

From the Townsend Letter for  
Doctors & Patients  
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**Letter to the Editor:  
Chelation Study  
Criticized  
by Stuart H.  
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Editor:

Many of our patients may have heard about a study published in *JAMA*, January 23, 2002, (*Chelation Therapy for Ischemic Heart Disease, A Randomized Controlled Trial*) that claims to prove that chelation therapy has no benefit over placebo. I implore you to read the publication for yourself and I think you will conclude, as I did, that this study reaffirms the clear benefit of chelation therapy for cardiovascular disease.

The study was reported as a double blind, randomized, placebo controlled trial. This means that neither doctors nor patients knew who got which treatment (double blind), and that participants were assigned to placebo or treatment group in a random fashion, and that one group got the “real thing” and the other group got a placebo. Unfortunately, in this study both groups got the real thing though one group got a more complete version of the real thing, so in fact, there was no placebo group. As anticipated, both groups improved significantly, and the “real thing” group improved more than the “placebo” group, but because the difference was small, the study could not demonstrate a *statistically significant difference* and therefore the conclusion was that chelation doesn’t work any better than placebo.

All patients had to have positive stress tests at 2-14 minutes of exercise to be included in the study. Both groups (39 patients in each group) were treated with a comprehensive evaluation of risk factors and both were given comprehensive vitamins and supplements as recommended by chelating physicians (but ignored by many conventional cardiologists). Both groups were also given 30 intravenous treatments twice weekly and then every four weeks for a total of 33 treatments. All intravenous treatments contained all the vitamins and minerals recommended by the American College for the Advancement of Medicine (ACAM) except the “placebo” group did not get one of the ingredients – EDTA.

Though EDTA has been touted as the cornerstone of chelation therapy, it has never been felt to be the only important component of the treatment. If it were, then the other ingredients would not be used. In fact, each of the ingredients in the protocol serves important additive roles and the sum of the parts creates the benefits even if some of the ingredients are omitted.

So what did the study show?

- Both groups had statistically significant improvement in time to ischemia on treadmill testing. (P<0.001 means the likelihood that this would be due to chance rather than the treatment is less than 1 in a thousand.) **The treatment group receiving EDTA had a 16.66% better improvement than the “placebo” group.** Because there were only 39 people in each group, this was not *statistically significant*. But if the same trend continued with a larger group, this would have been *highly significant*.

- Both groups improved in essentially all areas measured. The EDTA treated group improved more than the “placebo” group in essentially all measures, but again the study size was too small to *prove* differences between the groups. *But absence of proof is not the same thing as proof of absence!*
- Evaluation of treatment relied upon treadmill testing which is an unreliable predictor of cardiac events, which really primarily identifies obstructing plaque in the coronary arteries, not the inflammatory plaque that is now accepted as the most likely cause of heart attacks. EDTA chelation has never pretended to clear out hardened plaque, but does claim to improve functional capacity and prevent heart attacks. If clearing out hardened plaque was useful, then we would expect that bypass surgery and angioplasties would improve life expectancy, but this has not been the case except in a small select group of obstructing hard plaque lesions.
- All patients were followed for one year after treatment. In the “placebo” group one patient developed a documented MI and 6 others were admitted for worsening angina. Four of these 7 patients had angioplasties and 1 other patient had a bypass. In the EDTA group, there was 1 MI and 9 admissions for worsening angina but no patients went on to angioplasty or bypass surgery! If treatment was stopped after 27 weeks, it is not surprising that some patients had return of angina. **But it is very significant that NONE of the EDTA treated group went on to surgery compared to 5 out of 40 in the other group.**
- In the placebo group 4 patients were withdrawn (there were actually 43 initially), 2 of these had unrelated medical conditions and 1 had increased angina, the fourth had bypass surgery. Of the original 41 in the EDTA group, 1 was withdrawn for an increase in serum creatinine (an event that we see and just watch as we continue chelation treatments) and 1 that was hospitalized with angina. **So even in the dropouts there were twice as many cardiac problems in the group not receiving EDTA.**

Unfortunately, the publication did not specify individual data on each patient. In a study this small it is common to see trends in individuals that may not be seen when all data scores are grouped together. I am sure others will get the raw data and reassess the results and come to alternative conclusions. For example, in this study, all stress tests were stopped at 14 minutes and anyone still going at that time was considered to have ischemia at 14 minutes! That means that if an individual developed ischemia at 13.5 minutes before the treatment and was able to exercise for 35 minutes after treatment, he would have been stopped at 14 minutes and declared to have ischemia at that time. His improvement would be listed as 30 seconds rather than 22 minutes. This kind of data collection would very significantly skew the results to avoid finding benefits.

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