:

• Patients with prior heart attacks enrolled in a clinical trial of a weekly chelation infusion regiment that included disodium EDTA and vitamin C had fewer cardiovascular disease complications than those who received placebo infusions.

• Chelation therapy removes heavy metals like lead and iron from the body. Disodium EDTA, the agent used in the study, does not have an FDA indication.

• Investigators caution that the results need to be reproduced and understood before consideration of clinical application.

Why, when those results appear to be so positive, did JAMA feel the need to publish, in the same March 27, 2013 issue in which the TACT trial by Dr. Lamas, et al, appeared, an editorial by Steven E. Nissen, M.D., "Concerns About Reliability in the Trial to Assess Chelation Therapy (TACT)" which asserted, "the efforts of these investigators fell short of the minimum level of quality necessary to adequately answer the question they sought to investigate" as well as an editorial by Howard Bauchner, M.D., et al, to explain the Journal's decision to publish the findings? The latter editorial stated, among other things:

> Fourth, presentation of the study findings will enable cardiologists, other physicians, patients, and practitioners who provide chelation therapy to recognize that the possible benefit of chelation therapy, if there is any, is small, and to understand the important study limitations as discussed in the editorial by Nissen5 (such as marginal statistical significance of the main findings, relatively high dropout rates, and the potential for unmasking). This evidence and information should serve to dissuade responsible practitioners from providing or recommending chelation therapy for patients with coronary disease and should discourage patients with previous MI from seeking this therapy with the hope of preventing subsequent cardiovascular events.

"It's been interesting; you always hear stories about these kinds of things happening," says Roy Heilbron, M.D., a board certified cardiologist now based in Santa Fe, NM. "This trial finally proves scientifically, through the strongest possible scientific study ever done, that chelation works. I'm a clinician, and you always hear of this kind of thing going on; anything that reduces surgeries is going to be great for the patient but bad for the industry. Surgery is their biggest money maker."

Dr. Heilbron had a particular interest in TACT's results because he was involved in the trials from the start and knew Dr. Lamas before the study began. "When the trial started, I was the one who actually trained all the doctors on how to do it," explains Dr. Heilbron. "Nine of the original patients were ours. I was a traditional cardiologist, a Mount Sinai resident, and Dr. Lamas's Fellow. I had been interested in chelation therapy; my wife's uncle—my wife is Dr. Angelique Hart, from the Netherlands—had been performing it overseas, with great success, for 30 years. I went to a meeting about chelation in Ft. Lauderdale because it was nearby, and when I saw Dr. Lamas in the audience I asked him, "what are you doing here?" He said a patient had asked him about chelation therapy, and he wanted to find out about it."

According to Dr. Heilbron, "Dr. Lamas was the NIH investigator, but is not involved in chelation; he ran the trial, but did not do the actual procedures. Dr. Lamas honestly doesn't care whether chelation works or not; he just wanted to set up the study in the best way possible." But Dr. Heilbron cannot understand why the study's bottom-line results were seemingly de-emphasized, with attempts to refute them, right from the start.

"The AHA meeting where the study results were initially presented was in Los Angeles. I went there from Santa Fe, not knowing the results—people forget it was a double blind study. Dr. Lamas went up there and showed the slides. The person right after him [Paul W. Armstrong, M.D., University of Alberta] went up with a rebuttal saying we can't recommend it at this time." The exact same pattern was followed with publication of the findings in *JAMA*, and that unnerves Dr. Heilbron. "Nowhere in the articles does it give you clearly the percentages of what's going on. Nowhere is the statistical result of the benefits provided, even in Dr. Lamas's article. Nobody knows what the type of figures that are shown mean."

"This study shows percentages of reductions in each category. Overall, there was an 18% improvement, and every statistic was positive. Those percentages are presented only in a table in the study, and it's not very clear; most people don't know that .82 is the same as an 18% benefit. Nowhere in the article does it present these results in a straightforward manner. They're not even stating the outcomes. Why don't they even list the results? Every other study lists the results in the headline!"

The 18% improvement, insists Dr. Heilbron, should have been trumpeted, but to appease the anti-chelation establishment, was buried. "Just as an example," he notes, "Plavix is given to everybody based on a 15% benefit. Aspirin is given to heart patients based on a 13% benefit. We showed an 18% benefit and faced a backlash."

Can Often Be Overcome: Study
- *News:* Blood Test Might Spot Pancreatic Cancer Early, Study Finds

Dr. Heilbron contends that the medical establishment, dominated by the pharmaceutical and surgical industries, has a vested interest in derailing a potentially effective preventive procedure that could eliminate the use of many prescription drugs and surgeries. As if to emphasize this point, at the beginning of his rebuttal Dr. Armstrong quickly moved past a disclosure slide showing he had received research grants from seven different pharmaceutical manufacturers. At the end of his own *JAMA* rebuttal, Dr. Nissen lists no fewer than ten pharmaceutical companies from which his institution has received, or expects to receive, grants.

“Here’s what’s important,” says Dr. Heilbron. “When we started, people were saying chelation was dangerous. If the study has proved anything, it’s that chelation is safe. There were no side effects or negative outcomes. That it can be done safely was the first thing we showed. If you have elevated lead anywhere in the world, they'll do chelation. When used to treat high lead levels, it’s very simple: you measure, you see if you have it, you treat accordingly. Where chelation got into trouble was because many people were advocating it be used for everything.”

“The critics don’t know anything about chelation,” says Dr. Heilbron. “They’ve never done it. I have.”

Some links for additional information:

A documentary about the TACT study and reaction to it by filmakers Shereen Noon and Aaron William Star, "Unleaded" is scheduled for release on April 30.
See http://www.etsy.com/listing/125429159/the-download for details.

Effect of Disodium EDTA Chelation Regimen on Cardiovascular Events in Patients With Previous Myocardial Infarction, *The Journal of the American Medical Association*, http://jama.jamanetwork.com/article.aspx?articleid=1672238

Concerns About Reliability in the Trial to Assess Chelation Therapy (TACT),*The Journal of the American Medical Association*, http://jama.jamanetwork.com/article.aspx?articleid=1672219

Evaluation of the Trial to Assess Chelation Therapy (TACT) The Scientific Process, Peer Review, and Editorial Scrutiny, *The Journal of the American Medical Association*, http://jama.jamanetwork.com/article.aspx?articleid=1672221

Chelation Little Help for Heart Disease, Study Says, http://article.wn.com/view/2013/03/27/Chelation_little_help_for_heart_disease_study_says/#/video

Annual Meeting American Heart Association 2012, http://www.youtube.com/watch?v=Rewj-kDCyRM&list=PL6002BD4972841ED7

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