



henryford.com
1-877-434-7470

CARDIO BEAT

PUBLISHED BY HENRY FORD HEART & VASCULAR INSTITUTE

SUMMER 2016

Henry Ford Hospital Offers Minimally Invasive Mitral Valve Replacement

Henry Ford Hospital is one of seven U.S. hospitals using a new way to replace a mitral valve through a catheter instead of open heart surgery.

Henry Ford Hospital is the only site in Michigan participating in an experimental study of Abbott's Tendyne Bioprosthetic Mitral Valve. The site's principal investigators are Henry Ford Interventional Cardiologist Marvin H. Eng, M.D., and Cardiothoracic surgeon Gaetano Paone, M.D., division head of Cardiac Surgery.

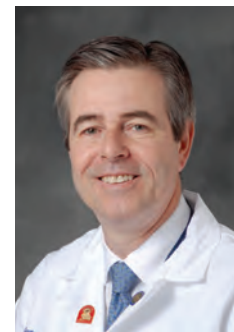
Until now, the only way to replace a dysfunctional mitral valve for any reason has been surgery. The new valve offers a minimally-invasive, catheter-based option. "Of those with mitral valve disease, almost half never get surgery," says Dr. Eng. "That's potentially who we can help."

The study is open only to patients whose doctors say they are too sick or do not qualify for open heart surgery. The study will include up to 110 patients at up to 25 centers throughout the world, and their progress will be followed for at least two years after the valve is replaced. "About nine percent of the population age 75 or older have moderate to severe mitral valve disease, with some requiring life-saving treatment," explains Dr. Paone.

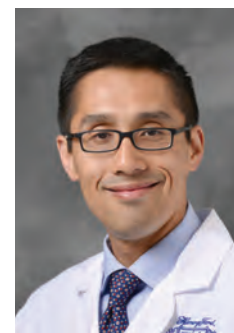
"We are pleased that we are able to offer this less invasive option to the patients of Henry Ford Hospital who might not otherwise be candidates for mitral valve surgery," he says. The valve had been used in about three dozen patients by mid-May, including patients in Australia and Norway. Patients with hardening, or stenosis, of the mitral valve do not qualify. Those patients with dysfunctional mitral valve leaflets still may have the option of a repair using a small, FDA approved mitral clip, inserted through a catheter.

During the new Tendyne valve procedure, doctors insert a catheter into the patient's chest through a small incision between the ribs. The catheter passes into a small hole made in the tip of the heart, then through the left ventricle and into the left atrium. Doctors carefully position the new valve – a porcine valve mounted on a collapsed metal frame – within the old mitral valve. When the cardiologist deploys the new valve, the metal frame opens in the same space as the old valve, replacing it. After checking the function of the newly inserted valve, the team removes the catheter and repairs the small hole with tiny sutures and a cap on the tip of the heart.

"It's a very challenging valve to get to, and it's a very complicated valve," says Dr. Eng. Henry Ford doctors began performing the new procedure in August 2016.



Gaetano Paone, M.D.



Marvin H. Eng, M.D.

Continued on page 2

»» INSIDE

FDA APPROVES FIRST LEADLESS PACEMAKER

MULTI-CENTER STUDY OF TRANSRADIAL VERSUS TRANSFEMORAL APPROACH

PARTNER III TRIAL BEGINS FOR PATIENTS WITH SEVERE AORTIC STENOSIS

SAVE THE DATE: HENRY FORD LIVE CTO PCI ADVANCED COURSE

LATEST BREAKTHROUGHS

FDA Approves First Leadless Pacemaker

Nearly one million people worldwide are implanted with pacemakers each year. Until recently, patients with Atrial Fibrillation (AF) received predominantly one type of pacemaker, a single chamber device with a lead implanted in the right ventricle and transvenously connected to the pulse generator located in the subclavicular area.

In April, approval by the Food and Drug Administration (FDA) gave AF patients another option – the first leadless pacemaker called Micra

Transcatheter Pacing System (TPS), which was developed by Medtronic. “This is a significant advancement and step forward in pacemaker technology,” says Arfaat Khan, M.D., senior staff cardiologist and director of Electrophysiology at Henry Ford Wyandotte Hospital.

Prior to approval, the FDA evaluated data from a clinical trial of 719 patients implanted with the Micra TPS, which found 98 percent of patients had adequate heart pacing six months after the implant.

“The leadless pacemaker is safer for the patient as it eliminates the possibility of lead breakdown and need for future lead extraction. Without the need for

implantation of leads, patients undergo an alternative minimally invasive procedure to deploy the pacemaker into the right ventricle. Once deployed, the device is embedded into the trabeculae of the myocardium by aid of ‘tines’ to hold it into place,” says Dr. Khan.

It still requires the pacemaker generator to be inserted into the sub clavicular area, but the risks associated with lead extraction should lead failure occur are eliminated. “This was the Achilles heel of pacemakers,” says Dr. Khan. “This advancement provides a safer alternative for AF patients and eliminates the need for lead extraction.” For the patient, the only procedure needed during the lifetime of the device is replacement of the pulse generator every 10-12 years.

To refer a patient for treatment using the FDA approved leadless pacemaker, call the Henry Ford Heart & Vascular Institute at 1-877-434-7470.



Arfaat Khan, M.D.



The leadless pacemaker is 93 percent smaller than conventional pacemakers.

Henry Ford Hospital Offers Minimally Invasive Mitral Valve Replacement

Continued from page 1

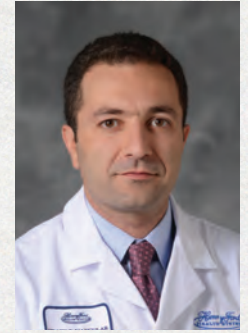
“The new procedure is expected to take less than two hours,” says Dr. Eng. Hospitalization is expected to be around five days, with most patients able to return to normal activity in a week or two.

“Typical mitral valve surgery takes four to five hours, followed by five to seven days in the hospital recovering from the open heart procedure,” explains Dr. Paone. Full recovery is typically four to six weeks.

The procedure is yet another offering by the Henry Ford Heart & Vascular Institute to help patients with heart disease survive and thrive. It is one of few in Michigan offering highly specialized evaluation and treatment all in one program.

Patients interested in enrolling in the mitral valve study can call 1-877-434-7470 for more information.

Operative Strokes After Repair Of Acute Type A Dissections: Predisposing Factors And Implications



Jamil Borgi, M.D.

Type A aortic dissection as a surgical emergency is associated with high mortality and morbidity, with stroke rates in up to 25 percent of cases. The objective of this study was to evaluate the predisposing factors associated with operative stroke complications and the effect on outcomes and survival.

Patients operated on over a span of 14 years (2000–2014) were evaluated and stratified based on the development of post-operative strokes. Among the cases evaluated, 219 patients underwent repair of acute ascending dissection. Of that population 200 patients had adequate data for analysis of pre- and intra-operative variables, and post-operative outcomes and survival.

Henry Ford Hospital researchers evaluated the predisposing factors linked to strokes and the implications of this complication on outcomes and survival at 30 days, one year, and five years were evaluated using the life-test method. Pre-operative, operative, and post-operative factors were compared between the two groups using chi-square or Fisher's exact tests for categorical variables, and using independent two-group t-tests for continuous variables.

	All (N=200)	No stroke (N=160)	Stroke (N=40)	Log-rank p-value
30 days	0.85 (0.03)	0.89 (0.03)	0.73 (0.07)	<0.001
1 year	0.73 (0.03)	0.78 (0.03)	0.56 (0.08)	<0.001
5 years	0.62 (0.04)	0.70 (0.04)	0.29 (0.10)	<0.001

The results showed that stroke occurred in 20 percent of patients. There were a number of significant differences in pre- and intra-operative variables and post-operative outcomes between the groups (see table above). Survival probability was lower for the stroke group at 30 days (0.73 vs 0.89), one year (0.56 vs 0.78), and at five year intervals (0.29 vs 0.70), $p < 0.001$.

The table to the left shows conclusions drawn from the study which indicate patients who developed strokes had a higher rate of ventilator dependent respiratory failure, pneumonia, hemodialysis, and longer length of stay. Stroke was associated with higher mortality at 30 days, one year, and five years. The femoral site of cannulation was the only identifiable technical factor that was associated with a higher rate of strokes.

Variable	Response (N= 200)	No (N= 160)	Yes (N= 40)	p-value
Age	56.3 ± 13.7	56.1 ± 14.0	57.1 ± 12.9	0.681
Race	Other (5%)	6 (4%)	3 (8%)	0.524
	Black (35%)	55 (35%)	15 (38%)	
	Caucasian (60%)	98 (62%)	22 (55%)	
Gender	Male (71%)	121 (76%)	20 (50%)	0.001
	Female (30%)	39 (24%)	20 (50%)	
Shock	No (83%)	135 (85%)	27 (71%)	0.035
	Yes (17%)	23 (15%)	11 (29%)	
Periop HD	No (89%)	140 (92%)	27 (77%)	0.015
	Yes (11%)	13 (8%)	8 (23%)	
PNA	No (74%)	124 (82%)	16 (44%)	<.001
	Yes (26%)	29 (18%)	20 (56%)	
VDRF >72 hours	No (59%)	101 (67%)	8 (23%)	<.001
	Yes (41%)	49 (33%)	27 (77%)	
LOS	17.6 ± 14.8	16.1 ± 13.5	23.9 ± 17.8	0.012
Cann site	Others	109 (69%)	20 (51%)	0.048
	Femoral	51 (32%)	19 (49%)	
Cann site	R axillary/ Aortic/ innominate	107 (67%)	19 (49%)	0.035
	Femoral/ L axillary	53 (33%)	20 (51%)	

Henry Ford Researchers Include: Jamil Borgi, M.D.; Hassan Nemeh, M.D.; Loay Kabbani, M.D.; Meredith Mahan, MS; Alexander Shepard, M.D.; Gaetano Paone, M.D.

For more information about this study, or to refer a patient, call 1-877-434-7470.

Multi-center Study Of Transradial Versus Transfemoral Approach For Coronary Chronic Total Occlusion

Percutaneous coronary intervention (PCI) of chronic total occlusions (CTOs) are most commonly performed using bilateral transfemoral access and eight French guide catheters. However, transfemoral access is associated with higher risk for vascular access complications compared to transradial access and warranted further study.

Early reports have shown encouraging outcomes with transradial CTO PCI, yet there is limited information on outcomes. In this study, the researchers sought to examine both the technique and outcomes of transradial versus transfemoral CTO PCI in a contemporary, multi-center U.S. registry.

The procedural techniques and outcomes were collected on 650 patients who underwent CTO PCI for lesions between January 2012 and March 2014 at six U.S. centers. This data was recorded in a dedicated CTO database (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention—PROGRESS CTO, ClinicalTrials.gov Identifier NCT02061436).

Coronary CTOs were defined as coronary lesions with Thrombolysis In Myocardial Infarction (TIMI) grade 0 flow of at least three-month duration. Estimation of the occlusion duration was based on the first onset of angina symptoms, prior history of myocardial infarction in the target vessel territory, or comparison with a prior angiogram.

Technical success of CTO PCI was defined as successful CTO revascularization with achievement of < 30 percent residual diameter stenosis within the treated segment and restoration of TIMI grade 3 antegrade flow.

Procedural success was defined as achievement of technical success with no in-hospital major adverse cardiac events (MACE) including death or any cause, Q-wave myocardial infarction, recurrent angina requiring urgent repeat target vessel revascularization with PCI or coronary bypass surgery, tamponade requiring pericardiocentesis or surgery, or stroke.

All statistical analysis, both descriptive and multi-variable, measuring for categorical and continuous variables were performed with JMP 11.0 (SAS Institute, Cary, N.C.).

Results of the Study

Most patients were men (87 percent) with a high frequency of diabetes mellitus (42 percent) and prior coronary artery bypass graft surgery (36 percent). The CTO target vessel was the right coronary (59 percent), left anterior descending (20 percent), or circumflex (17 percent) artery. Transradial (TR) access was used in 110 (17 percent) of the 650 cases, as follows: bilateral radial access (63 percent); bilateral radial access plus unilateral or bilateral femoral access (7 percent); unilateral radial access plus unilateral or bilateral femoral access (26 percent); and unilateral radial access (4 percent).

Khaldoon Alaswad, M.D., director of the Cardiac Catheterization Laboratory at Henry Ford Hospital, says, “The key finding of the study is that compared with transfemoral, transradial CTO PCI was associated with similarly high success and similarly low major complication rates.” However, transradial arterial access was associated with longer procedural and fluoroscopy times.

“This study demonstrates a high technical and procedural success rate for both radial and femoral approaches,” explains Dr. Alaswad. The research team concluded, “This is likely related to inclusion of experienced operators and centers, use of novel techniques, such as antegrade dissection/re-entry and retrograde, and use of the “hybrid” approach to CTO PCI.”

The complete study can be found in *Catheterization and Cardiovascular Interventions* 85:1123-1129 (2015).



Khaldoon Alaswad, M.D.

For more information about this study, or to refer a patient, call 1-877-434-7470.

PARTNER III Trial Begins For Patients With Severe Aortic Stenosis

Patients over 65-years old, who suffer with severe, symptomatic aortic stenosis, identified with low mortality risk in undergoing standard surgical aortic valve replacement, who meet the study criteria, the PARTNER III Trial has begun enrollment at Henry Ford Hospital, the only center in Michigan participating in this study.

This study is the next phase in research on the SAPIEN family of valves, which comes after the valve's maker, Edwards Lifesciences Corporation, announced that data on patients at intermediate risk for open-heart surgery demonstrated that transcatheter aortic valve replacement (TAVR) with the SAPIEN XT valve was superior to surgery at one year on a composite primary endpoint of mortality, stroke and moderate or severe aortic regurgitation. In addition, the SAPIEN XT valve demonstrated clinical superiority at one year on individual assessments of all-cause mortality and of stroke.

William W. O'Neill, M.D., medical director of the Center for Structural Heart Disease program and a pioneer of TAVR, along with his colleague Gaetano Paone, M.D., division head, Cardiac Surgery, are the primary investigators at Henry Ford Hospital.

Henry Ford was one of two centers in southeast Michigan participating in the earlier PARTNER II Trial. "Results from the PARTNER II Trial, presented at American College of Cardiology's 65th Annual Scientific Session, should establish the SAPIEN 3 valve as the new benchmark for the treatment of intermediate-risk patients with severe, symptomatic aortic stenosis," Dr. O'Neill explains. "What we accomplished in the PARTNER II Trial provided important data and improvements to the SAPIEN 3 valve. We can now move from intermediate severity to those patients with severe symptomatic aortic stenosis in the PARTNER III study."

The randomized PARTNER III trial will run for 10 years. Dr. Paone explains, "Researchers across the country will either use the femoral approach to implant a SAPIEN 3 valve or perform open-heart surgical valve replacement in 1,300 patients with severe aortic stenosis. The study will then compare the two approaches, specifically focused on death, stroke and rehospitalization rates to determine if one approach improves patient outcomes."

Criteria for inclusion in the study includes a NYHA Functional Class > II, symptomatic, severe, calcific aortic stenosis with the following TTE criteria: Jet Velocity > 4.0 m/s or mean gradient > 40mmHg and AVA < 1.0 cm² or AV index < 0.6 cm²/m² and an STS risk score of < 4 percent.

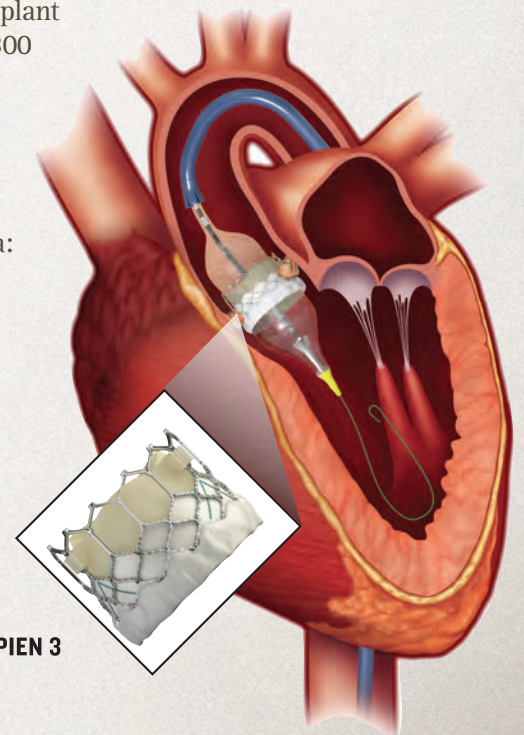
To learn more about this study or to enroll a patient, contact Ardit Kacori, research coordinator, at (313) 916-7452, or email akacorr1@hfhs.org.



William W. O'Neill, M.D.



Gaetano Paone, M.D.



SAPIEN 3

Henry Ford Hospitals Receive Approval to Perform Elective PCI



Mustafa Hashem, M.D.

A law passed by the state of Michigan in 2015 led to approval of two Henry Ford hospitals to provide angioplasty in non-emergent and scheduled cases in their Cardiac Catheterization Labs. Henry Ford Wyandotte Hospital and Henry Ford West Bloomfield Hospital have been approved and certified by the state to perform elective angioplasty, percutaneous coronary intervention (PCI), a non-surgical procedure used to open narrowed arteries in patients with heart disease. It is performed on patients having a heart attack or chest pain, or who have had an abnormal stress test.

Although more complex cardiac procedures were performed when a patient arrived having a heart attack, elective PCIs were not permitted by the state of Michigan. “We have performed angioplasties in emergencies, in a safe and timely manner, for years,” says Shalini Modi, M.D., service chief of Cardiology at Henry Ford West Bloomfield Hospital. “This new ruling will allow us to provide more complete and convenient care to our patients with heart disease in the community.”

Mustafa Hashem, M.D., chair of Cardiology and the medical director of the Cardiac Catheterization Lab at Henry Ford Wyandotte Hospital, says, “For more than a decade, with state authorization, we performed emergency PCIs on patients with heart attacks and ST-elevation myocardial infarction. All other patients needing PCIs would have to be transferred to other hospitals.”

Patients appreciate being able to have their cardiac care closer to home. “With this approval, we will be able to perform angioplasty procedures for non-emergency situations as well,” says Gerald Koenig, M.D., Ph.D., director of Henry Ford West Bloomfield Hospital’s Cardiac Catheterization Lab.

Dr. Hashem agrees and adds, “It just makes sense and is more cost effective to have elective PCIs performed for patients who have angina or abnormal stress tests, and for patients who have had heart attacks but do not fit the criteria of heart attacks with a completely blocked artery. If other diagnostic testing is required, all of that can be done at one location – these changes greatly benefit patients.”

Henry Ford interventional cardiologists’ preferred method for angioplasty procedures is to access an artery in the wrist, rather than the leg. Afterward, patients rest in an armchair for a few hours, rather than lying on a stretcher for six to eight hours, as required when the leg artery is used. Patients who are at high risk for a future heart event, but are not currently experiencing heart attack, may be candidates for this elective procedure.

For more information or to refer a patient for PCI or interventional cardiology services to Henry Ford Wyandotte Hospital, call (734) 324-3500 or Henry Ford West Bloomfield Hospital, call 1-877-434-7470.



Gerald Koenig, M.D., Ph.D. director of Henry Ford West Bloomfield Hospital’s Cardiac Cath Lab.

Advanced Imaging And 3D Printing

At the Advanced Imaging and 3D Printing Conference experts from the Center for Structural Heart Disease at Henry Ford Hospital presented training on advanced imaging and 3D printing in adult structural heart interventions. Through this material, you will gain an understanding of the newest breakthroughs in medical treatment and technologies in adult structural heart 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 the left atrial appendage occlusion

Visit henryford.com/shdvideoprocedures to see the videos.

Sent To Detroit For Surgery

Robert Hanselman's medical condition meant surgery was not an option to replace (repair) his 13-year-old heart valve. Luckily, Robert's Florida cardiologist knew Adam Greenbaum, M.D., at the Center for Structural Heart Disease at Henry Ford Hospital, where innovating and perfecting minimally invasive heart valve procedures happens every day.

Robert had one option – a minimally invasive procedure called TMVR (transcatheter mitral valve replacement). In his cardiologist's opinion, Robert needed to be in Detroit in the expert hands of Dr. Greenbaum and his very experienced team – with little time to spare.

“Mr. Hanselman's valve had failed over time and was now severely leaking. Like many patients in his condition, he was too ill to likely survive another open surgical procedure. To help Mr. Hanselman and others in his situation, we have developed transcatheter alternatives where a new heart valve could be delivered through a catheter in his femoral vein,” says Adam Greenbaum, M.D., cardiologist and co-director of the Structural Heart Disease Program at Henry Ford Hospital. “We are one of the largest single centers with extensive experience performing this procedure, we understand its intricacies, a procedure which has been life-saving for our patients.”



The entire team, which included Gaetano Paone, M.D., cardio thoracic surgeon and Dee Dee Wang, M.D., cardiologist, brought their expertise in mitral anatomy and 3D cardiac imaging, respectively to Mr. Hanselman's case. “When his particular anatomy presented us an unusual challenge, it was the expertise of our team that meant the procedure was successfully completed, which ultimately required three heart valves,” says Dr. Greenbaum.



Robert Hanselman's Florida cardiologist sent him to Henry Ford Hospital for his last option – a live-saving transcatheter mitral valve replacement (TMVR).

Today, Robert is home in Florida, busy in a cardiac rehab program, working out and getting stronger every day. “Dr. Greenbaum saved my life, I wouldn't be here to share my story without him,” says Robert.

At the Center for Structural Heart Disease at Henry Ford Hospital, innovations and advancements in treatments of the heart are bringing patients from all over the country for life-saving care.

To learn more about these advanced procedures and the team that creates them, visit henryford.com/shdvideoprocedures and actually watch these procedures.

To connect with a Henry Ford physician, call:

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

© 2016. All rights reserved.

PRESORTED
FIRST-CLASS MAIL
US POSTAGE PAID
DETROIT, MI
PERMIT NO.
6785

COURSE EVENT

REGISTER TODAY

Henry Ford Live CTO PCI Advanced Course

Monday, Sept. 19, 2016 – 7 a.m. to 5 p.m.
Henry Ford Hospital, Detroit, MI

Join the experts for a day filled with live cases and didactic presentations on enhancing the care of patients with coronary artery chronic total occlusion, angina, and high-risk ischemia.

The objectives of the course include:

- Strategies of catheter interventions to treat chronically occluded coronary arteries
- Introduction to new technologies used during catheter-based revascularization of coronary arteries with chronic total occlusion
- Program development and building alliances to treat patient with coronary artery chronic total occlusion

Course Directors:

Khaldoon Alaswad, M.D.
Director
Cardiac Catheterization Laboratory
Henry Ford Hospital

William W. O'Neill, M.D.
Medical Director
Center for Structural Heart Disease
Henry Ford Hospital



Khaldoon Alaswad, M.D.



William W. O'Neill, M.D.

Henry Ford Hospital - SIM Center
2799 W. Grand Blvd.
Detroit, MI 48202

To register or for more information, call Lawaun Everson
at (313) 916-2896 or email leverso1@hfhs.org.