Henry Ford Health System

CARDIO BEAT

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Center for Structural Heart Disease Program Continues to Grow

From the first transcatheter aortic valve replacement (TAVR) procedure in 2012, the Center for Structural Heart Disease program at Henry Ford Hospital has grown under the leadership of Medical Director William W. O'Neill, M.D., with expansion of the team in both size and expertise.

"From the late-night brainstorming sessions, and collaborative efforts from an outstanding group of physician-researchers who have advanced treatment options for our patients, our program has emerged as one of the largest in the country," explains Dr. O'Neill. While Transfemoral TAVR remains the most commonly performed route for transcatheter aortic valve replacements, the team has successfully developed multiple alternate approaches for those who may not be candidates for the femoral route.

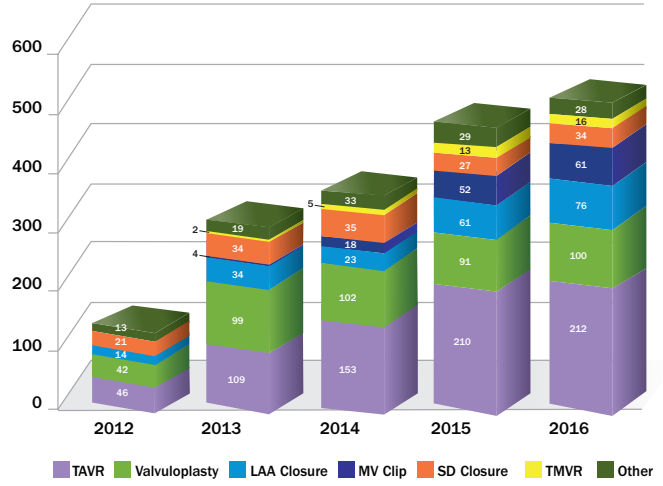
For example, the team, led by Adam Greenbaum, M.D., co-director, Center for Structural Heart Disease program at Henry Ford, partnered with Robert Lederman, M.D., senior investigator, National Institutes for Health, to develop the transcaval approach specifically for difficult-access patients. The safety and efficacy of the transcaval route was published in the *Journal of the American College of Cardiology*, establishing transcaval access as an option not only with TAVR, but opening the door for other clinical scenarios. In addition, Gaetano Paone, M.D., division head of Cardiothoracic Surgery, Henry Ford Hospital, has led the team in successfully using transcarotid access on a routine basis.

William W. O'Neill, M.D.

"Our commitment to safe and effective care has significantly advanced with the use of 3D imaging and printing technology," says Dr. O'Neill. Under the leadership of Dee Dee Wang, M.D., director, Structural Heart Imaging at Henry Ford Hospital, creating a 3D model of a patient's heart provides the opportunity to precisely plan the best approach and treatment. As our data indicates, using 3D imaging is safer with efficient procedure times for each patient.

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

CENTER FOR STRUCTURAL HEART DISEASE PROGRAM AT HENRY FORD – GROWTH



INSIDE

EDUCATION IN PRACTICE

Unique Fellowship Benefits Patients, Communities and Health Systems

A unique Complex Percutaneous Coronary Intervention (PCI) and Chronic Total Occlusion (CTO) fellowship was awarded to Babar Basir, D.O., in July 2017. The unique position brought together leading Henry Ford educators: Kaldoon Alaswad, M.D., director of the Cardiac Catheterization Lab, William W. O'Neill, M.D., medical director of the Center for Structural Heart Disease, and Henry Kim, M.D., division head of Cardiology, to facilitate the mentorship of a one-of-a-kind training program. The fellowship is three-fold:

The CTO PCI component of the fellowship is proctored by Dr. Alaswad, nationally renowned for his skill in opening chronic total occlusions. With success rates nationally hovering between 60 to 70 percent, Dr. Alaswad's CTO PCI procedures result in more than a 90 percent success rate. These tend to be difficult lesions, to help patients whose symptoms are not responding to medications. "It is anticipated that there may be up to 200 patients locally who will require these complex procedures in the next year," says Dr. Basir. "I have the unique opportunity to be proctored in these complex techniques by one of the best operators in the world and become a leader in the field."

The research component of the fellowship moves the Detroit Cardiogenic Shock Initiative beyond the region onto a national platform. In 2016, research among five major Detroit-area health systems demonstrated that survival rates among patients who experience cardiogenic shock improved to 80 percent by quickly supporting the circulatory system. As a result, the collaboration ensured this proven protocol for treating patients arriving in cardiogenic shock became the standard of care in the Detroit region.

Babar Basir, D.O.

Dr. Basir, who leads the initiative under Dr. O'Neill's mentorship, provides education on a national and international level about the treatment of acute myocardial infarction complicated by cardiogenic shock. He will be presenting the most up-to-date results through formal presentations at the Acute Cardiac Unloading and Recovery Working Group in Barcelona, Spain and scientific sessions such as the Transcatheter Cardiovascular Therapeutics (TCT) in Denver, Colo. Thus far, national collaborators in Philadelphia and Knoxville have begun implementing this standard of care as their own best practice, with support from Dr. Basir.

Further explaining, Dr. Basir says, "A health system that has a strong left ventricular assist device (LVAD) program and a heart transplant center make cardiogenic shock initiatives even stronger as these patients frequently require this form of advanced care, at Henry Ford Hospital we have the best of both."

The third component of this year-long fellowship is Dr. Basir's appointment as a junior attending to care for patients at Henry Ford Hospital. "This fellowship further educates Dr. Basir as he becomes a national educator, and it also benefits patients, communities and health systems alike," shares Dr. Kim.

WOMEN'S HEART CARE

Pregnancy Related Risks for Cardiovascular Events

Dierdre Mattina, M.D.

Emerging research shows that women with pregnancy complications of gestational hypertension, preeclampsia/eclampsia or a history of gestational diabetes are at higher risk for cardiovascular events in the 10-15 years following pregnancy.

In response, the Henry Ford Women's Heart Center, a comprehensive cardiovascular clinic focused specifically on the effects of heart disease in women, initiated the Postpartum Heart Program to identify, address and minimize ongoing cardiovascular risk in women with prior pregnancy related complications. During the initial assessment, women receive the following:

- A thorough risk assessment by a board-certified cardiologist
- Risk-assessment labs or cardiovascular imaging if indicated
- Small group nutrition counseling with a Henry Ford registered dietitian
- Small group exercise and healthy lifestyle counseling by an RN Integrative Wellness Advocate and Certified Wellness Practitioner

"It's important that we collaborate with our OB/GYN and primary care colleagues," explained Deirdre Mattina, M.D., cardiologist and director of Henry Ford Women's Heart Center. "Risk factor modification should begin in the first postpartum year as these women are twice as likely to develop cardiovascular disease and two of three women with a history of preeclampsia will die from heart disease."

At this time, hypertensive pregnancy disorders are sporadically reported by treating physicians and obstetric history is rarely addressed by treating cardiologists. "When treating younger women, it is important that physicians document these historical and current conditions to advance our understanding of this disease process and potentially identify risk markers before significant cardiac events occur," said Dr. Mattina.

Women with one or more of the following are at increased risk of preeclampsia:

- 1st pregnancy (excluding miscarriages & abortions)
- Chronic hypertension
- Kidney disease
- Lupus
- Diabetes Mellitus or Gestational Diabetes
- Multiple gestations (i.e. twins or triplets)
- Family history of preeclampsia
- Personal history of preeclampsia in prior pregnancy
- Obesity
- African-American heritage

Our team of specialists is committed to addressing these risk factors and providing our clients with the tools to minimize their future cardiovascular risks.

To refer a patient for assessment, call (313) 876-4540.

RESEARCH

AMPLATZER™ Amulet™ LAA Occluder Trial

The Amulet™ device will be evaluated for safety and efficacy by demonstrating non-inferiority to the commercially available WATCHMAN™ left atrial appendage closure device in patients with non-valvular atrial fibrillation.

Eligible patients for the trial will be randomized in a 1:1 ratio between the Amulet LAA occlusion device (treatment) or a Boston Scientific WATCHMAN® LAA closure device (control) and will be followed for five years after device implant. All subjects will undergo the protocol-required tests and assessments at each scheduled follow-up visit.

William W. O'Neill, M.D., medical director at the Center for Structural Heart Disease at Henry Ford Hospital, is the primary investigator for Henry Ford Hospital. The trial, sponsored by St. Jude Medical, will enroll 1,600 participants at 69 sites worldwide.

Primary outcome:

- The primary safety endpoint is a composite of procedure-related complications, or all-cause death, or major bleeding through 12 months.
- The primary efficacy endpoint is a composite of ischemic stroke or systemic embolism through 18 months.
- The primary mechanism of action endpoint is device closure (defined as residual jet around the device ≤ 5 mm) at the 45-day visit documented by transesophageal echocardiogram (TEE/TOE) defined by Doppler flow.

Patients may be referred for inclusion review by calling 1-877-434-7470.

RESEARCH

An Interagency Registry for Mechanically Assisted Circulatory Support Analysis

BACKGROUND: Carefully selected patients with advanced, end-stage systolic heart failure have been shown to gain survival benefit from left ventricular assist device (LVAD) support. Adverse events after LVAD implant include stroke, LVAD thrombosis, and bleeding. This study sought to discover whether the interaction between LVAD flow configuration and the pre-operative left ventricular internal diastolic diameter (LVIDD) influences the development of adverse events after LVAD implementation.

Axial configuration (AC) and centrifugal configuration (CC) left ventricular assist devices (LVAD) have different flow characteristics. The HeartMate II (HMII) LVAD has an internal bearing and uses axial forces for pump flow generation. In contrast, the HeartWare HVAD has a bearingless hydrodynamic pump driven by magnetic forces, generating centrifugal flow. In addition, other differentiating factors between the pumps include inflow cannula design, rotor size, gap distances between rotor and housing, and importantly, the pressure gradient across the pump head. Due to difference in pump design, the relationships between pressure changes across the LVAD pump and pump flow (known as the H-Q curves) for the HMII and HVAD are markedly different. The centrifugal flow HVAD pump exhibits larger changes in flow with an equivalent change in pressure. As such, the HVAD pump is very afterload sensitive compared with the HMII, and the HVAD displays some inherent pulsatility during cardiac cycle change.

HYPOTHESIS: Interaction between the left ventricular internal diameter (LVIDD) on echo and device flow configuration would impact the occurrence of adverse events in LVAD recipients.

METHODOLOGY: The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) data was queried identifying 9,427 continuous-flow LVAD recipients between April 2008 to June 2015. The pre-operative LVIDD * flow configuration interaction term was tested in multivariable models to determine its relationship to adverse events which included gastrointestinal bleeding, device thrombosis, stroke and death, as defined by INTERMACS.

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

Descriptive statistics are presented as means ± standard deviations for continuous variables or as numbers with percentages for categoric variables. Continuous variables were compared with an independent t-test and categoric variables with the chi-square test. Prevalence rates of the adverse events were calculated and are presented in events per patient-year (EPPY). Time related event data were analyzed with Kaplan-Meier methods with censoring at transplant or explant for myocardial recovery.

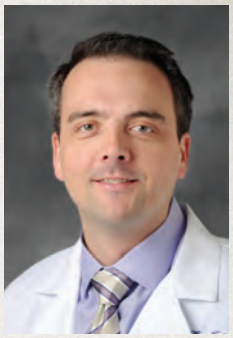
RESULTS: Jennifer Cowger, M.D., M.S., medical director of Mechanical Circulatory Support (in the Advanced Heart Failure and Cardiac Transplantation Section) at Henry Ford Hospital, and senior researcher of this study explains, "The growth of treatment options using durable mechanical circulatory support reaffirmed the need to conduct this study. While there was no difference in survival between AC and CC LVADs, we uncovered the importance of the pre-operative LVIDD in predicting adverse events of gastrointestinal bleeding, stroke and survival after LVAD." Dr. Cowger concluded, "We discovered that the previous increase in device thrombosis reported after 2011 is also seen with respect to stroke, regardless of device flow configuration." Collectively, all of the results, "support the implementation of a personalized approach to device selection based on the patient's pre-operative LVIDD and other pre-operative risk correlates for adverse outcomes after LVAD."

NOTE: The complete analysis is available: Shah P, et al. (June, 2017). *Journal of Heart and Lung Transplantation.*

Left Ventricular Assist Device Outcomes Based on Flow Configuration and Pre-Operative Left Ventricular Dimension: An Interagency Registry for Mechanically Assisted Circulatory Support Analysis.

RESEARCH

ROADMAP Study: Accuracy of Seattle Heart Failure Model and HeartMate II Prediction Models



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

In the ROADMAP study (Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device (LVAD) and Medical Management in Ambulatory Heart Failure Patients), researchers examined clinical outcomes when LVAD was implemented slightly earlier in the course of advanced heart failure; patients who had severe symptoms but not yet requiring inotropic therapy due to severe hemodynamic compromise.

The hypothesis was early LVAD implantation can be safe, and improve quality of life and overall outcomes. A key question in considering this strategy is whether physicians can accurately predict outcomes in these type of advanced heart failure patients whether treated with medical therapy alone or with LVAD therapy. Lead author, David Lanfear, M.D., M.S., head of Advanced Heart Failure and Transplant Cardiology, and his colleagues aimed to assess the best current risk models and how they perform in advanced heart failure patients.

ROADMAP was a prospective, multicenter, nonrandomized study of 200 advanced heart failure patients, not on inotropes but with accepted indications for LVAD implantation. Patient outcomes after one year were used to test accuracy of the Seattle Heart Failure Model (SHFM) and HeartMate II Risk Score (HMRS). These two models were chosen since they are the best established survival prediction models for medical therapy and LVAD therapy, respectively.

The findings showed that these models have important limitations in this challenging group of patients. The SHFM was predictive of overall survival, but not able to forecast the ≈20 percent of patients who crossed over to LVAD implementation in less than a year (most often due to worsening heart failure). Among the patients receiving an LVAD, the HMRS had marginal discrimination but poor calibration; it was still able to identify a relatively small but high-risk subset that had worse survival at one year (≈70 percent compared to ≈87 percent in the remaining cohort) but it generally overestimated risk of death post-LVAD implantation.

Dr. Lanfear shared, “Our results indicate that clinicians should be aware of the limitations of the scores and that the accuracy is likely different in non-inotrope-dependent advanced heart failure patients compared to the typical patient being considered for LVAD.” He also explained, “The SHFM did not perform as well in predicting severe worsening and delayed LVAD implant as opposed to mortality. This is certainly an important outcome that clinicians need new tools to predict.”

NOTE: The complete published study is available: Lanfear, D.E. et al., (May, 2017). *Circulation: Heart Failure.*

Accuracy of Seattle Heart Failure Model and HeartMate II Risk Score in Non–Inotrope-Dependent Advanced Heart Failure Patients Insights From the ROADMAP Study (Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients).

Available in the online version of this article at http://circheartfailure.ahajournals.org/

STAFF UPDATE

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

Medical Director of Mechanical Circulatory Support in the Advanced Heart Failure and Cardiac Transplantation Section

MEDICAL SCHOOL EDUCATION:
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Denison University – Granville, OH

POST-GRADUATE TRAINING:
Duke University Medical Center (Durham, NC) –
Internship and Residency in Internal Medicine

The University of Michigan Medical Center (Ann Arbor, MI) –
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The University of Michigan Medical Center (Ann Arbor, MI) –
Advanced fellowship training in Heart Failure and Transplant Cardiology with supplemental training in Adult Echocardiography

The University of Michigan School of Public Health Graduate Training Program in Clinical Research (Ann Arbor, MI) –
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Internal Medicine

American Board of Internal Medicine –
Cardiovascular Medicine

American Board of Internal Medicine –
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Jennifer Cowger, M.D., M.S.

Gillian Grafton, D.O.

Advanced Heart Failure and Transplantation

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University of Michigan (Ann Arbor, MI) –
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University of Michigan (Ann Arbor, MI) –
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BOARD CERTIFICATION:
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Internal Medicine

American Board of Internal Medicine –
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RESEARCH INTERESTS:
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Cardiac Transplantation
Left Ventricular Assist Devices
Pulmonary hypertension
Critical Care Cardiology

Gillian Grafton, D.O.

James C. Lee M.D., FSCCT

Internal Medicine, Cardiologist Attending Advanced Structural Imaging

MEDICAL SCHOOL EDUCATION:
Wayne State University School Medicine, MI

POST-GRADUATE TRAINING:
University of Washington Medical Center (WA) –
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University of Washington Medical Center (WA) –
Cardiology

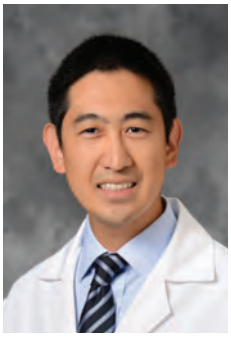
Piedmont Heart Institute (GA) –
Cardiovascular CT/MRI

Emory University (GA) –
Internal Medicine

BOARD CERTIFICATION:
American Board of Internal Medicine –
Internal Medicine

RESEARCH INTERESTS:
Dr. Lee's research interests are focused on the emerging field of advanced structural imaging which utilizes multiple imaging modalities and 3D printing to plan and guide complex minimally invasive cardiac procedures.

He is a co-author on the 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults with Aortic Stenosis and has written several articles on the use of cardiovascular MRI for the evaluation of valvular heart disease.



James C. Lee M.D., FSCCT

INNOVATIONS

3D Guided Imaging: Predict and Prevent Valve Placement Risk

Since 2013, the lives of 1,000 patients have been improved through the use of 3D guided imaging for the planning and guidance of transcatheter heart valve replacements or repair. "With 3D computer aided design technology and advanced 3D imaging we have the opportunity to provide personalized procedure plans for our high-risk patients who have been otherwise turned down for traditional open-heart surgery," says Dee Dee Wang, M.D., director, Structural Interventional Imaging, Henry Ford Hospital. "Henry Ford cardiology is helping transform the field of 3D imaging and 3D printing through the leadership and vision of William W. O'Neill, M.D., director of the Center for Structural Heart Disease program, and the support of Doctors Henry Kim, chair of Cardiology and Scott Dulchavsky, chair of surgery."

For the past five years, Dr. O'Neill and his team have been pioneering new valve technologies to help patients with mitral valve disease. However, not all new valve technologies are a match for each patient's specific heart anatomy. Subtle details in how these new devices are sized and placed can lead to complications such as valve embolization, leaking around the valve, and left ventricular outflow tract (LVOT) obstruction. With the use of multi-modality imaging, the team thinks outside-the-box to find ways to treat these diseases non-surgically.

A partnership with the Henry Ford Innovation Institute, led by Dr. Wang with her team: Marianne Rollet, Eric Myers, Michael Forbes and Tongwa Aka, multiple publications have been written, and a patented planning tool to identify patients best suited for high risk transcatheter mitral valve replacement procedures was developed. Using advanced CT technology, virtual valves are meticulously sized and virtually fit tested at different implantation depths and angles. This data is then computer-simulated in a virtual model to anticipate any complications or risks associated with the procedure, and in the end a 3D printed model helps to guide the individual patient's procedure.

Predicating LVOT obstruction after TMVR, published in *Cardiovascular Imaging*, provides clinical evidence of the importance of using 3D virtual valves. Dr. Wang explained, "This study offers new insight into safely performing these complex procedures. It's a significant advancement in the use of 3D imaging that allows the Henry Ford structural heart team to personalize treatment plans and procedures specific to each patient's body."

Dr. William W. O'Neill explains patient Eric Hurttgam's procedure using a 3D model of his own heart.

Planning with the use of advanced computer aided design 3D technology, imaging and 3D printing has changed the way cardiologists on the Henry Ford Structural Heart Disease team practice medicine.

ACKNOWLEDGEMENTS: Funding for this research made possible through generosity of the Ford Foundation grant.

NOTE: The complete study is available: Wang, D., et al. (Vol. 9, No. 11, 2016). JACC: *Cardiovascular Imaging*.

Predicating LVOT Obstruction After TMVR.

To connect with a Henry Ford physician, call:

Heart & Vascular Institute

1-877-434-7470

Center for Structural Heart Disease

1-855-518-5100

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ELECTROPHYSIOLOGY

Center for Cardiac Implantable Electronic Devices

Each year more that 4,000 patients visit the Center for Cardiac Implantable Electronic Devices (CCIED), led by Claudio Schuger, M.D., director of the CCIED Center and Electrophysiology (EP) Lab.

For nearly 20 years, electrophysiologists have inserted pacemakers (PPM) and implantable cardioverter defibrillators (ICD) in patients with heart arrhythmias. The continuing care needed to ensure the devices work appropriately require investment, skill and knowledge. The CCIED at Henry Ford Hospital is frequently updated and features special equipment to test the electrical activity of the heart and accurately follow patients through the CCIED. With the rapid development of technology, these PPM devices have advanced over the years to become leadless and wireless. So the possibilities to rapidly diagnose and treat patients, once rhythm abnormalities are discovered, has increased exponentially.

"Once implanted, we work closely with our physician partners to follow each patient's device and alert his or her physician of any special updates or adjustments that need to be made to the device," explains Dr. Schuger. "Patient's devices are remotely monitored, and – when necessary – we provide proactive maintenance or replacement, if a device malfunctions."

After years of use, maintenance might include lead extractions and generator upgrades.

The cardiac implantable electronic devices followed remotely by the CCIED include:

- Pacemakers
- Implantable loop recorders
- Implantable defibrillators
- Cardiac resynchronization pacemakers, and defibrillators

Claudio Schuger, M.D.

From the most complicated case to the more routine follow up, the EP team who are members of the Heart Rhythm Society, indicates the CCIED nurses and technicians are truly electronic device specialists. Acting under the supervision of highly qualified physicians they bring decades of experience to deliver the right treatment for the heart arrhythmias experienced by each individual patient.

To refer a patient or collaborate with the Center for Cardiac Implantable Electronic Devices, call (313) 916-2417.