

A Transcatheter Valve for All Cardiac Positions

Today's decision-making and management of adult congenital and geriatric patients have been transformed by transcatheter valve therapies (TVT). Sapien valves are being implanted in the mitral, tricuspid, pulmonic and caval positions for compassionate use in treatment of inoperable valvular heart disease.

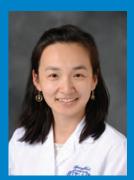
Commercially in the United States, several transcatheter heart valves are available for implant in different cardiac positions. While not all valves can be placed in various positions, there are multiple brands and types of valves which can be used, and more are likely to be approved in the near future.

Through the use of routine chest radiographs, Dee Dee Wang, M.D., director of Structural Heart Imaging; Marvin Eng, M.D., fellowship director; and Medical Director William O'Neill, M.D., of the Center for Structural Heart Disease at Henry Ford Hospital, place several transcatheter Sapien valves in each of the four cardiac valves, and additionally extra-cardiac at the level of the right atrial inferior vena cava junction.

For physicians of all training backgrounds, these transcatheter devices will appear more frequently on routine imaging. The aim of the chest radiograph pictorial is to create awareness to the prevalence of this emerging field of transcatheter cardiac interventions for

NOTABLE WOMAN IN HEALTH CARE – 2018

Dee Dee Wang, M.D., director, Structural Heart Imaging and Cardiac CT CoreLab at Henry Ford Hospital, Center for Structural Heart Disease and Medical director of 3D printing at the Henry Ford Innovation Institute was recently recognized by Crain's Detroit Business as one of many area notable women in health care – 2018.



Dee Dee Wang, M.D. Director, Structural Heart Imaging

She was also recognized by the American College of Cardiology, earning the 2017 ACC Emerging Faculty award. She and her team take on the challenge of caring for patients in the most critical situations with the most innovative therapies possible for this frail population.

She has been recognized for her research and advancing patient safety and outcomes using 3D and 4D imaging for the most high-risk structural heart conditions. Dr. Wang is seeking a patent on 3D reconstruction of the heart models used in these complex structural heart cases.

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INNOVATIONS

A Transcatheter Valve for All Cardiac Positions

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patients deemed not optimal candidates for open-heart surgery. The chest radiographs presented represent valve placement at:

- 1. Transcatheter aortic valve replacement with Edwards 23 Sapien 3.
- 2. Transcatheter mitral valve replacement in mitral annular calcification with Edwards 26 Sapien 3.
- 3. Transcatheter pulmonic valve replacement in left and right pulmonary arteries with two Edwards 29 Sapien 3.
- 4. Transcatheter tricuspid valve replacement in degenerative surgical bioprosthesis with Edwards 26 Sapien 3.
- 5. Transcatheter caval valve implantation at the right atrium-inferior vena cava junction.

Note: To view the xrays, visit Structural Heart (Jan. 16, 2018). https://doi.org/10.1080/24748706.2017.1413492.

STAFF UPDATE

Babar Basir, D.O. *Interventional Cardiology*

MEDICAL SCHOOL EDUCATION Lake Erie College of Osteopathic Medicine, PA, 2010

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FELLOWSHIPS

Henry Ford Hospital, Cardiology -Interventional, MI, 2017

Henry Ford Hospital, Cardiology, MI, 2016

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American Board of Surgery – Surgery

American Board of Thoracic Surgery – Cardiothoracic Surgery

RESEARCH INTERESTS

Multiple injuries in blunt abdominal trauma.

Aortic valve pathology in combination with ascending aortic aneurysms.

Aneurysms and dissections of the thoracic aorta.



Dimitrios Apostolou, M.D.

UPDATE

Local Cardiogenic Shock Initiative Becomes A National Research Study



Henry Ford Hospital – National CSI Team. FRONT ROW (seated) L-R: William W. O'Neill, M.D., principal investigator, Babar Basir, D.O., investigator. BACK ROW L-R: Tyrell Johnson, research assistant, Tia Seale, R.N., research nurse, Michael Hacala, RCIS, EMT-P, study coordinator, and Ruth Fisher, MBA, vice president, Heart & Vascular Institute.

A collaboration of cardiologists across metro Detroit were assembled in 2016 by William W. O'Neill, M.D., medical director of the Center for Structural Heart Disease at Henry Ford Hospital. This working group of physicians, known as the Detroit Cardiogenic Shock Initiative, developed a standardized approach of supporting the circulatory system during an acute MI (heart attack) with shock, using Impella[®], a straw-sized heart pump and right heart monitoring to rapidly reduce the use of inotropes.

In their retrospective study, a 76 percent survival rate was demonstrated using early mechanical circulatory support, compared to 50 percent historically with traditional treatment. This hemodynamic support protocol for treating cardiogenic shock was announced at a press conference on Feb. 8, 2017. "In the world of cardiology, these changes in the algorithms are a momentous shift in previous protocols for cardiogenic shock during a myocardial infarction," explains Dr. O'Neill. Further data shows that survival rates improve by reducing the number of inotropes used on a patient. Yet, their experience shows reducing drugs is not enough. Decreasing mortality comes from supporting the heart early to ensure blood is pumped to the rest of the body, which allows the heart to rest and recover.

"We saw such success in Detroit; it's important to share this lifesaving knowledge with others," said Dr. O'Neill. In a standing-room-only crowd at the American College of Cardiology's Spring 2017 Scientific Sessions in Washington, D.C., he presented the hemodynamic support study and its results. Within hours of this presentation, cardiologists from around the country started to contact Henry Ford requesting to participate in the initiative.

By July 2017, the National Cardiogenic Shock Initiative (National CSI) was established. To support the Detroit Cardiogenic Shock Initiative's move to a national platform, Babar Basir, D.O., cardiology fellow, was

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Local Cardiogenic Shock Initiative Becomes A National Research Study

awarded a unique 'shock' fellowship with the Henry Ford Center for Structural Heart Disease. Under Dr. O'Neill's mentorship, Dr. Basir provides education on a national and international level on the treatment of acute myocardial infarction complicated by cardiogenic shock.

In October 2017, Dr. Basir, now an attending physician in the Henry Ford Medical Group, presented the protocol in a standing-room-only session at the Transcatheter Cardiovascular Therapeutics (TCT) conference. He also presented the results of the original study through formal presentations at the Acute Cardiac Unloading and Recovery Working Group in Barcelona, Spain.

"It's obvious that cardiologists find the algorithms, protocols and outcomes to be effective in reducing deaths from cardiogenic shock," explains Dr. Basir. "Physicians are seeking us out to learn more and all the participants in the registry have contacted us to join. As Dr. O'Neill likes to say, 'it's a *Coalition of the Willing*' and it's working to save lives."

National CSI: Protocols and Screening Process

Michael Hacala, RCIS, EMT-P, study coordinator of the National CSI, explains that overwhelming interest in the Detroit CSI protocol led to the development of a single-arm prospective national registry.

"Our team did a lot of work to make it easier for hospitals across the country to implement the algorithm and participate in the study," Hacala explains. "We first obtained approval of the study through the Henry Ford Health System IRB, then immediately worked with Western IRB (WIRB) to create a national IRB structure that is available to support hospitals without an IRB and expedite that part of the implementation for those sites."

As each clinical site joins National CSI, Hacala conducts an initial visit that includes on-site training for the study. "The rationale for on-site training is to ensure that all of the clinical and research staff understand the aspects of data collection and submission into the study," Hacala says. "This requires clear communication from the ER to the Cath Lab to the ICU/CCU, from the patient's arrival to discharge." Currently, more than 100 hospitals from across the United States and four countries have contacted Henry Ford Hospital to join the National CSI national registry.

"Our goal is to collect data on 500 patients from over 75 clinical locations across the country, then analyze the data to validate the effectiveness of the protocol and, if necessary, make adjustments during the study," explains Hacala.

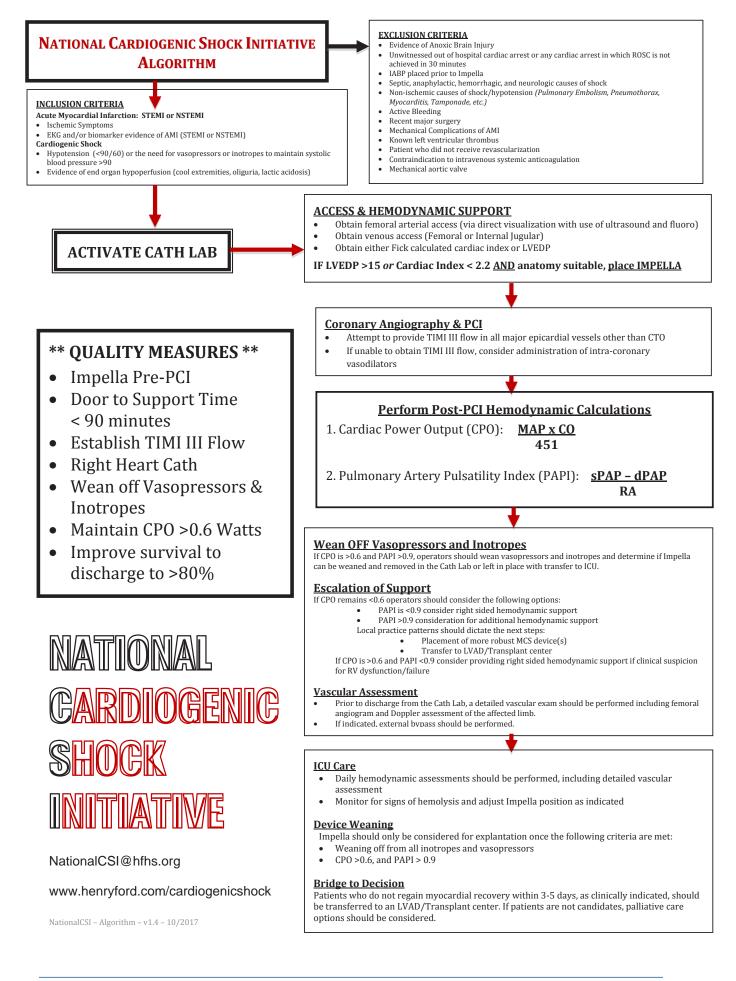
The Screening Process:

Prior to bringing an organization into the study, Dr. O'Neill, Dr. Basir, and Hacala pre-screen on a variety of levels to determine if the physicians and hospital meet a number of criteria. Basic criteria include:

- Cardiologists within the hospital must have performed a minimum number of Impella[®] cases during the previous one-year period.
- The hospital has adopted the National CSI treatment algorithm as standard of care for patients who present with acute MI with cardiogenic shock.
- Identification of a local Primary Investigator (PI) to coordinate the study requirements on-site.

"It's not just large academic institutions that are reaching out to us – many community and rural hospitals are seeking to participate. It's exciting to see this lifesaving initiative grow on a national level," concludes Dr. O'Neill.

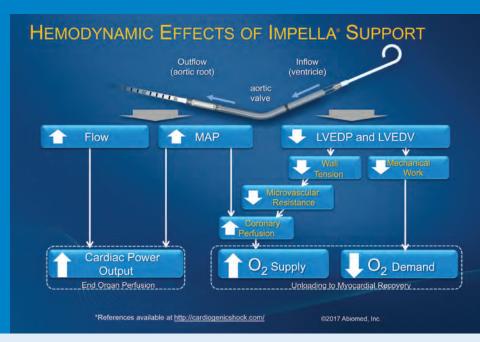
To learn more about the National CSI study, visit: https://www.henryford.com/cardiogenicshock.



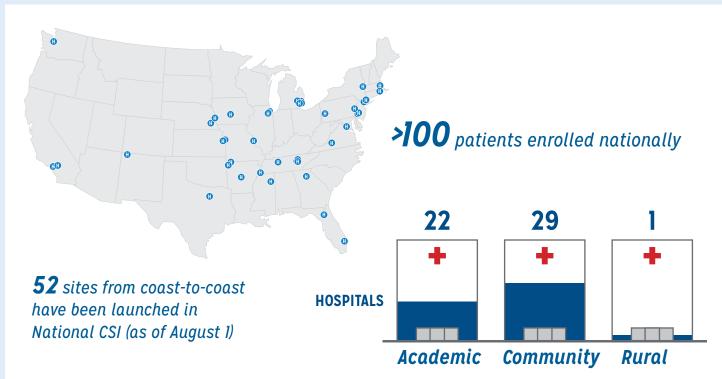
The First Improvement in Cardiogenic Shock Survival in Over 20 Years Early Identification and Circulatory Support Improve Outcomes

A massive heart attack suppresses the heart's pumping function, depriving vital organs of blood flow and sending the patient into shock. The National CSI algorithm calls for supporting the circulatory system quickly. Door-to-support time is 90 minutes, making identification of these patients *early* a critical factor in supporting the circulatory system.

Per the protocol, the Impella® heart pump is inserted through the femoral artery *before* the cause of the heart attack is treated with traditional procedures to open the blocked artery. "There is no doubt that early circulatory support is critical to improve the chance of a successful outcome in these critically ill patients," explains Dr. O'Neill. Quick support of the circulatory system, followed by rapid transport to a hospital equipped to open the blocked artery may be required, especially when equipment, skill or cardiologists are not available. "The mindset should now be changed from 'door-to-balloon' (angioplasty) to 'door-to-support.' Timing is key in the survival of these patients," Dr. O'Neill explains.



NATIONAL CSI: CLINICAL SITES LAUNCHED



RESEARCH

Targeted Metabolomic Profiling of Plasma and Survival in Heart Failure Patients

"The cumulative success of neurohormonal interventions for heart failure (HF) remains an enormous health problem. There is a substantial residual disease burden that exhibits a wide range in the course of the disease and response to treatment. Powerful risk prediction models of survival have been produced using clinical risk scores and natriuretic peptides. But crucial knowledge gaps still exist regarding variability in disease progression, the additional biological axes at play, and the limited ability to recognize varying pathophysiological subgroups that comprise the overall HF population," explains David Lanfear, M.D., head of Advanced Heart Failure and Transplant Cardiology at Henry Ford Hospital.

"Our ability to biologically characterize patients has increased due to powerful technology platforms such as genomics and proteomics, which offer new hope of answering this challenge," Dr. Lanfear said. "A recently maturing platform is metabolomics, which measures the levels of many small molecules of intermediary metabolism such as metabolites in tissues or fluids. Metabolomics is increasingly used to probe organ function and dysfunction, as well as to identify novel disease pathways."

To help better understand variability across patients with HF in terms of disease progression, this study sought to derive and validate plasma metabolite associations with survival in HF patients. The study was enabled by The Henry Ford Heart Failure Pharmacogenomic Registry, an observational study started by Dr. Lanfear, which includes more than 1,700 Henry Ford patients with either HFpEF or HFrEF. Participating patients included in the registry met the Framingham criteria for diagnosis of HF, and submitted blood samples and detailed phenotypic information.

The analytical cohort for the metabolomic study included patients with a reduced ejection fraction (<50 percent) and who had metabolite levels measured in plasma (n=1,032). These patients were randomly divided into two groups, a derivation cohort and a validation cohort (n=516 each).

Amino acids, organic acids, and acylcarnitines were quantified using mass spectrometry in fasting plasma samples. A prognostic metabolite profile (PMP) in the derivation cohort was developed using Lassopenalized cox regression. Validity was assessed by 10-fold cross validation in the derivation cohort and by standard testing in the validation cohort. The PMP was analyzed as both a continuous variable and dichotomized at the median (i.e. high vs. low), in univariate and multivariate models adjusted for clinical risk score and N-terminal pro-B-type natriuretic peptide.*



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

Among the study patients 48 percent were African American, 35 percent were women, and the average age was 69-years-old. After a median follow-up of 34 months, there were 256 deaths (127 and 129 in derivation and validation cohorts, respectively). The metabolite panel was highly associated with the risk of death in validation testing and remained so even when adjusted for our best clinical risk score and strongest current biomarker (NtProBNP). The study also showed many metabolites associated with other factors important in heart failure patients, like the presence of diabetes, or the degree of symptoms/functional impairment.

Dr. Lanfear concluded, "These findings suggest that the plasma metabolite profile might be a useful tool to better understand phenotypic subgroups of heart failure and potentially further illuminate the pathophysiology of heart failure."

He added that "The importance of these observations was not that our metabolite panel should be considered the next biomarker of interest in heart failure, but rather that the plasma metabolome may be a quantitative tool for recognizing important variations in this disease that are not clinically obvious and dissecting the causes."

The results of the study indicated that additional investigation is warranted to define underlying mechanisms and potential clinical applications.

*NOTE: The complete study can be reviewed at: Lanfear DE, Gibbs JJ, Li J, She R, Petucci C, Culver JA, Wilson Tang WH, Pinto YM, Keoki Williams L, Sabbah HN, Gardell SJ. Targeted Metabolomic Profiling of Plasma and Survival in Heart Failure Patients. *JACC: Heart Failure*. 2017;5:823–32.

RESEARCH

Impact of Center LVAD Volume on Outcomes After Implantation

As more centers are opening for mechanical circulatory support (MCS) implantation, the need to study the impact of surgical volumes on short- and long-term patient outcomes became apparent. For a center to qualify for reimbursement, Centers for Medicare and Medicaid Services (CMS) requires center doctors to implant \geq 10 LVADs (left ventricular assist device) or total artificial hearts over a 3-year period. But the impact of center LVAD surgical volumes on patient outcomes had not been thoroughly scrutinized.

Jennifer Cowger, M.D., M.S., lead researcher and medical director of Mechanical Circulatory Support (in the Advanced Heart Failure and Cardiac Transplantation Section) at Henry Ford Hospital explained, "The objective of the study was to examine patient outcomes after LVAD implantation across a range of center surgical volumes as earlier studies demonstrated association between mortality and surgical volumes in certain cardiac surgeries."

In contrast, a previous study of 88 academic medical centers in the United States found no association between hospital LVAD surgical volume and inpatient mortality, but operative survival was greatest when the LVAD operation was performed by the highest volume surgeons. Aside from age, center volume (hazard ratio [HR]) was also the only predictor of longer-term survival after HeartMate II implementation.

Using patient data entered in the INTERMACS (Interagency Registry of Mechanically Assisted Circulatory Support), comparisons were made between patient outcomes and the center's VAD volume. Center volumes were provided for 7,416 patients undergoing LVAD implantation. Center LVAD volume was categorized as either very low (≤ 10 implants/year, n=617), low (11 to 30 implants/year, n=2,561), medium (31 to 50 implants/year, n=2,458), or high (>50 implants/year, n=1,750). The main outcome of interest was patient survival



Jennifer Cowger, M.D., M.S.

based on center volume derived from Kaplan-Meier and multivariate Cox regression.*

Analysis of the results of 7,416 patients enrolled in the INTERMACS, had a biomodal risk of adverse outcomes associated with center volume: very low volume centers have a lower adjusted average survival than centers that perform 30 to 50 VADs a year. The increased mortality association persisted even after adjusting for known correlates of LVAD candidate operative risk. After controlling for known correlates of LVAD mortality, adjusted mortality remained 32 percent higher at very-low-volume LVAD centers than at medium volume centers.

Dr. Cowger says, "We concluded that center volume does correlate with post-VAD survival, with worse survival noted at very-low volume centers. These findings suggest that current U.S. VAD center standards warrant reconsideration."

*NOTE: The complete study can be reviewed at: Cowger JA, Stulak JM, Shah P, Dardas TF, Pagani FD, Dunlay SM, Maltais S, Aaronson KD, Singh R, Mokadam NA, Kirklin JK, Salerno CT. Impact of Center Left Ventricular Assist Device Volume on Outcomes After Implantation: An INTERMACS Analysis. JACC: Heart Failure. 2017;5:10: 691-9. Dx.doi.org/10.1016/j.jchf.2017.05.011.

COMMUNITY ADVANCED HEART FAILURE CLINICS

For over 10 years, the Henry Ford Heart Failure Team has brought care to heart failure patients in a collaborative effort with physicians from other health systems. Patients have the ease of selecting a clinic within their own hospital: Beaumont Hospital, Providence Hospital or St. John Hospital and Medical Center. "We bring our expertise of treating heart failure to the patients, and collaborate with their private physician," explains David Lanfear, M.D., head of Advanced Heart Failure and Transplant Cardiology at Henry Ford Hospital. Henry Ford also has Advanced Heart Failure Clinics in its own community hospitals.

Advanced Heart Failure Clinics are located at:

Ernst Cardiovascular Center Beaumont Hospital 3601 W. 13 Mile Road Royal Oak, MI 48073

Providence Hospital 22250 Providence Dr., Ste 705 Southfield, MI 48075

St. John Hospital and Medical Center 22201 Moross Road, Ste 356 Detroit, MI 4823 Henry Ford Macomb Hospital 15855 19 Mile Road Clinton Township, MI 48038

Henry Ford West Bloomfield Hospital 6777 W. Maple Road West Bloomfield, MI 48322

Henry Ford Wyandotte Hospital 2333 Biddle Ave. Wyandotte, MI 48192

To refer patients to one of the clinics, call (313) 916-2895.

RESEARCH

AAA Repair: Comparing Renal Function in Endovascular to Open Repair

The Division of Vascular Surgery at Henry Ford Hospital recently presented and published their results of a study evaluating the outcome of patients undergoing AAA repair via either open or endovascular means. The objective of the study presented to the Society for Vascular Surgery and published in *Vascular Specialist*, a publication of the Society for Vascular Surgery, sought to determine if endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAAs) increased renal insufficiency over longterm compared to open repair (OR). The researchers used their own experience with AAA repair to determine if a significant difference exists in postoperative and long-term renal outcomes between EVAR compared to OR.

In a retrospective cohort study, all patients who underwent AAA repair between January 1993 and July 2013 at a tertiary referral hospital (Henry Ford Hospital) were considered. Data collection included demographics, comorbidities, preoperative and post-operative laboratory values, morbidity and mortality.

Of the 675 AAA repairs, 317 were ORs and 358 were EVAR. The mean patient age was 73.9-years-old, 79 percent of the patients were male, 18 percent had diabetes and 78 percent were hypertensive. Excluded from the study were patients with ruptured AAAs, preoperative hemodialysis, juxtarenal or suprarenal aneurysm origin, and no followup laboratory values.

Pre- and post-operative, six-month, and yearly serum creatinine values were collected. Glomerular filtration rate (GFR) was calculated on the basis of the Chronic Kidney Disease Epidemiology Collaboration equation. Acute kidney injury (AKI) was classified using the Kidney Disease Improving Global Outcomes guidelines. Change in GFR was defined as preoperative GFR minus the GFR at each follow-up interval. Comparison was then made between EVAR and OR groups using multivariate logistics for categorical data and linear regression for continuous variables.

Loay Kabbani, M.D., vascular surgeon at Henry Ford Hospital, and lead author noted, "We found that among the 675 patients in



Loay Kabbani, M.D.

the perioperative period, acute kidney injury was more common after open repair. However, with long-term follow up it was apparent that EVAR patients had a greater decline in GFR compared to the open repair patients. This difference was not evident until four years after the procedure."

Tim Nypaver, M.D. head of vascular surgery at Henry Ford Hospital, study coauthor said, "This is an important study, as most randomized control studies and registries do not follow patients for four years, and do not follow renal function."

"This study is significant as it allows a meaningful synthesis of the literature both to define the pathophysiologic mechanisms behind renal dysfunction and to develop effective renal protective measures to prevent or to reduce this problem," concludes Dr. Kabbani.

***NOTE:** The complete analysis is available: Al Adas Z, Shepard AD, Nypaver TJ, Weaver MR, Maatman T, Yessayan LT, Balraj P, Kabbani LS. *J Vasc Surg.* 2018 Mar 20. pii: S0741-5214(18)30169-1. doi: 10.1016/j. jvs.2017.12.051. [Epub ahead of print] Long-term Decline In Renal function Is More Significant After Endovascular Repair Of Infrarenal Abdominal Aortic Aneurysms.

CARDIOVASCULAR SCREENING

Human Performance Clinic For Athletes to Weekend Warriors

The Henry Ford Human Performance Clinic, in collaboration with the Multidisciplinary Sports Program, offers a comprehensive cardiovascular screening and performance evaluation for elite/competitive athletes, recreational exercisers and weekend warriors. Based on training habits and test results, training recommendations are provided to help athletes achieve performance goals. Risk for cardiovascular disease is also assessed.

Each evaluation includes:

- Cardiovascular screening examination
- Cardiopulmonary exercise stress test
- Maximum aerobic capacity (VO2max)
- Anaerobic (lactate) threshold
- Body composition analysis with body fat percentage and lean body mass

- Lipid and blood glucose values
- Consultation with clinical exercise physiologist
- Training recommendations based on test results
- Risk factor analysis to determine 10-year risk for heart disease
- Nutrition guidelines to optimize peak performance

For more information or to refer a patient, call (313) 972-4030.

To connect with a Henry Ford physician, call:

Heart & Vascular Institute



Center for Structural Heart Disease

1-855-518-5100



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IN THE NEWS



Consumer Reports

Henry Ford Macomb Hospital has been recognized by *Consumer Reports 2018* as a top hospital in the region for coronary artery bypass graft (CABG) and aortic valve replacement (AVR) procedures.



Health Care Hero

Crain's Detroit Business, now in its 17th year of honoring Health Care Heroes, selected William W. O'Neill, M.D., for "saving lives before and after people have major heart attacks since the 1980s." In his recent work leading the National Cardiogenic Shock Initiative to improve survival rates, an algorithm for the new protocol is being implemented across the nation – the first major change for treating heart attacks in 30 years.



Michigan Vascular Quality Improvement Study Group

Congratulations and recognition to Alexander D. Shepard, M.D., vascular surgeon, at Henry Ford Hospital for his successful leadership to improve quality though a collaborative of regional quality groups collecting and analyzing data to improve patient safety and care. He served as the medical director from 2010 to 2018; at a recent Michigan Vascular Study group meeting, he was recognized for his significant contributions as the first study group leader dedicated and committed to improvement in statewide patient outcomes. Dr. Shepard now serves as a member of the Board of Governors of the Henry Ford Medical Group; in 2018, Dr. Shepard was elected Chair, Board of Governors, Henry Ford Medical Group.



#Cardiologists Teach Through Twitter

Henry Ford Hospital structural heart experts have taken to Twitter in a viral fashion to share new techniques and provide advanced knowledge on all matters of structural heart and interventional cardiology plus provide updates on the National Cardiogenic Shock Initiative (NationalCSI). Join the conversations with:

William W. O'Neill, M.D. @BillO'NeillMD Babar Basir @Babar_Basir Khaldoon Alaswad, M.D. @KalaswadMD Dee Dee Wang, M.D. @DeeDeeWangMD Mike Hacala @Mike_Hacala Akshay Khandelwal, M.D. @KhandelwalMD Janet Wyman @g2wym



Multidisciplinary Aortic Center Expands

Now among the top 10 of Aortic Centers in the country, the expanded Henry Ford Aortic Center brings together a multidisciplinary team of cardiologists, cardiac and vascular surgeons, vascular medicine specialists, and radiologists, to discuss, review, and treat patients with complicated thoracic and thoracoabdominal dissections and aneurysms. Novel minimally invasive methods, thoracic endovascular/aortic/aneurysm repair (TEVAR) and complex hybrid open debranching and endovascular operations are frequently offered and performed for those in life-threatening conditions requiring surgical intervention.