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## Chelation is option for heart patients

Process using fluid drip is less invasive, complicated than traditional treatments

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Edith Pye watches the slim needle enter her veins. She rests her head back on the large, overstuffed easy chair and closes her eyes. It will take about three hours for the fluid to drip slowly into her body.

Pye, 63, is undergoing chelation therapy for a heart condition she has had for the past six years. She was originally treated with a stent, a wire metal mesh tube used to prop open an artery to ease the flow of blood to the heart. The operation is less invasive than the more complicated bypass, open-heart surgery.

Saddled with a heart condition that could worsen, Pye was prescribed several medications to keep her cholesterol down and her blood moving. The medications were a big part of Pye's regimen. But it was a regimen that didn't agree with her.

"The negative side effects and reactions I had to the medications were just horrendous," she recalled. "I could barely walk a block without getting out of breath."

After her stent operation, doctors watched Pye's progress. If her condition didn't improve, she would need a heart bypass, a more serious operation that Pye wished to avoid.

She started seeking alternative approaches, especially clinics that administered chelation therapy, which she had heard about from family and friends. The therapy wasn't anywhere near her home in Pittsfield, Mass., and she eventually found herself on the doorstep of the Rhinebeck Health Center, long known for treating heart disease with chelation therapy. Within a year of starting the therapy, her condition improved, and her cardiologist nixed the dreaded operation.

Chelation therapy involves the use of a synthetic amino acid known as ethylene diamine tetra-acetic acid, or EDTA. When administered intravenously, EDTA speeds removal of heavy metals and minerals such as lead, iron, copper and calcium from the blood. The amino acid acts as a cleanser and is used to treat coronary artery disease because of its ability to flush out fatty substances, known as plaque, that clog the arteries.

Heart disease patients who have already been under the surgeon's knife for bypass surgery or balloon angioplasty — a procedure to keep arteries open — may opt for chelation therapy because it's less invasive.

"We first started treating people with chelation therapy around 30 years ago," said Steven Bock, who, together with his brother, Kenneth Bock, founded the Rhinebeck Health Center. The center treats about 10,000 patients a year for a variety of ailments, integrating mainstream medical practices with alternative approaches.

One of Steven Bock's first patients at the center was his father.



Chelation therapy patient Edith Pye receives a treatment from IV supervisor nurse Debra Truin at the Rhinebeck Health Center. Chelation therapy is administered locally at the Rhinebeck Health Center  
(Abby Luby/For Living & Being)

"He had a heart attack when he was 62. We gave him about 80 chelation treatments, and eventually his vessels were like those of a 50-year-old. He lived to age 82."

Although EDTA is not approved by the Food and Drug Administration to treat coronary artery disease, some physicians and alternative medicine practitioners, such as Bock, have seen patients respond positively over the last 30 years and are convinced the therapy works.

The alternative approach has steadily grown and an estimated 800,000 patients were treated with chelation therapy in the U.S. in 1997 alone, according to the American College for Advancement in Medicine.

The growing use of EDTA to cure heart disease caught the eye of the National Institutes of Health. In 2002, it launched the first large-scale clinical trial to determine if EDTA was safe and effective in treating coronary artery disease. The five-year "Trial To Assess Chelation Therapy" or TACT, set out to canvas more than 2,300 patients receiving the therapy at more than 100 research sites across the country and overseas. The Rhinebeck Health Center was chosen as one of the sites.

The study requires patients to be older than 50 and either to have had a heart attack or suffer from other coronary diseases. To date, not enough patients have enrolled in TACT and the study is still under way. According to Susan Dambrauskas of the National Heart, Lung and Blood Institute (a component of the National Institutes of Health), as of Nov. 1, the trial had enrolled 1,599 participants.

"Enrollment has been slower than expected, and now investigators aim to enroll between 1,700 and 1,900 participants for the study," Dambrauskas said.

TACT is a placebo-controlled, double-blind study.

"What this means is that patients, nurses or doctors don't know who is getting EDTA or who is getting a placebo," Dambrauskas said. "Since everyone is 'blinded,' it helps rule out any bias."

All patients enrolled in the study receive standardized care minimizing the risk of those taking placebos. The data about patients enrolled in the study are reviewed every six months by the study's Data and Safety Monitoring Board, which monitors individual sites involved in TACT. A final report on the effectiveness of chelation therapy for heart disease is expected two years after TACT is ended, which could be in 2010 or 2011, Dambrauskas said.

As part of the therapy, patients are given vitamins, minerals and certain antioxidants. They are advised to eat healthfully and exercise as an integral part of the treatment. Although adopting a healthier lifestyle while undergoing EDTA treatment makes sense, skeptics claim the lifestyle change is the real reason chelation therapy works.

On its Web site, the American Heart Association doesn't endorse the treatment: "After carefully reviewing all the available scientific literature on this subject, the American Heart Association has concluded that the benefits claimed for this form of therapy aren't scientifically proven. That's why we don't recommend this type of treatment."

Bock shrugs off the accusations.

"We aren't surprised by this reaction, but I know what I've seen over the last 30 years. We are now part of the whole health debate." Bock agrees a nutritional plan is essential to the treatments and prescribes an assortment of fish oils, garlic, enzymes and B vitamins. "Cutting out sugar, red meat, trans-fats — you have to do the whole ... thing," he said.

If the TACT study eventually determines EDTA benefits those with heart disease, the therapy could get a nod from the FDA. That would be good news for chelation therapy patients, whose health insurance companies do not cover the treatments. "It's expensive," Pye said. "So I try to space out the visits."

With treatments costing about \$200 per session, 30 to 40 sessions ultimately raises the final bill. Supplements are an additional cost not covered.

In the modest-sized L-shaped treatment room at the Rhinebeck Health Center, half a dozen people hooked up to intravenous apparatus lounge on recliners, some dozing, reading or sipping tea. Across from Pye sits Douglas Minard, also hooked up to an IV.



Chelation therapy patient Douglas Minard with IV supervisor nurse Debra Truin at the Rhinebeck Health Center. (Abby Luby/For Living & Being)

Minard requested chelation therapy not for a heart condition but as maintenance after suffering for years with a severe case of Lyme disease.

"I was very, very sick for about 10 years with Lyme. I'm doing this as a preventative," he said. Minard, 54, lives in Clintondale. He comes in for chelation therapy once a month.

Darting around the room from patient to patient like a mother hen checking everyone's pulse and vital signs is Debra Truin, a registered nurse who has been the supervisor of the IV department for nine years. Before attaching the IV, she gets patients settled in.

"You check how they are doing and ask about any changes since the last treatment," she explains. "We also check their urine and blood pressure, and make sure they have eaten before they come in and if they've taken their vitamins."

Triun said it's important to make patients relax during the long session.

"We encourage them by telling them this is the time to take care of themselves."

Over the years, Triun estimates that she has treated more than 200 heart patients with EDTA.

"Many suffered with angina for five, 10 years and got to the point where nothing was helping. Some had a heart attack and didn't want another. After about 12 treatments, they start to feel more energy and have less shortness of breath."

Pye smiles at Truin as the nurse checks the IV and takes Pye's pulse.

"Debra is one of the best reasons to come here," Pye said. "She is so bubbly, you forget why you're here."

## Additional Facts

### Resources

- For information on the TACT study, contact the National Center for Complementary and Alternative Medicine Clearinghouse at [info@nccam.nih.gov](mailto:info@nccam.nih.gov), 888-644-6226, TTY (for deaf and hard-of-hearing callers): 866-464-3615, or visit <http://nccam.nih.gov/health/chelation/studysite.htm>. Write to NCCAM Clearinghouse, P.O. Box 7923, Gaithersburg, MD 20898-7923.
- The National Institutes of Health Web site also has clinical trials information at [clinicaltrials.gov](http://clinicaltrials.gov)
- Call the Rhinebeck Health Center at 845-876-7082, visit [www.rhinebeckhealth.com](http://www.rhinebeckhealth.com), or write to the center at 108 Montgomery St., Rhinebeck NY 12572-1196.

### About EDTA chelation therapy

- Chelation is a chemical process in which a substance is used to bind molecules, such as metals or minerals, and hold them tightly so they can be removed from the body.
- Chelation has been scientifically proven to rid the body of excess or toxic metals. For example, someone with lead poisoning may be given chelation therapy to bind and remove excess lead from the body.
- In the case of EDTA chelation therapy, the substance that binds and removes metals and minerals are the salts of EDTA (ethylene diamine tetra-acetic acid), a synthetic, or man-made, amino acid delivered intravenously.

- EDTA was first used in the 1940s for the treatment of heavy metal poisoning. Calcium disodium EDTA chelation removes heavy metals and minerals from the blood, such as lead, iron, copper and calcium, and is approved by the U.S. Food and Drug Administration for use in treating lead poisoning and toxicity from other heavy metals.

Does EDTA chelation therapy have side effects? The most common side effect is a burning sensation where the EDTA is delivered into the vein. Rare side effects include fever, headache, nausea and vomiting. More rare and serious side effects include heart failure, a sudden drop in blood pressure, abnormally low calcium blood levels, permanent kidney damage and bone marrow depression (meaning blood cell counts fall). Reversible injury to the kidneys has been infrequently reported.

How might EDTA chelation therapy work to clear blocked arteries? Several theories have been suggested by those who recommend this form of treatment. One theory suggests EDTA chelation might work by directly removing calcium found in fatty plaques that block the arteries, causing the plaques to break up. Another is that chelation may stimulate the release of a hormone causing calcium to be removed from the plaques or causing cholesterol levels to drop. A third theory is that EDTA chelation therapy may reduce the damaging effects of oxygen ions on blood vessel walls, decreasing inflammation in the arteries and improving blood vessel function. None of these theories has been well tested in scientific studies.

Information courtesy of the National Institutes of Health

### **Chelation study**

If you're interested in joining the study, you should discuss it with your doctor. Participation in the study lasts up to five years. During that time, it is important to continue standard heart disease treatments. Participants are randomly assigned to receive one of several treatment combinations. Randomly assigning people to treatment groups helps ensure the treatments can be compared objectively.

Participants may receive:

- Either chelation therapy or placebo solution (an inactive treatment).
- Either high-dose vitamins or placebo pills.
- All participants receive low-dose vitamins.

Participants visit study sites for treatments once a week for 30 weeks. Then they have 10 more visits, between two weeks and two months apart. Each treatment takes about three hours.