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# CARDIO BEAT

PUBLISHED BY HENRY FORD HEART & VASCULAR INSTITUTE

SPRING 2016

## Surgery And Stenting Equally Safe And Effective At Lowering Long-Term Risk Of Stroke

One of the largest randomized stroke prevention trials ever, CREST (Carotid Revascularization Endarterectomy versus Stenting Trial) studied the efficacy of lowering long-term risk of stroke in surgery (endarterectomy) and stenting. The 2,502 patients, with an average age of 69, were studied for up to 10 years at 117 centers in the U.S. and Canada, including Henry Ford Hospital.

The federally funded study found the risk for stroke after either endarterectomy or stenting was about 7 percent. The 10-year comparisons of restenosis (re-narrowing of the carotid artery) were low for both endarterectomy and stenting – about 1 percent per year. Equal benefit was found for older and younger individuals, men and women, patients who had previously had a stroke, and those who had not.

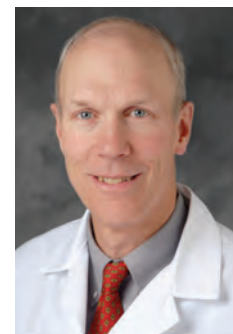
Alexander Shepard, M.D., vascular surgeon and principal investigator at Henry Ford Hospital explains, “This very low rate shows these two procedures are safe and also very durable in preventing stroke especially in Medicare age patients with carotid narrowing who are living longer. We believe the durability of endarterectomy and stenting will be reassuring to patients and their families.”

The trial was led by researchers at Mayo Clinic’s campus in Florida. The research centers were coordinated through Rutgers-New Jersey Medical School, and the patient results were analyzed at the University of Alabama at Birmingham.

In 2010, phase one of CREST found endarterectomy and stenting to be equally safe procedures, with fewer strokes among those who underwent endarterectomy, and fewer heart attacks among those who received stents. “The second phase completes the story, and the results are very encouraging with two safe procedures that are very effective over time,” says Dr. Shepard. “Now patients and physicians have the option to select endarterectomy

or stenting, based on an individual patient’s medical condition and preferences.”

In February, phase two results were published online in the *New England Journal of Medicine* and presented at the American Heart Association’s International Stroke Conference in Los Angeles.



Alexander Shepard, M.D.

Carotid narrowing causes up to 20 percent of all strokes in the U.S. Dr. Shepard says, “Since there are about 800,000 strokes a year, we’re talking about 150,000 strokes a year. Finding the best way to prevent those strokes will be a positive service to those patients.”

Despite the results of CREST, the question of the best way to manage stroke risk has not been answered yet. Because of that, CREST-2 was launched in December 2014 to compare endarterectomy and stenting to aggressive medical management. CREST-2, which is expected to end in 2022, is being funded by a \$39.5 million grant from the National Institute of Neurological Disorders and Stroke and the National Institutes of Health.

### INSIDE

» HENRY FORD MACOMB HOSPITAL NAMED TOP 50 CARDIOVASCULAR HOSPITAL IN U.S.

PRECISION MEDICINE IMPROVES ANTI-REJECTION DRUG ABSORPTION

YEAR ONE: WATCHMAN™ DEVICE RESULTS

NEW WOMEN’S HEART CENTER BRINGS EDUCATION AND SUPPORT

# Best Treatment For Patients With Critical Limb Ischemia Study Seeks Participants

Lower extremity peripheral arterial disease (PAD) remains a significant cause of morbidity with atherosclerosis within the blood vessels of the leg leading to extremity pain and/or debilitating and non-healing wounds. This can ultimately lead to major amputation and limb loss. PAD has a prevalence of 3 to 10 percent in the general population and is common in individuals who smoke or have diabetes mellitus.



**Timothy Nypaver, M.D.**

A subset of patients with PAD have critical limb ischemia (CLI) marked by intractable foot pain and/or the presence of open and non-healing wounds or even gangrene. These patients are at very high risk of limb loss. As there is no beneficial medical therapy, revascularization methods with either an open surgical bypass or endovascular means to open up the blocked arteries have served as the two major treatment options for CLI patients. Unfortunately, the determination of which is chosen as first line of therapy is based not on any evidence, but more often by physician practice patterns and physician bias, resulting in significant variability in treatment.

The vascular surgeons and interventional cardiologists at Henry Ford Hospital, working together in a collaborative manner, are now involved in a study to determine the best option for those patients presenting with critical limb ischemia. The study is a randomized controlled trial sponsored by the National Institutes of Health and designed to provide much-needed data on which treatment strategy is the better first option. The study (Best Endovascular vs Best Surgical Therapy in Patients with Critical Limb Ischemia or BEST-CLI) will specifically compare the outcomes and overall benefits to patients with CLI between the two different approaches.

Timothy J. Nypaver, M.D., a vascular surgeon at Henry Ford Hospital, is the site principle investigator for the study. He says, "This is a unique collaborative study that is attempting to answer a very important question in the care of patients with critical limb ischemia. With this study, hopefully, we will be able to determine just what is the best option for our patients."

Dr. Nypaver explains, "The physician is allowed to perform what he or she views as the best means to perform the intervention or operation, using all present standard of care commercially available technologies. This results in a real-world practice trial that is not restricted to one method or technique. We want to be able to provide our patients with the best chance for success in the treatment of critical limb ischemia and be confident in that decision."

*For more information about the trial, visit [www.BESTCLI.com](http://www.BESTCLI.com).*

*To refer a patient with critical limb ischemia for possible enrollment in the trial call the Henry Ford Heart & Vascular Institute at 1-844-725-6424.*



## STAFF UPDATE

### Steven Harrington, M.D.

Regional Medical Director, Cardiothoracic Surgery

#### MEDICAL SCHOOL EDUCATION:

Wayne State University School of Medicine

#### POST-GRADUATE TRAINING:

St. John Hospital and Medical Center (MI) – General Surgery  
Wayne State University (MI) – Thoracic Surgery

#### BOARD CERTIFICATION:

American Board of Surgery  
American Board of Thoracic Surgery

#### AREAS OF CLINICAL EXPERTISE INCLUDE:

Dr. Harrington's area of clinical expertise is robotic minimally invasive heart surgery and Hybrid approaches to revascularization as well as mitral valve surgery. Additionally, his expertise extends to minimally invasive robotic lung surgery.

#### RESEARCH INTERESTS:

Dr. Harrington is a noted speaker on robotic minimally invasive heart and lung surgery. He also has a special interest in applying lessons from aviation safety to improve safety and team skills in the OR and speaking regularly on this subject.

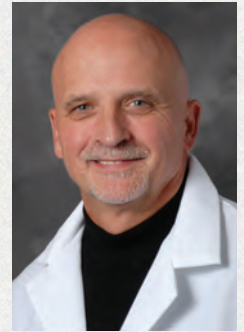
#### PUBLICATIONS:

Sources of variation in hospital-level infection rates after coronary artery bypass grafting: an analysis of the society of thoracic surgeons adult heart surgery database. *Ann Thorac Surg.* 2015 Nov;100(5):1570-5; discussion 1575-6. doi: 10.1016/j.athoracsur.2015.05.015. Epub 2015 Aug 28.

Red blood cell transfusions impact pneumonia rates after coronary artery bypass grafting. *Ann Thorac Surg.* 2015 Sep;100(3):794-800; discussion 801. doi: 10.1016/j.athoracsur.2015.03.089. Epub 2015 Jul 21.

Individual peer support: a qualitative study of mechanisms of its effectiveness. *Community Ment Health J.* 2015 May;51(4):445-52. doi: 10.1007/s10597-014-9801-0. Epub 2014 Dec 23.

Center-level variation in infection rates after coronary artery bypass grafting. *Circ Cardiovasc Qual Outcomes.* 2014 Jul;7(4):567-73. doi: 10.1161/CIRCOUTCOMES.113.000770. Epub 2014 Jul 1.



Steven Harrington, M.D.

## COMMUNITY NEWS

# Henry Ford Macomb Hospital Named Top 50 Cardiovascular Hospital In U.S.

Henry Ford Macomb Hospital in Clinton Township has been named a Top 50 Heart Hospital, selected from more than 1,000 hospitals evaluated across the United States.

The award is part of the 100 Top Hospitals program by Truven Health Analytics, based on publicly available data that compares patient outcomes, operational efficiencies and financial metrics. Study winners had better outcomes while operating more efficiently and at a lower cost than others included in the analysis.

The Truven data showed 2016 winners had:

- Significantly higher inpatient survival than non-winning cardiovascular hospitals (20 to 33 percent higher)
- Fewer patients with complications (8 to 11 percent fewer)
- Lower readmissions rates for acute myocardial infarction, or heart attack, and heart failure patients (1.05 percentage points lower)
- Hospital stays that are one-half to one day lower than average

Joseph Naoum, M.D., Henry Ford Macomb Hospital cardiologist, attributes the award to fast, efficient and highly effective treatment for everything from the time it takes to treat a patient experiencing chest pain to the costs associated with cardiovascular care.

“Door-to-balloon times are lower than average with very good outcomes,” says Dr. Naoum, medical director of the hospital’s cardiac catheterization laboratory.

The rate of patients who need blood transfusions during surgery is low, as are the number of vascular complications. “The number of patients who receive aspirin prior to angioplasty to open blocked or narrowed heart arteries, which is recommended for all patients to prevent stroke, is 100 percent at Henry Ford Macomb Hospital, something other hospitals are trying to achieve,” he said.

“The utmost compliment is that other health systems are now looking at us as a model for cardiovascular treatment,” says Dr. Naoum, adding that the system is sharing best practices with other medical professionals to improve treatment for all patients.

*For more information about the cardiovascular services available through Henry Ford Macomb Hospital or the Henry Ford Heart & Vascular Institute, visit [henryford.com/heart](http://henryford.com/heart) or call 1-800-532-2411.*

TRUVEN HEALTH ANALYTICS

50 TOP  
CARDIOVASCULAR

2016



# Precision Medicine Improves Anti-Rejection Drug Absorption

You may hear a lot of talk about “Precision Medicine” (tailoring medical treatment to the individual using biomarkers, genetics, or other characteristics), but real examples in current clinical care are still few. However, the delivery of precision medicine for heart transplant patients to more quickly reach their immune suppression goal is reality at Henry Ford Hospital.

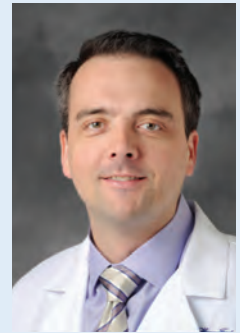
This innovative approach-to-care takes into account the patient’s genetic make up, rather than just weight, when initiating Tacrolimus, an important anti-rejection medication nearly all transplant patients are prescribed, say David Lanfear, M.D., M.S., head of the Advanced Heart Failure and Cardiac Transplant Section. Precision medicine is Dr. Lanfear’s area of interest which he has presented on at medical schools and academic associations throughout the country.

Many research studies have advanced the importance of pharmacogenomics (impact of genetics on drug treatments) in delivery of the right dose of Tacrolimus. “Most of the studies were actually on kidney transplant recipients, but it’s still relevant and applicable to heart transplant recipients,” says Dr. Lanfear.

Why is getting the dose right, right away so important? “If the dosing is too low there could be an increased chance of organ rejection, if too high it’s more likely kidney dysfunction can occur. Genetics tell us if the medication will be cleared more quickly or slowly so we can better estimate what dose

a particular patient will need. These same genetic factors likely drive some differences we see by race; African Americans often need higher doses relative to Caucasians.”

While this genetic approach is proven to get to target dose faster, improved patient outcomes have not been demonstrated, and consequently genetic dosing of Tacrolimus has not been adopted at all hospitals. However, Dr. Lanfear says “the testing isn’t very expensive and while it takes some extra work, I feel that its definitely worthwhile if we can do even a little better for our patients, which clearly we can.”



**David Lanfear, M.D., M.S.**



*David Lanfear, M.D., head of advanced heart failure and cardiac transplant section and sonographer Margret Onyeaghor examine John Payne, the longest-living heart transplant patient in Michigan.*



## RESEARCH

# Henry Ford Named Trial Site For HeartMate® 3

Henry Ford Health System has been chosen as one of a select number of U.S. trial sites for a new heart pump that cardiologists say is lighter, smaller and may have fewer complications than previous models.

A 56-year-old southeast Michigan resident received the first HeartMate® 3 left ventricular assist device (LVAD) in metro Detroit at Henry Ford Hospital on July 9, 2015. Doctors at the Henry Ford Heart & Vascular Institute say there is great enthusiasm about the way the new pump can significantly improve the quality of life in patients with heart failure.

Henry Ford Hospital, one of the leaders in LVAD in the country, was asked to participate in the largest U.S. heart pump trial ever, Momentum 3. The trial involves 1,000 patients at 31 locations across the nation receiving the HeartMate® 3 LVAD.



LVADs originally were used to keep patients alive as they waited for a donor heart and a heart transplant. But about 30 percent of patients experienced complications within the first two years. But as technology has advanced, making the pumps more dependable, smaller and more portable, LVADs are being seen as a way to improve the quality of life for heart failure patients, regardless of whether a transplant is an option.

The pump action makes the HeartMate® 3 drastically different from previous models. Instead of a continually moving drive shaft pushing blood through, the new pump uses the centrifugal force of magnets to create blood flow. That cuts the pump's size by half, making it much more comfortable and less intrusive in the body. The patient's red blood cells also do less bumping around on internal parts, keeping them healthier.



Jamil Borgi, M.D.

Also, previous pumps moved blood in a continual flow, most noticeable in patients' lack of a pulse. The new pumping action mimics a heartbeat, with a 2,000 rpm uptick every two seconds. Researchers and doctors believe that the changes in pressures – or pulsatility – along the insides of the patient's circulatory system may help with some bleeding issues associated with older models, like gastrointestinal bleeding.

The inside of the new pump is also lined with titanium. That allows the blood to flow more smoothly and may translate into a lower requirement of blood thinners in some patients, lowering the risk of clots and stroke.

*The primary investigator at Henry Ford Health System is Jamil Borgi, M.D., cardiac surgeon. For information about the study, contact Research Coordinator Bridget Makhlof, MS, at [bmakhlo1@hfhs.org](mailto:bmakhlo1@hfhs.org) or 313-916-8006.*

## LEADERSHIP

# Khandelwal To Lead American College Of Cardiology in Michigan

Henry Ford Heart & Vascular Institute interventional cardiologist Akshay Khandelwal, M.D., F.A.C.C., F.S.C.A.I., has been elected to lead the Michigan Chapter of the American College of Cardiology through 2019.

Dr. Khandelwal will begin his three-year term as President and Governor of the Michigan Chapter of the The American College of Cardiology (ACC) in January 2016. As governor, Dr. Khandelwal will represent the state's legislative and regulatory concerns, practice needs, and recommendations to improve patient care on the national ACC Board of Governors. As chapter President, Dr. Khandelwal will also serve as the voice of the Michigan cardiology community when advising local and state government officials, other professional organizations and leaders throughout the state on issues related

to cardiovascular disease, while sharing messages related to cardiac care with Michigan residents.

"I've spent my life striving to bring the highest level of cardiac care to my patients," says Dr. Khandelwal. "I'm honored to be chosen by my peers to continue that mission on behalf of the people of Michigan, with leaders in the cardiology community from across the United States and the world."

Dr. Khandelwal is the director of outpatient cardiology services at Henry Ford Hospital, one of the busiest heart hospitals in the Midwest. As Director of the STEMI program and Cath Lab Quality at the Henry Ford Heart & Vascular Institute, Dr. Khandelwal oversees complex coronary disease treatment for hundreds of critically-ill patients annually.



Akshay Khandelwal, M.D.

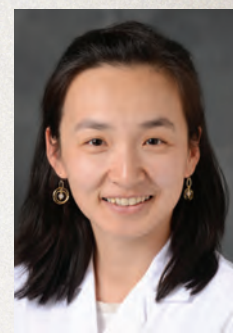


# Year One: WATCHMAN™ Device Results

A left atrial appendage closure implant device for patients with non-valvular atrial fibrillation, called WATCHMAN™, reduces stroke risk. Henry Ford Hospital patients experienced significantly lower complications compared to national trials.

Henry Ford has taken safety steps further with the application of 3D CT, and advanced 3D modeling of each patient’s left atrial appendage prior to their procedure date. Each WATCHMAN™ procedure is customized to each patient’s heart and LAA anatomy.

Henry Ford’s experience with 48 patients showed the use of 3D CT guided imaging produced fewer complications and a safer procedure. “The 3D CT allows us to map out the best route to implant the device,” explains Dee Dee Wang, M.D., advanced structural heart imaging, senior staff cardiologist. “Our data indicates safer patient outcomes with more efficient procedure times as added benefits of patient-specific 3D CT modeling guided imaging.”



**Dee Dee Wang, M.D.**

## RESULTS: WATCHMAN™ CLINICAL TRIAL MAJOR INTRAPROCEDURAL CLINICAL EVENTS COMPARED TO HENRY FORD CENTER FOR STRUCTURAL HEART DISEASE 3D CT GUIDED CASE PLANNING MAJOR ADVERSE CARDIAC EVENTS

Major Clinical Event	Protect AF n(%) N=463	CAP n(%) N=566	PREVAIL n(%) N=269	CAP2 n(%) N=579	HENRY FORD n(%) N=48
Pericardial effusion with cardiac tamponade	13 (2.8)	7 (1.2)	4 (1.5)	8 (1.2)	0 (0.0)
Device embolization	3 (0.6)	1 (0.2)	2 (0.7)	0 (0.0)	0 (0.0)
Pericardial effusion – no intervention	4 (0.9)	5 (0.9)	0 (0.0)	3 (0.5)	0 (0.0)
Cardiac perforation (surgical repair)	7 (1.5)	1 (0.2)	1 (0.4)	3 (0.5)	0 (0.0)
Device migration	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

*Clinical trials data obtained from WATCHMAN™ package FDA insert*

CMS (Medicare) recently issued a National Coverage Decision (NCD) for coverage of the FDA approved WATCHMAN™ device. Its announcement stated the device has been shown to be a safe and effective alternative to oral anticoagulant therapy for stroke prophylaxis in patients with chronic or paroxysmal atrial fibrillation.

Further, the announcement stated four-year overall mortality was significantly lower in WATCHMAN™ patients at their four-year follow-up.

“Based on our year one experience with 48 patients, the device was successfully deployed without a major clinical event,” says William W. O’Neill, M.D., medical

director of the Center for Structural Heart Disease.

*Physicians with questions concerning patient eligibility or an interest in the deployment technique should contact the Center for Structural Heart Disease at (313) 916-1878.*



# New Women's Heart Center Brings Education And Support

The new Women's Heart Center is a comprehensive cardiovascular clinic focused on the screening, diagnosis and management of coronary heart disease, heart failure, valvular heart disease, weight management and stress reduction.

Deirdre Mattina, M.D., director of the Women's Heart Center explains, "At the center there is a multidisciplinary team of specialists to create a client-centered treatment plan that promotes healthy lifestyles and improves quality of life. This is one of the few outlets within the Henry Ford Health System where patients meet one-on-one with a registered dietician and exercise physiologist for an evaluation to develop a personalized fitness plan." The Women's Heart Center recognizes the critical roles women play in their families and aims to shape the future of healthcare by providing high quality cardiovascular care that empowers women to become active partners in their health.

At the end of the evaluation, each patient receives a personalized Nutrition Plan and a Prescription of Exercise Plan, which is based on the most recent guidelines from the American Heart Association.

*To make an appointment at the Women's Heart Center located at the Center for Athletic Medicine (CAM), please call (313) 876-4540.*



Deirdre Mattina, M.D.

WomenHeart® is a National Coalition for Women with Heart Disease and is the only national organization dedicated to advancing women's heart health through advocacy, community education and patient support.

Through their advocacy a support network meets monthly from 6 to 8 p.m. on Wednesday evenings at the Center for Athletic Medicine. Female patients from private practices are welcome to attend these educational support group meetings.

*For more information, visit [henryford.com/womensheartcenter](http://henryford.com/womensheartcenter) or to register email [WH-HenryFordHospital@womenheart.org](mailto:WH-HenryFordHospital@womenheart.org).*



*Henry E. Kim M.D., MPH, Division Head, Cardiology, Edith and Benson Ford Heart & Vascular Institute and Deirdre Mattina, M.D., director, Women's Heart Center are joined by State Representative Julie Plawecki (District-11, Dearborn Heights) for the opening of the Women's Heart Center at the Center for Athletic Medicine (CAM) on Thursday, March 10, 2016.*

To connect with a Henry Ford physician, call:

Heart & Vascular Institute  
**1-877-725-6424**

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



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# SAVE THE DATE

## *Structural Heart Innovations: Advanced Imaging & 3D Printing*

Friday, April 29, 2016 – 7:30 a.m. to 5:30 p.m.  
Henry Ford Hospital, Detroit, MI

Join the experts from the Center for Structural Heart Disease at Henry Ford Hospital for some firsthand training on advanced imaging and 3D printing in adult structural heart interventions.

As a participant, you will gain an understanding of the newest breakthroughs in medical treatment and technologies in adult cardiovascular interventions, including:

- The role 3D imaging plays in adult structural heart interventions
- Updates in the application of 3D echocardiogram and 4D CT imaging in planning percutaneous mitral valve interventions
- Novel techniques in the application of 3D printing in left atrial appendage occlusion with WATCHMAN™ implantation
- Hands-on 3D QLab ultrasound training sessions and hands-on 3D printing software training
- Gain expertise on the integration of 3D and 4D multimodality imaging in left atrial appendage occlusion

CME certified: 4.75 AMA PRA Category 1 Credits™



Henry Ford Hospital - E&R Building  
2799 W. Grand Blvd., Detroit, MI 48202

To register or for more information,  
visit [henryford.com/3dcme](http://henryford.com/3dcme) or call (313) 916-8214.