Henry Ford Health System

CARDIO BEAT

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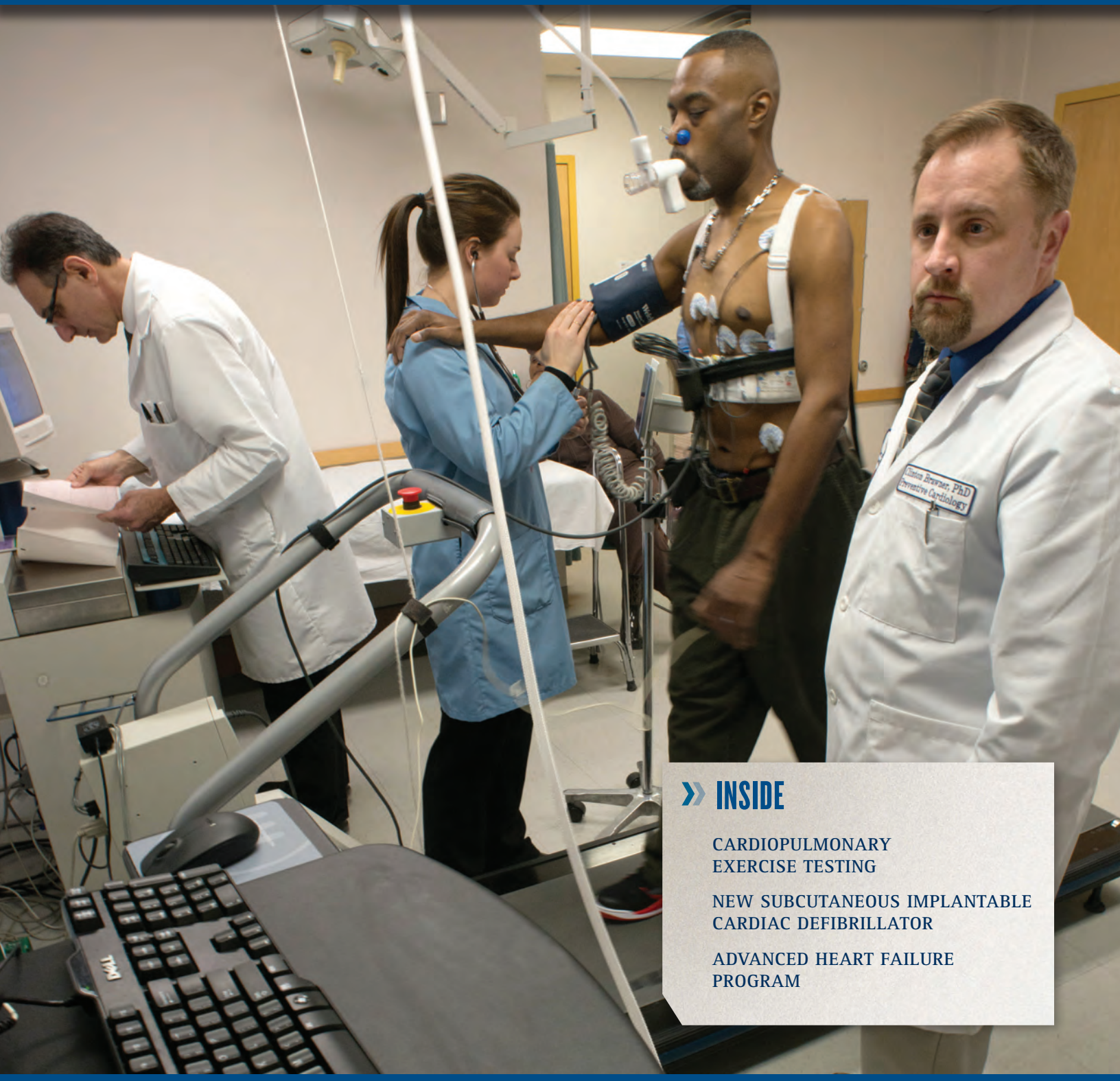
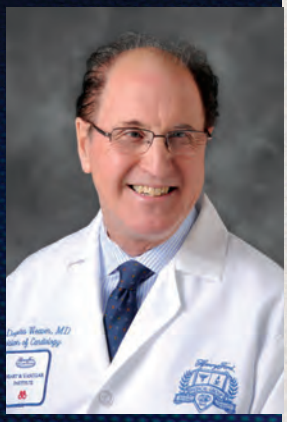


» INSIDE

ON A MISSION TO DEVELOP TOMORROW'S INNOVATION.

HENRY FORD HEART & VASCULAR INSTITUTE



W. Douglas Weaver, M.D.

Watch the new "Minds of Medicine - Last Chance: Saving Hearts and Lives" featuring the Henry Ford team of experts. The show follows two structural heart disease patients from Lansing and Warren and highlights the new telemedicine clinic. To view the show, visit henryford.com/structuralheart

From the Desk of W. Douglas Weaver, M.D.

Vice President and System Medical Director
Henry Ford Heart & Vascular Institute

This year will be one of opportunity for the Henry Ford Heart & Vascular Institute (HVI). We will build on our accomplishments in 2013 to continuously improve and expand our patient care services and quality outcomes – making us most-preferred by patients, physicians and payers.

Last year, we began implementation of an enterprise-wide HVI IT system by launching a cardiac echo- and vascular-imaging platform at Henry Ford Hospital, Henry Ford Macomb Hospital, Henry Ford Wyandotte Hospital and Henry Ford West Bloomfield Hospital. When completed, this advanced IT system will enable any Heart & Vascular Institute provider to access all of the cardiovascular tests, procedure images and reports at all four of our hospitals and at all of our ambulatory locations, which includes our aligned private practice colleagues. This database will also support our training and quality improvement efforts.

During 2013, the Center for Structural Heart Disease program, led by William W. O'Neill, M.D., continued to expand and explore new treatments which are not available elsewhere. Nearly 300 patients have undergone procedures with benchmark results. The Advanced Heart Failure program, under the direction of David Lanfear, M.D. and Hassan Nemeh, M.D., provided patients with more lifesaving Ventricular Assist Devices (VAD) and heart transplants than it has in recent years.

The four-hospital STEMI program provides quick, accurate diagnosis and angio-plasty under the leadership of Akshay Khandelwal, M.D., Mustafa Hashem, M.D., Gerald Koenig, M.D., Ph.D. and Natesh Lingam, M.D., and is consistently achieving benchmark-level care for heart attack patients in 90 minutes or less.

Last year the Cardiac Surgery program, under the direction of Gaetano Paone, M.D. at Henry Ford Hospital and Steven Harrington, M.D. at Henry Ford Macomb Hospital continued its growth and to demonstrate superior quality. The program received a three-star rating – the highest possible rating – from the Society of Thoracic Surgeons for outcomes in isolated coronary artery bypass surgery.

In 2014 and beyond, our focus will continue to be on growth, quality and innovation. Jeffrey Morgan, M.D., is becoming widely recognized as an expert in the outcomes of VAD patients. David E. Lanfear, M.D., continues his research into heart failure and transplantation while Hani N. Sabbah, Ph.D., continues to uncover new treatments in his basic research laboratories that will translate into new therapies for patients. Physicians throughout HVI published more than 70 scientific studies, all focusing on transforming patient care well into the 21st century.

On behalf of the outstanding physicians throughout HVI, we thank you for your continued support, confidence and collaboration.

W. Douglas Weaver, M.D.
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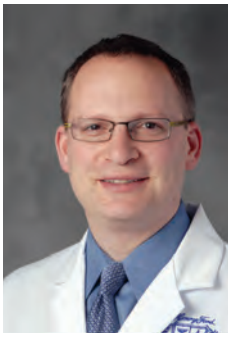
CARDIAC CATH

MITRACLIP™ DEVICE STUDIED IN Clinical Trial of High-Risk Functional Mitral Regurgitation Patients with Heart Failure



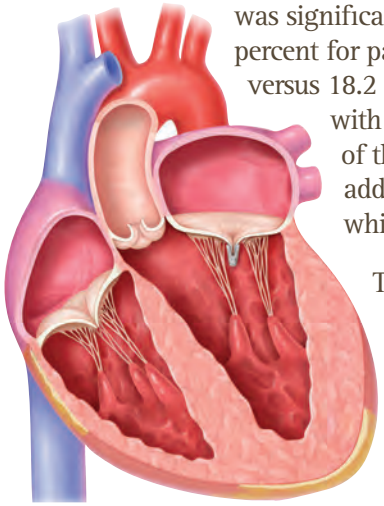
Adam Greenbaum, M.D.

An investigational study is evaluating whether a metal clip called a MitraClip™ will reduce heart failure hospitalizations in certain patients more often than existing non-surgical options. The device, covered with a polyester fabric, "clips" the leaflets of the mitral valve to reduce functional mitral regurgitation (MR).

Functional MR is caused by dilation of the heart, which prevents the leaflets of the mitral valve from closing properly, allowing leakage backwards into the lungs, often leading to congestive heart failure. In 2009, severe MR affected 1.7 million people in the United States between the ages of 50 and 60. There are 250,000 new cases of MR diagnosed each year. In 2013, it is estimated that 1.5 million people have not been treated for functional MR. The major symptom patients experience is shortness of breath, causing their quality of life to be reduced.

The MitraClip™ device was recently approved by the U.S. Food and Drug Administration (FDA) for patients with significant symptomatic degenerative MR who are at prohibitive risk for mitral valve surgery. Degenerative MR is a type of MR caused by an anatomic defect of the mitral valve.

Adam Greenbaum, M.D., medical director of the Cardiac Cath Lab, Henry Ford Heart & Vascular Institute, explains how the MitraClip device is deployed. "A catheter is delivered percutaneously through the femoral vein, advancing the guide and dilator through the left atrium of the heart. The clip is positioned above the leak in the valve and opened in the left atrium for final positioning. The clip is then advanced into the left ventricle below the valve leaflets. The clip is retracted and closed to 'clip' the valve leaflets to reduce MR."



"Transesophageal echocardiography is used during the procedure to evaluate the positioning of the clip and determine if the backward flow of blood has been effectively reduced. If repositioning of the clip is needed, it is done at this point, prior to removing the catheters."

Patients with severe MR and heart failure who are not appropriate for mitral valve surgery following evaluation by the local heart team are candidates for participation in the COAPT clinical trial. The minimally invasive procedure is performed under general anesthesia, and patients are generally hospitalized for two to three days and return to routine activities much sooner than in an open-heart procedure to repair the valve. Potential benefits include reduced pain, fewer potential complications, increased cardiac function and improvements in their quality of life. Potential risks involved include, but are not limited to, stroke and/or damage to the valve.

"Overall, this procedure may benefit patients with congestive heart failure beyond what currently available therapies provide," says Dr. Greenbaum. "These patients with FMR who have been turned down for open mitral valve surgery may benefit from percutaneous MR reduction with the MitraClip™."

Earlier results of the EVEREST II High Risk study, sponsored by Abbott, the maker of the MitraClip™, indicated high-risk patients who were not candidates for mitral valve surgery due to risk of mortality, had a 30-day mortality rate which was significantly lower than expected for surgery (4.8 percent for patients treated with the MitraClip™ system versus 18.2 percent predicted surgical mortality, $p<0.0001$) with a 96 percent implant success rate. The results of the EVEREST II High Risk study called for additional research to address its limitations, which are now being studied in the COAPT study.

The COAPT study is being conducted at the Henry Ford Heart & Vascular Institute. In this randomized study, 50 percent of the patients do not receive the MitraClip™ procedure and 50 percent undergo the MitraClip™ procedure. Dr. Greenbaum placed the first MitraClip™ in a patient with severe MR, making him the third patient in the COAPT study in the United States.

The COAPT study is open to participants who have met the eligibility criteria, which includes patients who have heart failure symptoms after treatment with medications, and who have been told by a surgeon they are not a candidate for mitral valve surgery.

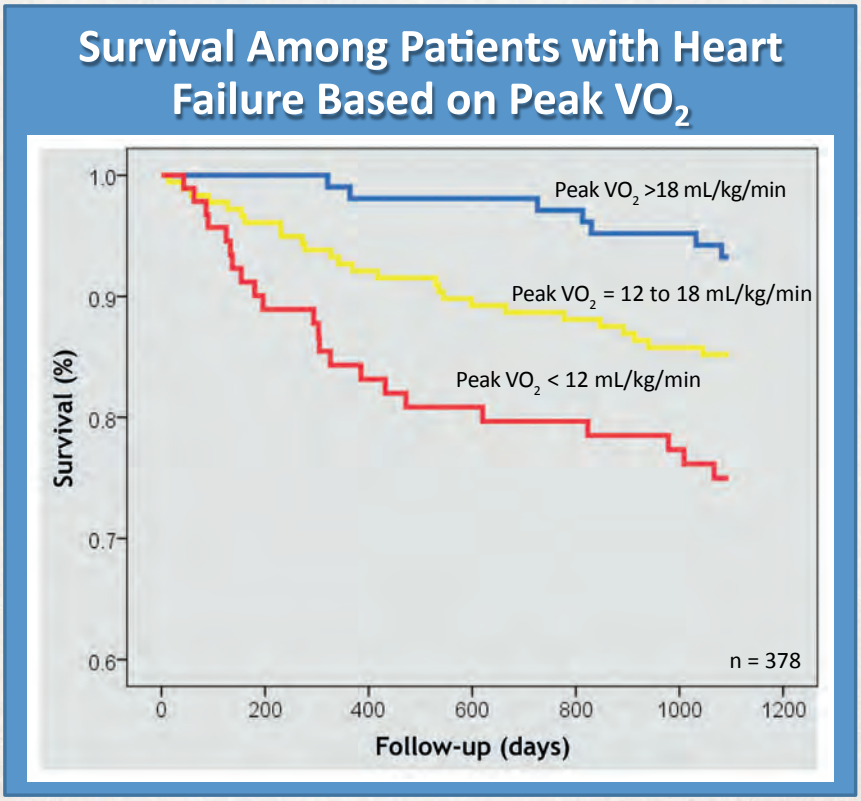
To enroll a patient, call the Center for Structural Heart Disease, 1-855-518-5100.

CARDIAC REHAB

CARDIOPULMONARY EXERCISE TESTING: A Valuable Diagnostic and Prognostic Tool for Patients with Chronic Heart Failure

Conventional exercise stress tests are often used to evaluate patients for obstructive coronary ischemia and assess heart rate and blood pressure responses during exercise; however, additional information can be obtained by direct measurement of respiratory gas exchange during stress, called cardiopulmonary exercise (CPX) testing. The data obtained from CPX testing can be particularly valuable in several patient groups, specifically patients with chronic heart failure, to help determine prognosis and guide clinical decision-making.

CPX testing provides several key measurements including peak VO_2, which is the maximum volume of oxygen a patient can consume during exercise. It's an objective measure of exercise capacity and is useful in risk stratifying patients who may benefit from advanced therapies. Peak VO_2 quantifies the extent of physical disability a patient is experiencing and can be useful to track a patient's functional capacity over time. In patients with undiagnosed dyspnea, data from CPX testing can be useful in determining whether the problem is a cardiac or pulmonary abnormality, or deconditioning.



"An elite athlete may have a maximal VO_2 of 70 to 80 mL/kg/min," said Clinton A. Brawner, Ph.D., director of the Henry Ford Heart & Vascular Institute's Cardiopulmonary Exercise Testing Laboratories in Detroit and West Bloomfield. "The average 50-year-old might be around 30 mL/kg/min and the patient with stable heart disease might be 18 to 22 mL/kg/min. Patients with chronic heart failure often have a peak VO_2 of 10 to 20 mL/kg/min."

To put that in perspective, simply getting up and slowly walking down the hall requires a VO_2 of about 7 mL/kg/min. For someone with a peak VO_2 of 14 mL/kg/min or less, even simple activities of daily living cause fatigue.

Patients with chronic heart failure and a peak VO_2 below 14 mL/kg/min may benefit from advanced therapies such as a heart transplant or a left ventricular assist device. "But there are a limited number of hearts to transplant and undergoing implant of a left ventricular assist device involves major surgery," says Dr. Brawner. "So one wants to be judicious about how we use those resources. The peak VO_2 is the strongest predictor of three to five year survival in patients with chronic heart failure and is just one of many factors that the physician may consider."

The lower the peak VO_2, the greater the risk. Dr. Brawner adds "With more advanced heart failure, the cardiac output is insufficient to provide oxygen to the exercising skeletal muscle at a level that is commensurate with oxygen demand. When this occurs, symptoms such as fatigue and dyspnea with exertion are manifested."

Based on data from Henry Ford's CPX Laboratory (see figure), compared to patients with a peak VO_2 >18 mL/kg/min, a peak VO_2 of 12 to 18 is associated with twice the risk of mortality over three years, and a peak VO_2 of <12 mL/kg/min is associated with four-times the risk. A CPX test for those patients that qualify for a three- to five-year risk may help guide clinical decisions.

CPX testing can also be useful in tracking the progress of patients who are not yet candidates for an advanced therapy, as well as quantifying response to therapies that target improving exercise tolerance (e.g., cardiac

resynchronization therapy or exercise training). For example, implantation of a cardiac resynchronization device can improve cardiac output and thereby improve oxygen delivery to the working muscles as measured by peak VO_2. After an initial baseline test, repeat testing every six to 18 months is not uncommon. "This helps monitor whether functional capacity is stable or the underlying disease is progressing," says Dr. Brawner. A peak VO_2 that trends downward over time is associated with worse prognosis, so physicians may choose to adjust the course of treatment for each patient as needed.

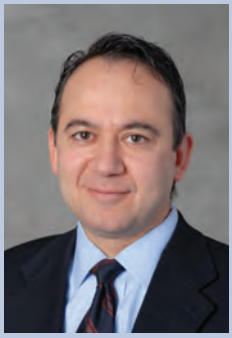
In addition to identifying a patient's peak VO_2, several other useful measures are determined from the CPX test, such as the V_E-VCO_2 slope. This is known as ventilatory efficiency. It is a measure of the change in ventilation (VE) to the change in the amount of carbon dioxide produced (VCO_2) during exercise. Like peak VO_2, V_E-VCO_2 slope is strongly associated with prognosis in patients with chronic heart failure.

While the CPX test is typically performed on a treadmill, Henry Ford Preventive Cardiology Units also offer the test using other exercise modalities for patients who cannot walk on a treadmill. Both a stationary bicycle and a seated stair-stepping machine are available as needed.

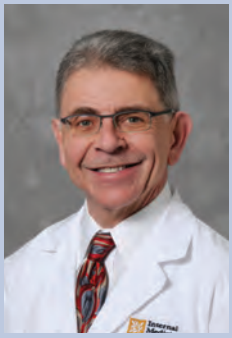
CPX tests are performed regularly at the William Clay Ford Center for Athletic Medicine in Detroit and at Henry Ford West Bloomfield Hospital, Henry Ford Wyandotte Hospital and Henry Ford Macomb Hospital.

INDICATIONS FOR CPX TESTING?

- Patients with chronic heart failure
- Patients with dyspnea in whom the etiology is unclear
- Patients in whom measured exercise capacity is needed to help guide return to work, or for a disability evaluation



Luay Sayed, M.D.



Joseph Naoum, M.D.

CHRONIC TOTAL OCCLUSION: A Different Way to Place Stents

Interventional cardiologist Luay Sayed, M.D., is using a new procedure to treat patients with a long-term, 100 percent blocked coronary artery, or chronic total occlusion (CTO).

"This procedure is for patients who are not ideal candidates for heart surgery and CTOs traditionally have a low success rate with traditional angioplasty techniques and equipment," says cardiologist Joseph Naoum, M.D., medical director of the Cath Lab at Henry Ford Macomb Hospital.

Cardiologists need additional training to use this new type of equipment, using special wires or snares for this percutaneous procedure. Unlike a traditional angioplasty, the wire is threaded through the coronary arteries, using a different path to cross the blockage. This often takes much longer to perform than a traditional angioplasty/stent procedure.

Estimates indicate there may be 10 to 15 patients each year who fit the criteria of having had heart surgery and experience one of the three bypassed arteries becoming blocked again or a new artery is chronically blocked. Lack of adequate blood flow through the blocked artery causes chest pain with even a small amount of activity.

"These individuals probably won't have a heart attack, but their quality of life could be vastly improved, allowing them to be much more active without chest pain. This different type of angioplasty/stent procedure offers us another way to open up that artery," says Dr. Naoum.

Referring physicians may call the Henry Ford Heart & Vascular Institute at 1-800-532-2411 for more information.

ELECTROPHYSIOLOGY

FIRST MICHIGAN IMPLANT OF The New Subcutaneous Implantable Cardiac Defibrillator

Claudio Schuger, M.D.

Arfaat Khan, M.D.

Cardiac electrophysiologists at Henry Ford Hospital are the first in Michigan to implant the new subcutaneous implantable cardiac defibrillator (S-ICD), the world's first entirely subcutaneous defibrillator for treatment of patients at risk for sudden cardiac death.

Sudden cardiac arrest (SCA) is a leading cause of death in the U.S., claiming more than 350,000 lives each year, according to the Heart Rhythm Society. Approximately 92 percent of patients who suffer a SCA do not survive. Most episodes are caused by ventricular tachycardia or ventricular fibrillation – an abrupt loss of heart function. Each year in the U.S., approximately 200,000 traditional ICDs are implanted in patients who are at risk for SCA. ICDs have proven to be effective in the treatment of sudden cardiac death, yet risks are associated from implantation and long-term use.

"ICDs have two major components: (1) pulse generator, which lies beneath the chest wall and powers the system, monitors heart activity, and delivers a shock if needed, and (2) the wire or lead, which lies in the major blood vessels and the heart chambers and enables the device to sense the cardiac rhythm and serves as a pathway for shock delivery or pacing when necessary," says Claudio Schuger, M.D., director, Cardiac Electrophysiology. "Though ICD technology continues to improve, the lead, remains its Achilles heel."

Implantation risks are introduction of blood-stream infection, perforation through the heart wall, or puncturing of the lining of the lung. Long-term risks include normal wear- and-tear and eventual breakdown, as the leads are subject to the constant beating motion of the heart and the possibility of infection.

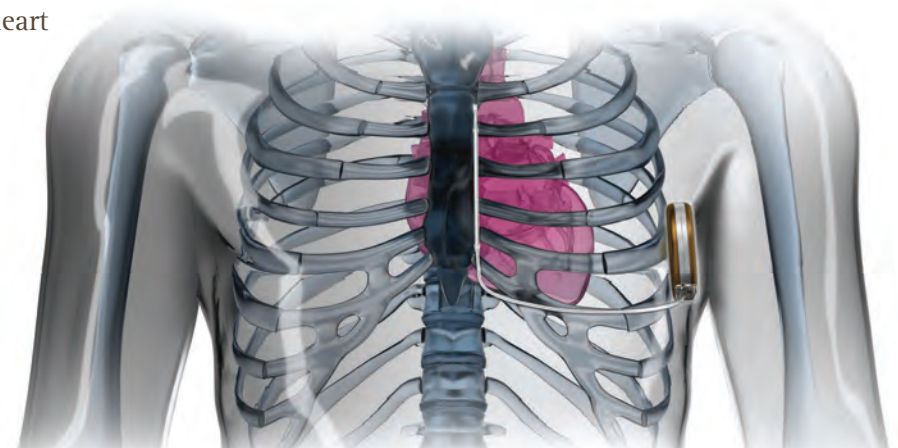
Dr. Schuger says, "A lead extraction can be risky if the leads adhere to the blood vessels and heart chambers due to formation of scar tissue." Further risk comes if both the pulse generator and leads are subjected to recalls which force extraction of the ICD system.

The S-ICD system is designed to provide the same protection from SCA as traditional implantable defibrillators. However, the lead is implanted just under the skin, rather than into a vein and into the heart, then along the bottom of the rib cage and breast bone. The need for fluoroscopy with x-rays to place the lead is eliminated.

"This device should be considered as first-line treatment for certain patients at risk for sudden cardiac arrest," says Arfaat Khan, M.D., cardiac electrophysiologist. "Many patients are candidates for this new therapy but patients that will benefit the most are those who have an increased risk of infection, such as diabetic or dialysis patients and young patients that may need to undergo extraction of their leads due to breakdown over time. The S-ICD system has the potential to become the new standard of care."

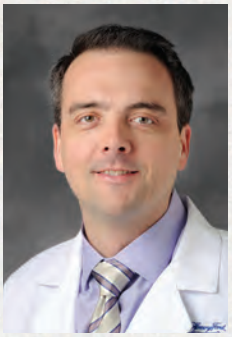
The U.S. Food and Drug Administration has approved the S-ICD System, manufactured by Boston Scientific. Read about Michigan's first patient to receive a new subcutaneous implantable cardiac defibrillator on page 7.

For more information on implantable defibrillators, or to schedule an appointment for your patient, call 1-877-434-7470.

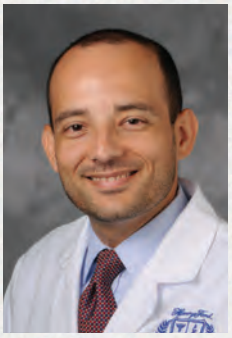


CARDIAC SURGERY

RESEARCH AND INNOVATION
Key to Treating Patients with Heart Failure



David E. Lanfear, M.D.



Mauricio Velez, M.D.

The Advanced Heart Failure program at the Henry Ford Heart & Vascular Institute (HVI) provides the full spectrum of innovative medical and surgical therapies to patients with heart failure – including everything from retrospective studies, to genetic studies, to novel device trials.

"Patient care and improving the lives of heart failure patients is clearly our top priority," says David E. Lanfear, M.D., head of Advanced Heart Failure and Transplant.

This was the case when Dr. Lanfear and his colleagues began studying a newer class of anti-diabetic agents that target the glucagon-like peptide-1 (GLP-1) pathway. Type 2 diabetes is a major risk factor for the development of heart failure. In fact, patients with diabetes are four to five times more likely to develop heart failure, even when other risk factors such as coronary artery disease are controlled. Past studies of oral anti-diabetic drugs in heart failure patients have shown mixed results, or are sometimes associated with worse cardiac outcomes. For one relatively new drug class, those that target the GLP-1 pathway, these outcomes are not yet known but early studies in animals and humans with heart failure have shown favorable cardiovascular effects. This caused Henry Ford researchers to determine how use of these agents may impact development of heart failure in diabetic patients.

"That's what we wanted to better understand," says Dr. Lanfear. "So we developed a study to test whether the time to first hospitalization for heart failure in patients with Type 2 diabetes is affected by exposure to GLP-1 medications."

The retrospective study, spearheaded by Henry Ford cardiologist Mauricio Velez, M.D., collected data on over 19,000 subjects who were 18 years old or older, had received care through Henry Ford, had a diagnosis of Type 2 diabetes, and had an oral anti-diabetic medication fill between Jan. 1, 2000 and July 1, 2012. Patients receiving the agents of interest were matched 2:1 to those receiving other classes of medications, and the time to a first diagnosis of heart failure was examined. The results revealed anti-diabetic medications that enhance the GLP-1 pathway were associated with risk of heart failure hospitalization being reduced by one half. This included adjustment for the use of ACEi, ARBs, and beta-blockers.

"Further study is definitely warranted, but for now our results suggest that the use of GLP-1 medications can reduce the risk of heart failure in patients with Type 2 diabetes," concludes Dr. Lanfear.

For more information or to refer a patient to the Heart Failure Program, call 1-877-434-7470.

FIRST PATIENT IN MICHIGAN
Receives New Subcutaneous Implantable Cardiac Defibrillator

Eighty-six-year-old Gale Irwin of Taylor is a retired letter carrier who walks regularly. But he was getting short of breath in the spring, and his doctor discovered he had had a small heart attack. After having a triple heart bypass, his doctor did not feel his heart was functioning well enough – although he did not need a pacemaker. Irwin became the first person in Michigan to receive the new subcutaneous implantable cardiac defibrillator, and was discharged from Henry Ford Hospital the next day.

The risk of sudden cardiac arrest increases with age or heart disease, and men are two to three times more likely to have it than women. Many people who have sudden cardiac arrest have had previous, undiagnosed heart attacks, with no symptoms and they are unaware that they've had one. Other risk factors for sudden cardiac arrest include heart failure, a history of arrhythmia, or substance abuse.

The major risk factor for sudden cardiac arrest is coronary heart disease, including those who are unaware of their disease until their cardiac arrest. However, healthy people who have no known heart disease or other risk factors may experience sudden cardiac arrest.

The following phone numbers provide access to:

Heart & Vascular Institute
1-877-434-7470

Center for Structural Heart Disease
1-855- 518 -5100

Heart & Vascular Institute
Henry Ford Hospital
2799 West Grand Boulevard
Detroit, MI 48202

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CARDIAC CATH

DOOR-TO-BALLOON
Rapid Response Time Improves With Teamwork

Ameen Abdulmalik, M.D.

Over the last five years, more than 4,000 patients have arrived at Henry Ford Wyandotte Hospital with cardiac issues. Of these, 500 patients required emergency intervention. One such patient arrived with one artery 100 percent blocked and the other three had significant blockage. "It took 12 minutes from the time he hit our doors to clear the blockages, shattering a previous record of 32 minutes" says Ameen Abdulmalik, M.D.

At Henry Ford Wyandotte, the goal for door-to-balloon time is 60 minutes. "Although studies have not shown a significant difference between 60 and 90 minutes, we still recognize that every minute can mean muscle damage. In fact, our cardiology group has agreed to arrive at the hospital in 30 minutes or less when called by the ER. Working with EMS crews, a field EKG can quickly be transmitted to the hospital and doctors. By the time the patient arrives, our team is prepared for the procedure," says Dr. Abdulmalik.

Servicing the Downriver area, Henry Ford Wyandotte offers its patients the speed needed to receive immediate care when minutes matter and uses the highest level of technology. While 99 percent of Wyandotte patients require only angioplasty, that Wyandotte percent can also be assured the expertise of the Henry Ford Heart & Vascular Institute means a patient can be transported quickly to Henry Ford Hospital in Detroit and returned to Wyandotte, where they can recover close to their families and receive continuity of care.

Heart Attack Prevention

A comprehensive approach to heart attack prevention is offered through the accredited Chest Pain Center at Henry Ford Wyandotte Hospital. At the center, individuals will receive fast, critical care from a team of cardiovascular specialists, who will deliver a prompt diagnosis and treatment plan, which often results in faster recovery times. The cardiology team will work with each patient to establish prevention goals and the right treatment options.

To refer a patient to a Henry Ford Wyandotte Hospital cardiologist or Chest Pain Center, call (734) 246-6909.