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A Look into the Effectiveness of Dietary Supplements

Dr. Sorrentino:
Americans spend a whopping $50 billion a year on dietary supplements claiming to improve heart health and lower cholesterol according to a new study published in the *Journal of the American College of Cardiology*. However, the research study found that six commonly used supplements did not show any significant reduction in total cholesterol or LDL cholesterol. So are we wasting our money? And what do we know about these supplements?

Welcome to *Heart Matters* on ReachMD. I'm Dr. Matthew Sorrentino. And joining me today to discuss the findings of the Supplements, Placebo, or Rosuvastatin Study, or the SPORT trial, is lead author Dr. Luke Laffin. Dr. Laffin is the Co-Director of the Center for Blood Pressure Disorders at the Cleveland Clinic.

Dr. Laffin, thanks for joining us today.

Dr. Laffin:
It's wonderful to be here. Thanks for having me, Dr. Sorrentino.

Dr. Sorrentino:
It's great to talk to you again, Luke, and this study is really interesting because, as pointed out, so many of our patients use these supplements. So let's first go over the background of the SPORT trial. What was the purpose of the study? What were you trying to analyze in this study?

Dr. Laffin:
Well, as you alluded to, the genesis of the study was really as clinicians we see patients' medication lists increasingly littered with X, Y, and Z dietary supplements, and so we really wanted to see—do those make a difference in terms of changing lipid or inflammatory biomarkers? And so we identified six common supplements that are often times marketed for cholesterol health or cholesterol management heart health, and we compared them to a low dose of a statin, which was five milligrams of rosuvastatin and placebo. The supplements were fish oil, turmeric, cinnamon, garlic, red yeast rice, and plant sterols.

Dr. Sorrentino:
So how did you design the study? Tell me what the patient population was like. Did they have high cholesterol? And then how did you decide on who would take what supplement?

Dr. Laffin:
So the study was a prospective, randomized clinical trial. Us as investigators, were formally blinded to what participants received, and we randomized patients to one of the eight groups, so five milligrams of rosuvastatin, one of the supplements, or placebo. They had blood work done at day zero, so before they started things, and then again at day 28, and the blood work that was obtained was a CMP, a lipid panel, and an hs-CRP. The participants that were included in the trial were anybody between 18 and 75 years of age. They had

to be a primary prevention patient, so no history of atherosclerotic cardiovascular disease. They couldn't be taking a statin or other lipid-lowering therapy at this time. They needed to have an LDL cholesterol between 70 and 189 milligrams per decilitre. And they needed to have a 10-year risk of ASCVD based on a pooled cohort equation of between five and 20 percent. We randomized 199 individuals to the study and did biomarkers at the beginning, as I said, and at the end.

Dr. Sorrentino:
So it sounds like this is a population of patients that if they came into our office we would usually recommend some sort of lipid-lowering strategy. They were at the risk group that a lipid-lowering agent would be recommended.

Dr. Laffin:
And that's what we really wanted to reflect in the study itself. Nobody is saying that everyone needs statins in this scenario, but this is a group that they should have a discussion based on those 2018 American College of Cardiology and American Heart Association lipid guidelines. And in fact, the time period to follow-up of the response to either statin therapy or lifestyle changes as reflected in the ACC guidelines is in that 4-week to 12-week period, so it's very much in line with contemporary lipid-management guidelines.

Dr. Sorrentino:
That was actually going to be my next question. Would you expect with five milligrams of rosuvastatin, for example, that within four weeks you would be at a new cholesterol level? Does it get down to your new steady-state level in that short period of time?

Dr. Laffin:
Yes, it does. Actually, really within about 14 days it does. But we carried it on a little bit longer to, again, be consistent with those guidelines that say it had assessed adherence and response to lipid-lowering therapy in that 4- to 12-week period, so we picked four weeks.

Dr. Sorrentino:
And you would expect then that if the supplements were working, we would see some effect within four weeks, as well.

Dr. Laffin:
You would think so, right? I mean, one of the criticisms that the study has received from the supplement industry is that, "Oh, you have to take it for longer." Well, our question for them is, "How long does one take it?"

Do you have to take it for 50 years to see a difference? If you look back at other studies of garlic or fish oil, they have been anywhere from four to 12 weeks in this scenario. It doesn't really make a difference what you look at. They don't really work.

Dr. Sorrentino:
So did any of these supplements at all get close to what rosuvastatin was able to do?

Dr. Laffin:
No, they didn't. So the primary endpoint was reduction in LDL cholesterol for rosuvastatin five milligrams compared to placebo and then each of the supplements in a hierarchal fashion, so what that means was it was so we could limit our total number of individuals enrolled. So there was stepwise comparison, and if comparison didn't meet statistical significance, then all future comparisons or further comparisons stopped. And what we saw was from baseline, LDL cholesterol was decreased 37.9 percent with the rosuvastatin, which was vastly superior to any of the placebo or other studied supplements in this area, so it clearly met its primary endpoint.

Secondary endpoints that we looked at, as well, were other changes in lipid biomarkers, so total cholesterol, triglycerides, HDL cholesterol, and hs-CRP. And so we looked at rosuvastatin compared to placebo and then each of the supplements, and then an additional secondary endpoint was just looking at the supplements compared to placebo, as well.

Dr. Sorrentino:
For those just joining us, you're listening to *Heart Matters* on ReachMD. I'm Dr. Matthew Sorrentino, and I'm speaking with Dr. Luke Laffin about the findings from the SPORT trial.

Luke, you just talked about some of the supplements many people use for very specific reasons; fish oils, for example, is one that I'm thinking of. I wouldn't have expected it to lower LDL very much, but some people use fish oils to lower triglycerides. Did you see any impact of the fish oils on triglycerides in your study?

Dr. Laffin:
We didn't. We didn't see any statistically significant impact in a positive direction for any of the supplements compared to placebo for any hs-CRP or any of the lipid biomarkers. In fact, when you look at LDL cholesterol, Garlique actually increased LDL cholesterol 7.8 percent, and plant sterols, when we looked at placebo, corrected HDL levels, actually lowered HDL cholesterol significantly, so any type of significant finding with the supplements was actually moving in the wrong direction.

Dr. Sorrentino:
So with this type of information that you've gotten from the study, why are our patients still using these supplements if there really is no good data showing that what we're trying to achieve, a lower cholesterol for example, is not being achieved at all and sometimes going in the opposite direction?

Dr. Laffin:
Well unfortunately, we see a lot of misinformation around statins and their purported benefits and risks associated with them. There's a lot of belief out there that statins cause all kinds of bad symptoms. So people are searching for something "natural," whatever that means, because these are pills manufactured in some type of plant anyway, and so that was another important thing that we wanted to really address in the SPORT trial or aspect is the safety of a low dose of statin. So numerically, really most of the supplements and placebo had about the same number of adverse events associated with them. They weren't common. And actually, if you look at it just on a numerical basis, plant sterols and red yeast rice were a little bit more numerous in terms of their adverse events. Importantly, when you looked at the low dose of rosuvastatin, no one had any musculoskeletal complaints, so no statin-associated muscle symptoms, no one had any neurological complaints, and there was no significant elevations in blood glucose or AST and ALT, all the things that are commonly prescribed to statins but obviously are more beliefs rather than actual evidence.

Dr. Sorrentino:
So how do you counsel your patients then who come to you and say, "I want a natural supplement?" "Which one should I take for my heart health or for my cholesterol?"

Dr. Laffin:
I say, "Get all your dietary supplements through your diet, really." Try and eat a balanced diet as much as possible. If we need to refer them to a nutritionist or a dietitian, we definitely can do that, but I don't recommend these supplements because there's just not the consistency that we see in terms of how they're produced and what you're actually getting as a known product. And these are not necessarily benign. Because we don't necessarily know what's in them, we can see drug-drug interactions. And it doesn't have to be with cardiovascular medications. It can be with other medicines taken for other issues, so that's not insignificant. An analysis in *The New England Journal* a few years ago showed that there's about 23,000 visits a year to the emergency department for dietary supplements.

Dr. Sorrentino:
And as a final question, how do you counsel your patients who are very reluctant to take a statin? They clearly fit into the risk category that a statin would give them clear benefit. Is there something from this trial or how you counsel patients to relieve them of their fears about statins?

Dr. Laffin:
In folks in this specific category—so primary prevention, LDL is a little high, elevated cardiovascular risk—one thing we'll do is, if they're very reluctant, we'll have a discussion about is there certain tests we can do to maybe say we don't have to start a statin, so that's a great scenario where you'd order a coronary calcium score to really get a better sense, and if it's zero, then we can defer it for a few years. But if we know that really they would benefit from a statin, then it's starting low and going slow and showing them the data. Five milligrams of rosuvastatin is a great example because it's such a good combination of efficacy and tolerability. I've had so many patients who they have been resistant for years for starting, and I say, "Let's just start on low dose, five milligrams," and then they come back three months later, and they're just like, "Thank you. My numbers look so better."

Dr. Sorrentino:
Well this has been a very informative discussion on the impact of dietary supplements, or I really should say the lack of impact of dietary supplements on our patients' cholesterol levels. I want to thank my guest, Dr. Luke Laffin, for sharing his findings from the recently published SPORT trial.

Dr. Laffin, it was a pleasure talking with you today.

Dr. Laffin:
Great speaking with you. Thanks for getting the message out about this trial.

Dr. Sorrentino:
For ReachMD, I'm Dr. Matthew Sorrentino. To access this and other episodes in our series, visit ReachMD.com/HeartMatters where you can Be Part of the Knowledge. Thank you for listening.