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### Chelation Therapy: An Alternative Approach to Vascular Disease

Cardiovascular disease still remains the #1 cause of death in western societies. Standard treatments for coronary, cerebral and peripheral disease generally include medications and surgery. These treatments have resulted in disappointing outcomes, and as a result, more and more people are looking for options and alternatives in the prevention and treatment of vascular disease. Moreover, standard therapies are expensive and are fraught with high complication rates and significant mortality. As a result, ethylenediamine tetraacetic acid (EDTA) chelation therapy has been gaining wider popularity as a treatment that may provide a safer and less expensive option to more standard treatments.

Although chelation therapy may be viewed as a controversial treatment for vascular disease, the preponderance of evidence indicate that it can provide an effective treatment modality that is safe, has a low morbidity rate, and a mortality rate that is virtually non-existent.

#### *Historical Perspective*

Chelation therapy was initially used for treatment of lead toxicity after it was developed in Europe in the 1930's and 1940's. The term chelation is derived from the Greek work "chele" which means "claw onto". Naturally occurring chelated compounds that occur in living systems include chlorophyll (a chelate of magnesium) and hemoglobin (a chelate of iron). It was noted that patients who were treated for lead toxicity with EDTA chelation therapy had coincidentally reported improvement in symptoms of angina pectoris and other cardiovascular symptoms. That observation lead to further research on other cardiovascular benefits of EDTA in the treatment of atherosclerotic vascular disease.

It has been estimated that EDTA chelation therapy has been administered to more than 800,000 people accounting for more than 12 million treatments. Chelation therapy is always recommended as part of a more comprehensive program which includes nutritional and dietary recommendations, a regular exercise program, lifestyle modifications, stress reduction, nutritional supplements and prescription medications when indicated.

### *Course of Therapy*

A typical course of chelation therapy may involve an intravenous infusion of sodium ascorbate, magnesium, B vitamins and EDTA which is diluted in sterile water and infused over a three to four hour period. The treatment is usually administered one or two times per week until a total of 30-40 treatments. More symptomatic patients may require 50-60 treatments until relief of symptoms occur. The average patient, however, seems to notice symptomatic improvement between 10-20 treatments. A maintenance treatment program is usually recommended after the initial course of therapy.

Patients are closely monitored for kidney function via creatinine clearance, BUN, creatinine and urinalysis. Blood pressure and weight are also monitored.

### *Who May Benefit?*

Most of the patients who seek chelation therapy have previously been diagnosed with some form of vascular disease. Most commonly, this can include coronary artery disease, peripheral vascular disease, or cerebral vascular disease. People who have previously undergone bypass surgery or angioplasty or have been told that these invasive procedures may be necessary may also be candidates for chelation therapy. Many people with heavy metal toxicity, or Alzheimer like conditions have also reported improvement after receiving a course of chelation therapy.

### *Is There Evidence Supporting the Effectiveness of EDTA Chelation Therapy?*

Chappell and Stahl completed a meta-analysis which evaluated 41 studies using EDTA chelation therapy in patients with vascular disease. In looking at 22,765 patients, 87% had measurable improvement after chelation treatment in parameters such as exercise activity, walking distance, Doppler studies, EKG results and ankle/brachial index. They concluded that chelation therapy was effective in the treatment of vascular disease.

In another study by Olszewer and Carter, in which they looked at 2870 patients who primarily had vascular disease, 90% were found to have good to excellent improvement as measured by walking distance, EKG and Doppler changes.

Joe Holliday, a vascular surgeon, reported that chelation-treated patients had lower amputation rates compared to surgically treated patients with comparable lower-extremity vascular disease. In addition, symptom relief was superb after chelation therapy and none of the patients progressed to amputation.

A study by Rudolph et al. found improvement on Doppler ultrasound measurements in patients who were previously diagnosed with carotid artery disease. They found a 30% average reduction in stenosis in 30 patients when comparing before and after chelation carotid blood flow. Rudolph also published a case report indicating significant improvement in macular degeneration after chelation therapy.

A study by Hancke and Flytlie treated 65 patients with chelation therapy who were on the waiting list for cardiac bypass surgery. After an average of six months, 58 (89%) of the 65 patients were able to cancel their surgery after chelation therapy as a result of significant symptomatic improvement. They also performed chelation therapy on 27 patients who were awaiting limb amputation and 24 were able to cancel their surgery after treatment. It has been speculated that if we extrapolate these numbers to the large number of bypass surgeries and amputations performed in the United States, 363,000 of the 407,000 bypasses may have been avoided and 102,000 limbs may have been saved if chelation therapy was administered to these patients in 1992. Furthermore, nearly 8 billion dollars in health care costs could have been saved.

In his 1993 study, Hancke reported that surgery was obviated in 82 of 92 patients with atherosclerosis who were referred for surgical intervention (either bypass surgery or limb amputation) after they received at least 20 treatments with EDTA chelation therapy. After 6-12 years, he was able to locate 47 patients to evaluate the long-term effectiveness of their treatment. His findings indicated that 34 of 47 subjects had still not required surgical intervention, far more than would be expected from the natural course of disease. The majority of patients who did well followed the recommended maintenance program, and even after 6 to 12 years, remained well after being treated with the protocol taught by the American College for Advancement in Medicine.

There have been two widely quoted studies claiming to have performed randomized, well-controlled, double-blind clinical trials indicating a lack of efficacy with EDTA chelation therapy. Both of these studies have been widely criticized. They had not followed the protocol established by the American College for Advancement in Medicine (ACAM) although they claim to have done so. In addition, many of the patients selected were still smoking cigarettes, which greatly limits the effectiveness of chelation therapy. One of these studies was criticized in at least four medical journals and also by the Danish Council on Scientific Dishonesty. Despite their limitations, both studies found that nearly 60% of the treated group improved whereas the placebo group also had a similar response.

In both studies, patients received only 20 treatments whereas standard therapy usually consists of 30 to 40 or more treatments in patients with severe disease. In one study which claimed to be a placebo-controlled trial, both groups actually received a chelating solution, one with EDTA and the other with thiamine (vitamin B-1) and ascorbic acid (vitamin C). Both groups showed a significant overall improvement (approximately 60%). Had the EDTA chelation group been compared to a true placebo group, patients receiving chelation therapy may have shown statistically significant improvements.

### *Mechanisms of Action*

It has been proposed that there are at least two primary theories which may explain the mechanisms by which EDTA chelation therapy may work. One of the plausible explanations is that chelation therapy functions as an antioxidant and quenches free

radicals. It is also speculated that heavy metals in the bloodstream can increase the production of free radicals which can then be removed by chelation therapy.

Chelation therapy has also removed metastatic calcifications from rabbit aortas. It has also been shown to inhibit platelet aggregation thereby favorably affecting blood flow. Some studies have demonstrated improved lipid metabolism and the restoration of electromagnetic potential across cell membranes.

Although large-scale, well-controlled, randomized, placebo-controlled trials supporting the use of EDTA chelation therapy for vascular disease have not been completed, further studies are currently underway to elucidate the effectiveness and mechanisms of EDTA chelation therapy. I feel, however, that at this time, we do have sufficient information and data to support the off-label use of chelation therapy as long as informed consent is provided to each patient.

### ***Learning More About Chelation Therapy***

The American College for Advancement in Medicine (ACAM, 800-532-3688, [www.acam.org](http://www.acam.org)) offers a two-day training workshop for physicians and medical personnel twice per year. A rigorous certification process to certify physicians who have demonstrated knowledge and proficiency in this field is advised. Physicians are then required to attend continuing medical education programs and to recertify on regular intervals.

### ***Conclusion***

After 15 years of experience in treating people with chelation therapy and supervising more than 70,000 treatments, I have been most impressed with the clinical response that I continue to observe in my patients. However, in clinical practice, I do not use chelation therapy in isolation. It is combined with oral nutritional supplementation, recommendations for regular exercise and weight loss (if indicated), methods for stress management, and dietary recommendations, which emphasizes the importance of nutrient-rich, wholesome and unrefined, unprocessed foods.

I have found chelation therapy to be an effective adjunct to conventional medical treatment. It can provide an option for various types of vascular disease and can frequently be attempted before bypass surgery or amputation is carried out. Thousands of patients have been benefited, have been able to improve their quality of life, and have avoided more invasive, more expensive, and more disabling treatments. It is also a treatment that may help to reduce the need for medications or perhaps to completely eradicate pharmaceutical agents. However, this should only be done under the supervision of a trained physician. When effectively applied by a skilled physician who has been trained and has appropriate experience in chelation therapy, a comprehensive program that includes appropriate dietary changes, oral antioxidants and nutritional supplements, exercise, lifestyle changes, and chelation therapy should be considered in patients with stable vascular disease.

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