WHAT IS CHELATION THERAPY – AN OVERVIEW

The word chelation means "claw" and refers to the chemical process of binding metals and other minerals in the body and removing them through the urine. A variety of chelating agents have been developed since the 1930’s, each having different chemical properties that made them useful for certain purposes. Three agents are now the most commonly used: DMSA, an oral chelator that binds to lead, mercury and other metals; DMPS, an intravenous or oral chelator that is especially good at removing mercury; and EDTA, an intravenous binder of lead and other metals. Of these three, EDTA has been the most studied for the treatment of atherosclerosis and diabetes due to its unique ability to remove calcium from the plaque in artery walls, reducing the size of blockages and improving blood and oxygen flow.

EDTA was initially developed to pull calcium out of hard water for use in the textile industry, but was later discovered to be an antidote for nerve gas poisoning. After WWII, EDTA was shown to be effective in treating lead toxicity, pulling lead out of the body and removing it through the kidneys. Soon, researchers were taking note that EDTA had many other effects including the removal of radioactive substances in acute radiation poisoning, lowering blood cholesterol levels, treatment of elevated blood calcium levels, beneficial effects in treating arthritis and other auto-immune disorders, improvement in the elasticity of blood vessels, and removal of excess iron. One of the most impressive results, however, was the ability of EDTA chelation to lessen chest pain in patients with heart disease. It is this effect that often leads patients to seek this therapy either as an alternative to or to complement conventional pharmaceutical and surgical treatment.

THE HISTORY OF CHELATION THERAPY

First conceived by chemist Alfred Werner in the 1890’s, it wasn’t until the 1930’s that the first chelators were developed with the patent for Ethylene Diamine Tetra Acetic Acid or EDTA being first granted in Germany in 1935. EDTA was used by the textile industry to remove calcium from water so that dyes would adhere to fabric better. Shortly afterward, it was discovered that EDTA also had the ability to bind to lead and other toxic heavy metals, making them useful in World War II in the treatment of soldiers with nerve gas poisoning. After the war there was greater interest in the medical uses for this compound, one discovery being as an anti-coagulant, used to this day in purple top laboratory tubes in which EDTA has been placed to prevent the blood from clotting. Health conditions in which individuals had elevated blood calcium were also being treated with EDTA leading to FDA approval by the late 1940’s for the two forms of EDTA: Calcium EDTA for lead removal and Di-Sodium EDTA for lowering blood calcium.

By the 1950’s, EDTA was in common use as treatment for lead poisoning and with the burgeoning automotive industry, there were increasing numbers of workers exposed to lead as they manufactured batteries for all the new cars the baby boomers were buying. It was during the treatment of a number of these men in Detroit when it was observed that those who had preexisting cardiovascular disease causing chest pain, shortness of breath, and leg pain with walking all experienced improvements of these symptoms. This sparked an interest in research to try to understand the biochemical mechanism of action of EDTA and ushered in the “Golden Age” of chelation when numerous researchers began publishing articles on a variety of benefits from chelation including cardiovascular disease and diabetes. These and subsequent studies showed how EDTA would not only bind to lead and other metals, but also mobilize calcium from the plaque in atherosclerotic vessels, opening up blockages and improving
blood flow and oxygenation. Subsequent studies have demonstrated other mechanisms likely contributing to the effectiveness of EDTA, one being how the chelator will transiently lower blood calcium which causes a surge of parathyroid hormone to be released which results in calcium being removed from areas in the body where it isn’t supposed to be such as in the walls of arteries and other tissues, moving it back where it should be, such as in the bones. These findings helped EDTA become part of mainstream medicine and began an era of public interest in this therapy for a condition, cardiovascular disease, which prior to that time had no effective treatment.

The tide started turning in the mid 1960’s, however, with the development of coronary artery bypass surgery, a procedure that could instantly fix a blocked artery. So now instead of doing a series of intravenous EDTA infusions to open blood vessels throughout the body, a single surgical procedure could save a person’s life, but the downside is that it only addressed the 3 or 4 major coronary arteries that typically are blocked and didn’t do anything for the rest of the body. Nevertheless, this was a groundbreaking procedure and brought a lot of publicity to the hospitals and surgeons performing them. From here, further developments have occurring including the use of balloon angioplasties and stents, creating the specialty of Interventional Cardiology, which was very profitable and is now the standard of care. Because EDTA had never been FDA approved for the treatment of cardiovascular disease, the final nail in the coffin was the expiration of Abbott Pharmaceutical’s patent in 1969. Since the cost to get a drug FDA approved can approach $1 billion in today’s dollars, there is no incentive for any pharmaceutical company to invest in this process unless it has the exclusive right to produce and sell the product by owning a patent on the drug. This allows them to be able to charge a very high price due to lack of competition and thus make back the money they spent to get the drug approved. The result of these events was that EDTA became an “orphaned drug”, a fate that has befallen many other promising medications resulting in their true potentials never being fully demonstrated. EDTA was no longer on the radar for the conventional world and was soon forgotten by most in the medical establishment.

However, many of the physicians who had worked with EDTA chelation up to that point were not deterred and continued to administer chelation infusions, publishing small but significant studies documenting its benefits. In 1973, the American Institute of Medical Preventics, later called the American College for the Advancement in Medicine (ACAM) was founded to promote and teach chelation therapy. The definitive Textbook of Chelation Therapy was soon published, being updated regularly since. More and more physicians began providing this treatment and the benefits were speaking for themselves, leading to greater public interest and demand.

The 1980’s saw an even greater volume of publications including those showing improvements in patients with congestive heart failure, improved carotid blood flow, lung function and bone density. Studies were published showing no adverse effect on kidney function from EDTA chelation, a criticism left over from the 1950’s when safe dosing guidelines had not yet been established. Public demand grew even more as our culture began evolving into a greater awareness of the need for less invasive and more natural approaches. The American Medical Association called for studies to see if chelation worked and at the same time, conventional cardiologists who were obviously threatened by the popularity of chelation wrote several articles critical of the therapy but most were shown for what they were as blatantly biased. During this decade The American Board of Chelation Therapy was formed to certify doctors who provided the therapy, later changing its name to the American Board of Clinical Metal Toxicology.

The first major randomized clinical trial to evaluate the effects of chelation therapy was started at Walter Reed Army Hospital in the late 1980’s but less than half the study had been carried out when it was suddenly discontinued allegedly because the investigators were called to serve in the Gulf War and did not return to complete the study. Instead a smaller cross-over clinical trial was undertaken being published in 1990 showing significantly positive results in the treatment of peripheral vascular disease. Throughout the 1990’s, small studies continued to be published showing benefits from chelation while at the same time other articles were being published in conventional medical literature stating that there
was too much heart surgery being done in the United States and that outcomes from non-surgical therapies were just as good if not better for many patients. This opened the door for the re-evaluation of chelation therapy within the conventional establishment with a landmark 100 page article published in 1998 by Steven Olmstead, a research cardiologist at the University of Washington Medical School explaining the mechanisms, chemistry and scientific evidence regarding chelation therapy. One of his conclusions was that the preponderance of evidence was in favor of the therapy for peripheral vascular disease.

Support for chelation continued to be documented with a 1993 study showing that 90% of patients scheduled for coronary artery bypass surgery or amputation due to poor circulation were able to cancel their surgery after undergoing a series of EDTA chelation treatments. Shortly afterward a comprehensive analysis of 19 studies on chelation therapy was carried out, evaluating the effectiveness of the treatment in 22,795 patients showed 90% effectiveness in measurable improvements in cardiovascular disease in patients undergoing chelation.

While not specifically looking at the effects of chelation, a study that led to further refinement of thinking as to the mechanism of action of chelation in the treatment of cardiovascular disease was published in 1999 in the Journal of the American College of Cardiology. This study evaluated the amount of lead and mercury in the heart muscle tissue of patients who died of heart disease and found that mercury levels were 22,000 times higher and lead levels were 18,000 times higher in the heart muscle of individuals dying of heart failure compared to people not dying of heart failure. This reinforced the concept that chelation does more than just act as a roto-rooter; that the removal of highly toxic heavy metals could likely also be helping improve heart function and improve symptoms of heart disease.

In spite of this apparent renaissance in academic appreciation of chelation, remember that without a patent, there is no interest by private, for-profit pharmaceutical companies in paying for research to prove safety and effectiveness. They have no ability to generate income from the sale of EDTA because any manufacturer can produce it. Competition drives down price so it is not possible to make enough profit to pay back their investment. The only way an orphaned drug has any chance of coming back in a new incarnation is for the research to be carried out by our tax-payer supported research institution, the National Institutes of Health (NIH).

THE TRIAL TO ASSESS CHELATION THERAPY (TACT)

In 2000 Rep. Dan Burton, chairman of the Congressional Oversight Committee, held a hearing about chelation with testimony from researchers at the National Institutes of Health (NIH) and from experienced chelation physicians. This hearing was prompted by Rep. Burton’s experience with chelation as a therapy for his autistic grandson whose condition improved significantly following chelation therapy for heavy metal toxicity. The conclusion was that a large study was clearly indicated leading to the Trial to Assess Chelation Therapy (TACT) and a team of researchers, medical schools and experienced chelation physicians agreed to participate.

The principal investigator chosen to carry out the TACT was Gervasio Lamas, M.D., director of cardiovascular research and academic affairs at Mount Sinai Medical Center-Miami Heart Institute. He explained how chelation gathered momentum in the 1970’s and 1980’s as a treatment for cardiovascular disease but after a couple of small studies did not show particularly positive results, the therapy was discredited in conventional cardiology and it went into the realm of alternative medicine where it continued to grow. Anecdotal reports and case studies were published describing marked improvement in cardiovascular disease and better blood flow after chelation therapy. It was because there were hundreds of thousands of infusions of chelation each year in the United States that the NIH felt a clinical trial was needed.
The TACT study was approved in 2002 and was funded at $30 million. The study began in April 2003 with eligibility requirements including participants over 50 years of age, having a documented heart attack at least six months prior and having had no cardiac procedures for the prior six months. Such individuals are at high risk of a subsequent cardiac event so the goal was to find out if chelation therapy provided any benefit in terms of reduced or less severe cardiac events. The study was originally planned for 2372 patients but was reduced 1708 patients due to difficulty with recruitment. The group was evenly divided with one half receiving 3 grams of EDTA or less based on kidneys function along with magnesium, B-vitamins and other components that are used in the standard protocol. The other half was given a placebo which was an infusion of sugar water. No oral supplementations were incorporated beyond a basic multi-vitamin. Participants were given 30 weekly infusions, then 10 additional infusions every other month for a total of 40 infusions going through this process over approximately 24 months. Originally planned for only three years, the enrollment period was extended to five years with another two years of observation after the last treatments were completed. The final number of participants was 1708 with 55,222 infusions given in 134 sites in US and Canada.

Almost 60 years after the first discovery that EDTA chelation therapy could be effective in the treatment of heart and blood vessel diseases, results of the first large randomized double-blind trial were reported at the American Heart Association meeting in November 2012. The study showed that those patients undergoing EDTA infusions had 18% fewer cardiac events that those patients who received the placebo, a statistically significant finding that suggests a beneficial effect. There were 6 fewer deaths in the EDTA group as well as 15 fewer heart attacks in comparisons to those receiving the placebo. The longer that patients were followed, the greater the difference better the treatment group and the placebo group suggesting the benefits held for the long term and were not just temporary. The results were then published in the Journal of the American Medical Association in March 2013 with a final statement that the study results were not sufficient to say that everyone should get this treatment but that benefits were positive enough to warrant further study.

One of the most significant finding of the study was the effect of EDTA on the 37% enrolled patients who were diabetics. The inability to maintain a stable a normal blood sugar can lead to damage to the microcirculation causing peripheral vascular disease, chronic kidney disease, and many other complications include vision loss and stroke. 322 diabetics in the study received EDTA and 311 received the placebo. The 322 patients undergoing EDTA experienced the greatest benefits of any in the entire study, seeing a 41% reduction in cardiac events, a 52% drop in recurrent heart attacks, and a 43% reduction in deaths compared to the placebo group.

Given the increase in diabetes in the American population – including the younger age of onset for many victims – any treatment offering significant benefit should, in the best of possible worlds, be readily embraced. Most remarkable were the benefits observed by diabetics with severe peripheral vascular disease, losing the circulation in their extremities which in most cases leads to amputation. There were 24 such patients in each group. None of those who received real EDTA in their infusions had to undergo amputation while all but one in the placebo group did have to undergo amputation.

While the overall results of the TACT study were very positive and encouraging of more research, it was this even more significant benefit observed among diabetic patients that got the greatest attention. There is now a second Trial to Assess Chelation Therapy, TACT 2, which will evaluate the effectiveness of chelation in diabetics more extensively, enrolling 1000 participants and dividing the group so more will receive the real therapy, 2/3rds with only 1/3 getting the placebo. This second study will also explore the mechanisms of action in greater detail and seek to understand the role of heavy metals in more detail. The ultimate outcome of these trials is that insurance and Medicare may slowly start covering the therapy in selected cases.
DIABETES AND CHELATION

Diabetes is a growing epidemic in the United States with 21 million people being diagnosed with Type 1 or Type 2 diabetes in 2014. It is estimated that 8.1 million are undiagnosed and a huge 86 million are pre-diabetic. Diabetes is one of the most costly diseases as well with estimates at $245 billion annually in the US. Diabetes is the 7th leading cause of death in the US mostly due to the various complications that can occur when poorly treated. These secondary conditions include hypertension, hyperlipidemia, coronary artery disease, cerebral vascular accidents, chronic kidney disease, amputation, retinopathy, and neuropathy. Type 2 diabetes is clearly linked to obesity so as obesity rates climb, so does the diagnosis. 80-90 percent of patients diagnosed with type 2 diabetes are classified as obese. The International Diabetes Foundation was quoted, “Diabetes and obesity are the biggest public health challenges of the 21st century”. The link here is clear; obesity drives insulin resistance and an inflammatory response. Prolonged insulin resistance puts an extreme amount of stress on the pancreas. When resistance is accompanied by dysfunction of the pancreatic islet b cells that is what ultimately leads to the disease.

A dietary goal should be to minimize refined sugars and starches. Modern carbohydrate staples, like potatoes, breads, and cereals, have a high glycemic index and a very strong link to chronic disease. Foods low on the glycemic index scale like sweet potatoes, winter squash, and beans help to stabilize blood glucose levels. This can be achieved with whole structured foods and selection of less sugary carbohydrates. Clinical trials support low glycemic index diets with greater fat content are more effective than low fat diets in preventing complications associated with cardiovascular disease. Often a low fat diet contains the highest glycemic index carbs, which leads to increased insulin resistance. Low glycemic index diets improved whole body insulin sensitivity throughout the trials with no increase in LDL cholesterol.

While dietary management is the key to prevention, when complications of diabetes have already developed, chelation has a long history of providing benefits. Reports of chelation improvements in diabetics have been peppered throughout the medical literature over the past 50 years. In 1964, Carlos P. Lamar, MD, offered his diabetic patients a real chance at a more normal life, saving limbs scheduled for amputation, saving vision in those going blind, and lowering insulin dosages. Kansas City, Missouri, chelation specialists Ed W. McDonagh, DO, and Charles J. Rudolph, DO, PhD, were joined by research professional Emanuel Cheraskin, MD, DMD, to publish 31 papers documenting their clinical practice experience over the 1980s and 1990s. Topics included significant improvements of vital importance to diabetics and nondiabetics alike: blood sugar, cholesterol, HDL cholesterol, triglycerides, kidney function and serum creatinine levels, artery blockage disease (even of the aorta), severe heart artery blockage, blockage of neck carotid arteries, hardening of the arteries, platelet clotting functions, fatigue, pulse rate and blood pressure, serum calcium and iron levels, trace element patterns in degenerative diseases, psychological status, and general “clinical change” (improvements) observed in chelation patients. One of the most promising findings was the ability of chelation to reverse macular degeneration (commonly seen in diabetics) reported by McDonagh and Rudolph’s group in 1994. Their evidence included retina photographs, documenting improvement consistent with increased circulation to the eyes.

NEGATIVE MEDIA REPORTING ABOUT CHELATION

Even as the TACT study was underway, negative publicity about chelation continued to be spotlighted in the media leading to confusion about its safety. This all stems from a single event in 2005 in Pennsylvania involving a medication error. The physician administering chelation therapy was blamed for giving the wrong medication. In fact, however, he had ordered Calcium EDTA, but his nurse misunderstood the order and gave Sodium EDTA instead. Calcium EDTA which is used solely as a binder of lead and has no known cardiovascular benefits can be administered quickly without any risk. Sodium EDTA exerts clinical effects mainly through its ability to transiently lower blood calcium levels and must be infused slowly so as to not lower calcium too quickly. In this case, a medication error led to
the infusion of Sodium EDTA at too quick a rate causing calcium levels to fall to a level that resulted in cardiac arrest – a tragic mistake.

By analogy, this same medication error occurs in hospitals on a daily basis, resulting in many adverse and even deadly reactions—as well as millions of dollars of malpractice payments. Clearly the problem is not with chelation itself, but with the use of the wrong form of EDTA which was administered incorrectly. In addition, physicians who do not provide antioxidant and essential mineral support to their patients run the risk of having adverse reactions occur following chelation treatment. It is essential that you receive chelation therapy from a physician who understands these issues. Chelation, like surgery, is a tool that must be wielded in a skillful and judicious manner by a well trained practitioner.

THE ROLE OF HEAVY METALS IN CHRONIC ILLNESS

As noted above, studies have also linked heart disease to the presence of high levels of mercury and lead in heart tissues leading to the conclusion that the removal of these toxic metals is likely contributing to benefits observed when patients undergo chelation therapy. These metals along with many others have been linked to cancer and numerous degenerative conditions with there being no levels of these toxins in our body which is considered safe. Low dose exposures to lead and mercury have been found to have adverse effects on cognitive ability, particularly in the first few years of life. Any therapy that reduces the body burden of toxic metals could help combat or control these chronic diseases.

It is the small amounts of toxic metals that are the cause of the problems, not industrial exposure or poisoning. There are thousands of references in the medical literature linking small amounts of lead to hypertension. Studies have shown numerous links between cadmium exposures from fertilizer to cancer. Studies on rats have shown the toxic effects are synergistic not additive as chronic exposure is accumulative. Significant links between mercury and Alzheimer’s have been documented.

The future of chelation will likely result from the growing recognition that in spite of spending 5 times what other countries spend on healthcare we are 27th in the world in health quality and with 70% of all deaths being due to chronic disease, addressing the most likely underlying causes which include heavy metal burden should be considered in any preventive healthcare regimen. Understanding the synergy of metals is also important as we appreciate the dangers we face. When rats are fed lead containing water, you find that LD1 is the lethal dose that kills one, LD 25 is the lethal dose that will kill 25 out of 100. The LD100 is the dose that will kill all of them. If you take the LD1 for mercury and 1/20th of the LD 1 for lead and put both in the rat’s water, the result will be an LD100 effect – all 100 will be killed with just the tiniest amount of both toxic metals. This means that small amounts of several toxic metals matter more than you expect – synergism and inflammation.

THE CAROLINA CENTER’S HISTORY WITH CHELATION THERAPY

Opening in October 1994, the Carolina Center is the Triangle’s oldest Integrative Medical practice. Dr. Pittman’s training in chelation began in 1995 with his certification by the American Board of Clinical Medical Toxicology being granted in 2000. Over the subsequent 15 years, the role of toxic metals has become even more apparent as numerous studies have continued to show connection between these environmental toxins and degenerative diseases. In the wake of the successes of the TACT Study, there is an even greater value to this procedure provided by the Carolina Center.

THE CHELATION PROCESS

Prior to beginning chelation, it is important that a patient be in a strong nutritional state, especially in terms of minerals as chelators not only remove lead and other metals but also some important trace
minerals such as zinc and selenium. Replacement of the minerals regularly while undergoing chelation is critical to avoid complications from treatment. We typically recommend that patients undergo two to three intravenous Mega Mineral infusions prior to starting chelation to be in the strongest place possible nutritionally. Periodic mineral testing and adjustment in supplement recommendations will be carried out to insure ongoing safety. The first chelation treatment incorporates the Urinary Chelation Challenge Test; a procedure is to assess the body’s toxic metal burden which accumulates over months and years. This is very different from procedures used to diagnosis acute or severe metal toxicity which is typically noted through elevation of metals in the blood or through non-challenged urine testing. For most of us, metals accumulate gradually over years of mild exposure so they aren’t going to be seen in the blood, having been bound in tissues and locked deeply in the body.

These stored metals when combined with other environmental toxins the body has accumulated ultimately result in chronic oxidative stress overload along with inflammation and other forms of biological dysfunction. Having very high levels of metals following the challenge test can provide some indication as to the degree that toxic metals may be contributing to oxidative stress and compromising your health on an ongoing basis.

The challenge test involves the administration of two chelating agents, Calcium EDTA and DMPS, followed by a 6 hour urine collection which is then sent to the lab to determine the types and amount of metals being removed. While not a true picture of the metals stored in the body, this can give a fairly accurate representation of heavy metal burden. The more metals that can be shaken loose and come out, the more likely that there are more where that came from. The challenge test can then be done again periodically to assess the response to chelation in terms of observing a gradual reduction in the amount of metals being released.

The chelation treatment itself consists of a 90 minute infusion of Sodium EDTA along with magnesium, various B vitamins and other nutrients. Treatment frequency depends on various factors but for the majority of patients, infusions are recommended on a weekly basis with the goal of completing 30 infusions after which infusions are done every month or other month for 10 additional treatments. Further maintenance on a less frequent basis may be recommended beyond these 40 sessions depending on the underlying health issues and overall response to therapy. IV Mega Mineral infusions are interspersed after every 5th chelation to insure no mineral deficiency issues arise.

It is important to understand that Chelation Therapy is a comprehensive treatment protocol that incorporates more than just the IV infusion of Sodium EDTA. The key to therapeutic success is the combination of dietary, lifestyle and nutritional support incorporated during this process. Important oral supplements with minerals and antioxidants are needed between chelation treatments. Research reported in the April 2007 issue of Cellular & Molecular Biology indicates that chelation therapy is most effective when combined with specific antioxidant nutrients and herbals to support optimal detoxification. Other oral strategies may be used to accelerate toxic metal removal beyond what can be accomplished with chelation therapy alone.

**WHAT CAN EDTA CHELATION DO FOR YOU?**

Because this is a non-specific treatment which removes toxins, redistributes calcium, and ultimately improves circulatory flow and oxygenation of all tissues, its benefits are far reaching. This is very different from the highly selective prescription drugs in use today. Most conventional physicians view this "one symptom, one drug" approach as standard medicine and look skeptically upon a therapy which can improve so many different conditions. However, understanding the basic mechanism of action (restoring oxygen to body tissues) allows one to see how EDTA chelation can be beneficial in treating a variety of conditions. In addition to being successfully applied in heavy metal poisoning and atherosclerosis, chelation therapy has also found usefulness in the following conditions: myocardial and
coronary insufficiency, cerebral arteriosclerosis, Alzheimer’s disease, senile dementia, schizophrenia, rheumatoid arthritis, osteoarthritis, gouty arthritis, calcific tendinitis, calcific bursitis, kidney stones, gallbladder stones, multiple sclerosis, lupus erythematosus, Parkinson’s disease, Lou Gehrig’s disease, cataracts, glaucoma, cancer, osteoporosis, varicose veins, hypertension, scleroderma, Raynaud’s disease, digitalis intoxication, heart arrhythmias, hypercalcemia, heart valve calcification, peripheral vascular insufficiency, intermittent claudication, aortic calcinosis, aneurysm, cerebral ischemia, stroke, diabetes, diabetic ulcers, diabetic gangrene, diabetic retinopathy, macular degeneration, emphysema, leg ulcers, venomous snake bite, and any other condition where the problem is an interruption in blood flow because of atherosclerotic plaque, arterial spasm, due to excessive calcium ion concentration, a sluggishness of parathyroid glands in calcium metabolism, or a lack of collateral circulation.

Patients in our facility have reported being able to stop using nitroglycerin tablets for chest pain if they had heart disease, a reduction in the amount of insulin used if they are diabetics, stopping all leg pain on exertion if they have peripheral vascular disease, reduction in arthritic pain and swelling, and an overall improved sense of wellbeing. There are reports of increased energy levels, improved sleep, reduction in food cravings, improved ability to cope with stress, and a feeling of youthfulness and vitality. The more seriously advanced the illness, the more noticeable are the improvements.

**WHAT DOES CHELATION COST AND DOES INSURANCE COVER IT?**

Understanding the history of chelation therapy as reviewed above, it should come as no surprise that insurance and Medicare do not currently pay for this treatment. Only drugs that have gone through the full FDA approval process for a specific indication such as cardiovascular disease will be accepted as legitimate by the conventional medical establishment and be considered reimbursable by insurance companies. Also, there is tremendous pressure from the cardiac surgeons and cardiologists to suppress this therapy because it directly affects their very lucrative business. Cardiac by-pass surgery, stents and angioplasty account for tremendous revenue for these physicians as well as hospitals they use. We are in a different age now, post the TACT study, and with the second TACT study in the works, doors may eventually open that will allow coverage for this treatment but this is likely still a long way off.

For now, chelation therapy along with the supportive therapies and medical supervision that are integral to its success are not covered by insurance and therefore must be paid for out of pocket. These costs are not insignificant as regulations regarding the dispensing of EDTA and other components of the infusion have tightened in recent years, driving up the cost of supplies. The cost for this program is divided between the initial and periodic office visits necessary for monitoring and assessing response to treatment and the costs for the actual IV infusions and other components of the treatment. The individual chelation therapy cost is $172 for each infusion with patients undergoing a series of 30 infusions given on a weekly or every other week basis after which treatments are reduced to every 1-2 months for a year then every 3-4 months for maintenance after that.

While insurance will not reimburse for the IV chelation therapy itself, for individuals with certain insurance plans with good out of network coverage, the cost of office visits, labs and many other services may be covered at least partially. Laboratory testing is generally covered for all patients, with Medicare being one of the best in terms of paying for a variety of specialty testing. We work with all patients to balance what is medically needed for each patients versus costs, both what insurance can cover as well as what the patient has to pay directly. We are where to do as much or as little as patients wish or are able.
PATIENT DECISION MAKING

While the TACT study is clearly the best evidence available showing that chelation therapy might benefit those with vascular disease, new guidelines for addressing vascular problems call for the treating physician to have a conversation with his or her patients explaining the risks and potential benefits of all options of therapy meaning that chelation now must be offered to such patients as a treatment option. It is then imperative that the patient decides what mode of therapy sounds best to him or her. This is the new “gold standard” with the patient as the decision-maker, not the doctor. Chelation therapy should be discussed in light of the evidence of TACT. If TACT-2 replicates TACT-1, chelation might be suggested for all diabetic patients. With the current status of evidence, chelation therapy should be offered to patients as an option for treatment, especially if they have signs of vascular disease.

Physicians trained in providing intravenous chelation report better overall results than TACT. One reason that clinical practice might be better is that continued monthly maintenance is commonly offered after the basic course of treatment. TACT treated patients intravenously for 18-24 months then stopped treatment but followed them for 5 years, still finding that those treated with EDTA fared better than those who received the placebo. Another reason chelation doctors see better results could because in the TACT study, they did not follow patients using chelation challenge tests for heavy metals to assess how well the metals were coming out. A re-accumulation of toxic metals is not unlikely. Finally, other nutritional therapies are often added by integrative physicians. All of these measures contribute to the best care for each individual patient and would likely improve the overall results.

THE COMPLETE PROGRAM

As effective as chelation has been shown to be in clinical studies, in the real world, the greatest benefit in any health program is recognizing that many different components must integrate for optimum results. Chelation is not a magic bullet cure or a miracle drug. It is a tool to be used along with others for total health. At the very top of the list are dietary and lifestyle factors. Proper nutrition and a complete reevaluation of dietary patterns are necessary for patients who have always eaten a typical American diet (and particularly a typical Southern diet). Lifestyle awareness including proper exercise, avoidance of toxic substances, and control of alcohol, tobacco, and drug use are also top priority issues. Very specific nutritional supplements must be included in one’s daily routine to replenish any that are removed from the effects of the chelation. Also very important is the proper assessment of the function of each organ system of the body, including the digestive system, endocrine system (hormones), and organs of elimination. The ultimate goal is to insure that the highest quality food is taken into the body, thoroughly digested and completely absorbed, and then efficiently transported to the cells where nutrients can be taken in and utilized by the cell for energy. Then, most importantly, the wastes products from the burning of this fuel must be removed from the cell, transported to the organs of elimination, and efficiently removed from the body. When this cycle is working properly through the use of these integrative therapies, every cell in the body will be working at peak efficiency and this will create a situation in which disease simply cannot exist. This is optimum health. When maintained, life can be lived to its fullest and sustained with great vitality.