It has been my privilege to bring together such a highly qualified and innovative team of internationally known cardiology experts to form the Center for Structural Heart Disease program at Henry Ford Hospital. This outstanding team, along with co-director Adam Greenbaum, M.D., lead the field in developing the latest in transcatheter procedures for heart valve disease and other structural heart conditions. The outcomes of our work in 2016 are presented in this booklet.

Collectively, our focus is about safely providing options for those with structural heart disease by constantly advancing treatments. Our commitment to safe and effective care has significantly advanced with the use of 3D imaging and printing technology, under the leadership of Dee Dee Wang, M.D., director, Structural Heart Imaging. 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 more efficient procedure times for each patient. (See page 6).

We are excited to work with our colleagues in metro Detroit to advance best practice in cardiac care. The Cardiogenic Shock Initiative was the first of what we hope will be many collaborative efforts among local health systems. (See page 12).

Conducting research with our local and national colleagues both proves our work and challenges each of us to bring our patients the next best practice. Throughout this booklet, you will notice footnotes to our published research, which are listed on pages 14-15.

We are honored to partner in the care of patients referred to the Structural Heart Disease program from local physicians, and from across the country and around the world. We’ve created a comprehensive physician resource portal, including videos, to share our work and innovations with our peers. See for yourself at: MindsofMedicineinAction.henryford.com
Center for Structural Heart Disease at Henry Ford Hospital

ACTIVITY AND OUTCOMES

It’s all about the people. It’s the patients who come to our structural heart team with no treatment options available to them that challenges us to create a new treatment for their care. It’s the interventional cardiologists, cardiac surgeons, inpatient and outpatient nurses and catheterization laboratory staff who continue to innovate, giving each patient a chance.

With each new innovation, one more patient benefits by access to a procedure not previously available, which creates new treatment options for many others. The countless hours and dedication that goes into research, clinical trials and late-night brainstorming over challenging cases are validated by our exceptional outcomes.

To each patient, we dedicate this report to you, for being our partners to move cardiology to the next frontier. For questions regarding this report or to refer a patient, please call the Center for Structural Heart Disease at 1-855-518-5100.
HENRY FORD TAVR VOLUME

Since the program’s first transcatheter aortic valve replacement (TAVR) procedure in 2012, the Center for Structural Heart Disease (CSHD) at Henry Ford Hospital has grown to one of the top volume programs in the country.

DIVERSITY IN APPROACH

Transfemoral TAVR remains the most commonly performed route for transcatheter aortic valve replacements. However, at Henry Ford the team successfully developed multiple alternate approaches for those who may not be candidates for the femoral route. The team, led by Adam Greenbaum, M.D., co-director, Center for Structural Heart Disease program, partnering with Robert Lederman, M.D., senior investigator, National Institutes for Health, developed the transcaval approach specifically for difficult-access patients. The safety and efficacy of the transcaval route was recently 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. Additionally, Gaetano Paone, M.D., division head of Cardiac Surgery, Henry Ford Hospital, has lead the team in successfully using transcarotid access on a routine basis.
ACTIVE ENROLLMENT RESEARCH PROTOCOLS

The PARTNER 3 - Trials - To establish the safety and effectiveness of the Edwards SAPIEN 3 Transcatheter Heart Valve in patients with severe, calcific aortic stenosis or failing bio-prosthetic valve who are at low operative risk for standard aortic valve replacement.

Early TAVR - To establish the safety and effectiveness of the Edwards SAPIEN 3 Valve compared with clinical surveillance in asymptomatic patients with severe, calcific aortic stenosis.

Reprise IV - To evaluate safety and effectiveness of the LOTUS Edge Valve in symptomatic subjects with severe aortic stenosis who are considered at intermediate risk for surgical valve replacement, including those who have a bicuspid native valve.

MANTA Vascular Closure Device Clinical Study (MANTA) - The safety and effectiveness of a new vascular closure device to close the femoral access puncture.
BETTER TRANSITIONS, BETTER OUTCOMES

A higher discharge-to-home rate has demonstrated an improvement in long-term survival among octogenarians undergoing aortic or mitral valve surgery. Physical therapists at Henry Ford Hospital investigated and discovered that they could improve patient discharge-to-home rate by 14.5 percent, discharging 83.8 percent home.

An interdisciplinary team comprised of staff from Structural Heart, Physical Therapy and Occupational Therapy implemented a post-TAVR procedure pathway to increase patient mobility, decrease time in the hospital and enhance discharge planning for the next stage of care.

The pathway required earlier physical therapy, occupational therapy evaluations, and patient education of post-procedure activity. In addition to improving discharge-to-home rate by 14.5 percent, it also reduced patients’ mean hospital LOS by 1.5 patient days.

RESULTS: HIGHER DISCHARGE TO HOME RATES WITH TAVR

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre Pathway* N=127</th>
<th>Post Pathway* N=68</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOS post procedure (days)</td>
<td>5.6</td>
<td>4.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge to Rehab Facility</td>
<td>30.7%</td>
<td>16.2%</td>
<td>0.027</td>
</tr>
<tr>
<td>Discharge to Home</td>
<td>69.3%</td>
<td>83.8%</td>
<td></td>
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</tbody>
</table>

Planning of navigation through the left atrium requires a unique perspective and is most effective when replicated by 3D imaging. In a study that spanned 2015 into 2016, Henry Ford Hospital patients experienced significantly lower complications during the WATCHMAN™ procedure compared to national trials.

The use of WATCHMAN™, a left atrial appendage (LAA) closure device for patients with non-valvular atrial fibrillation, reduces stroke risk. It also takes safety further when the application of 3D CT and advanced 3D modeling of each patient’s LAA is used prior to their procedure, allowing the cardiologist to customize the device and procedure to each patient’s heart and LAA anatomy.

The actual results among 112 patients indicate an added value of 3D CT-guided case planning by simplifying the WATCHMAN™ implantation process.

“Successful implantation of the WATCHMAN™ device depends on accurate sizing of the LAA landing zone and position of the catheter at the correct depth for device unsheathing,” explains Dee Dee Wang, M.D., director, Structural Heart Imaging, Henry Ford Hospital. “Given the questionable accuracy of TEE imaging, high-resolution volumetric imaging with CT should be the preferred method to mitigate improper sizing that could lead to a peri-WATCHMAN™ leak, device embolization and other potentially major adverse catastrophic events.”

BETTER PLANNING, BETTER OUTCOMES WITH 3D CT IMAGING OF WATCHMAN™ PLACEMENT
RESULTS: WATCHMAN™ CLINICAL TRIAL MAJOR INTRAPROCEDURAL CLINICAL EVENTS COMPARED TO THE CENTER FOR STRUCTURAL HEART DISEASE 3D CT GUIDED CASE PLANNING MAJOR ADVERSE CARDIAC EVENTS

<table>
<thead>
<tr>
<th>Major Clinical Event</th>
<th>Protect AF n(%) N=463</th>
<th>CAP n(%) N=566</th>
<th>PREVAIL n(%) N=269</th>
<th>CAP2 n(%) N=579</th>
<th>HENRY FORD n(%) N=112</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardial effusion with cardiac tamponade</td>
<td>13 (2.8)</td>
<td>7 (1.2)</td>
<td>4 (1.5)</td>
<td>8 (1.2)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Device embolization</td>
<td>3 (0.6)</td>
<td>1 (0.2)</td>
<td>2 (0.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Pericardial effusion - no intervention</td>
<td>4 (0.9)</td>
<td>5 (0.9)</td>
<td>0 (0.0)</td>
<td>3 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Cardiac perforation (surgical repair)</td>
<td>7 (1.5)</td>
<td>1 (0.2)</td>
<td>1 (0.4)</td>
<td>3 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Device migration</td>
<td>1 (0.2)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Clinical trials data obtained from WATCHMAN™ package FDA insert

ACTIVE ENROLLMENT RESEARCH PROTOCOLS

AMPLATZER™ Amulet™ LAA Occluder Trial (Amulet IDE) - 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.
ADVANCED MITRAL DISEASE TREATMENT PROVIDES BETTER OUTCOMES

Whether it is a failing bio-prosthetic valve, or the less common mitral stenosis, or the very prevalent mitral regurgitation, the Center for Structural Heart Disease remains a leader in performing and developing innovative transcatheter mitral valve procedures to treat this complicated valve.

The most complex of the heart’s four valves, the mitral valve is most commonly associated with disease. Historically, surgical strategies were the only treatment, precluding those who are at increased or prohibitive risk to undergo open heart surgeries. For these patients, less invasive strategies including transcatheter mitral valve replacements and repairs can be the patient’s only option.

The unique position and structures of the mitral valve makes transcatheter replacement technically difficult. Transcatheter mitral valve replacements (TMVR) are limited when the current generation of valves obstruct the left ventricular outflow tract (LVOT) and make implantation suboptimal.

To address this, Adam Greenbaum, M.D., co-director, Center for Structural Heart Disease, through a unique partnership with Robert Lederman, M.D., from the National Institutes of Health and Vasilis Babaliaros, M.D., from Emory University School of Medicine in Atlanta, developed the LAMPOON procedure. Dr. Greenbaum explains, “LAMPOON is the intentional transcatheter Laceration of the Anterior Mitral leaflet to Prevent LVOT Obstruction immediately prior to TMVR.” This lifesaving procedure is performed at Henry Ford Hospital, one of only two centers in the world offering the procedure.

Using 3D Imaging of the left heart structures, Dee Dee Wang, M.D., director, Structural Heart Imaging, can accurately predict the amount of area through the outflow tract following valve replacement, allowing for a safer procedure and more optimal valve-sizing. Dr. Wang explains, “Successful TMVR depends on accurate sizing of the mitral annulus and avoidance of LVOT obstruction. Incorporation of computer-aided design and generation of 3-dimensional, printed heart models allows for ex vivo device bench testing in patient specific anatomy. With 3-dimensional models we can predict and avoid LVOT obstruction in TMVR.”

![Henry Ford Transcatheter Mitral Valve Replacement Volumes (TMVR)](chart.png)
LAMPOON - Closed chest transcatheter laceration of the anterior mitral leaflet to prevent LVOT obstruction during TransCatheter Mitral Valve Replacement.

TENDYNE Trial - Early Feasibility Study of the Tendyne Mitral Valve System in adult patients with symptomatic mitral regurgitation who are not suitable candidates for conventional mitral valve repair or replacement.

Mitral Implantation of TRAnscatheter vaLves (MITRAL) - Establish the safety and feasibility of the Edwards SAPIEN XT and SAPIEN 3 device and systems in patients with severe symptomatic calcific mitral valve disease with severe mitral annular calcification who are not candidates for standard mitral valve surgery.

COAPT Clinical Trial (COAPT) - Assess safety and effectiveness of MitraClip™ system for the treatment of moderate to severe functional mitral regurgitation deemed not appropriate for surgery.
IMPROVEMENTS IN HEART FAILURE SYMPTOMS

The New York Heart Association (NYHA) Functional Class III/IV categorizes patients’ heart failure by severity of symptoms. This graph offers a snapshot of the level of improvements in heart failure symptoms in clinical trials, real world and at Henry Ford Hospital prior to and after a MitraClip™ device is positioned to reduce degenerative mitral regurgitation.

In the clinical trials and real world experiences, patients presented with NYHA Class III and IV symptoms 86.6 percent and 86 percent of the time. Henry Ford Hospital patients arrived with a greater symptom burden showing NYHA Class III/IV symptoms with 91.3 percent occurrence. However, 30 days post procedure the Henry Ford patients showed a greater absolute reduction in NYHA III/IV symptoms (71.3 percent) compared to Clinical Trial and Real world experiences (68.9 percent and 64.8 percent respectively).

Source: https://mitraclip.com/hcp/tmvr_mitraclip_therapy/treatment_outcomes

SICKER PATIENTS, BETTER OUTCOMES

Patient characteristics and 30-day results are consistent with prohibitive risk DMR cohort.
The Center for Structural Heart Disease at Henry Ford Hospital offers the following procedures and devices:

- **Transcatheter Aortic Valve Replacements (TAVR)**
  - Native and dysfunctional bioprosthetic valves
  - Edwards: SAPIEN 3 Valves, Medtronic CoreValves and Melody Valves
- **Transcatheter Mitral Valve Repair (TMVr)** with MitraClip® device
- **Valvuloplasty**
- **Perivalvular leak repairs of prosthetic valves**
- **Left atrial appendage occlusion with Watchman™ device**
- **Valvuloplasty**
- **Patent foramen ovale, atrial and ventricular septal defect repairs**

Referring physicians have the commitment of the Structural Heart Disease team to return patients for follow-up care. Training to provide follow-up care in referring physician offices is also available.

**COMMERCIAL PROCEDURES AND DEVICES**

**TAVR** - Transcatheter Aortic Valve Replacement. A replacement valve is collapsed on a catheter, delivered through the vessels and implanted in the existing aortic valve.

**Valvuloplasty** - A minimally invasive procedure in which a balloon-tipped catheter is used to expand stenotic or tight valves.

**LAA Occlusion** - Sealing the left atrial appendage (LAA) with a closure device or procedure to reduce stroke risk in atrial fibrillation. Performed primarily with the Watchman™ device.

**Mitral Valve Clip** - A catheter-based “valve repair” procedure for leaky, regurgitant mitral valves. The valve leaflets are clipped together using an edge-to-edge technique, reducing the leak, improving the seal and increasing the forward flow.

**TMVR** - Transcatheter Mitral Valve Replacement. A replacement valve is collapsed on a catheter, and implanted in the existing mitral valve. The catheter travels either through the atrial septum or percutaneously through the apical wall.

For questions regarding this report or to refer a patient, please call the Center for Structural Heart Disease at 1-855-518-5100.

**DEFINITIONS OF PROCEDURES**
UNPRECEDENTED COLLABORATION BY METRO DETROIT CARDIOLOGISTS INCREASES HEART ATTACK SURVIVAL RATES

Improving survival rates among patients who experience cardiogenic shock, a life-threatening side-effect to a heart attack, presented an opportunity for five major health systems in metro Detroit to collaborate. Together, cardiologists innovated a best practice that increased survival rates in cardiogenic shock patients.

Among the hospitals participating in this initiative, a retrospective analysis of 30 patients having a heart attack and showing signs of cardiogenic shock demonstrated an 80 percent survival rate, compared to 50 percent with traditional treatment.1

“This unprecedented effort shows the powerful advances we can make to save lives by working together,” said lead investigator William W. O’Neill, M.D., medical director, Center for Structural Heart Disease at Henry Ford Hospital.

The initiative began in July 2016 as doctors in the participating hospitals studied the approach of supporting the circulatory system quickly during a STEMI. Akshay Khandelwal, M.D., director, Outpatient Cardiovascular Services at Henry Ford Hospital explains, “To support the circulatory system, 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.”

Khaldoon Alaswad, M.D., director, Cardiac Catheterization Lab at Henry Ford Hospital points out, “We have proven that circulatory support is critical to improve the chance of a successful outcome in these critically ill patients and has moved the needle on heart attack survival. We count this as a huge success.”

A larger national study presented in the American Journal of Cardiology supported the results of the metro Detroit-based retrospective analysis.1
Top Left: Patient Dan Ralston expresses his gratitude after his experience as a STEMI patient in cardiogenic shock.

Top Right: Dr. O’Neill announces the Detroit Cardioshock Initiative at a news conference on Feb. 8.

Bottom: Gathered to announce the new best practice are doctors from Henry Ford Hospital, Detroit; Beaumont Hospital in Royal Oak, Troy and Dearborn; St. John Hospital, Detroit; Providence Hospital, Southfield; and St. Joseph Mercy Health System, Pontiac and Ann Arbor; participated in the Cardiogenic Shock Initiative. Also shown are patients Nate Thomas of Ferndale and Dan Ralston of Wyandotte.
2017


2016


Meet Kristin Sexton, RN, Outreach Coordinator. Kristin is available to assist physicians who choose to refer patients to the Center for Structural Heart Disease at Henry Ford Hospital in Detroit. Contact Kristin directly with questions about the program or to connect with one of the physicians.

Kristin can assist with facilitating outpatient consultations, inpatient transfers, enrolling patients into a clinical trial and can also assist physicians who are interested in observing procedures at Henry Ford Hospital. Kristin will arrange for concierge services for referred patients and helps with guest housing for patients who will require an inpatient stay.

Kristin Sexton, RN, BSN  
Outreach Coordinator  
Center for Structural Heart Disease  

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For more information, visit: henryford.com/structuralheart
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