



Oklahoma Heart Institute

VOLUME 10 | NUMBER 1 | SPRING 2015

Weight Loss and Wellness at Oklahoma Heart Institute

By Eric G. Auerbach, MD

Transcatheter Mitral Valve Repair — MitraClip

By Kamran I. Muhammad, MD

IMPROVE-IT Trial Confirms Lower LDL-Cholesterol Levels Are Better

By Wayne N. Leimbach, MD

Move More, Eat Less: Diabetes Prevention

By Cassie Stanzak, RD

Heart Failure Patients Now Eligible for Cardiac Rehabilitation

By Chris Bousum

Advancing Endovascular Management of Lower Extremity Peripheral Artery Disease

By Raj H. Chandwaney, MD

Whole Heart Healthy Recipes



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to our readers



Cardiovascular disease prevention has become one of the great successes in cardiology. It is estimated that the majority of heart attacks and strokes are preventable by treating the known risk factors. The current issue of Oklahoma Heart Institute Magazine presents three articles regarding prevention.

Dr. Auerbach discusses a very successful weight loss management program that addresses the epidemic problem of obesity. The recently reported IMPROVE-IT Trial shows that aggressively lowering cholesterol levels is still the way to go to prevent heart attacks, strokes and cardiovascular death. This study refutes the recently published guidelines regarding cholesterol lowering and reaffirms the LDL-cholesterol hypothesis that “lower LDL cholesterol is even better”. Cassie Stanzak, RD, LD, CDE, emphasizes the importance of diet for diabetes prevention in her article Move More, Eat Less: Diabetes Prevention.

Heart failure remains the number one discharge diagnosis for U.S. Hospitals. Chris Bousum, Direc-

tor of Cardiac Rehabilitation at Oklahoma Heart Institute, discusses the newly CMS-approved heart failure cardiac rehabilitation program at Oklahoma Heart Institute.

Technology continues to advance and provide new treatment options for patients with difficult to treat cardiac illnesses. Dr. Chandwaney discusses the drug-eluting balloons for patients with peripheral vascular disease. Dr. Muhammad presents the new MitraClip, which addresses the problem of severe mitral regurgitation in patients too sick or too frail to have surgical mitral valve replacement or repair.

We hope that you enjoy the articles and welcome any comments or suggestions regarding the magazine content.

Sincerely,

Wayne N. Leimbach, Jr., MD

Publisher/Editor, Oklahoma Heart Institute Magazine

ON THE COVER

“Blair Pond at A Gathering Place for Tulsa”

Blair Pond is a major nexus of park activity that brings the excitement and tranquility of water into the main heart of the park, creating a more diverse landscape experience and program. Fed by groundwater, Blair Pond will provide multiple opportunities for recreation, including boating, fishing and wildlife habitat observation. All of the major program elements in the north portion of the park, including the Lodge, the Boathouse, the Great Lawn, the Adventure Playground and Mist Mountain, border Blair Pond.



Rendering provided by A Gathering Place for Tulsa

Move More, Eat Less: Diabetes Prevention

By Cassie Stanzak, RD, LD, CDE



In 2012, 29.1 million Americans had diabetes. Even more astonishing, 86 million Americans, age 20 and older had prediabetes. Not only does diabetes cause serious health complications including heart disease, blindness, kidney failure, and lower-extremity amputations, it is the seventh leading cause of death in the United States. This is the reality.

So how can this “epidemic” be stopped? How can you decrease your risk of ever developing type 2 diabetes? These are the questions that everyone should be asking and taking seriously. The good news is that type 2 diabetes is largely preventable and the answer is easy for everyone to understand: know your risk, move more, eat less. If that was all you knew, and that was all you did, that would be a great start.

It is very important to make diabetes prevention

a priority. The risk factors for diabetes include: obesity (especially around the waist), inactivity, being over the age of 45, high blood pressure or on medication for high blood pressure, low HDL cholesterol, a family history of diabetes, or a personal history of gestational diabetes (diabetes with onset during pregnancy). Often there are no symptoms with onset of type 2 diabetes; therefore early screening may help people avoid the more serious complications of the disease. According to the American Diabetes Association, all patients should be screened for diabetes at 3-year intervals beginning at age 45, especially people who are overweight or obese. If multiple risk factors are present, screening should be done at an earlier age and more frequently. As far as what to do if you are at risk, focus on the things you can change and do not dwell on the things you cannot. No matter how frustrating it is, we can't get

any younger! Let's narrow it down to the modifiable factors: weight, activity, cholesterol and blood pressure. Knowing that cholesterol and blood pressure can be much improved by a healthy weight and activity leads us back to the basics: move more, eat less.

Let's get moving. Working your muscles more often improves their ability to use insulin and absorb glucose, putting less stress on your insulin-making cells. Being physically active on a regular basis not only helps prevent type 2 diabetes, but it also helps prevent heart disease, aids in weight loss, improves cholesterol and blood pressure, and increases your chances of living longer and living healthier. What defines physical activity? The 2008 Physical Activity Guidelines for Adults defines physical activity as “anything that gets your body moving.” For health benefits, adults need at least

30 minutes of physical activity, 5 days per week (a total of 150 minutes per week). Going for a walk, taking a dance class, mowing the yard, riding a bike, swimming, bowling, tennis, playing basketball. These are some, but not all activities that can get you started. If you are new to exercise, understand that you may not be ready for 30 minutes at one time, and that is okay. The important thing is that you find what works for you. The 30 minutes can be divided into three 10-minute increments if necessary. Do something you enjoy. Find a partner. Listen to music. Understand that exercise needs to be part of everyone's daily routine.

There is no magic diet, special diet or fad diet to prevent diabetes. The key is portion control while following a balanced, healthy eating plan. Practicing portion control can help reduce fat and calorie intake, resulting in lower cholesterol and weight loss, both of which are helpful in preventing type 2 diabetes.

Portion sizes have gotten out of hand, especially at restaurants. The average restaurant meal today is more than four times larger than in the 1950s, according to the Centers for Disease Control and Prevention. In the 1950s, the average burger sandwich was 3.9 ounces. Now a burger sandwich is 12 ounces. And possibly one of the biggest culprits of weight gain and obesity, soda/sweetened beverages,

averaged 7 ounces per serving in the 1950s. Now the average soda is 42 ounces. As life gets more hectic, fast food consumption has become a growing part of the American diet. With "Super-Sized" options and the consumer wanting to get the most for their money, people are consuming very high fat, high calorie meals. Yes, fast food restaurants now provide healthier options, smaller portions, and junior meals, but we, the consumers, have to make the decision that those portions are normal, appropriate sizes and choose them.

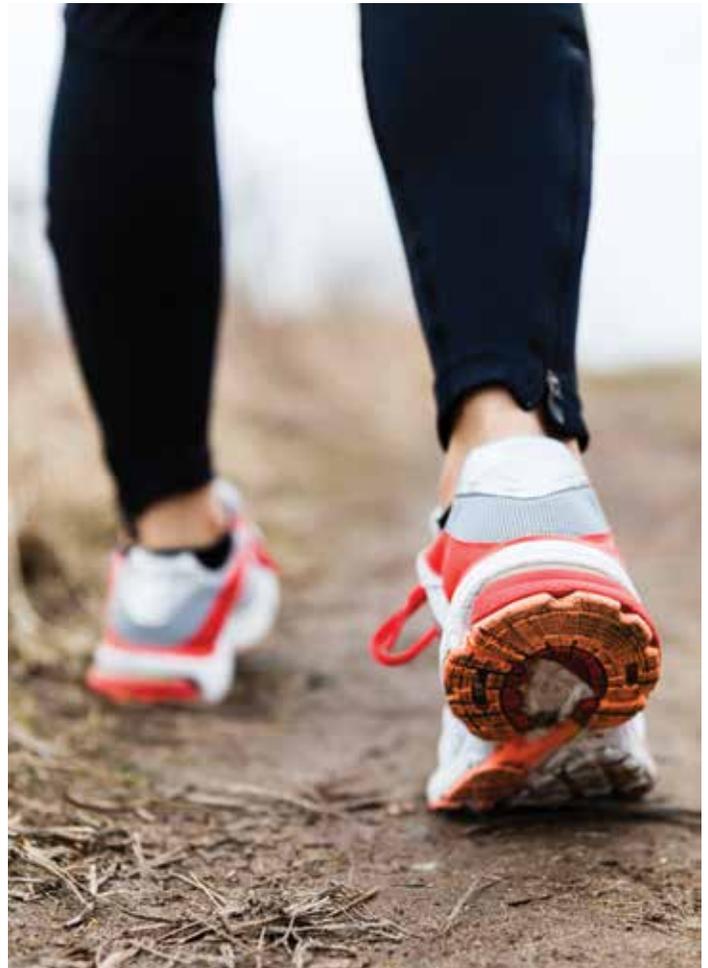
When preparing meals at home, portion control is also the key. Like the restaurants, home meals have increased due to the increased size of plates, bowls, and glasses. If you feel that overeating at meal time is a problem area for you, try using a smaller 9-inch plate. Using a smaller plate will help small portions of food look like more, because the plate will appear full. With that 9-inch plate, fill half of it with non-starchy vegetables (i.e. green beans, carrots, broccoli, cucumbers, spinach, celery, etc). These foods are very low calorie, yet high in nutrients. With the other half plate remaining, fill $\frac{1}{4}$ of the plate with a high fiber carbohydrate (i.e. sweet potatoes, black beans/lentils, whole wheat pasta, brown rice, whole grain toast, etc.) Then fill the last $\frac{1}{4}$ of the plate with a palm-size portion (about 3 ounces) of lean protein (chicken

breast, fish, turkey, pork tenderloin, etc.). You have just created a balanced, healthy plate. This method of planning the meal is called the Plate Method. Consuming a plate like this will result in smaller portions and less fat and calories. The more consistently you try to use the Plate Method, the more your body will get comfortable with these smaller portions and balanced eating. Try to envision this plate even when eating out. Everyone in the family can use the Plate Method. This is a healthy eating plan that everyone should be following. If the focus is on eating less, that will also result in consuming fewer calories and less fat. Remember: portion control is the key.

Diabetes prevention really is as basic as becoming more physically active and eating less. Also, as mentioned above, eating healthy and losing weight can get you started on a path to avoid serious health complications. The time is now. Today is the day to start. Making a few diet and lifestyle changes can really help in creating the long healthy road ahead.



Cassie Stanzak is a Registered Dietitian and Certified Diabetes Educator who has been working at the Hillcrest Diabetes Center for over 6 years.



CHICKEN AND ARTICHOKE WITH FARRO

Serves 6

Fresh artichokes and browned chicken make a wonderful combination. Farro is a classic Italian whole grain that pairs beautifully with this dish, but you could prepare brown rice, pasta or couscous instead.

- 1 whole chicken, cut into 8 serving pieces**
- 1 3/4 teaspoons fine sea salt, divided**
- 2 teaspoons extra-virgin olive oil**
- 8 cloves garlic, peeled and halved**
- 3/4 cup white wine**
- 4 artichokes**
- 1 1/4 cups cups farro**
- 3 tablespoons chopped fresh dill**

Preheat the oven to 325°F. Sprinkle chicken on all sides with 1 teaspoon salt. Heat oil in a large skillet over medium-high heat. Add chicken and brown on all sides, turning pieces occasionally. Transfer pieces to a roasting pan. Discard excess fat from skillet, then add garlic and cook, stirring, until lightly browned. Add wine to the pan and reduce slightly, scraping bottom of pan to release any browned bits. Pour wine over the chicken.

Cut off and discard the top 2/3 of each artichoke. Run a paring knife around base of each, removing tough leaves until you get to tender yellow-green ones. Use a teaspoon to scoop out and



discard the small petals and hairy chokes at the center of each artichoke, exposing the heart. Peel the stems. Cut artichokes in quarters and nestle them around the chicken in the roasting pan.

Cover securely with foil and roast until chicken is cooked through and artichokes are very tender, about 45 minutes.

Meanwhile, bring 2 cups water and remaining 3/4 teaspoon salt to boil in a medium saucepan. Add

farro, lower heat, cover the pan and simmer until farro is very tender and water is absorbed, about 35 minutes. Transfer to a platter. Place chicken and artichokes on top, ladle the liquid and garlic in the pan over the top and sprinkle with dill.

Nutritional Info: 680 calories (340 from fat), 38g total fat, 10g saturated fat, 165mg cholesterol, 1040mg sodium, 28g carbohydrate (9g dietary fiber, 4g sugar), 47g protein



PINEAPPLE-GINGER RICE WITH EDAMAME

Serves 8 as a side dish

Serve as a vegetarian main course or as a side dish with steamed fish or roasted chicken. If you don't have any leftover brown rice on hand, use a package of frozen cooked brown rice as a shortcut.

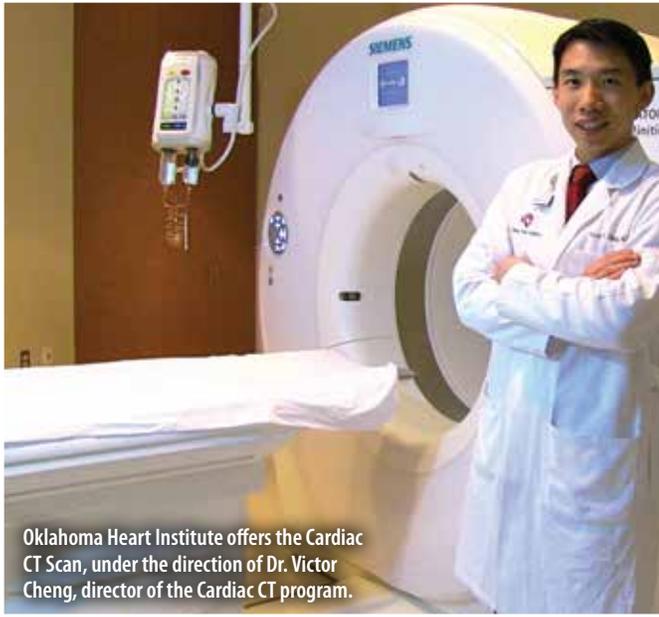
- 3/4 cup low-sodium vegetable broth**
- 1 tablespoon finely grated ginger**
- 2 tablespoons brown rice miso or light yellow miso**
- 4 cups cooked brown rice**
- 2 cups shelled edamame**
- 1 1/2 cups chopped fresh pineapple**
- 1/4 cup chopped fresh cilantro**

In a large, deep skillet, bring broth and ginger to a simmer over medium high heat; simmer for 2 minutes. Remove skillet from heat and whisk in miso. Return to heat, add rice, edamame and pineapple, toss gently and cook

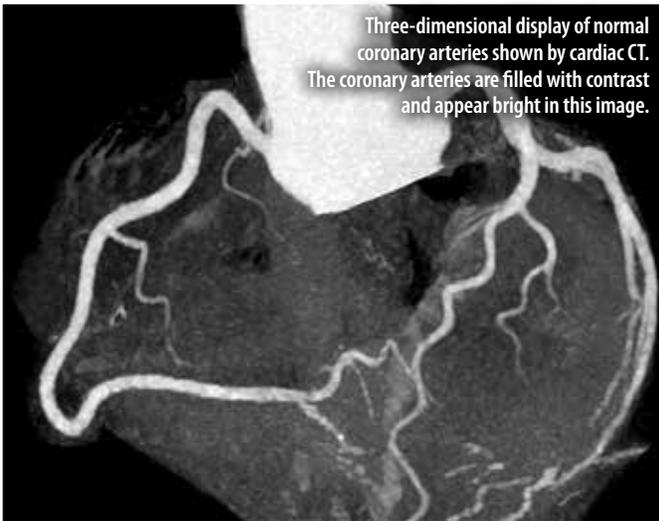
until liquid is absorbed and rice is hot throughout, 3 to 5 minutes more. Stir in cilantro and serve.

Nutritional Info: 180 calories (20 from fat), 2.5g total fat, 0g saturated fat, 0mg cholesterol, 190mg sodium, 33g carbohydrate (5g dietary fiber, 4g sugar), 7g protein





Oklahoma Heart Institute offers the Cardiac CT Scan, under the direction of Dr. Victor Cheng, director of the Cardiac CT program.



Three-dimensional display of normal coronary arteries shown by cardiac CT. The coronary arteries are filled with contrast and appear bright in this image.



Cardiac CT at Oklahoma Heart Institute

State-of-the-art scanner detects your risk for heart disease

Heart disease is the leading cause of death in the United States for men and women. But for many, the first symptom of heart disease is a heart attack.

In Tulsa, Oklahoma Heart Institute is changing that by offering a Cardiac CT Scan performed by a state-of-the-art ultrafast scanner that is more than 95 percent sensitive in detecting heart disease. The scanner creates detailed and accurate images of the heart and arteries in just seconds, all meaning easy and early detection of heart disease.

Dr. Victor Cheng administers this new technology at Oklahoma Heart Institute. Cheng, who came to OHI via Los Angeles' Cedars-Sinai Hospital, says using the Cardiac CT Scan is a good way to test if a patient's symptoms are due to heart disease or if a patient with significant risk factors has developed heart disease.

"For both symptomatic and asymptomatic individuals, Cardiac CT detects the presence and amount of plaque in the coronary arteries," Cheng says. "This information helps doctors tailor the intensity of recommended therapies to reduce heart attack risk and can motivate individuals to live a more heart-healthy lifestyle."

He adds, "For individuals with chest pain or breathlessness, Cardiac CT is the most reliable noninvasive test to show that the person does not have significant

coronary artery blockage. The use of Cardiac CT in this situation determines whether additional evaluation or treatment for coronary artery disease is needed."

Cardiac CT is a painless screening test that uses an X-ray machine to take clear, detailed pictures of a heart and blood vessels. The scanner uses 50-90 percent less radiation than earlier generation scanners. The average patient is exposed to a radiation dosage comparable to a mammogram. This one-time radiation exposure is considered quite safe.

For individuals concerned about, or are at risk for, heart disease, Cardiac CT detects if there is no disease, mild disease or severe disease. Cardiac CT also effectively determines presence of heart disease in those who have undergone a stress test with an inconclusive result.

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Weight Loss and Wellness at Oklahoma Heart Institute

By *Eric G. Auerbach, MD, FACC*



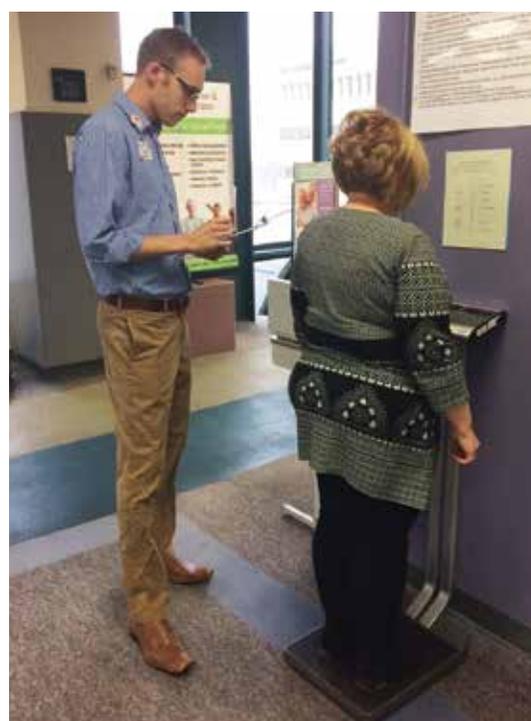
(Left to right) Chris Bousum, Supervisor; Terri Thames RN, BSN; Elizabeth Busten, Program Operations Specialist; and Tom, Health Educator.

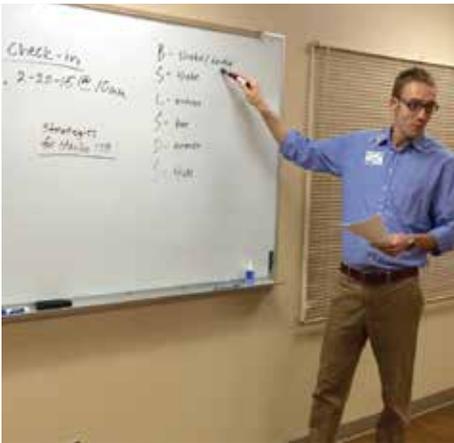
Obesity is an increasingly prevalent problem worldwide. Certainly, the state of Oklahoma is no exception. In the year 2013, 32.5% of adults in Oklahoma were obese, up from 24.1% in 2004, making Oklahoma the seventh fattest state in the nation.

Of course, not everyone who is obese is in poor health. Recent studies, however, challenge the concept of “healthy obesity.” The risk of cardiovascular disease and of all-cause mortality is clearly substantially higher in the obese than in non-obese healthy individuals of the same age. Moreover, a recent review of British government workers who were followed over decades demonstrated that the apparently “healthy obese” were eight times more likely to develop signs of metabolic syndrome than their normal weight counterparts. Even when obesity is not

obviously associated with poor health, it is typically a harbinger of metabolic deterioration that will develop over time.

From the perspective of a cardiologist, overweight and obesity are conditions associated with metabolic syndrome — that constellation of high blood pressure, high triglycerides, low HDL-cholesterol, and high blood sugar — all of which are related to insulin resistance. Metabolic syndrome is a pre-diabetes state. But, more than that, it is itself associated with inflammation and vascular disease. Today, 70% of vascular disease occurs in individuals with metabolic syndrome. And, beyond vascular disease and its metabolic risk factors, other common cardiac ailments including atrial fibrillation and heart failure are increasingly recognized as complications of obesity in many individuals. For all of these cardiac patients, weight loss is





... overweight and obesity are conditions associated with metabolic syndrome — that constellation of high blood pressure, high triglycerides, low HDL-cholesterol, and high blood sugar — all of which are related to insulin resistance.

an integral component of effective care.

For physicians, then, providing patients with an effective and health promoting weight loss strategy is very important. For some patients, particularly those trying to prevent and reverse high blood pressure, diabetes, dyslipidemia, and other complications of metabolic syndrome, an effective weight loss strategy is essential. As physicians, however, we typically fail at this task. In a recent survey that reviewed the medical records of over 90,000 patients in a primary care setting, it was determined that in 59% who were morbidly obese, and in 90% who were overweight, their doctors had not recommended any sort of weight management intervention. Perhaps this failure is because of the complexity of the subject matter and our limited time in the exam room. After all, the typical fifteen minutes allocated to visits leaves little time to take a detailed dietary history and carefully consider and discuss helpful improvements. Or perhaps the failure is related to a lack of data and lack of consensus regarding the best, most evidence-based approach to take. Many of us have long been aware of the poor quality of science and general lack of data with which so many dietary recommendations have been crafted. Regardless of the cause, however, the result has been a failure to assist our patients in achieving their best possible health.

At Oklahoma Heart Institute, in partnership with the HMR Program for Weight Management, we have recently launched “The Weight Loss and Wellness Center,” an initiative squarely aimed at curing obesity and its metabolic complications. As with other medical conditions, the treatment of obesity is challenging and requires a treatment plan that is both proven and evidence-based. At “The Weight Loss and Wellness Center,” we utilize the HMR Program, which consists of a structured diet along with a behavioral component that teaches realistic and sustainable lifestyle changes. The program utilizes meal replacements for calorie control, emphasizes physical activity, and encourages vegetable and fruit consumption.

Results of the HMR Program have been truly exceptional. Typical initial weight loss for patients in the program is between 43 and 61 pounds. Based on a study of 422 patients in HMR pro-

grams across 10 AMGA (American Medical Group Association) member groups, average weight loss at three years was 44 pounds, representing 18% of initial body weight. In conjunction with this weight loss, 35% of medications were eliminated. Specifically, 51% of participants were able to eliminate oral diabetes medication, 29% were able to eliminate insulin, 33% eliminated blood pressure medication, and 30% eliminated cholesterol medication. A stunning 90% of participants had improvements in all of the tracked risk factors.

With its effectiveness and reproducibility, the HMR Program has been an obvious choice for use in medical research trials studying the effects of weight loss. To date, over forty peer reviewed studies have been published in which the HMR Program of diet and behavioral modification has been utilized to facilitate weight loss. One such study, for example, evaluated the impact of a low calorie diet on progression from pre-diabetes to diabetes. All subjects had a fasting blood glucose between 100 and 125 mg/dL prior to the behavioral intervention, and none had been diagnosed with diabetes or started on medication for diabetes. Of the 259 individuals studied, only three (1%) had progressed to diabetes at over three years of follow-up. A separate publication, also studying a population of pre-diabetics, found that those individuals who lost the most weight were the least likely to progress to diabetes.

Published trials of patients with established diabetes are equally encouraging. These studies consistently demonstrate an improvement in glycemic control that is proportional to the amount of weight lost, even well beyond the 10% of body

weight threshold that is touted as a goal for metabolic improvement. In one study, for example, diabetics who had a weight loss of greater than 20% were more than twice as likely to have discontinued insulin or oral diabetes agents as those who lost 5-10%.

Indeed, one theme to emerge from the clinical trials utilizing the HMR Program is that moderation may not be particularly desirable when it comes to a weight loss program. The studies consistently indicate that improvements in blood sugar, blood pressure, and lipid parameters are proportional to weight loss. Medical trials also suggest that relatively greater amounts of weight loss at a more rapid pace may be associated with greater long term success in weight maintenance.

And it is that long term success with weight loss and weight loss maintenance that is our aim. In the words of Dr. Lawrence Stifler, founder of the HMR Program, “weight management is health management.” The number of Americans with three or more chronic illnesses has increased by 85% over the past decade. This increase is largely related to obesity and inactivity. Fortunately, an effective treatment is available. At “The Weight Loss and Wellness Center at Oklahoma Heart Institute,” our goal is to empower our members to achieve and maintain their ideal body weight, and to receive a lifetime of health benefits in the process. ❤️

Dr. Eric G. Auerbach is the Director of Preventive Cardiology at Oklahoma Heart Institute and Medical Director of The Weight Loss and Wellness Center at Oklahoma Heart Institute

An HMR Program Single Center Experience: Published Results from the Palo Alto Medical Foundation

(76 patients with average follow-up of 2.5 years)

	Initial	Follow-Up	Change	Medications Eliminated
Weight	248 lbs	195 lbs	↓ 53 lbs	<ul style="list-style-type: none"> • 56% cholesterol medications eliminated • 42% hypertension medications eliminated • 50% oral diabetes medications eliminated • 100% insulin eliminated
Total/HDL Cholesterol	3.97	3.46	↓ 13%	
Triglycerides	147	93	↓ 37%	
Systolic BP	135	124	↓ 11 mmHg	
Diastolic BP	101	92	↓ 8 mmHg	
Fasting Glucose	101	92	↓ 9%	

Advancing the Endovascular Management of Lower Extremity Peripheral Artery Disease:

Drug Eluting Devices to Treat Femoropopliteal Disease

By Raj H. Chandwaney, MD, FACC, FSCAI, FSVM

Figure 1
Blood vessels that provide blood supply to the feet

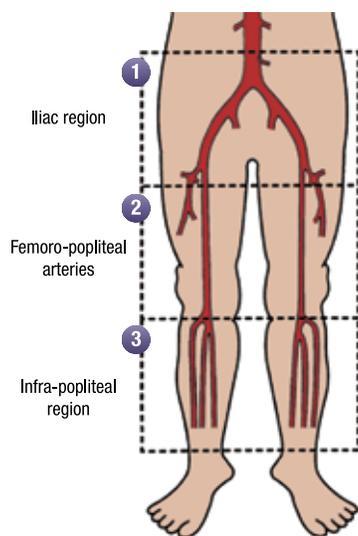


Diagram demonstrates the blood vessels that provide blood flow to the feet. Note that the femoro-popliteal arteries are in region 2.

Lower extremity peripheral arterial disease refers to the presence of plaque accumulation in the blood vessels that deliver blood to the feet. These blood vessels may include the distal abdominal aorta, iliac arteries, common femoral arteries, superficial femoral arteries, popliteal arteries, and/or infrapopliteal arteries (Figure 1). The plaque accumulation in these blood vessels is due to a disease called atherosclerosis. Atherosclerosis is also the disease that causes heart attacks when the plaque accumulates in the blood vessels that feed the heart. Atherosclerosis causes strokes if the plaque accumulates in the blood vessels that feed the brain.

Lower extremity peripheral artery disease is very common. The disease is present in 25-30%

Figure 2
Femoropopliteal artery during knee extension and knee flexion
(Note the severe bending and tortuosity that occurs in the artery during knee flexion)



Diagram of the femoropopliteal artery during knee extension (left image), and knee flexion (right image). Note the severe bending and tortuosity that occurs in the artery during knee flexion.

of people over age 70. The disease is also present in 25-30% of high-risk individuals over age 50. Individuals who have a history of diabetes or tobacco use are considered to be at high risk for developing lower extremity peripheral artery disease. Femoropopliteal peripheral artery disease is a term used to describe the disease when it is present in the arteries located between the hip joint and the knee joint (Figure 1). It is especially common. A large majority of peripheral endovascular interventions performed in the United States are performed in the femoropopliteal vessels.

Achieving durable patency with endovascular techniques in the femoropopliteal arteries has been a challenge. Randomized studies have proven that endovascular stents improve long-term outcomes compared to balloon angioplasty alone. The ABSOLUTE study demonstrated that primary patency at 1 year is significantly higher for patients treated with a nitinol stent compared to balloon angioplasty, (63% versus 37%, respectively).¹ Similarly, the RESILIENT trial also

showed significantly improved 1 year primary patency rates with the use of another nitinol stent compared to angioplasty alone (81% versus 36%, respectively).² Despite the proven benefits of stents compared to angioplasty alone, long-term restenosis rates are still suboptimal. Limitations in long-term patency may be related to the stresses placed on stents at this location secondary to the bending and twisting of the artery that occurs with flexion of the knee joint (Figure 2).

Over a decade ago, drug eluting devices were approved by the FDA to reduce restenosis rates in the coronary arteries. Randomized trials examining the original sirolimus eluting coronary stents consistently demonstrated their superiority over bare metal stents in the coronary vasculature.³⁻⁵ Interestingly, original efforts to create a sirolimus eluting nitinol stent for femoropopliteal disease were unsuccessful. The SIROCCO trial demonstrated no benefit with the original drug eluting nitinol stent compared to bare metal nitinol stents.⁶ Fortunately, the biotechnology industry continued their efforts to study and develop drug eluting devices for the femoropopliteal arteries despite initial disappointments.

Research and development shifted toward the use of paclitaxel eluting devices rather than sirolimus eluting devices. Paclitaxel, a cytotoxic compound naturally derived from the Pacific Yew tree that inhibits the M phase of the cell cycle, possesses theoretical advantages in the femoropopliteal vessels over sirolimus. Research efforts were also redirected from the polymer based drug elution platform tested in the SIROCCO trial, to a polymer-free drug elution platform. The culmination of these efforts is the Zilver-PTX paclitaxel eluting nitinol stent manufactured by Cook.

The Zilver-PTX randomized controlled trial proved that 1 year primary patency rates can be significantly improved using the paclitaxel eluting nitinol stent (90% primary patency with the drug eluting stent versus 73% primary patency using

the bare metal stent).⁷ Five year follow up results were recently presented in the fall of 2014 at a national scientific meeting. The relative benefits of the Zilver-PTX drug eluting stent over bare metal stents have widened as the data now shows a 41% risk reduction for repeat intervention rates compared to the control arm.⁸

Despite the advances with drug eluting stent technology, many experts hypothesized that further advantages might be achieved by developing a drug eluting strategy that does not require stent use. This belief has led to the development of drug coated balloons for use in the femoropopliteal arteries. In the fall of 2014, the FDA approved use of the Lutonix drug coated balloon manufactured by Bard as the first of what will likely be many drug coated balloons that can be used for endovascular interventions. The Lutonix drug coated balloon is an angioplasty balloon coated with a non-polymer based coating consisting of the drug paclitaxel as the active pharmaceutical agent, and the inactive ingredients sorbitol and polysorbate, which act as drug carriers. The paclitaxel coating is evenly distributed across the working length of the balloon at a surface concentration of 2 mcg/mm². The key functional characteristic is to deliver the pharmaceutical agent to the tissue of the vascular wall during balloon inflation.⁹ The Lutonix drug coated balloon was approved by the FDA based on the LEVANT-2 randomized study which demonstrated that 12 month primary patency rates are significantly improved from 52.6% using standard angioplasty, up to 65.2% using the drug coated balloon.¹⁰

More recently, the FDA just approved the Medtronic IN.PACT Admiral drug coated balloon. It is the second drug coated balloon to receive approval in the United States. The IN.PACT Admiral drug coated balloon is an angioplasty balloon coated with a non-polymer based coating consisting of the drug paclitaxel as the active pharmaceutical agent, and the ingredient urea to act as an excipient. The paclitaxel coating is distributed across the working length of the balloon at a surface concentration of 3.5 mcg/mm². Upon balloon inflation, the drug coating on the balloon comes into contact with water in the blood stream that hydrates the urea and facilitates release of the paclitaxel into the target lesion. Paclitaxel penetrates the vessel wall, where it remains at a therapeutic dose for over 180 days, addressing the causes of restenosis.¹¹ The IN.PACT Admiral drug coated balloon was approved by the FDA based on the IN.PACT SFA randomized study which demonstrated that 12 month primary patency rates are significantly improved from 52.4% using standard angioplasty, up to 82.2% using the drug coated balloon.¹²

The IN.PACT SFA trial demonstrates an important therapeutic advantage over the existing alternative treatments for peripheral artery disease. Drug coated balloons are an attractive alternative, because it offers the promise of improved

patency in comparison with percutaneous transluminal angioplasty and a reduction in the need for stents. This might be particularly important in the dynamic environment of the superficial femoral and popliteal arteries.

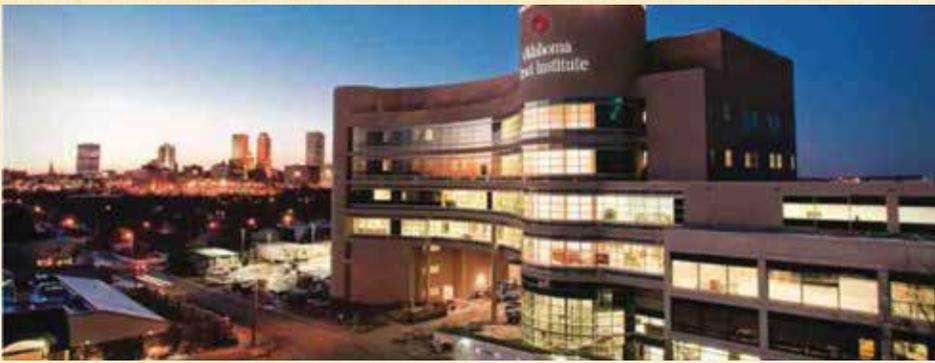
The results achieved with novel drug eluting endovascular strategies for femoropopliteal disease, should be compared to the outcomes achieved with surgical bypass. Although surgical revascularization generally provides durable outcomes in other vascular territories, femoropopliteal bypass surgery does not achieve similar sustained results. Femoropopliteal bypass surgery is usually performed with autologous saphenous venous conduits, or artificial synthetic bypass conduits. A large published meta-analysis reveals that the 5 year primary patency rates for femoropopliteal bypass surgery are only 49% for artificial synthetic bypass grafts and 69% with saphenous venous bypass grafts, respectively.¹³ Despite the superiority of venous bypass conduits over artificial synthetic bypass grafts, the majority of femoropopliteal bypass graft surgeries performed in the United States are performed with artificial synthetic bypass grafts because of lack of available suitable venous conduit, prolonged surgical time, and/or concerns that the patient may ultimately need the venous conduit for a potentially life-saving coronary artery bypass graft surgery. Nevertheless, five year primary patency rates from the Zilver-PTX randomized trial were recently reported to be 66%, which is a numerical value that compares favorably with venous bypass grafts, and appears superior to the more frequently used synthetic bypass grafts. Five year primary patency rates from the LEVANT-2 and IN.PACT SFA randomized trials are not yet available.

In conclusion, femoropopliteal artery disease is very common. Although endovascular revascularization techniques provide very good acute results, achieving long-term durable patency has been a challenge. Drug eluting balloons and stents are now available that have been shown to improve the long-term outcomes achieved with endovascular revascularization. Although more data is required, recently published studies suggest that endovascular revascularization performed with drug eluting devices may compare favorably with surgical revascularization techniques. The endovascular specialists at Oklahoma Heart Institute will continue to monitor this evolving area of medicine so that we may continue to offer our patients the most progressive treatments available. ❤️

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THE DOCTORS OF OKLAHOMA HEART INSTITUTE

Wayne N. Leimbach, Jr., MD, FACC, FACP, FSCAI, FCCP, FAHA



Dr. Leimbach is a specialist in interventional cardiology with expertise in cardiac catheterization, coronary intervention (including angioplasty, stent placement, atherectomy, intravascular ultrasound), peripheral vascular interventions, such as carotid stenting, as

well as interventional therapies for structural heart disease, such as percutaneous closure of PFOs, ASDs and PDAs, and percutaneous placement of stent valves (TAVR). He is Director of the Cardiac and Interventional Laboratories at Oklahoma Heart Institute Hospital and also is Chief of Cardiology. Dr. Leimbach is Co-Founder of the Lipid and Wellness Clinic at Oklahoma Heart Institute. He is Director of the James D. Harvey Center for Cardiovascular Research at Hillcrest Medical Center, as well as Director of the Oklahoma Heart Research and Education Foundation. He also serves as Clinical Associate Professor of Medicine at the University of Oklahoma College of Medicine – Tulsa. Dr. Leimbach completed a Clinical Cardiology Fellowship and a Research Fellowship at the University of Iowa Hospitals and Clinics. He completed his Internal Medicine Internship and Residency programs at Iowa, where he was selected Chief Resident in Medicine. He received his medical degree from Northwestern University in Chicago and his Bachelor of Science degree from the University of Michigan.

Board certified in Internal Medicine, Cardiovascular Disease and Interventional Cardiology

Robert C. Sonnenschein, MD, FACC, ASE, RVT, RPVI



Dr. Sonnenschein specializes in echocardiography and noninvasive peripheral vascular imaging. He is past Director of Peripheral Vascular Ultrasound Imaging at Hillcrest Medical Center and Oklahoma Heart Institute and serves as Clinical Associate Professor of Medicine at the University of Oklahoma College of Medicine – Tulsa. He completed his Cardiology Fellowship at the State University of New York Upstate Medical Center in Syracuse, where he also completed his Internal Medicine Internship and Residency programs. Dr. Sonnenschein received his medical degree from Rush Medical College in Chicago and his Bachelor of Arts degree from the University of Pennsylvania.

Board certified in Internal Medicine, Cardiovascular Disease, and Adult Echocardiography Registered Vascular Technologist

Robert E. Lynch, MD, FACC



Dr. Lynch is a specialist trained in noninvasive and invasive cardiology with a special interest in the prevention of cardiovascular disease. He is former Chief of Cardiology at Hillcrest Medical Center, where he also has served as Chief of Medicine and President of the medical staff. Dr. Lynch is former Co-Director of the Lipid and Wellness Clinic at Oklahoma Heart Institute and Director of the Executive Health Program. Dr. Lynch is also a Clinical Assistant Professor at the University of Oklahoma College of Medicine – Tulsa. He completed his Cardiology Fellowship, as well as his Internal Medicine Internship and Residency, at the University of Oklahoma Health Sciences Center. Dr. Lynch received his medical degree from the University of Oklahoma School of Medicine and his Bachelor of Science degree from the University of Tulsa. Before establishing his practice in Tulsa, he served as Chief of Medicine at the U.S. Army Hospital, Bangkok, Thailand.

Board certified in Internal Medicine and Cardiovascular Disease

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Dr. Nemeč is a specialist in echocardiography, stress echocardiography and nuclear cardiology. He serves as Director of Nuclear Cardiology for Oklahoma Heart Institute. Dr. Nemeč has served as Assistant Professor of Internal Medicine, Division of Cardiology, at Creighton University and as Assistant Professor, Depart-

ment of Radiology, also at Creighton University. He completed his Clinical Cardiology Fellowship at the Cleveland Clinic Foundation and his Internal Medicine Internship and Residency at Creighton University. Dr. Nemeč also completed a year of training in pathology at the University of Missouri, Columbia, MO. He received his medical degree from Creighton University, where he also received his Bachelor of Arts degree.

Board certified in Internal Medicine, Cardiovascular Disease and Nuclear Cardiology

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Dr. Johnsen is an interventional cardiologist with expertise in cardiac catheterization, angioplasty and related interventional procedures, such as stents and atherectomy. He is Director of Cardiac Rehabilitation at Hillcrest Medical Center and Director of the

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Dr. Kaneshige is a noninvasive cardiologist with expertise in adult echocardiography, stress echocardiography and transesophageal echocardiography. He is Chief of Cardiology at Oklahoma Heart Institute, where he is Director of the Congestive Heart Failure C.A.R.E. Center and the Adolescent and Adult Congenital Heart Clinic. He is past Chief of Cardiology at Hillcrest Medical Center. Dr. Kaneshige completed his Internal Medicine Internship and Residency at Creighton University School of Medicine, where he also received his medical degree. He received a Bachelor of Science in chemistry at Creighton University. Dr. Kaneshige completed his Clinical Cardiology fellowship at Creighton, where he also served as Chief Cardiology Fellow for two years. He completed an additional Cardiac Ultrasound Fellowship at the Mayo Clinic in Rochester. Dr. Kaneshige served as Assistant Professor of Medicine at Creighton University School of Medicine, where he was Director of the Noninvasive Cardiovascular Imaging and Hemodynamic Laboratory.

Board certified in Internal Medicine, Cardiovascular Disease, Adult and Transesophageal Echocardiography

Edward T. Martin, MS, MD, FACC, FACP, FAHA



Dr. Martin is a noninvasive cardiologist with specialty expertise in non-invasive imaging. He is Director of Cardiovascular Magnetic Resonance Imaging at Oklahoma Heart Institute and Hillcrest Medical Center. In addition, he is a Clinical Associate Professor of Medicine at the University of Oklahoma College of Medicine – Tulsa. Dr. Martin has specialty training in Nuclear Medicine, as well as additional training dedicated to Cardiovascular Magnetic Resonance Imaging. He completed his Cardiology Fellowship at the University of Alabama. Dr. Martin's Internal Medicine Internship and Residency training were performed at Temple University Hospital in Philadelphia. He received his medical degree from the Medical College of Ohio. Dr. Martin completed his Master of Science degree in mechanical engineering at the University of Cincinnati and his Bachelor of Science degree in physics at Xavier University. Dr. Martin is a founding member of the Society of Cardiovascular Magnetic Resonance and is an editorial board member of the Journal of Cardiovascular Magnetic Resonance.

Board certified in Internal Medicine and Cardiovascular Disease

Roger D. Des Prez, MD, FACC



Dr. Des Prez is a noninvasive cardiologist with specialty expertise in echocardiography, nuclear cardiology and cardiac computed tomography. He is Director of Cardiac Computed Tomography at Oklahoma Heart Institute Hospital, at Hillcrest Medical Center and Bailey Medical Center. Dr. Des Prez received his medical degree and Bachelor of Arts degree from Vanderbilt University. He completed his Residency in Internal Medicine and Pediatrics at University Hospital of Cleveland. Dr. Des Prez practiced for six years as an internist with the Indian Health Services in Gallup, NM. He returned to Vanderbilt University as a member of the Internal Medicine Faculty, at which time he also completed his cardiology training.

Board certified in Internal Medicine, Cardiovascular Disease, Echocardiography, Pediatrics and Nuclear Cardiology

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Dr. Hanson is a specialist in Endocrinology, Metabolism and Hypertension at Oklahoma Heart Institute with expertise in diabetes, lipids and hypertension. He also serves as Clinical Associate Professor of Medicine in the College of Osteopathic Medicine – Oklahoma State University. He completed a Fellowship in Endocrinology, Metabolism and Hypertension at the University of Oklahoma in Oklahoma City. Dr. Hanson's Internal Medicine Residency and Rotating Internship were completed at Tulsa Regional Medical Center. He received his medical degree from Oklahoma State University and his Bachelor of Science degree from Northeastern Oklahoma State University in Tahlequah.

Board certified in Internal Medicine, Endocrinology and Metabolic Diseases

David A. Sandler, MD, FACC, FHRS



Dr. Sandler is a cardiologist with subspecialty expertise in electrophysiology, complex ablation, and atrial fibrillation management. Dr. Sandler is Director of Electrophysiology at Oklahoma Heart Institute Hospital. He completed his Cardiac Electrophysiology Fellowship and his Cardiovascular Medicine Fellowship at New York University Medical Center, New York, NY. Dr. Sandler performed his Internal Medicine Internship and Residency at Mount Sinai Medical Center, New York, NY. He earned his medical degree from Georgetown University School of Medicine in Washington, DC. Dr. Sandler received his Bachelor of Arts degree at the University of Pennsylvania in Philadelphia.

Board certified in Internal Medicine, Cardiovascular Disease and Cardiac Electrophysiology

Raj H. Chandwaney, MD, FACC, FSCAI, FFSVM



Dr. Chandwaney is an interventional cardiologist with expertise in cardiac catheterization, coronary angioplasty and related interventional procedures such as coronary stents, atherectomy, intravascular ultrasound and peripheral vascular interventional procedures.

Dr. Chandwaney is Director of the Chest Pain Center and Cardiology Telemetry Unit at Oklahoma Heart Institute Hospital. He completed his Clinical Cardiology Fellowship at Northwestern University Medical School in Chicago, IL., where he also completed an Interventional Cardiology Fellowship. Dr. Chandwaney's Internal Medicine Internship and Residency were performed at Baylor College of Medicine in Houston, TX. He received his medical degree from the University of Illinois at Chicago. Dr. Chandwaney completed his Master of Science degree at the University of Illinois at Urbana-Champaign, where he also received his Bachelor of Science degree.

Board certified in Internal Medicine, Cardiovascular Disease, Interventional Cardiology and Endovascular Medicine

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Board certified in Internal Medicine, Endocrinology and Metabolic Diseases

Frank J. Gaffney, MD, FACC



Dr. Gaffney is an interventional and noninvasive cardiologist with subspecialty expertise in transesophageal echocardiography, nuclear cardiology, and coronary angiography. He completed his Cardiovascular Medicine Fellowship at Scott & White Memorial Hospital in Temple, Texas. Dr. Gaffney completed his Internal Medicine Internship and Residency at Brooke Army Medical Center in San Antonio. He then remained on staff at Scott & White Memorial Hospital for several years, before entering his Fellowship in Cardiovascular Medicine. Dr. Gaffney earned his medical degree from New York Medical College, Valhalla, New York, and he received his Bachelor of Arts degree at Hofstra University in Hempstead, New York.

Board certified in Internal Medicine, Cardiovascular Disease and Nuclear Cardiology

Eric G. Auerbach, MD, FACC



Dr. Auerbach is a general cardiologist who is particularly interested in preventive cardiology and cardiovascular risk reduction. He completed his cardiology fellowship at the University of Miami/Jackson Memorial Hospital in Miami, FL, following which he obtained additional subspecialty training in cardiovascular MRI, nuclear cardiology, and cardiac CT imaging. His areas of expertise also include echocardiography, transesophageal echocardiography, stress testing, and management of lipid disorders. Dr. Auerbach's Internal Medicine Internship and Residency were performed at the University of Miami/Jackson Memorial Hospital. He earned his medical degree at the University of Miami, Miami, FL, and his Bachelor of Arts degree at Princeton University, Princeton, NJ.

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Board certified in Internal Medicine, Endocrinology, Diabetes and Metabolic Diseases

Robert L. Smith, Jr., MSc, MD, FACC, FSCAI



Dr. Smith specializes in interventional cardiology including cardiac catheterization, coronary angioplasty, and related interventional procedures such as coronary stents, atherectomy, intravascular ultrasound, and peripheral vascular interventional procedures.

He completed an Interventional Cardiology Fellowship at the University of Florida College of Medicine in Jacksonville, FL. Dr. Smith performed his Clinical Cardiology Fellowship at Vanderbilt University School of Medicine in Nashville, TN and Tulane University School of Medicine in New Orleans. He received his medical degree from the University of Oklahoma College of Medicine in Oklahoma City and then completed his Internal Medicine Internship and Residency at Emory University School of Medicine in Atlanta, GA. Dr. Smith received his Bachelor of Arts, Bachelor of Science

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Board certified in Internal Medicine, Cardiovascular Disease, Interventional Cardiology and Nuclear Cardiology

Craig S. Cameron, MD, FACC, FHRS



Dr. Cameron is a specialist in cardiac electrophysiology, including catheter ablation of arrhythmia, atrial fibrillation management, pacemakers, implantable defibrillators, and cardiac resynchronization devices. He completed his Cardiac Electrophysiology Fellowship and his Cardiovascular Disease Fellowship at Baylor University Medical Center in Dallas, TX. Dr. Cameron's Internship and Internal Medicine Residency were performed at Baylor College of Medicine in Houston. He earned his medical degree from the University of Kansas School of Medicine in Kansas City, KS. Dr. Cameron received his Bachelor of Science degree at Pittsburg State University in Pittsburg, KS.

Board certified in Cardiovascular Disease and Cardiac Electrophysiology

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Dr. Ichinose specializes in interventional cardiology including cardiac catheterization, coronary angioplasty and related interventional procedures such as coronary stents, atherectomy, intravascular ultrasound and peripheral vascular interventional procedures. He completed his Interventional and Clinical Cardiology Fellowships and his Internal Medicine Residency at the University of Massachusetts Memorial Health Care Center in Worcester, MA. Dr. Ichinose received his medical degree from Louisiana State University in New Orleans. He earned his Bachelor of Science degree from Texas Christian University in Fort Worth, TX.

Board certified in Internal Medicine, Cardiovascular Disease, Interventional Cardiology and Nuclear Cardiology

Cristin M. Bruns, MD



Dr. Bruns is a specialist in Endocrinology, Diabetes and Metabolism at Oklahoma Heart Institute, with expertise in diabetes, thyroid disease (including thyroid cancer) and polycystic ovary syndrome. She completed her Internal Medicine Internship and Residency and Endocrinology Fellowship at the University of Wisconsin Hospital and Clinics in Madison, WI. Dr. Bruns earned her medical degree from Saint Louis University School of Medicine in St. Louis, MO and her Bachelor of Arts and Bachelor of Science degrees in biology from Truman State University in Kirksville, MO. Prior to joining Oklahoma Heart Institute, Dr. Bruns worked as a clinical endocrinologist at the Dean Clinic in Madison, Wisconsin.

Board certified in Internal Medicine, Endocrinology and Metabolic Diseases

Gregory A. Cogert, MD, FACC, FHRS



Dr. Cogert is a cardiologist who specializes in electrophysiology, including catheter ablation of arrhythmia, as well as the implantation and management of cardiac pacemakers, defibrillators, and cardiac resynchronization devices. He completed his Cardiac Electrophysiology Fellowship at Mayo Clinic in Rochester, MN and his Cardiovascular Fellowship at Cedars-Sinai Medical Center in Los Angeles, CA. Dr. Cogert's Internal Medicine Internship and Residency were completed at UCLA Medical Center in Los Angeles. He earned his medical degree from the University of California in Irvine and received his Bachelor of Science degree in microbiology and molecular genetics from the University of California in Los Angeles.

Board certified in Internal Medicine, Cardiovascular Disease, Echocardiography, Nuclear Medicine and Cardiac Electrophysiology.

John S. Tulloch, MD



Dr. Tulloch is a noninvasive cardiologist with expertise in adult echocardiography, peripheral vascular imaging, nuclear cardiology, cardiac computed tomography and MRI. Dr. Tulloch is Director of the Cardiac and Vascular Ultrasound Department of Hillcrest Medical Center's Cardiovascular Diagnostics. He completed his Cardiovascular Fellowship at the University of Kansas Medical Center in Kansas City, KS. Dr. Tulloch's Internal Medicine Internship and Residency also were completed

at the University of Kansas Medical Center. He earned his medical degree from Ross University School of Medicine in New Brunswick, NJ and received his Bachelor of Science degree in biology from Avila University in Kansas City, MO.

Board certified in Internal Medicine, Cardiovascular Disease, Cardiovascular Tomography, and Nuclear Cardiology

Anthony W. Haney, MD, FACC



Dr. Haney is a noninvasive cardiologist with expertise in nuclear cardiology, echocardiography, peripheral vascular imaging and MRI. He also performs diagnostic cardiac catheterization. He completed his Cardiovascular Fellowship at the Medical College of Virginia in Richmond. Dr. Haney's Internal Medicine Internship and Residency were completed at the Mayo Clinic in Scottsdale, AZ. He earned his medical degree from the University of Oklahoma School of Medicine.

Board certified in Internal Medicine, Cardiovascular Disease and Nuclear Cardiology

Ralph J. Duda, Jr., MD, FACP, FACE, FASH



Dr. Duda is a specialist in Endocrinology, Diabetes and Metabolism at Oklahoma Heart Institute, with expertise in diabetes, lipids, hypertension and thyroid diseases. He completed his Fellowship in Endocrinology and Metabolism at the Mayo Graduate School of Medicine, where he also completed his Residency in Internal Medicine. Dr. Duda received his medical degree from Northwestern University School of Medicine in Chicago, IL. He earned his Bachelor of Science degree from Benedictine University in Lisle, IL.

Board certified in Internal Medicine, Endocrinology, Diabetes and Metabolism, Clinical Lipidology, Clinical Hypertension, Clinical Bone Densitometry and Thyroid Ultrasonography

Douglas A. Davies, MD, FACC



Dr. Davies is a hospital-based cardiologist who provides continuity of care for patients admitted to Oklahoma Heart Institute - Hospital. He completed a Clinical Cardiology Fellowship and additional training in nuclear cardiology at the Medical College of Virginia, where he also completed his Internal Medicine and Residency programs. Dr. Davies received his medical degree from Johns Hopkins University School of Medicine in Baltimore.

Board Certified in Internal Medicine, Cardiovascular Disease, Nuclear Cardiology and Cardiovascular Computed Tomography Angiography

Neil Agrawal, MD



Dr. Agrawal is a noninvasive cardiology specialist with expertise in adult echocardiography, nuclear cardiology, cardiac computed tomography and MRI. He completed his Cardiovascular Fellowship at the University of Vermont. Dr. Agrawal's Internal Medicine Internship and Residency were completed at the University of Louisville, and he earned his medical degree from St. George's University in Granada, West Indies. Dr. Agrawal completed his Bachelor of Science degree in biochemistry at the University of Texas at Austin.

Board certified in Internal Medicine

Kamran I. Muhammad, MD, FACC, FSCAI



Dr. Muhammad is a subspecialist in interventional cardiology. In addition to expertise in traditional areas of interventional cardiology, such as coronary intervention (angioplasty, stent placement, atherectomy, intravascular imaging) and peripheral vascular and carotid artery intervention, Dr. Muhammad has a special interest and expertise in interventional therapies for structural and valvular heart disease including the percutaneous non-surgical replacement and repair of heart valves — TAVR and MitraClip. As such, he currently serves as the Director of the Structural Heart Disease Program at OHI.

With dedicated and advanced training in structural heart disease intervention from the world-renowned Cleveland Clinic, Dr. Muhammad has been a pioneer in this field in Oklahoma. He led a team of OHI physicians in performing the first transcatheter aortic valve replacements (TAVR) and first transcatheter mitral valve repairs (MitraClip) in Tulsa and the region. Under his direction, these programs are the most experienced and comprehensive programs of their

kind in the state, providing our patients with expert care and class-leading technologies for the non-surgical treatment of structural and valvular heart diseases.

In addition to his clinical experience, Dr. Muhammad has authored many peer-reviewed articles and textbook chapters on important cardiology topics. He also serves as Clinical Associate Professor of Medicine at the University of Oklahoma College of Medicine — Tulsa.

Dr. Muhammad completed his Clinical Cardiology and Interventional Cardiology Fellowships at the Cleveland Clinic which included additional dedicated training in peripheral vascular and structural cardiac intervention. Dr. Muhammad completed his Internal Medicine Internship and Residency at Yale University where he was selected and served as Chief Resident. He earned his medical degree from the University of Massachusetts Medical School, graduating with top honors and election to the Alpha Omega Alpha (ΑΩΑ) honor society. Dr. Muhammad earned his Bachelor of Science degree in computer science from the University of Massachusetts, Amherst.

Board certified in Internal Medicine, Cardiovascular Disease, Nuclear Cardiology and Interventional Cardiology

Arash Karnama, DO, FACC



Dr. Karnama is a specialist in interventional cardiology, including cardiac catheterization, coronary intervention, nuclear cardiology, echocardiography (TEE/TTE), cardioversion, peripheral angiography, peripheral intervention, carotid angiography, intravascular ultrasound, atherectomy, and PTCA/stenting for acute myocardial infarction. Dr. Karnama completed his Interventional and Clinical Cardiology Fellowships at Oklahoma State University Medical Center and his Internal Medicine Internship and Residency at the Penn State Milton S. Hershey Medical Center in Hershey, PA. Dr. Karnama received his medical degree from Des Moines University in Des Moines, IA and his Bachelor of Arts degree from the University of Iowa in Iowa City.

Board certified in Internal Medicine, Interventional Cardiology, Cardiovascular Disease, Nuclear Cardiology, and Cardiovascular Computed Tomography

Victor Y. Cheng, MD, FACC, FSCCT



Dr. Cheng joins Oklahoma Heart Institute after serving as cardiology faculty at Cedars-Sinai Medical Center and assistant professor at the University of California in Los Angeles for the past four years. He is a specialist in noninvasive heart and vascular imaging, particularly

in cardiac computed tomography (CT), a topic on which he has published numerous original research publications addressing quality, clinical use, and novel applications. Dr. Cheng's training included a Clinical Cardiology Fellowship and Advanced Cardiac Imaging Fellowship at Cedars-Sinai Medical Center, and an Internal Medicine Internship and Residency at the University of California in San Francisco. Dr. Cheng received his medical degree from Northwestern University in Chicago, IL and his Bachelor of Science degree from Northwestern University in Evanston, IL.

Board certified in Internal Medicine, Cardiovascular Disease, Nuclear Cardiology, Echocardiography and Cardiovascular Computed Tomography

Jana R. Loveless, MD



Dr. Loveless is a sleep specialist, with expertise in the diagnosis and treatment of sleep disorders. Prior to joining Oklahoma Heart Institute, Dr. Loveless was with Nocturna of Tulsa, Warren Clinic and Springer Clinic. She completed her Internal Medicine Residency program at the University of Oklahoma, Tulsa, where she was Chief Resident. She also earned her medical degree from the University of Oklahoma, Tulsa. Dr. Loveless completed graduate studies at Texas Tech University, and she earned her Bachelor of Arts degree at Davidson College in Davidson, North Carolina.

Board Certified in Internal Medicine and Sleep Medicine

Mathew B. Good, DO



Dr. Good is an invasive/noninvasive cardiology specialist with expertise in adult echocardiography, nuclear cardiology, cardiac computed tomography, peripheral vascular ultrasound and MRI. He completed his Cardiovascular Fellowship at the University of Kansas Medical Center in Kansas City, KS, where he also completed his Internal Medicine Internship and Residency. Dr. Good received his medical degree from the Oklahoma State University Center for Health and Sciences in Tulsa and his Bachelor of Arts degree from the University of Colorado in Boulder.

Board certified in Internal Medicine and Cardiovascular Computed Tomography

Stanley K. Zimmerman, MD, FACC, FSCAI



Dr. Zimmerman is a specialist in interventional cardiology, including cardiac catheterization, coronary angioplasty, and related interventional procedures such as coronary stents, atherectomy, vascular ultrasound and peripheral vascular interventional procedures.

He completed his Interventional and Cardiovascular Fellowships at the University of Kansas Medical Center in Kansas City, KS, as well as his Internal Medicine Internship and Residency. In addition, Dr. Zimmerman received his medical degree from the University of Kansas Medical Center and his Bachelor of Arts degree from the University of Kansas in Lawrence.

Board certified in Internal Medicine, Cardiovascular Disease and Interventional Cardiology

Stephen C. Dobratz, MD, FACC



Dr. Dobratz specializes in diagnostic and interventional cardiology, including cardiac catheterization, peripheral angiography, pacemakers and defibrillators, cardioversion, cardiac nuclear studies, cardiac computed tomography, transesophageal echo and echocardiograms. He completed his Fellowship in Cardiology at Allegheny General Hospital in Pittsburgh, Pennsylvania. Dr. Dobratz completed his Internal Medicine Internship and Residency at the University of Arizona in Tucson. He earned his medical degree at Eastern Virginia Medical School in Norfolk and his undergraduate degree at James Madison University in Harrisonburg, Virginia.

Board certified in Cardiovascular Disease

Paul Kempe, MD



Dr. Kempe is a Cardiovascular Thoracic Surgeon at Oklahoma Heart Institute. He completed his Residency in Cardiothoracic Surgery at Boston University Medical Center in Boston, MA. He completed his General Surgery Internship and Residency at Richland Memorial Hospital in Columbia, South Carolina. Dr. Kempe earned his medical degree at the University of Texas Southwestern Medical School in Dallas. He received his undergraduate degree in Chemistry at Abilene Christian University.

Board certified in Thoracic Surgery

Michael Phillips, MD, FACC, FACS



Dr. Phillips is a Cardiovascular Thoracic Surgeon at Oklahoma Heart Institute. He completed his fellowship at Mid America Heart Institute in Kansas City, MO and his general surgery residency at the Mayo Graduate School of Medicine. He earned his medical degree from the University of Missouri. Dr. Phillips received his undergraduate degrees in Biology and Chemistry at William Jewell College in Liberty, MO.

Board certified by in Thoracic and General Surgery

James B. Chapman, MD, FACC, FSCAI



Dr. Chapman is a specialist in interventional cardiology, including cardiac catheterization, coronary angioplasty and related interventional procedures such as stents, atherectomy, laser, intravascular ultrasound imaging and direct PTCA for acute myocardial infarction. He completed a Clinical Cardiology Fellowship St. Vincent Hospital and Health Care Center in Indianapolis, IN. He also completed his Internal Medicine Internship and Residency programs at St. Vincent. Dr. Chapman received his medical degree from Indiana University School of Med-

icine in Indianapolis and his Bachelor of Science degree from Indiana University in Bloomington, IN.

Board certified in Internal Medicine, Cardiovascular Disease and Interventional Cardiology

Sandra E. Rodriguez, MD



Sandra Rodriguez is a noninvasive cardiology specialist with expertise in congestive heart failure and transplants. She completed an Advanced Heart Failure and Transplant Fellowship at the University of Colorado Hospital in Aurora, Colorado and her Cardiology Diseases Fellowship at Texas Tech University Health Sciences Center in Lubbock Texas. Dr. Rodriguez completed her Internal Medicine Residencies at Texas Tech and the Universidad El Bosque in Bogota, Colombia. She earned her medical degree from Medicine School, Escuela de Medicina "Juan N. Corpas," in Bogota.

Board certified in Internal Medicine, Cardiovascular Disease and Advanced Heart Failure/Transplant Cardiology

Joseph J. Gard, MD, FACC, FHRS



Dr. Gard is a cardiologist who specializes in electrophysiology, complex ablation and atrial fibrillation management. He completed his Cardiac Electrophysiology Fellowship and his Cardiology Fellowship at the Mayo School of Graduate Medical Education in Rochester, Minnesota. Dr. Gard also performed his Internal Medicine Residency at Mayo. He earned his medical degree from the University of Nebraska in Omaha, Nebraska. Dr. Gard received his Bachelor of Science degree from Boston College in Chestnut Hill, Massachusetts.

Board Certified in Internal Medicine, Cardiovascular Disease and Electrophysiology

Edward J. Coleman, MD, FACC, FAHA, FACS, FCCP



Dr. Coleman is a cardiovascular surgeon who specializes in cardiac, thoracic and vascular surgery. He completed his residency in cardiothoracic surgery at State University of New York at Buffalo in Buffalo, New York. He was Senior & Chief Resident at Mary Imogene Bassett Hospital/Columbia University College of Physicians & Surgeons in Cooperstown, New York. Dr. Coleman performed his Internship and Residency in general surgery at the University of Rochester School of Medicine & Dentistry in Rochester, NY. He earned his medical degree from State University of New York at Buffalo School of Medicine, Buffalo, New York. Dr. Coleman received his Bachelor of Arts degree from Norwich University in Northfield, Vermont.

Board Certified in General Surgery and Thoracic Surgery

Michael B. Newnam, MD



Dr. Newnam is a Board Certified specialist in the diagnosis and treatment of sleep disorders. He completed his Family Practice Internship & Residency programs at the Womack Army Medical Center in Ft. Bragg, NC. Dr. Newnam earned his medical degree from the University of Oklahoma and his Bachelor of Science degree from Oral Roberts University in Tulsa, OK.

Board Certified in Family Medicine and Sleep Medicine

IMPROVE-IT Trial Confirms Lower LDL-Cholesterol Levels Are Better

By Wayne N. Leimbach, MD, FACC, FACP, FSCAI, FCCP, FAHA

The majority of heart attacks and strokes are preventable by aggressively treating the major risk factors for cardiovascular disease. These risk factors include: high blood levels of LDL cholesterol, hypertension, diabetes mellitus, smoking and a sedentary lifestyle.

Lowering of LDL cholesterol (LDL-C) has been a mainstay for heart attack and stroke prevention. Numerous clinical trials have shown reductions in morbidity and mortality with the use of medications called statins to lower LDL cholesterol.

The most recent guidelines for lowering LDL cholesterol levels were based primarily on the use of statin medications. In addition, the new guidelines departed from previous guidelines where the primary concept was that “the lower the LDL cholesterol levels the greater the reductions in cardiovascular events.” Previous guidelines were based upon both randomized clinical trials and a full spectrum of scientific studies, from epidemiologic trials to newer genetic trials. These guidelines emphasized an optimal target for LDL cholesterol of less than 70 mg/dL for higher-risk patients with known coronary disease, peripheral vascular disease or strokes.

Based on a full spectrum of scientific studies, the old guidelines supported the concept of an “even lower LDL cholesterol is even better”. The new guidelines presented in 2013 were based solely on randomized clinical trials. The new guidelines recommend that higher-risk patients be placed on top doses of the most potent statins and did not recommend targeting any specific LDL cholesterol levels as the goal of therapy.

This approach raised significant controversy among leading experts in the field of cardiovascular disease prevention. The American Society of Lipidology and The American Society of Endocrinology refused to endorse the new guidelines.

Just one year after the presentation of the new cholesterol treatment guidelines, the IMPROVE-IT Trial was presented at the American Heart Association 2014 Scientific Sections in November, 2014 and refuted the new guidelines. The study included more than 18,000 patients who were hospitalized for an acute coronary

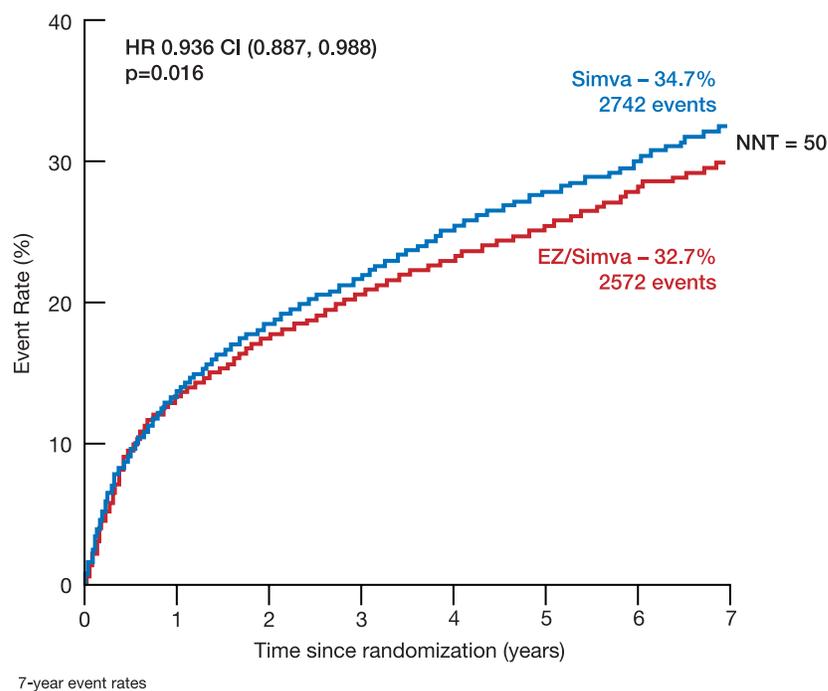
syndrome (ST segment elevation myocardial infarction, non-ST segment elevation myocardial infarction, or unstable angina). The patient’s mean baseline LDL cholesterol levels were 95 mg/dL in both treatment arms. The patients were randomized to a statin, (simvastatin 40 mg a day plus placebo) or the combination of simvastatin 40 mg a day along with a non-statin medication, ezetimibe 10 mg a day. Ezetimibe works by partially blocking the absorption of cholesterol from the gut.

With simvastatin 40 mg a day, the LDL cholesterol levels were reduced to 69.9 mg/dL by one year. With the combination of simvastatin 40 mg a day plus ezetimibe 10 mg a day, the LDL cholesterol levels were further reduced to 53.2 mg/dL at one year.

Figure 1

Primary Endpoint – ITT

Cardiovascular death, MI, documented unstable angina requiring rehospitalization, coronary revascularization (≥ 30 days), or stroke

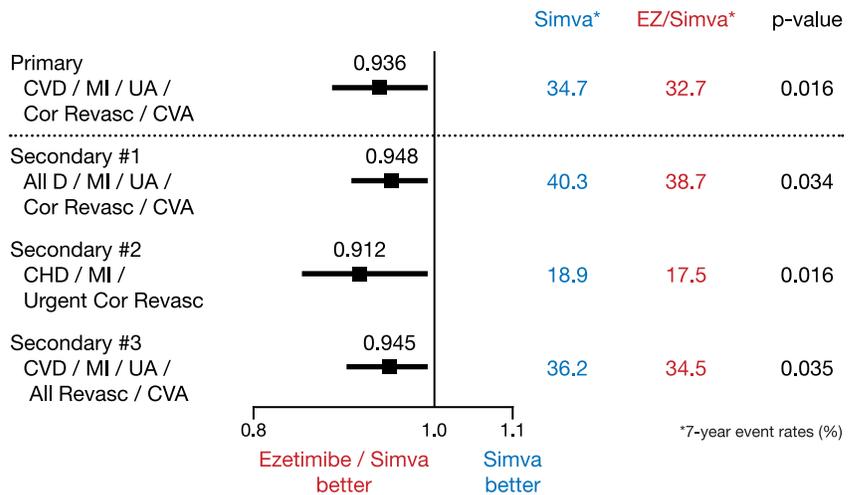


Both groups achieved a target LDL cholesterol level of less than 70 mg/dL, but the combination group using simvastatin and ezetimibe had a further lowering of the LDL cholesterol to 53.2 mg/dL.

The study lasted 7 years with a minimum duration of follow up being 2-1/2 years. The primary endpoint to the trial was the combination of: CV death, MI, stroke, or hospitalization for unstable angina or coronary revascularization.

The study found a 6.4% reduction in the primary endpoint by further lowering the LDL cholesterol with the combination of simvastatin and ezetimibe (Figure 1). The result was highly statistically significant ($P = 0.016$). The number of patients needed to be treated to prevent one CV event of CV death, MI, stroke or hospitaliza-

Figure 2
Primary and Three Prespecified Secondary Endpoints – ITT



UA, documented unstable angina requiring rehospitalization; Cor Revasc, coronary revascularization (≥30 days after randomization); All D, all-cause death; CHD, coronary heart disease death; All Revasc, coronary and non-coronary revascularization (≥30 days)

tion for unstable angina or revascularization, was 50 patients. If the data were analyzed based on whether the patients actually stayed on their medications, the number needed to treat to prevent one cardiovascular event was only 38 patients.

In the IMPROVE-IT Trial, there was a 13% relative reduction in the risk of having a heart attack and a 21% relative reduction in the risk of an ischemic stroke. These incremental benefits occurred in patients treated well below the previously recommended guidelines for LDL cholesterol. In addition, the significant reductions in cardiovascular events seen with the combination of simvastatin and ezetimibe occurred on top of statin therapy, where patients achieved an LDL cholesterol of 69.9 mg/dL, i.e., at the previously recommended levels (Figure 2).

The conclusions of the authors of the IMPROVE-IT Trial were that the addition of a non-statin agent (ezetimibe) to statin therapy produced:

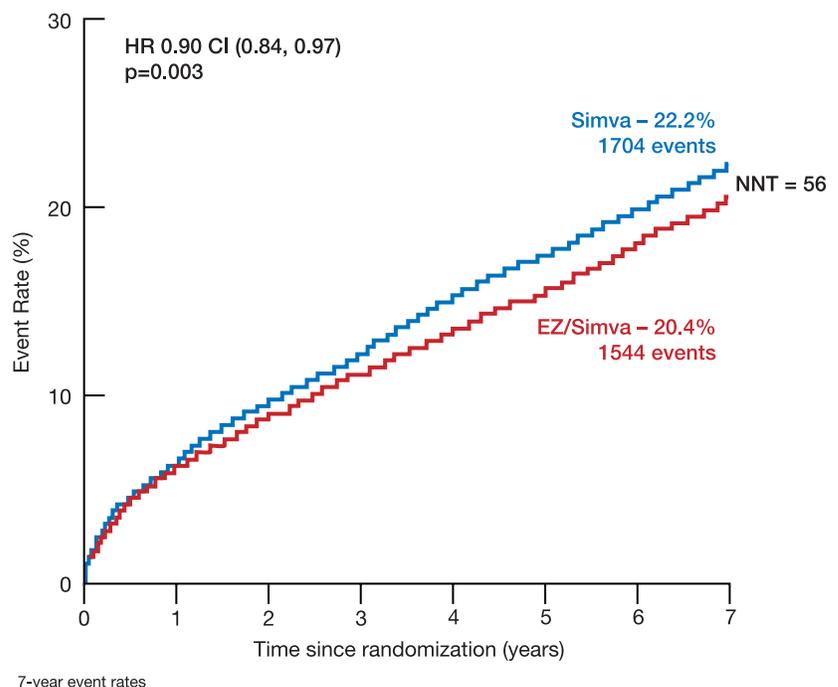
- Further reductions in serious cardiovascular events, such as myocardial infarctions and stroke.
- The conclusion that even lower LDL cholesterol levels are better at reducing CV events.
- The safety profile of ezetimibe was confirmed that there are no increased side effects seen in the statin plus ezetimibe group as compared to the statin plus placebo group.

Thus, the IMPROVE-IT Trial reaffirmed the LDL hypothesis that by reducing LDL cholesterol, further reductions in LDL cholesterol produced greater reductions in cardiovascular events. These reductions occurred with additional medication added to statin therapy. The IMPROVE-IT Trial, therefore, questions whether the most recent guidelines for cholesterol lowering truly provide optimal reductions in cardiovascular risk for patients with known cardiovascular disease (Figure 3).

Wayne N. Leimbach, Jr., is a specialist in interventional cardiology with expertise in cardiac catheterization, coronary intervention (including angioplasty, stent placement, atherectomy, intravascular ultrasound), peripheral vascular interventions, including carotid stenting, as well as interventional therapies for structural heart disease, including percutaneous closure of PFOs, ASDs and PDAs, and percutaneous placement of stent valves (TAVR).

Figure 3

CV Death, Non-Fatal MI, or Non-Fatal Stroke



Heart Failure Patients Now Eligible for Cardiac Rehabilitation

By Chris Bousum



After years of debate about the benefit of cardiac rehabilitation (CR) for heart failure (HF) patients, Medicare has announced coverage for the service is now in effect. “This is an important development,” says Dr. Greg Johnsen, Medical Director of the OHI/Hillcrest Cardiac Rehab program. “With our aging population, the number of people with heart failure will continue to increase in the coming years.

“Heart failure is the leading (DRG) discharge diagnosis for hospitals in the United States,” Dr. Johnsen continues. “Anything that we can do to improve the functional capacity of heart failure patients and keep them out of the hospital is well worth our effort. Research has clearly shown that cardiac rehab exercise training not only improves heart failure symptoms, but it also reduces cardiac mortality and reduces hospital admissions.”

Heart failure is one of the most debilitating and expensive diseases considering that:

- About 6.5 million people in the United States have HF.
- One in 9 deaths in 2009 included HF as contributing cause.
- 650,000 new cases of HF are diagnosed each year.
- About half of people who develop heart failure die within 5 years of diagnosis.
- HF costs the nation an estimated \$32 billion each year. This total includes the cost of health care services, medications to treat heart failure, and missed days of work.

The decision to include HF patients for CR was largely based on the HF-Action Trial, a 2,300-patient study to measure the effects of exercise training on the clinical outcomes. The conclusion of the Trial noted that exercise training was associated with significant modest reductions for both all-cause mortality or hospitalization and cardiovascular mortality or HF hospitalization. One of the outcomes notes that regular exercise training was safe, which was previously thought to be unsafe for HF patients. As well, modest increases in health-related quality of life were reported, as were improvements in peak oxygen consumption, which is a measure of fitness.

Heart failure patients meeting the following criteria are eligible to be referred for cardiac rehabilitation:

- Have an ejection fraction $\leq 35\%$ and/or
- Stable chronic patients who are classified as NYHA class II – IV symptoms despite being on optimal heart failure therapy for at least six weeks
- Have not had a recent (\leq six weeks) or planned (\leq 6 months) major cardiovascular hospitalization or procedure

CR is a medically supervised, multi-disciplinary program that helps improve the health and well-being of people who have heart problems. The program offers an individualized and personalized treatment plan, including evaluation and instruction on exercise activity, education on heart healthy eating, counseling to reduce stress, and other health related areas to help patients return to an active life.

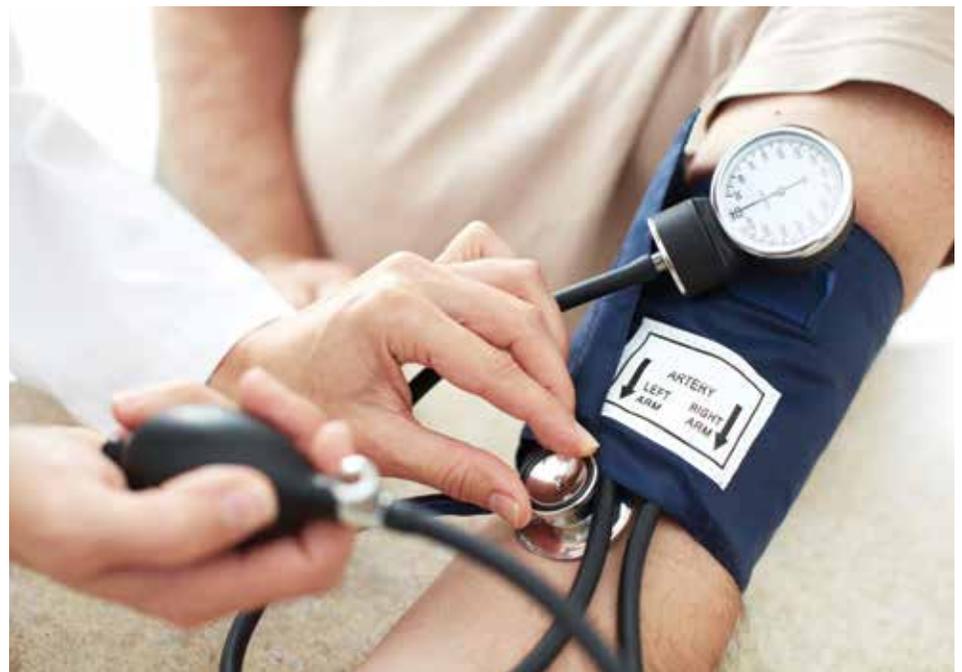
Eligible patients will participate in 36 sessions, 3 days per week over a 12 week period. The

multi-disciplinary staff includes CR nurse specialists, dietitian, behavioral health specialist and exercise physiologist who help the patients by:

- Teaching skills to self manage their condition.
- Preventing future hospital stays, heart problems, and death related to heart problems.
- Addressing risk factors that can lead to heart disease and other heart problems. These risk factors include high blood pressure, high blood cholesterol, overweight or obesity, diabetes, smoking, lack of physical activity, and depression and other emotional health concerns.
- Adopting healthy lifestyle changes. These changes may include the following: following a heart healthy diet, being physically active, and learning how to manage stress.
- Improving health and quality of life.

HF patients should discuss their condition with their cardiologist to see if they may be eligible to participate in the CR program at Hillcrest Exercise & Lifestyle Programs on the Hillcrest Medical Center campus or the program at Hillcrest South. ♥

Chris Bousum is Supervisor of the Hillcrest Exercise & Life Style Program.



“Cardiac rehabilitation in heart failure patients has demonstrated an increase in oxygen consumption when measured by a cardiopulmonary exercise stress test by as much as 15-50% from baseline. This is a marker used for adequacy for advanced therapies such as heart transplant and left ventricular device placement. Cardiac rehabilitation also improves functional capacity and quality of life for heart failure patients.”

— Dr. Sandra Rodriguez, Heart Failure specialist with Oklahoma Heart Institute

Transcatheter Mitral Valve Repair — MitraClip

By Kamran I. Muhammad, MD FACC FSCAI

Mitral regurgitation occurs due to the failure of one of the main valves of the heart to fully close. This results in the backwards flow of blood and can cause disabling symptoms of congestive heart failure, heart muscle dysfunction and an increased risk of death (Figure 1). Patients with significant mitral regurgi-

tation can suffer from severe symptoms including shortness of breath, fatigue, lightheadedness, cough, swollen legs and ankles and palpitations. Untreated mitral regurgitation can result in cardiac dysfunction, including enlargement and weakness of the heart muscle, causing decreased function and efficiency of this vital organ. Mitral

regurgitation is one of the most common valvular disorders in the United States, with 6% of people over 65 years of age, and almost 10% of people over 75 years of age being affected by significant mitral regurgitation.

The traditional therapy for severe, symptomatic mitral regurgitation has been open heart

Oklahoma Heart Institute physicians (right to left) Dr. Kamran Muhammad, Dr. Wayne Leimbach Jr. (interventional cardiology), and Dr. Paul Kempe (cardiovascular thoracic surgery) performing the first MitraClip procedure in Tulsa on November 18, 2014.



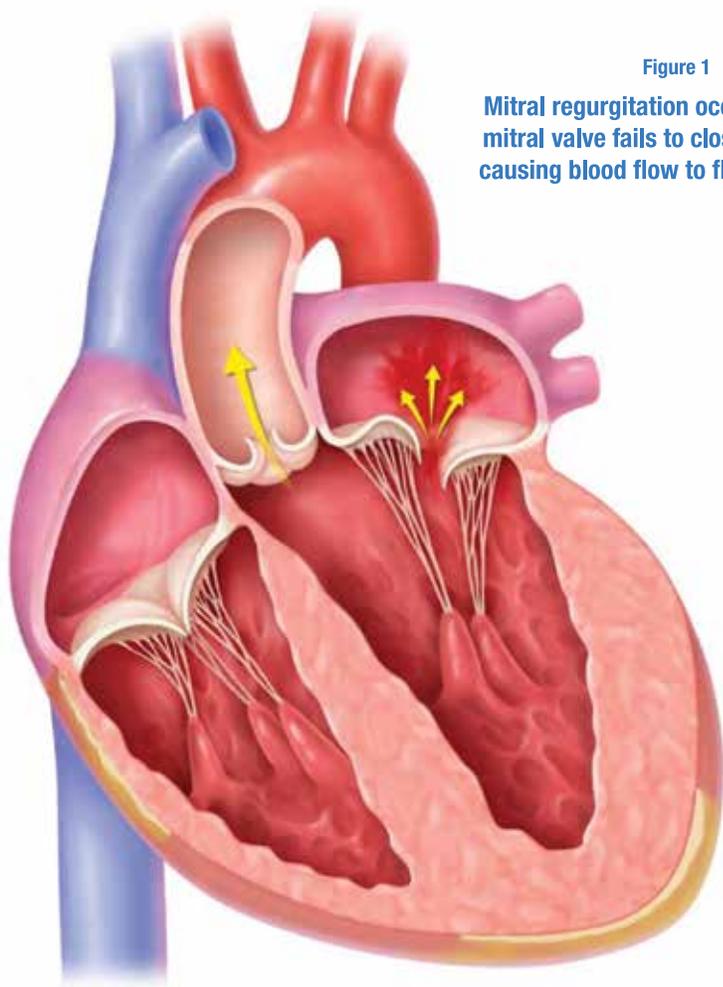


Figure 1

Mitral regurgitation occurs when the mitral valve fails to close completely, causing blood flow to flow backward.

surgery for mitral valve repair or replacement. Although this type of surgery is generally very effective for reducing mitral regurgitation severity, alleviating symptoms, and improving the function of the heart muscle, it is a highly invasive therapy requiring median sternotomy (cutting through the breast-bone) and cardiopulmonary bypass (use of the heart-lung machine) while the heart is stopped. Because of the highly invasive nature of this surgery, many patients with severe symptomatic mitral regurgitation are often considered too high-risk for mitral valve surgery and therefore go untreated. Indeed, studies have shown that as few as 2% of patients with severe, symptomatic mitral regurgitation undergo surgery for this condition. As a result of this significant under-treatment, many patients are left to suffer significant negative effects.

Up until recently, the only alternative to mitral valve surgery for high-risk patients with severe symptomatic mitral regurgitation was medical therapy. While medical therapy can be effective in relieving some of the symptoms of this condition, it is generally not a definitive therapy, and symptoms can recur and progress as the function and efficiency of the heart muscle deteriorates. Ironically, as these patients become sicker with progressive heart muscle dysfunction, they become even poorer candidates for mitral valve surgery.

As is apparent, there was a great need for a non-surgical and minimally-invasive alternative to open-heart surgery for high-risk patients with significant mitral regurgitation. This type of therapy would provide the benefits associated with mitral valve surgery without the stress and risks of surgery. To meet this need, transcatheter mitral valve repair with the MitraClip system was developed.

Transcatheter mitral valve repair with the MitraClip device allows for repair of the leaky mitral valve using one or more small clip-like devices placed on the valve percutaneously via femoral venous access (through the vein in the leg without surgery), similar in concept to a cardiac catheterization procedure (Figure 2). The MitraClip mitral valve repair procedure is performed on a beating heart, and there is no need for cardiopulmonary bypass (heart-lung machine). This revolutionary procedure simulates an edge-to-edge surgical repair of the leaky mitral valve without the need for any surgery (Figure 2).

Studies of transcatheter mitral valve repair with the MitraClip system over the past decade have demonstrated that it is effective in reducing the

Continued on p. 22

Figure 2
The MitraClip transcatheter mitral valve repair system allows for edge-to-edge mitral valve repair through a percutaneous non-surgical approach from the femoral vein.



Continued from p. 21

degree of mitral regurgitation (Figure 3). Additionally, patients treated with MitraClip have improvement in congestive heart failure symptoms, improvement in quality of life, reduced rates of hospitalization for heart failure and improvement in heart muscle function (Figure 3). The safety of the MitraClip procedure was also demonstrated in these studies. Because of the minimally-invasive nature of the MitraClip procedure, patients generally have a very quick recovery and typically have a hospital stay of less than 3 days. Compared with surgery, there is less pain, a shorter hospital stay and a quicker overall return to normal life and activities.

The first successful MitraClip transcatheter mitral valve repair procedure was performed in 2003 in Caracas, Venezuela. Since then, more than 20,000 patients have successfully been treated worldwide. The MitraClip device was approved by the United States Food and Drug Administration for commercial use to treat high-risk, severe, symptomatic, degenerative mitral regurgitation in October of 2013. Currently, only 100 centers in the U.S. offer this first-in-class technology, and Oklahoma Heart Institute is proud to be part of this select group of elite medical centers.

In keeping with its role as the premier cardiovascular institution in the region, Oklahoma Heart Institute is currently the only facility offering the commercial MitraClip procedure in Oklahoma. Oklahoma Heart Institute was also the first facility to perform the MitraClip procedure in Tulsa, in November of 2014 (Figure 4). The first patient's procedure was highly successful, and he was subsequently featured in a TV news story (<http://www.fox23.com/news/news/local/new-life-saving-procedure-being-offered-tulsa/njT7rt/>). Our facility offers a comprehensive and multi-disciplinary program for therapy of all valvular heart diseases, including mitral regurgitation. By offering the MitraClip procedure, we add an important technology to our comprehensive valve and structural heart disease program, so that we may continue to provide cutting-edge, world-class care to our patients. ❤️

Dr. Muhammad is a subspecialist in interventional cardiology. In addition to expertise in traditional areas of interventional cardiology, such as coronary intervention (angioplasty, stent placement, atherectomy, intravascular imaging) and peripheral vascular and carotid artery intervention, Dr. Muhammad has a special interest and expertise in interventional therapies for structural and valvular heart disease including the percutaneous non-surgical replacement and repair of heart valves — TAVR and MitraClip. As such, he currently serves as the Director of the Structural Heart Disease Program at OHI.

Figure 3
Decrease in mitral regurgitation grade, reduced hospitalizations for heart failure, improved symptoms and improved heart muscle function after MitraClip.

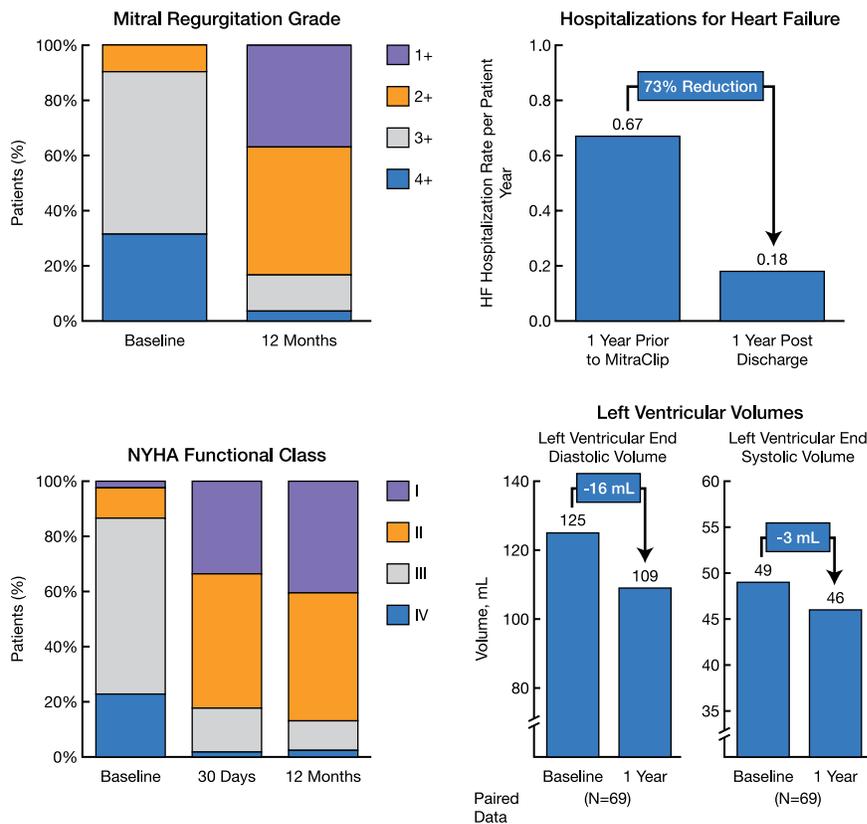


Figure 4

Oklahoma Heart Institute Team that performed the first MitraClip procedure in Tulsa on November 18, 2014.





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