



TACT TALK Special Edition

September 2004

Message from the TACT Clinical Coordinating Center

Since our last newsletter, several new sites have joined us, and I would like to take this opportunity to welcome all of all the newcomers.

The summer has been hard on TACT. Our enrollment has lagged, and, while we are still keeping up with projections, we are edging ever closer to the red. Thus, I need your help. TACT is definitely not an easy trial, and I recognize this. In recognition of this, we have developed extensive public relations material, and have numerous coordinator and PI calls to hone enrollment strategies. Please re-double your efforts to screen and randomize patients. With continuous screening, patients can be identified and randomized. To exemplify this point, this issue features interviews with two very successful TACT sites, Dr. Patrick Golden and Dr. Russell Silverman.

Please contact me directly or the clinical coordinating center, with any problems you encounter. **OUR GOAL FOR SEPTEMBER IS FOR EACH SITE TO TARGET 2 PATIENTS. IT IS NOT TOO LATE TO DO SO, AND YOU CAN HELP TURN TACT AROUND.**

We wish you well in your endeavor. Through teamwork, we will succeed. We are always here to help. ***Let's work together to meet and exceed our enrollment goals!***

Dr. Gervasio A. Lamas
TACT Principal Investigator

TACT TOP 15 ENROLLERS

<u>Site</u>	<u>Investigator/ Coordinator</u>	<u>Patients</u>
234	Rajiv Chandra/ Terry Murphy	36
227	Sangeeta Shah/ Janet Dunbar	23
220	Theodore Rozema/ Dolly Corbin	19
239	Randy Hartman/ Amy Heineman	17
113	Russell Silverman/ Sherri Loucks	15
312	Tammy Born/ Judy Schneide	15
406	Patrick Golden/ Kathy Sasser	13
115	Robert Weiss/ Diane Cass	10
112	Reed Shnider/ Jean Provencher	9
212	Joseph O'Bryan/Mary Barr	8
302	Greg Flaker/ Jamie Easley	8
326	Ken Ganapini/ Venus Barney	7
232	John Griffin/ Terri Mellinger	7
131	Terry Chappell/ Marcia Arnold	7
249	Connie Ross/ Michelle Simpson	7

TACT Total: 339
As of 9/13/2004



Congratulations!!!
To site 234, Dr. Rajiv Chandra, Terry Murphy, Michelle Pacetti and Jane Pauley who have randomized 36 patients.

From left to right: Michelle Pacetti, LPN, Terry Murphy (Study Coordinator), Rajiv Chandra, MD (Site Investigator), Jayne Pauley, RN



TACT SPOTLIGHT INTERVIEW



The first TACT spotlight interview is with Dr. Patrick Golden from Fresno, CA. Dr. Golden is a cardiologist who also practices chelation therapy. Currently Dr. Golden has 13 patients enrolled in the trial.

Pictured : Kathy Sasser, RN (left) and Dr. Patrick Golden

By Daniela Lamas

When Dr. Patrick Golden’s patients speak, he listens.

That’s why he started a medical website – askthedoctor.com – that aimed to grant patients worldwide access to medical information. That’s why the Fresno-based cardiologist started researching chelation six years ago, reading books like *Bypassing Bypass* on his patients’ recommendations. And that’s why his practice is now a TACT site, with 13 patients and counting.

Dr. Golden, who is a traditionally trained, non-invasive cardiologist, was so intrigued by his chelation research that he joined the American College for Advancement in Medicine in 1998. At his first ACAM meeting, he took a two-day course in chelation and returned to his practice to complete 1,000 treatments required (along with written and oral exams) to be certified in chelation. Dr. Golden’s patients and colleagues were receptive to the doctor’s foray into alternative treatments.

“I had established myself in Fresno as a traditional cardiologist/internist with a solid reputation. When I began to practice CAM it was met with little or no resistance from my colleagues. At least not openly to me. I was not ostracized by the community as my CAM colleagues were before me.”

Before chelating, Dr. Golden requires patients to undergo a urine provocation test for heavy metals. Most commonly, he sees elevated levels of lead, cadmium, aluminum or mercury. If he can’t demonstrate heavy metal toxicity, he doesn’t offer Chelation. “The only thing I’ve ever promised anyone is that I’ll remove the metal that shouldn’t be in your body, and good things can happen by doing that – which includes improved circulation.”

Dr. Golden currently has 13 patients enrolled. He started by recruiting solely within his own practice, where he had many post MI patients who’d never been chelated. (Although Dr. Golden performed chelation before TACT, he didn’t routinely offer the treatment to his cardiac patients. He mainly chelates patients who’ve sought him out explicitly for the intravenous infusions.) Now, he’s facing the “challenge” of actively recruiting beyond his practice, with TV and radio interviews in the works. He hopes to recruit at least 20 patients – and promises to share tips and success stories as they come.

“The way I look at it, that’s my part. If there are 120 sites and we each do 20 patients, then we have our study covered. We have our numbers.”

Florida Weather: Hurricane Season

Florida’s hurricane season is upon us! We would like to thank all the sites affected by this season’s weather for their efforts.



TACT SPOTLIGHT INTERVIEW



By **Daniela Lamas**

This second TACT spotlight interview is with Dr. Russell Silverman from Syracuse, NY. Dr. Silverman is a cardiologist who had never conducted chelation therapy prior to TACT. Currently Dr. Silverman has 15 patients enrolled in the trial.

Pictured : Sherri Loucks, NP (left) and Dr. Russell Silverman

As a mainstream cardiologist, Dr. Russell Silverman had never conducted chelation infusions before he became involved in the TACT pilot study.

But research and an open-minded attitude toward alternatives sparked Dr. Silverman's interest in the controversial intravenous infusions. "We tend to look at all options, particularly as it relates to the possibility of reducing vascular inflammation," Silverman said.

When Dr. Silverman started participating in the study, some of his patients had heard of chelation and some hadn't. But more and more, Dr. Silverman noted, patients are inquiring about complementary therapies. Now, his New York TACT site has 15 patients enrolled in the study.

While Dr. Silverman's site has faced some disappointment with patients who haven't wanted to participate, he attributes their successes to an honest, up-front approach.

"We always present this as non-mainstream therapy – that it's been done for many, many years without much knowledge in terms of whether it's a valid therapy," Dr. Silverman said.

Specifically, Dr. Silverman noted, some patients might hesitate to participate because they're afraid they won't receive EDTA chelation, but intravenous infusions of placebo. "The retort is that if you were going to get the drug, then it wouldn't be a study," Dr. Silverman responded.

To fellow TACT sites, he advised: "Be upfront with your patients. **Ask everyone you can possibly ask**, and be positive about the fact that it's a study, and it may or may not benefit them, and they may or may not get the actual drug."

REMINDER

Before submitting **ANY** advertisements or press releases, please make sure to send a copy to the TACT CCC for review. Upon review at the CCC, we will determine if IRB approval is needed. In addition, please notify the CCC of any future television or radio interviews one week prior to their occurrence.



MEDIA HIGHLIGHTS

WHAT OTHERS HAVE DONE...

Study investigators have been reaching out to local newspapers, broadcast stations, and even national outlets such as CBS Newspath, which is used by CBS affiliates nationwide. Here's just a sampling of recent headlines and study investigator quotes:

- Controversial heart therapy gets major study—CBS Newspath, 4/12/04

Study investigator quoted: Dr. Harmony Reynolds, NYU Medical Center

“Chelation therapy is being pursued by about 60,000 patients a year for coronary heart disease, and with so little evidence that it’s effective—if it is at all.”

“It’s a very important point of this study that all of the patients are receiving standard proven therapies for heart disease, and we’re trying to find out if chelation is useful with those therapies, not instead of them.”

Below are links to Harmony's interviews with the ABC affiliates in NY and DC:

- http://abclocal.go.com/wabc/news/health/wabc_ontcall_041204chelation.html?DCMP=EMC-wabc
- <http://www.wjla.com/news/stories/0804/165674.html>

- Beach doctor lends hand to see whether therapy can help hearts—The Virginian-Pilot, 5/15/04

Study investigator quoted: Dr. John Griffin, Sentara Virginia Beach General Hospital

Dr. John Griffin has fielded the question, "Does chelation work?" dozens of times from his patients over the years.

The cardiologist always gives the same answer about the alternative medicine treatment: "There's no scientific data to show if it does or doesn't."

Griffin, who practices at Sentara Virginia Beach General Hospital, hopes to help change that answer.

<http://home.hamptonroads.com/stories/story.cfm?story=68834&ran=144730>

- *Large study to examine effectiveness of chelation therapy— Pittsburgh Post-Gazette, 5/18/04*
Study investigator quoted: Dr. Ralph Miranda, Wholistic Health Center

“We needed to have a definitive study.”

<http://www.post-gazette.com/pg/04139/317741.stm>

- *National study evaluates therapy for heart patients - A Mount Dora doctor is among the investigators in a study to determine whether chelation can help improve blood flow—Orlando Sentinel, 8/16/04*
Study investigator mentioned: Dr. Jack Young, Tri Health Alternative Medical Center

The research is meant to answer a long-running debate in medicine: Does chelation prevent and treat heart disease? Or, as critics contend, is it a waste of time and money?

Young . . . said he will accept the conclusions of the research, even if it turns out chelation isn't beneficial for heart patients.

Link is no longer valid. If you would like a copy of the story, please contact Amy Lange at 202-745-5116.

Link to an Orlando Business Journal article also generated by Young:

<http://www.bizjournals.com/orlando/stories/2004/07/19/story5.html?page=1>

Note to Study Sites: If you have clips you would like to highlight in this column, please contact Alyssa Cotler at 301-451-3851 or at cotlera2@mail.nih.gov.