

Podcast Transcript

Dr. David Becker & Dr. Ram Gordon

Change of Heart/Red Yeast Rice Study- *Annals of Internal Medicine*

Conducted by Radio Talk Show Host Dom Giordano

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DOM GIORDANO:

Statins like Lipitor, Zocor, and Crestor are life-saving cholesterol lowering drugs that have been available for over 2 decades. They are some of the most prescribed medications in the world and we have all seen them advertised on television and in magazines.

Twenty million Americans take statins and recent studies have found that 11 million more Americans might benefit from taking them. Although these medications are usually well tolerated, they may have side effects, most commonly muscle pain and fatigue.

Many patients, especially those with these side effects, are interested in alternatives to statins. Joining us on this edition of the Cardiac Health-Cast are David Becker and Rom Gordon, two Philadelphia area cardiologists who are doing cutting-edge research in this field. Their latest study was recently published in *Annals of Internal Medicine*, one of the leading medical journals in the world. Dr. Becker and Dr. Gordon also practice medicine at Chestnut Hill Cardiology in suburban Philadelphia, and are on the staff of Abington Memorial Hospital and Chestnut Hill Hospital.

DOM GIORDANO: Dr. Gordon, let's start with you. I know a lot of our listeners take statins. What are some of the benefits and risks of these drugs, and why are these muscle problems such an important issue?

DR. GORDON: Statins have been around for over two decades, they have really revolutionized the way doctors have taken care of cardiac patients, they're really effective at lowering LDL or bad cholesterol and have modest effects at lowering triglycerides and raising HDL or good cholesterol. They are proven life saving drugs for people with really high cholesterol and anyone with a history of strokes, peripheral vascular disease, heart attack, stents or bypass surgery.

Most patients have absolutely no problem taking statins, but a small percentage of patients do have side effects, which can be serious and can cause them to stop taking them. Some folks have trouble with abnormal liver tests (which can be found only in a blood test), some people have problems with upset stomach, and some people do not think clearly.

But the most common problem is the development of muscle pain or fatigue. This is called statin-associated myalgia. Most people have muscle pain or fatigue without any damage to their muscles but some people can actually develop what's called myositis, which is actual muscle damage and a blood test called a CPK can tell the difference.

DOM GIORDANO: Dr. Becker, at some point, some of your patients with statin-associated myalgias started taking a nutritional supplement called red yeast rice, which supposedly lowers cholesterol levels. Tell us more about red yeast rice and how you became interested in studying its effects on your patients.

DR. BECKER: A couple of years ago I saw several patients that came to my office, and they were supposed to be taking Lipitor or Zocor. At the end of the visit I was commenting on just how perfect their cholesterol was. Their LDL was just within range. I was congratulating them for what a great job they were doing. These patients sort of sat back in their chairs, they got this silly grin on their face and they looked at me and said, "Doc I know I should have called you and told you this, but I stopped the Lipitor, it didn't make me feel quite right, and I took something call red yeast rice that a friend of mine told me about."

I started seeing this again and again over the next few years- people who were taking this supplement that I had never heard of. I didn't know where they were getting it. They told me they were getting it from the internet, TV ads, and ads on radio talk shows. It was working - it was lowering their cholesterol. I thought rather than just using this anecdotally and suggesting my patients take it, I would put together a study and that's what we've done.

DOM GIORDANO: Now is there's a particular red yeast rice though that you recommend or is this a general recommendation in this study?

DR. BECKER: There is a problem with red yeast rice, as there is with many nutraceuticals, because they're not regulated by the FDA. It's very difficult to know when you pick up a bottle in your health food store, your market, or your

pharmacy if it's a red yeast rice that actually both safe or effective. There are a couple of brands that we've recommended over the years, there's a particular great supplement which is available at a website www.natsub.com. I don't usually recommend particular products but this is one we have used in our study and we know that it works quite well as far as supplements go. It's tested, and it seems to be effective, and I think you couldn't go wrong with that one if you were going to choose a red yeast rice product.

DOM GIORDANO: Dr. Gordon, you two first collaborated about 3 years ago on a study published last July in the Mayo Clinic Proceedings. Tell us about that study and what you learned from it.

DR. GORDON: This was our first study and we took 74 folks with high cholesterol and simply divided them in two groups. One group (called the alternative group) took red yeast rice, fish oil and participated in "Change of Heart". This is a twelve-week holistic heart program founded by Dr. Becker about 15 years ago. The other group we simply asked to take 40 mg of simvastatin or Zocor. That's a pretty hefty dose of statin, and they took it every night for 12 weeks and were simply given the usual literature we would give to a patient when putting them on a statin drug.

We followed these guys for 12 weeks and the results of the study were remarkable. Both groups had similar drops in their LDL (or bad cholesterol) of about 40%. The other interesting thing is the alternative group lost more weight and had lower triglycerides than the statin group. We presented the results of the trial at the American Heart Association meeting that year and published them last year in the Mayo Clinic Proceedings.

Now the study got a lot of attention both good and bad, some folks were intrigued with the drop in the cholesterol in the alternative group and really wanted to know more about that. But there were some criticisms too; most of them asked why we would use an unproven alternative regiment when statin drugs which are proven and overseen by the FDA are available to everybody. The other folks wanted to know why we had used so many variables in our study and argued that we essentially compared apples to oranges. In other words, they wanted to know why we didn't put all the patients in the "Change of Heart" program. Now these critiques we took with a grain of salt, and they really helped us develop our next study.

DOM GIORDANO: Dr. Becker, before we get to the study you recently published in *Annals of Internal Medicine*, let's briefly talk about Change of Heart, the therapeutic lifestyle change program you developed about 15 years ago, since it is such an integral part of your research. What were the reasons you conceived such a program? How did you get that brainstorm?

DR. BECKER: Well I wouldn't call it a brainstorm as much as frustration. At this time, about 15 years ago, I was in private practice, (I still am in private practice) and I kept seeing my patients come into the office gaining five pounds every year, not exercising, their cholesterol going up. Next, they would flunk a stress test, and the next thing they knew they were on their way to bypass surgery or having an angioplasty.

It seemed like something was wrong with that approach, and it just didn't seem like the way I wanted spend practicing cardiology for the rest of my career. I saw some research that was being done by a physician named Dean Ornish, in California. He was an innovative internist who was putting people on a very, very, strict diet, (people would say it was so restrictive it was like eating cardboard). It was primarily carbohydrates and not much else, very, very spartan, but people did really, really well.

I got together with dietician Patti Morris, who help me to develop a diet that we call Modified Mediterranean, which is easier to follow than the strict carbohydrate approach of Ornish. I also worked with Jackie Yorko, an exercise physiologist and the three of us put together a multi-disciplinary program to change the way I was treating my patients - coming to the doctor's office for six months and getting a prescription and walking away with medication for the rest of their lives.

Just turning this whole thing upside down, and saying maybe there another way of dealing with these problems,-to help people to make life style changes, lose weight, exercise, and if they do all these things maybe they won't need quite so many medications, and we might actually improve their health without them needing bypass or angioplasty.

DOM GIORDANO: Dr. Gordon, when you joined Dr. Becker in practice a few years back, you immersed yourself in David's research and you became a co-collaborator and a co-presenter in the "Change of Heart" program. What convinced you that this approach could offer patients a real alternative?

DR. GORDON: Well that's a great question, when I first met Dr. Becker about four years ago, I had never heard of "Change of Heart" and I certainly had never heard of red yeast rice. In cardiology training programs, we are taught that statins should be given to nearly everybody and there's really very little emphasis on educating patients.

DOM GIORDANO: And for listeners- you're a relative young guy coming through this, I've met you and know that, you're coming through it not in the dark ages of twenty or twenty-five years ago you've just come through this ... and if you Dr Gordon didn't get what I think was any more cutting edge than what I thought just as an observer would be something you would at least discuss, that's kind of surprising.

DR. GORDON: It is. I finished up my training in 2005 and I came out getting the traditional teaching that medications are good, statins are for everybody, with very little emphasis on educating patients about their medical conditions. I think the biggest reason for that is because it takes a long time to explain all of these things to patients, and in the office I often do not have that time.

When Dr. Becker asked me if I was interested in getting involved, I really had no idea what to expect. And in the last few years I've become so impressed with this program and this research that I've really signed on as his partner. I like to tell people that he showed me the light. The testimonials from people that have gone through "Change of Heart" are amazing. They look great, they feel great, they lose weight, their blood tests are amazing. Many of them really feel like we've given them a new lease on life.

And as far as being involved in his research, I've now met many patients who refuse to take statins or have significant side effects from them. The biggest problem is in medicine there is no agreement there is no consensus on how to treat these folks and I've become convinced that our research may lead to some answers.

DOM GIORDANO: Dr. Gordon, let's talk about the most recent study that was published in the Annals of Internal Medicine. Tell us about the patients who were involved, where you found them and how they were randomized and treated.

DR. GORDON: This study came out in the June 16th edition of the Annals of Internal Medicine and we came up with the idea a couple of years ago. As I mentioned, there were some criticisms of the original study, which we incorporated into the new study. Specifically, all of the patients in the study had myalgias or muscle pains when they took statin drugs, and had to stop them. Everyone had taken at least one statin and most took two or more statins and could not tolerate it.

In studies that have been done to demonstrate that statins like Lipitor, Crestor, or Zocor work, only about two percent of people developed these muscle aches. However, what most doctors have found in their actual clinical practice is that up to 15 % of people have these muscle problems, and have to stop their medication.

We recruited these folks from the Philadelphia area, mostly from our office in Flourtown, Pennsylvania. We screened potential participants using a simple questionnaire and we found 62 patients with high cholesterol who had stopped their statin drugs because of muscle pains. Anyone who had actually developed muscle damage (and not myalgia, which is muscle aching) was not allowed to be in the study because of the high risk of that happening again.

DOM GIORDANO: Let me ask Dr. Becker to discuss a very important aspect of the study. Where I work in the media and talk radio, when something is in the news, credibility is an important issue. And in the medical field, we've seen lots of stories about studies that tout a particular course of treatment, only to find out that it was conveniently and coincidentally funded by a pharmaceutical company. So where did you find funding for your research?

DR. BECKER: Our studies have been funded through a grant from the Commonwealth of Pennsylvania. The money was to study the effects of lifestyle changes and how we might help people's health in this great state we live in. Now that's a really great thing on multiple levels.

Many of the studies that are coming out today have a hidden agenda -they are often funded by pharmaceutical companies or people that make medical devices. And in cardiology, much of the research that is presented has some agenda, as somebody's funding it. Although the results might be good, I think it's smart to look at these results with a jaundiced eye.

Obviously our research is not being funded by a pharmaceutical company, because I don't think they would have a whole heck of a lot of interest in funding

something like this. But I would also like to mention that we are not being funded by a nutraceutical company. This is research that, not to sound corny, is being done to answer a question that our patients have raised: how do we find a treatment for people with high cholesterol that can't tolerate statin medications?

As we do this research and learn more about different options that really seem to work, sometimes Ram and I feel a little bit frustrated. We see more and more information coming out in cardiology that statins should be used for everything, and we see more and more side effects in our practice. The general consensus among many cardiologists seems to be that these statin drugs are just so great they should be everywhere, perhaps even in the drinking waters. Well I would take a step back before we would put this stuff in the drinking water- it would make me want to drink bottled water!

DOM GIORDANO: Dr. Becker let's get back to the findings of the study. Tell us about the results of the study and why they might be important for our listeners, some of whom may have statin-associated myalgias and even for those that don't but are wary of this and hear all this information that is out there tell us what you found in this study.

DR. BECKER: We took 62 folks who had statin-associated myalgias. They were all in the Change of Heart study, half of them were given red yeast rice, three 600mg capsules twice a day, and half got identical placebo pills. The red yeast rice that was used was sent to an independent laboratory to make sure it was red yeast rice of the appropriate strength, and had no potential contaminants. We followed these folks for a total period of 24 weeks and asked them to get blood tests for cholesterol and liver abnormalities, and surveyed them for muscle pain and damage. None of our patients knew which group they were in.

In the end, we had dramatic responses in both groups. Both groups lost the same significant amount of weight, but the group that took red yeast rice had significant drops in LDL cholesterol and in total cholesterol. There was no significant difference in the development of myalgias. This was surprising because folks who develop statin myalgias often will redevelop muscle pain if you give them another statin. So these were very promising and interesting results.

DOM GIORDANO: Dr. Gordon, red yeast rice sounds like it has a lot of potential as an alternative therapy for statin association myalgias. Are there any problems or concerns about red yeast rice that our listeners should be aware of?

DR. GORDON: Absolutely. One of the problems with red yeast rice that Dr. Becker mentioned before is that it is not regulated by the FDA. When you buy it off the shelf you really don't know what you're going to get. Again, the red yeast rice we used was sent to an laboratory for analysis, but in the real world there is no such oversight.

We presented a recent abstract at the American College of Cardiology meeting last March where we tested 12 different products and found that they all have very different amounts of red yeast rice. One was actually spiked with a prescription statin drug, some had absolutely no active ingredient at all, and about third of the products had potential kidney toxin. So again, we believe that red yeast rice has a lot of potential for folks with high cholesterol who have these muscle aches, but we can't fully recommend it until there is better oversight and regulations.

I do want to mention that red yeast rice does have a small amount of statin in it, so if you do take it you should have your cholesterol levels monitored and blood test every few months to check for liver problems. So no one should take red yeast rice without first talking to their doctor.

DR. BECKER: I liked to echo that I think it's very important to that people talk to their doctor. One thing I've seen as well that some people come to the office and they're taking Lipitor or Crestor and red yeast rice and you would certainly never want to take both of these things together.

DOM GIORDANO: And Doctor, if their doctor doesn't approve of this and they still want more information what can you advise, Dr. Becker, around that? What do they do if they're listening and they have the doctor that doesn't agree with this or is not up on this or whatever it might be, what do they do?

DR. BECKER: Well one of the things that we do in "Change of Heart" program is try to help people that who participate in the program to go back and talk to their doctor.

DOM GIORDANO: Arm them with information?

DR. BECKER: Yes, arm them with information. And also realize a lot of time you can go back and talk with your doctor and make it almost seem like it's his or her idea.

For example, it's a total success if you see your doctor and say, "you know, I've been really doing great, I've been exercising, and I've been dieting, I've been following this wonderful program, and I was hoping if you don't mind since I don't have known coronary disease, and I really think I could do this, and I realize that diet and exercise might not be enough alone could I take some red yeast rice. Now that might work. On the other hand, if you go into the doctor's office and say I stopped my Lipitor because Dr. Becker said this red yeast rice it's really great. Then I'm not going to have much of a program and we're going to have a problem.

DOM GIORDANO: Dr. Becker, your research has been very well-received over the past few years. What's next for you and Dr. Gordon?

DR. BECKER: We have an exciting new study which we are currently getting started in July. We are going to look at people who are both in the "Change of Heart" program and also people who are not part of the program but are just going about their regular business. And everybody in both parts of the study are going to be taking red yeast rice. But one of the things that has concerned me is the red yeast rice alone might not be enough to bring cholesterol down to the low levels that we know prevent coronary disease. We are adding (for half the patients in the trial) something called a phytosterol, which is an over-the-counter natural ingredient which lowers cholesterol by preventing cholesterol absorption in the intestine and the stomach. It seems to be extremely very well tolerated, it is the same substance that is in many of the margarines that are sold in your local supermarket.

The hope is that the combination of aggressive life style changes in a program like a "Change of Heart", red yeast rice and this phytosterol might bring cholesterol values down just as much as the super strong statins that are so effective to lower cholesterol, but yet many people can't tolerate. We are going to try to get as many people as we can in this study who can't tolerate statins as the main goal is to show that this is an alternative for people who just can't take them. Other people that will get in the study will be people who have been recommended a statin but just refuse to take them.

DOM GIORDANO: I want to thank my guests, Dr. David Becker and Dr. Rom Gordon, for their insights about statin-associated myalgias and about the promising

role of red yeast rice in treating this condition. For the Cardiac Health-Cast, I'm Dom Giordano.

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