Introduction to Dr. Earls and Cleerly Health

Hi, everybody, this is a really great session we got coming up. So pay attention and put the dog in the other rooms. You don't have any distraction. You want to really learn with one of the best.

We brought really a premier academic and leader in the field and I want to give him full justice. James Earls, MD goes by J., Dr. J. Earls, Professor Radiology.

Before he joined the company, called Cleerly Health C L E E R L Y health. He was vice chairman of radiology at a big place, George Washington University and of course, Washington, DC He also has served as medical director, vice president of a radiate radiology consulting group in Fairfax, Virginia, board of directors of the International Society of Magnetic Resonance in Medicine and a lot of others.

150 articles. He is this consummate academic doctor and clinical doctor. And if you want to know about heart arteries, if you want to know about reversing heart artery disease, this is the guy if you remember last year we had Dr.

James Min, who founded a company called Cleerly Health. And this team of Dr. Earls and Dr. Min is literally a one two punch that we're bringing the year to understand.

And as I say, you can't really have a good discussion about reversing heart disease. Do you know how to measure it and know how to reverse it? And Dr.

Ornish achieved that using technology available in 1990. But that's not what we do now. Things have advanced. So thank you so much, Dr. Earls Thank you. It's a pleasure to be here this evening.

Yeah, maybe take a couple of minutes and not all the audience and my podcast anywhere. Again, I talk about Cleerly Health all the time and it's a huge portion of my practice, but not everybody knows what it is.

Why don't you just break it down in simple terms, what it is and how it's different? Anything else we've ever had in the heart imaging field here? We do at Cleerly as we take a CT scan of the heart and for the first time we actually measure coronary atherosclerosis or the disease process itself.

And so we actually are able to separate the plaque out from the arteries and we can accurately determine the quantity of plaque. And there are actually several different types of plaque.

And these plaques have different risks to the patients. And so we're able to also determine how much of each of the different types of plaque that are present.

So sounds like a relatively simple advance, but in fact, for many years we measured many other things about heart disease, but we didn't actually measure the disease process itself.

And so that's what we have introduced to the marketplace in the last few years. Oh, well, excellent. So it's a CT study. So it is involving some radiation.

We're not talking now about calcium scoring. Many of the audience knows about calcium scoring because we're here talking about a procedure where a I. V.

is placed, where iodine contrast agents are injected. They're not radioactive. They're iodine. They make you feel warm. You do have to have healthy kidneys.

How Cleerly Measures Coronary Plaque

You do have to be free of a serious allergy to iodine and you have to chill out and get your heart rate down either spontaneously. When I had my study, I had a very low heart rate without medication or you take a little bit of medication to make sure your heart rates low for the quality of the study.

But really, it's about a 25 second, 30 second study when you really get down to the brass tacks and as you said, we can measure black what kind of black produce amazing reports and quantify it and get great pictures and great numbers.

And what do we got? I first heard of Cleerly Health CT Angiogram studies using artificial intelligence. I first heard of them in early 2021. Maybe I was a few months late to the game.

You know about when the they started to roll out. Yeah, we were founded in 2017, but of course it took us a few years to develop a product who is right early or late 2020 or early 2021 that we first commercialized and started to scan patients here in the U. S..

Okay. And I will say, no matter where you're listening in the US, Idaho, Florida, California, Pennsylvania, Texas, Michigan, Ohio, Indiana, you can get a Cleerly Health CT angiogram.

You might get one at an imaging center that is designated as a Cleerly Health center. But I have ordered these at university centers and large hospitals all over the United States and my own patients takes just a little bit more work to get it done at UCSF or Harvard Hospital or wherever you want it. And there I'm sure the company can help you arrange that if you're interested after this conversation.

So I have an interesting case, but why don't you throw a case up that you brought? We we aren't doing these with PowerPoints. Typically, these are conversations, but this is such a visual thing.

Why don't you throw it up there if you have one, and then I'll do that too. I'm happy. I think you need to enable my Oh that may be. Screen share there.

That may be interesting that multiple the but that's try you tried there was some you said multiple participants can share. Yeah but. I do. Good. I've never done that before.

Thank you. Yeah. Here's a case of patients who actually shows what we call a regression. So on the left hand side is the patient's baseline study, which you can see was done back in 2017.

The patient came back in about a year and a half later in 2018. And I just want to tell people, look at the purple column and really small print says March 1, 2017, up and down with four circles.

And then look at the bold blue collar royal blue. And it says 10/31/2018, about a year and a half later, because most people have never seen that. And these these aren't the pictures.

These are the data. Maybe we'll see the pictures that are derived from analyzing the artery pictures. But go ahead. Right. We'll show a picture here in just a second. But starting with the total quantity, there's 445 cubic millimeters of plaque initially, the patient came back a year and a half later and that was actually down to 311.

And when we divided it into the different types of plaque, you can see the non calcified plaque. Second number in the row also went down substantially, but probably most importantly the low density plaque.

This is the plaque which is by far the riskiest plaque in the plaque that causes acute coronary events that went down by over 50% between the studies, something.

Never seeing that much. And, you know, a few hundred studies, 67.8 cubic millimeters of waiting to have a heart attack plaque Absolutely. And and we take that plaque and as you understand it is the risk is we color it red

because it is by far the risk is plaque to the patient.

So initially this image is up top. You can see this big plaque with all this red plaque within it. When they came back a year and a half later, you can see that it's sort of like taking air out of the balloon.

This plaque is much smaller, the amount of red plaque and there has substantially gone down.

Regression Case: Plaque Reduction With PCSK9 Therapy

There's still a fair amount of red and yellow plaque there, but really a tremendous change in a year and a half for this patient, you know, really represents a significant lowering of their individual risk of having a heart attack in the future.

And I just again, people are looking at numbers, but you kind of got to go from left to right for 444 was reduced to 311, which means the amount of I'll use a term not everybody likes crap in the arteries was reduced.

This is reversing heart disease everybody. But we're proving it in a way that's measurable and academic. And then there's different kinds of plaque. This patient was nothing but a fat blob because almost all the plaque is called non calcify plaque.

This patient would have had essentially a calcium score if you went for the low cost routine c.t scan of zero or one or two and but yet was carrying a huge burden of dangerous stuff.

Which is why your company doesn't really stress the calcium score because you're going to miss. Here's an example. You'd miss a enormous amount of risky disease in the heart arteries if you just went with a low cost calcium score. Wow.

That's right. And for many years, of course, we did predominantly use the calcium score because that was the only type of plaque we were able to follow.

But with advances in imaging as well as A. I., we can now actually look at the other types of plaque, and it's the other types of plaque which actually place you at risk.

And so, yes, certainly there's cases where patients have low calcium scores and that can give you a sort of false sense of security in some situations, because with a low calcium score, you could actually still have a relatively high amount of the other types of plaque, which are riskier.

Certainly there's times to, of course, where a low calcium score also means there's a low non calcified plaque burden, but in some cases it can go the other way around.

Yeah. And I would predict of course we're not presenting the whole patient here and their labs, but the few I've seen that are this dramatic, like almost no calcified hard plaque.

And I call the non calcified plaque, I call it fatty, buttery cheesy plaque in the office because I want them to understand that's not what they're supposed to be eating.

I would predict this patients over weight got the metabolic syndrome or pre-diabetic and inflammation and LDL particle numbers are crazy because to get this kind of, you know, fat filled heart arteries, you got to be metabolically just a disaster.

I mean, it's unusual. Yeah, I think you're right there. If you actually look at the background here, you notice this is a very noisy scan, which is something that generally happens in obese patients.

So I do believe this patient is substantially overweight. And that was one, you know, has metabolic syndrome or other metabolic abnormalities that contribute to this high amount of blood entity plaque.

And I don't think we've actually seen a picture yet of the arteries. Maybe you've seen it. Well, we're seeing is data, which is great. But can you guys all.

I'm sorry and unlike on my thing it was actually. Got it now we're looking at the actual arteries color coded like you mentioned red for risk risk risk and yellow for soft and blue would be the calcified plaque you can't even see any calcified black because the number was so low and this is that the baseline above and the follow up below and look how much of the red went away and do you know what they did?

I imagine massive pharmacologic you know drug therapy. This this patient was on a PCSK9 inhibitor for about 18 months. Okay. And that's for people that are aware drugs like Repatha, Praluent, you have to inject them every two weeks.

You have to get insurance pre-authorization. And I'll say because we got a lot of listeners that are plant based eaters, we don't know because it hasn't ever been studied.

If you can get these same results by just eliminating animal foods and eating whole plant foods, as Dr. Ornish talked, I think you could I don't think you could do it this quick.

Remembering Dr. Ornish, his study was five years follow up. And here we got about a year and a half. So in my clinic, we teach excellent nutrition, but we use supplements and pharmacologic agents to attack this from multiple routes.

So excellent. Wow. They got to see their drill. I think that plant based diets can also cause favorable plaque changes. I'd love to see a good randomized controlled trial proving that, but at least anecdotally, we have seen patients that we support who have come back, you know, within a couple of years and had very favorable plaque changes in those situations.

Good, good, good. Yeah. We need to get the Broccoli Sprout Growers Association to fund that thing, but they're going to have to come up with ten or $20 million.

All right. What do you want to show another one? And then I'll perhaps. Share another case here. I will see some similar favorable numbers in this case.

Actually, a larger overall reduction. So this patient had a 60% reduction in their total plaque volume over about a year and a half or a year and a couple months.

In this case, this patient also had Inclisiran, which is a new injectable medication. You can see that a much lower amount of low density plaque starting out at six cubic millimeters, but actually drove it down to zero.

And that what we typically see in these cases where the non calcified plaques are decreasing, we do have a little bit of an increase in calcified plaque as that non calcified plaque often gets transformed into calcified plaques.

Why Calcium Scoring Can Miss Risky Soft Plaque

So, you know, an increase in calcified plaque or an increase in the in the calcium score can actually sometimes be a good thing because it represents conversion of the non calcified plaque into the more stable and more benign calcified plaque.

And again, I want people to look we got a perfectly and before you go I just want to go back to yeah, we got a purple column, look up and down. That's January of 2022.

It's a new term for most people. TPV total plaque volume is 349 millimeters, then look to the right. 13 months later, 349 is down to 138. And you helped this out here.

60% of the plaque in the heart arteries disappeared in 13 months. That is amazing in this case, because of a

powerful drug agent that lowers cholesterol.

And this is a patient like the first one. Most of the plaque was fatty, buttery, cheesy. There's my bias again, plaque, non calcified plaque. So the calcium score wouldn't have been very impressive here, but the disease is impressive and 68% of their fatty plaque, it's just like sucking it out with a or with a suction machine.

But we did it with, in this case, maybe some lifestyle, I don't know the patient, but powerful medication. And I tell you, the number one question I get asked, how do I lower my calcium score? And it's what you just said.

I tell them, I don't think you can and I'm not sure you want to, and I'm not sure if your calcium score wanders up a little bit. It's so bad we got to get rid of this soft plaque, which we did here quite well, just shows the picture by clicking a number eight or nine.

Yeah, this is the same patient. Yes, this is same patients on the top. You can see that the blue plaque here is the calcified plaque, as we had said earlier.

But you can see it's sort of surrounded by the yellow plaque. We have yellow plaque there below it. And then when they came back a year and a half later, you can see really the the calcified or blue plaque remains.

A lot of that yellow plaque now has disappeared. So really, again, very favorable for him. Slight increase in the overall amount of calcium, but a dramatic decrease in the amount of non calcified plaque which as a result for this patient, dramatic decrease in this patient's individual risk of a future event.

Isn't that great? So people can get a clearly scan, they have to get a physician order it and I can tell you firsthand, the majority of cardiologists so far have not ordered clearly scans.

I think that will change. It is still largely a cash luxury item. If you call your health luxury item called luxury, I got essential, but I'm seeing more and more of my patients. I had one today.

Tell me, hey doc, half of my clearly scan was covered by my insurance. So it's changing somewhat, which is good. And you know, it defines better than anything else on the planet.

I tell patients that have a clearly you just got the same test that the wealthiest person in the world could get to evaluate the heart. There is nothing better and I don't mind shouting it out.

It's about 1500 dollars plus or minus a little bit. So it's not 15,000 or something completely out of range, you know, and people may have to dig into their pocket a bit to come up with it, but and then you might want to do another one and, you know, 15 months, 20 months, 36 months, depending on your risk to see how much it's improved.

Are there any you know, of course, clearly was developed out of research studies with Dr. Martin and the others around the country. Are there any research studies right now that, you know, an academic center is using this technology to study a drug or a gene therapy or anything else on the planet?

Oh, there's a tremendous amount of research currently going on. We have about 30 odd trials that we're participating in, in mostly in the United States, but also overseas.

You know, looking at the effect of different medications that the effect of sex, age and race, you know, other biomarkers of disease.

Second Case: Major Plaque Reduction With Inclisiran

And we're using our tool to quantify, quantify it and to see, you know, what changes may take place. So, yes, absolutely. A lot of research going on. We're standing up.

A very large trial of asymptomatic patients currently will enroll about 8000 patients over five years. We have, I think

the first patient should be enrolled in the next month or so, but we will be a quite a few places across the U. S.

enrolling for that trial. And better call me, I'll put a few in. So if anybody's listening and they're very wealthy and they want to fund a plant based, randomized study or just it would actually just be people with a baseline study completely plant based.

And a follow up called Dr. Earls Let's fund that thing. Maybe our friend John Mackey, you sold Whole Foods to Amazon is listening by chance wants to do that, improve that concept so.

Well we've been talking for a little bit and it certainly is fascinating. I think we're going to take a brief break and say goodbye to our general audience and stay for a little bit longer with our premiere package group.

I just want to ask you, I mean, a person that's excited about this and they should be everybody should be. Your website is a good place to start to learn a little bit more.

Yeah. So you certainly have information about the technology in our website, some of our research information is there. There's also information of what centers around the country.

You can put your zip code in. It'll tell you what centers are closest to you. I mean, we're still relatively new companies that we do have cities and towns in the U. S.

that we don't have a center at. But as you suggested, many people still have a place you can get a city locally and then you can get in touch with us for processing of the exam.

And I know I periodically get emails. Your company does fairly interesting webinars where you put in your email and you get alerted that it's there and if you missed it, you can watch recording.

It's okay and they're free. Of course that's okay. Members of the public want to participate in that. Yeah, absolutely. You know, we do design them for providers, health care providers, but we have lots of patients who actually join.

And I'm always surprised, frankly, at the sophistication of the questions that we get from our non-physician and non provider participants. And we've just seen some amazing examples.

They happen to be examples of extreme amounts of what is called non calcified soft plaque that fortunately with intensive therapy was a very dangerous black that shrunk significantly in a relatively short time.

You know, other people are different and there's, you know, largely calcified plaque and little harder to move the needle. I brought a case and let me see.

I may have to go. Let me see. Shared screen. I cut you off from sharing for a minute, but I can go back, all right? And I wasn't sure I was going to have the technology.

You can see that, Dr. Earls. Yes, I can see it. I'll get it. And I think you probably crafted this comparison. It was sent to me by a patient I had yesterday.

So it's very current. I don't yet know how to put these together in this beautiful way. And for everybody watching, there's a purple column that says compared.

And if you look, it has a date, 12 822 and then to the right is a royal blue column up and down. That's just about eight months later, July 26, 2023. And I know this language is all new, but there's total black volume.

That's the language of how much plaque is in the three heart arteries. That can be a problem leading to heart attack by stents. And it was 546. But this is not a happy case.

Research, Access, and Insurance Coverage

And I want to make a point from it, because if you look eight months later, it's gone up by 40% for 46 became 758. That soft, buttery, cheesy, non calcified plaque for 1730 7% increase went up.

That's not what we want to do. I was not involved in the patient's care during these eight months. Divide 72. Now, Dr. Earls Gray told us there's a particular kind of dangerous black called low density, non calcified black that did go down from 13 to 2, which helped this patient out.

And finally, the calcified plaque went from 128 up by about 45%, little bit more than you typically see in eight months. And the final thing I'd comment, there was one severe narrowing on the baseline study and there were two severe narrowing because that you do get that information.

We haven't really talked about that, but there were two narrowing. There were 71% narrowed on the follow up study where in the first one it was one. So the question is, what did this man, it is a man 60 years old, do in eight months to create this?

And this is such a fascinating case because he did see an integrative cardiologist. He was put on a few supplements. I will tell you, one of the supplements he was put on was aged, colic, garlic, which of course, has some data for shrinking soft black.

And I think that's why his low density, non calcified plaque went down because that's about the only agent he was on that might do that. But he chose I was not involved in his care to not dramatically change his diet or his lifestyle.

It wasn't that bad, but it shows that the change and he did not go whole food plant based. He did not want to go on a statin or other prescription medicine.

He did 25 treatments of relation with EDTA and he did 45 treatments with another agent some practitioners use called Plaque Acts. These are intravenous infusions.

He ended up spending over the eight months about $10,000 cash at a integrative clinic in the Chicago area. I'll say that. And expected when he did his follow up Cleerly Health to see dramatic improvement when indeed there actually is no data at this point for any kind of geography.

Analyzing key lesion therapy, something that's been around for decades and has little glimmers of hope that it may actually help patients, but not actually direct imaging studies to prove that it restores heart anatomy to better.

So this was a disaster for this guy in terms of what resulted. He was spending a lot of money and a lot of time because you sit in a chair for two, 3 hours to get these infusions and it didn't work for him.

And I point that out. I think I'm going to write this study up because I don't know how many other, you know, comparisons are like this. Does key lesion therapy work in many people in the audience of articulation therapy, it's usually intravenous.

You can try and do it orally. It used to be done with suppositories too. So there's that route so that girls. Have you seen other key examples. But only a handful?

I think it's not as widely done as perhaps it may have been done in the past, but I think here it clearly was not effective. I think what we're seeing is the, you know, coronary atherosclerosis is a progressive disease and left untreated or in a inappropriately treated, it continues to progress.

And, you know, many therapies work on some people, but they don't all work on everybody. And I think one of the the best parts about our ability now to actually quantify disease is, you know, we are actually able to show whether it's working or not.

Case of Plaque Progression Despite Chelation Therapy

And then you have the opportunity, as this man now does, to change therapies, do something else that may, in his particular case, work more effectively.

So I think this is you know, of course, we do see a benefit here in is low density plaque, but really the overall amount of plaque and the amount of non calcified plaque progressing here for him unfortunately represents a very opposite of what he was hoping to see here.

Yeah, no doubt. And you know, for the audience listening, is that the main focus of this presentation with Dr. Earls, but a very prominent cardiologist in Miami, I want to say his name right.

Gervasio Lamas, M. D., did pull off a $30 million study published in 2012 using Qi lation in 1700 men in the VA hospital system. They did not have enough funding to do calcium scoring before and after, so there was actually no imaging data and there clearly was no Cleerly Health imaging data because it didn't exist when the study was done.

But, you know, there was some evidence that the patients did better over the study, enough that they're actually repeating the study because actually only diabetic patients demonstrated some clinical benefit and we don't have the results of the second phase.

It's called TACT2 trial, but they also aren't doing hard imaging. They're not doing calcium scoring. So even when that studies done, we're not going to actually know what's happening in the coronary arteries.

But when you look at this single case, you have to say, wow, you know, how does relation even possibly work? Because there is some data for severe peripheral vascular disease, leg disease, leg circulation actually has some provocative data.

It's called TACT3A that there may be some role, but I was almost getting revved up to start recommending chelation again to my patients once in a while.

And after this example yesterday, I don't think I'm going to ask anybody to spend money on this. Do we have more data? Yeah. Yeah. Perhaps they are looking at some other marker of the disease that may have looked favorable.

But in fact, obviously the plaque itself, which is the disease, did not respond favorably. And that's I think we have for many years in cardiology, you often followed certain biomarkers of the disease that we would just assume would go hand in hand with the actual plaque or atherosclerosis.

And certainly sometimes they do. But there are times where, you know, all of your lipids could actually turn favorably, but your plaque can still be progressing, even in the light of very favorable lipid profile.

So, I mean, get an all in just a couple more minutes. We have an audience here that wants to stay healthy. They're very lifestyle oriented. I mean, should everybody over age 40 or 45 get some kind of cardiac blood vessel imaging?

And the two choices are a calcium score, which is without a dying die and low cost, but you don't see soft plaque. And we've seen today these examples how much you can miss or should the majority get the corner angiogram if they have a center and the finances to have one?

Or how how are you handling that recommendation? Yeah. You know, we hate to have a type of therapy that only people who can afford it can follow it. And, you know, we are working hard to one day get indications where and hopefully CT angiography can be used as a screening test and will be covered by insurance.

But we have to generate a lot of good data before that happens here in the U. S. So certainly I think if you are interested and you can afford it, it's a very compelling test that will tell you precisely where you are and what work you may need to do, or you may, in fact, find that, you know, you actually have a favorable study and what you've done already has actually been good for you.

So but yes, if people can afford it, it'll give them a lot of information can be very motivating for people to actually see their own plaque. And many of our providers tell us, you know, they've had patients who for years have tried to lose weight, tried to stop smoking, tried to get on a, you know, a better diet.

But once they finally saw their atherosclerosis, that was a great motivator to allow them to make that lifestyle change or to, in fact, perhaps start taking pharmacologic or supplements that they were originally resistant to.

So yeah, if people can afford it, it's great. But we do hope to generate evidence that where everybody will be able to afford it by using their health insurance at some point in the future.

Okay.

Who Should Get Coronary Imaging and Closing Remarks

And I'll say I had a patient today actually in the clinic, very boisterous, 70 year old attorney just walked in and said, we have an hour together, but it can be one minute.

I just want a Cleerly Healthy CT angiogram and I need a doctor like you to write the script and set it up. And we ended up spending an hour together talking about his health and golf and a whole bunch of other topics. But, you know, I think that was a good choice.

He has every risk factor in the book and he knew going right past the calcium score to a more informative test and he has good kidney function and no iodine allergy problem.

So no problem there. So it is kind of the cutting, cutting edge that we're all learning about. So thank you for sharing your time and your knowledge and your case studies.

And I think the audience has really enjoyed this and learned a lot. It's just we all talk about reversing heart disease, but you're the team that knows how to improve it, right?

Well, and you're the team that knows how to actually do it. So together. That's great. All right. Thank you, sir. All right. Thank you, Dr. Kahn.