

RICHARD What I want to do is cover what might appear to be several unrelated points, but hopefully within a few minutes, it'll come together. And we're going to talk about cardiovascular rehabilitation. Again, I'm a card carrying cardiologist. And I help oversee the cardiac rehabilitation programs, the pulmonary rehabilitation programs, and the vascular rehabilitation programs. And they're actually all very much intertwined.

Shifting gears for a second, there's a concept of treatment versus the concept of healing. Treatment, the act or manner or an instance of treating someone or something, the techniques or actions customarily applied to a specific situation. Treating appendicitis by doing an appendectomy, treating limb ischemia by revascularization. Healing is to become healthy or well again and to make someone or something healthy or well. I think it's fair to say that our patients want and deserve both. And I would submit that within a few minutes, you'll see how vascular rehab augments the treatment that many of us do to result in final healing.

If we look at cardiovascular disease in general and secondary prevention with medication, enormous strides over the latter half of the 20th century and the last 20 years. The death rate per person for cardiovascular disease in America was at its height in its '60s and has declined dramatically. And everyone in this room knows why. Treatment of blood pressure; treatment of lipids; antithrombotic therapy; treatment of the overactivation of the renin-angiotensin aldosterone system with ACE inhibitors, angiotensin receptor blockers, and aldosterone antagonists; blockade of the sympathetic nervous system with beta blockers. All of these are wide-- very successful. Probably it's the rare patient that any of us sees that isn't treated with one or more of these.

In general, if you look at all the studies, big picture, over about a period of two to five years, they produce about a 15% to 20% relative risk reduction in the odds of MI, death, stroke, things like that. A related study, very famous study, by Earl Ford that was in the *New England Journal* about a decade ago showed that, again, there's been this tremendous decrease in mortality for coronary artery disease over the past half century. Roughly, 40% is due to interventions such as CPR, thrombolytic therapy for MIs, aspirin, cabbage, PCI, beta blockers, ACE inhibitors, and statin. But 45%, fully 45% are due to profound changes in risk factors in the American population. More to go, but really, risk factor modification has been as helpful from a population health perspective as these other very, very potent therapies.

If you had to leave my talk with one thought, it would be that exercise is medicine. Exercise has a whole variety of physiologic and biochemical changes in our body that indeed change things as much as most medicines and indeed produce clear-cut health outcomes. They change not only things like cardiac output and functional capacity, but they change vasodilation, blood clotting, lipids, cognitive function, all in a good fashion. Another couple of very important studies in a whole variety of populations-- healthy people, healthy people with coronary disease, people with heart failure, people with vascular disease. In almost every population that's ever been looked at, the level of fitness, how much exercise someone can do, correlates inversely with their mortality risk.

The more fit people are, the lower their risk of dying. It is really that straightforward. One metabolic equivalent, which is not really very much-- doing something like doubles tennis, depending on who you're playing with. Maybe five, six mets. So just a fraction of that results in a 13% mortality reduction. So it really doesn't matter why the patient walks into your office, whether they're coming in to see you because they have a carotid bruit, whether they're coming in to see you because they have claudication, or they're coming in to see you because they want a cosmetic nose job. In all patient populations, better fitness is correlated with lower mortality.

Now let's focus on what's called Supervised Exercise Therapy for patients with claudication. That is the term picked by Medicare, SET PAD. In 2017, Medicare came out with this decision memo, saying that they would pay for Supervised Exercise Therapy for PAD. Everyone here knows the golden rule. He who has the gold makes the rules. So this really, with a lot of work by a lot of people in vascular medicine, this came into being. So at UH and at many, but not all, health systems now, patients can indeed benefit from SET by PAD.

There are guidelines for everything these days. Certainly, the American College of Cardiology and the American Heart Association have been leaders in the guideline space. And Level 1A, a program of Supervised Exercise Training is recommended as an initial treatment modality for patients with intermittent claudication. OK? So this is as strong a recommendation as it gets. This is just as strong as statins, just as strong as aspirin, just as strong as tobacco cessation. You get it.

And they say that Supervised Exercise Training should be performed for a minimum of 30 to 45 minutes. That doesn't mean people have to walk for a half hour straight. They might walk and stop and walk and stop. But it should go for 30 to 45 minutes, performed thrice weekly for a minimum of 12 weeks. Again, 1A, as strong as it gets. What are the goals of treatment of patients with claudication? Relieve exertion of symptoms and improve walking capacity. You want to decrease the risk burden associated with atherosclerosis. That will not only help their legs, but help their whole body. You want to enhance their quality of life, and associated with that, modify their cardiovascular risk factors.

When we do Supervised Exercise Training on patients, why can they walk further? There may be some collateral [INAUDIBLE] development. There may be changes in endothelial function. There are profound changes in the biochemistry in the individual muscles in terms of oxygen extraction, and energy utilization, and contractility. There are some minor functional changes in just the ability of patients to walk. These patients don't walk before all this, so there are some things like gait and balance issues that improve. And there may be did what they call here distal vascular disease, really microvascular disease. There is really no change in the ABI with exercise therapy. It's all distal to the large vessels.

Some of the details-- if you refer to patients to our program or any similar program, in some ways, you don't need to know the details, but so you know what's going on, the idea is to have patients walk at a speed and grade to reach moderate pain intensity, three exercise sessions a week, again because there are biochemical changes. Those changes go away with time. So unless patients keep it up, the benefit does not sum on itself. It really has to be several times per week. Initial intensity is generally 50% of the heart rate reserve or workload with gradual progression, up to 80% of the heart rate reserve.

So we're talking somewhere around 60 to maybe 90% of their age predicted maximum heart rate. In general, we have tried to have patients walk for eight to 10 minutes if they can, until they get substantial claudication. Stop until the pain subsides and repeat. And they do this again and again during the session. Once they're at a point where this amount of activity does not result in a moderate claudication, no pain, no gain. We don't want them to be in agony. But they do have to feel some symptoms. We increase the workload.

For patients who have trouble walking because of arthritic neurologic balance issues, cycling can be used. There are also some step machines that can be used. And it's also helpful in patients who've had amputations that make gait-- walking on a treadmill difficult. Resistance training is probably helpful as well. OK, here's a study from several years ago. There have been a lot of-- there were a lot of moderate size studies looking at the benefits of exercise training in PAD.

And if you look at this meta analysis by Gardner, a giant in the field, if you look for the onset of claudication pain, exercise training resulted in a change in treadmill walking distance of about 175%. That is almost tripling the amount of distance patients could walk. And in terms of maximal claudication pain, where they just couldn't walk anymore, it was over 100% gain, more than doubled. That results in dramatic functional improvement in patients' daily lives.

The world was changed in some ways by the CLEVER trial. Some people in the room here probably participated in that. This was a big NIH multi-center, multimillion dollar trial, looking at medical therapy, what was considered optimal guideline directed medical therapy. And everyone supervised exercise therapy and revascularization. And as you can see, compared to medical therapy alone, Supervised Exercise Therapy resulted in a dramatic improvement in the peak walking time.

Stenting also resulted in a substantial improvement. And if you look at the time, that was the main end point. The secondary end point was claudication walking time. And both exercise therapy and stenting both resulted in the claudication onset time changing substantially. And as you might imagine, the exercise program was substantially less expensive and much more cost effective than stenting. But importantly, they're not really competitors in our world. One adds to the other.

In March, I was asked to speak at the National American College of Cardiology meeting on vascular rehab and some other things on the present future. What do I think is going to go on? Right now, in most places, it's focused on treadmill walking. As I said, I think it'll be walking and/or strength training. There's really good data that people don't need claudication to benefit. That is, or at least, classic claudication, obstructive peripheral arterial disease is probably enough for patients to show benefit. Again, probably related to the fact that in all populations, improved exercise results in improved outcome.

We want to focus on comprehensive risk factor treatment. And one thing that has come out of this is that it really needs to be supervised. Just telling patients to walk seldom results in a focused and sustained effort by patients for it to be effective. Here's a JAMA article looking at resistance training or treadmill training. Both groups improved, and again, the improvements were seen in those with and without claudication. The National Institute for Clinical Excellence, which is in England, says supervised exercise is superior to structured home based programs. Again, just telling people in your office, go walk around your neighborhood, is unlikely to do the trick.

So what are we doing at the UH program? It's the vascular rehab program content I would submit is comprehensive. Again, this is where the vascular patients benefit from being with, for example, the cardiac patients. Because you have this big infrastructure that we could leverage. There is initial exercise assessment, typically a treadmill or six-minute walk test, individualized risk assessment, exercise prescription, supervised exercise, group education on things like medications, risk factors, the nature of the procedures. We have tobacco cessation. There's an enormous, unfortunately, prevalence of both depression and anxiety in these patients. We have behavioral health to help with that. We do it in a very individualized fashion. We try to transition patients to being able to do this when they're done on their own. And we have a variety of ways of communicating with referring physicians.

I think I've made the point, but I think just for emphasis that supervised exercise therapy for PAD should be set in a cardiac rehab program. Most patients with peripheral arterial disease have cardiac disease and diabetes. These might as well be treated in existing programs. The patients need the exact same risk factor modification, education, and supervision as patients who've just had coronary stent, or MIs, or heart failure. They use the same equipment and the same structure. Very cost effective. The hospital administrators love that. The nurses, the exercise physiologists, the pharmacists, social workers, and dietitians all have much of the core knowledge that's needed. We need to buff it up a little bit for atherosclerotic vascular disease and perhaps augment it even more for things like SCAD and FMD, non-atherosclerotic disease, but the bulk of the knowledge already exists.

Our program here, two to three times per week. Again, treadmills, bicycles. We have a recumbent bike. We have recumbent bikes, which are usually more user friendly for people with low back problems. We have what we call a New Step, which is a stepper which provides the needed exercise in people who have gait or balance problems. And we have resistance and strength training. Three dozen sessions, and we have maintenance program thereafter. I will go through this. But again, the golden rule-- there are rather rigid Medicare regulations for doing this. One advantage we have at UH is we've centralized sort of the back office or administrative things. And all our sites, which you'll see in a minute, can utilize this back office knowledge so that each site doesn't have to sweat all the rules.

But they talk about the number of sessions and how there has to be physician supervision. One important thing that people here need to know is for a patient to be referred to this, they're supposed to have a face-to-face visit with a physician, where the physician tells them that not only exercise therapy is important, but overall risk factor modification is important. It doesn't have to be a separate visit. It can be part of a post-procedure visit. But it needs to be a visit. There are no strict verbiage as to the content of that visit has to be in terms of precisely what you tell them. But certainly the notion of risk factor modification and exercise, which presumably is typically covered, needs to be documented.

And patients can't exercise if there's an absolute contraindication, like they have severe aortic stenosis. Referral is very easy. You can call us up. There's an email, vascularrehab@uhhospitals.org. Not to be confused with cardiacrehab@uhhospitals.org or pulmonaryrehab@uhhospitals.org. On the left of the screen is a paper form which should be in most offices. And we can certainly give you more. On the right is the EMR form. You'd basically just have to say it's for claudication. And you have to give some diagnosis. It should really take 30 seconds to fill out this EMR form.

The sites are all over the area. If they weren't geographically convenient, frankly, patients wouldn't go to them. So we've made an extra effort over the years to make sure we blanket the area with geographically convenient sites. Here's a page from our brochure, which we can get you copies, but there should be copies around the site here. And you can see there should be a vascular rehab site convenient to the patients wherever you are in the region. And with that, I thank you for your time.

[APPLAUSE]