HENRY FORD HEALTH®
Heart & Vascular

CardioBeat Summer 2023

Cardio-Obstetrics Program: heart healthy moms


Ryhm Radjef, M.D.

The leading cause of death in pregnant and post-partum women is increasingly related to cardiovascular disease, according to The American College of Obstetrics and Gynecology. "The most dangerous time for a new mother is between the last month of pregnancy and 5 months post-delivery," explained Cardiovascular Medicine Specialist Ryhm Radjef, M.D., director of Henry Ford Health's Women's Heart Center and Cardio-Obstetrics program. "During this time, peripartum cardiomyopathy (PPCM), although rare, triggers a new onset of heart failure with no determinable cause. Yet we know that women with a history of preeclampsia have a 4-fold higher incidence of hypertension and heart failure and a 2-fold elevated risks of heart disease, stroke, and venous thromboembolism." The World Health Organization reports that maternal-mortality rates in the U.S. rose 78% between 2000 and 2020, yet dropped in other countries.

To address the lack of awareness of pregnancy related cardiomyopathy or PPCM among both clinicians and women, Dr. Radjef reinvented the Henry Ford Women's Heart Center to include

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Iwan: A patient's experience with the Henry Ford Aortic Center

The decision not to take a shower might well have been a decision that meant the difference between life and death for Iwan Mich, 66, of Dearborn Heights.


Iwan Mich and Joanne Rose-Mich say, everyone was in the right place, at the right time to save Iwan's life.

Iwan described taking off his coat in a restaurant and feeling what he thought was a muscle pull across his chest, but he dismissed the pain and enjoyed his meal. After all, for five years he had pain that radiated from his right shoulder and his PCP said he was okay. "I now know that was a symptom of coronary artery disease," Iwan shared.

"I felt fine the next morning, then 10 minutes later I didn't. I asked my wife, Joanne, to take me to Emergency." Joanne recalls, "I asked him if he wanted to shower before we went to Emergency and he said, *no*. He *always* takes a shower before leaving the house, so I knew it was serious."

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Inside

Research

Trials study drugs to treat hypertrophic cardiomyopathy

Odyssey-HCM: Mavacamten in non-obstructive hypertrophic cardiomyopathy

Karthikeyan Ananthasubramaniam, M.D.

An international randomized, double-blinded study to examine the safety, tolerability, and efficacy of Mavacamten (Camzyos) as compared with a placebo in adult patients with non-obstructive cardiomyopathy (nHCM) is underway at Henry Ford Health.

Mavacamten is approved for treatment of hypertrophic cardiomyopathy (HCM), yet no specific medical therapy is available for the nHCM patients who have all the same symptoms of HCM, which includes shortness of breath, fatigue, and tiredness.

Karthikeyan Ananthasubramaniam, M.D., the primary investigator for this study at Henry Ford Hospital, explained, "The goal of this 52-week study is to determine if improvement in quality of life as evidenced by change from baseline in Kansas City Cardiomyopathy Questionnaire (23-item) Clinical Summary Score and a change from baseline in peak oxygen consumption at week 52. Most importantly cardiopulmonary stress testing will provide objective evidence to determine if the patient's exercise capacities improve."

The goal is to enroll 420 patients world-wide, but Dr. Ananthasubramaniam explains that finding the patients to screen will be a challenge as patients with nHCM represents a smaller group of the population. The Henry Ford team is actively screening with the goal of enrolling at least 5 - 6 patients. "I know there are physicians in our community who have patients with nHCM and because there is no drug to treat them, these patients remain symptomatic," said Dr. Ananthasubramaniam. "Thus this study fills a much needed gap and enables such patients to participate in this trial."

Dr. Ananthasubramaniam explains, "At the end of the trial these patients roll into the open-label extension making them eligible to receive the drug just because they were part of the trial and will have constant contact with the clinicians."

Inclusion criteria:

- Diagnosis of HCM consistent with current American College of Cardiology Foundation/American Heart Association and European Society of Cardiology guidelines: unexplained left-ventricular hypertrophy with non-dilated ventricular chambers in the absence of other cardiac or systemic disease which can produce the required magnitude of hypertrophy of a maximal left ventricular (LV) wall thickness ≥ 15 millimeters (mm) (or ≥ 13 mm with positive family history of hypertrophic cardiomyopathy [HCM]) as determined by core laboratory interpretation.
- Peak left ventricular outflow tract (LVOT) pressure gradient < 30 millimeters mercury (mm Hg) at rest and < 50 mm Hg with provocation (Valsalva maneuver and stress echocardiography).
- New York Heart Association (NYHA) Class II or III.

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To refer a patient for this trial contact Karthikeyan Ananthasubramaniam, M.D., kananth1@hfhs.org or Research Coordinator Meghan McCarthy mmccart8@hfhs.org.

SEQUOIA-HCM: safety, efficacy, and quantitative understanding of obstruction impact of *Aficamten*

Bashar Hannawi, M.D.

Advances in understanding the pathophysiology of hypertrophic cardiomyopathy (HCM) has led in recent years to the development of novel selective cardiac myosin inhibitors (CMI) that inhibit actin-myosin cross-bridging. In April 2022, the Food and Drug Administration (FDA) approved Mavacamten (Camzyos) based on the positive results of the pivotal EXPLORER-HCM trial in which Mavacamten led to improvement in exercise capacity, left ventricular outflow obstruction (LVOT) and New York Heart Class Association (NYHA).

Aficamten is a next in-class CMI that potentially favorable pharmacologic advances including shorter half-life allowing for faster up-titration, faster reversibility, and lack of drug-drug interaction. REDWOOD-HCM was a phase II randomized clinical trial, in which *Aficamten* showed a substantial reduction in LVOT gradient, improvement in NYHA, and cardiac biomarkers.

Henry Ford Hospital is currently enrolling patients for **S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of **A**ficamten in HCM (SEQUOIA-HCM). This is a phase III randomized, placebo controlled, double blinded clinical, international multicenter clinical trial to evaluate the effect of *Aficamten* in patients with symptomatic (NYHA 2 or 3) obstructive HCM (resting LVOT-G ≥30 mmHg, post-Valsalva peak LVOT-G ≥50 mmHg). Patient receiving Aficamten will begin with 5 mg dose once daily, which will be up or down-titrated based on echocardiogram results of ejection fraction and LVOT gradient.

Cardiovascular Medicine Specialist Bashar Hannawi, M.D., who specializes in advanced heart failure and transplant cardiology leads the study at Henry Ford Hospital. Dr. Hannawi explained, "The primary outcome of the study is to determine the change in peak oxygen uptake (pVO2) with cardiopulmonary exercise testing (CPEET) from baseline over a 24-week period."

SEQUOIA-HCM is expected to enroll 270 patients. The study offers the option for an extended open label study for study participants who completed SEQUOIA-HCM where all patients have the options to go on Aficamten for additional 5 years.

Contact Dr. Hannawi at bhannaw1@hfhs.org or Research Coordinator Zack Malouf at zmalouf1@hfhs.org

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To learn more about the study and inclusion criteria visit: https://www.clinicaltrials.gov/ct2/show/record/NCT05186818?view=record

Research

COSIRA-II: Safety and efficacy of the COronary SInus Reducer in patients with refractory angina

The **CO**ronary **SI**nus Reducer in Patients with **R**efractory **A**ngina II (COSIRA-II) study seeks to demonstrate the safety and effectiveness of the Neovasc Reducer™ System for treatment of reversible myocardial ischemia. Patients with refractory angina pectoris treated with maximally tolerated guideline-directed medical therapy who are deemed unsuitable for revascularization and have exhausted all other options may qualify for this study.

Gerald Koenig, M.D., Ph.D.

The Neovasc Reducer™ is a stainless-steel device implanted percutaneously in the coronary sinus, where it expands into an hourglass shape. It creates a local flow disruption with only the narrow central orifice of the device available for blood flow. The pressure forces deoxygenated blood to flow from the less ischemic epicardium to the more ischemic endocardium to relieve angina. The device is inserted percutaneously from the internal jugular vein in a minimally invasive procedure, while the patient is under light sedation.

Cardiovascular Medicine Specialist Gerald Koenig, M.D., Ph.D., is the primary investigator at Henry Ford Health. He explained, "Earlier COSIRA studies showed us at six months, 71% of patients in the treatment group improved by at least one angina class and 35% improved by at least two classes. These rates were statistically significantly higher than rates in the control group (42% and 15%, respectively).

Dr. Koenig further shared, "We hope to extend this study to the U.S. population, where it has met with significant success in Europe, and corroborate our own findings on two patients we implanted the device on a compassionate basis and found a marked response in their angina classification where there were no additional options of treatment available."

The FDA-approved this device in 2018, however it is not yet commercially available given the requirement for a dedicated U.S. study showing a significant clinical response beyond that of sham-control patients under optimal medical therapy.

COSIRA-II study is a multicenter clinical trial, randomized (1:1 ratio), double-blinded, and is the largest ever sham-controlled study undertaken for coronary artery disease. It is anticipated that 380 participants will be enrolled in this national study. Enrolled patients will receive one of the following: 1) treatment with Neovasc Reducer™ 2) implantation procedure with no device implanted or 3) become part of the unblinded, non-randomized single arm registry. Each participant will be evaluated at 6 and 12 months, and 2, 3, 4, and 5 years.

To be eligible, participants in this study will have had a maximally tolerated dose of at least three of the four (preferably all four) approved classes of anti-anginal agents: long-acting nitrates, calcium channel blockers (either a dihydropyridine or a non-dihydropyridine), beta blockers, and ranolazine. The regimen must be stable for at least 60 days prior to enrollment, must remain stable from enrollment to randomization, and there must be no intent to change the medical regimen for at least 12 months after randomization. The participants must have either no treatment options for revascularization by coronary artery bypass grafting or by percutaneous coronary intervention, or is otherwise unsuitable or high risk for revascularization as determined by the local heart team, and confirmed by a Central Screening Eligibility Committee. The left ventricular ejection fraction must be greater than or equal to 30% within the 12-months prior to enrollment.

To enroll a patient in the study, contact Henry Ford Principal Investigator Gerald Koenig, M.D., Ph.D., at (313) 627-1735 or email gkoenig1@hfhs.org and/or Henry Ford Research Coordinator Melanee Schimmel, R.N., at (313) 932-0382 or email mschimm2@hfhs.org.

For background on the device, scan the QR code.

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Research

CORRAL-AF left atrial appendage occlusion study opens enrollment

In April 2023 enrollment began for the *Can the Lambre Device Occlude IRRegular And Large Appendages in Patients With Non-Valvular AF: CORRAL-AF study.* The study seeks to demonstrate the safety and efficacy of the implantation of the LAmbre Plus™ Left Atrial Appendage (LAA) Closure System. The LAmbre Plus™ was developed to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with large or irregularly shaped appendages and non-valvular atrial fibrillation for those who are at increased risk for stroke and systemic embolism. The key criteria include those who:

- Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for oral anticoagulation (OAC) therapy; and
- Are deemed by their physician to be suitable for OAC; and
- Have an appropriate rationale to seek a non-pharmacological alternative to OAC, taking into account the safety and effectiveness of the device compared to OAC

In this randomized, multicenter study, patients who present with non-valvular atrial fibrillation and are at an increased risk for stroke and systemic embolism based on CHA2DS2-VASc scores may be eligible. The patient must also have been recommended for oral anticoagulation therapy but have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation (OAC) such as warfarin (Coumadin), dabigatran (Pradaxa), rivaroxaban (Xarelto), apixiban (Eliquis), edoxaban (Savaysa), or betrixaban (Bevyxxa).

Brian O'Neill, M.D.

The LAmbre Plus™ device is a self-expanding occluder, composed of a distal umbrella and a proximal cover laser welded together, delivered percutaneously via femoral venous access and trans-septal puncture. The distal umbrella is comprised of an elastic nitinol frame and outer PET membrane, and has circumferential anchors to secure the occluder to the LAA wall. The proximal cover is a disc of elastic nitinol mesh, which seals the orifice of the LAA and minimizes thrombus formation and includes a PET membrane to prevent the passage of blood into the LAA after implantation.

Patients will receive clinical follow-up in-hospital and at 45 days, 6 months, 12 months, and annually up to 5-years. CT/Imaging or Transesophageal echocardiographic (TEE) follow-up will occur at 45 days and TEE at 1-year.

Brian P. O'Neill, M.D., director of Structural Heart Research and Dee Dee Wang, director of Structural Heart Imaging are the co-primary investigators of the study which is sponsored by Henry Ford Hospital, in collaboration with Lifetech Scientific (Shezehn) Co., Ltd.

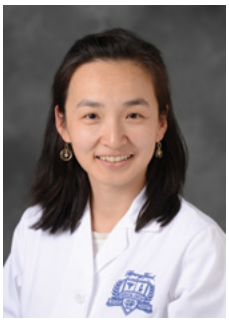
To enroll a patient in this study, contact Henry Ford Hospital Research Coordinator, Stephen Krafchak, MS, call (313) 916-3571 or email skrafch1@hfhs.org.

Research

Additive value of preprocedural CT planning in left atrial appendage occlusion: comparison of real-world practice

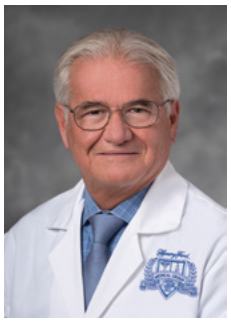
Researchers in the Division of Cardiology of the Center for Structural Heart Disease, Electrophysiology, and Radiology found Henry Ford's pioneering use of 3-Dimensional Computed Tomography (CT) imaging for planning left atrial appendage occlusion (LAAO) is associated with higher successful device implantation rates, shorter procedural times, and less frequent changes in device sizes.

Left atrial appendage occlusion is a non-surgical procedure that closes or seals the left atrial appendage, a small outpouching of the left atrium. from the formation of blood clots. This procedure can reduce the risk of blood clots that can lead to stroke and eliminate the need to take blood thinning medication for patients with non-valvular AFib.



Dee Dee Wang, M.D.

"The standard method for imaging the heart to guide LAAO procedures is 2-Dimensional transesophageal echocardiogram (TEE), which uses ultrasound waves to make a detailed image of the heart," said Dee Dee Wang, M.D., director of Structural Heart Imaging at Henry Ford Hospital. "This study aimed to assess the value of adding 3-Dimensional CT imaging to that process, versus using only TEE imaging. Our findings indicate significant benefit by adding CT imaging, to help create a more comprehensive 3-Dimensional image of the heart."



William W. O'Neill, M.D.

The 3-Dimensional model gives implanting structural heart and electrophysiology cardiovascular medicine specialists information needed to choose a device that properly fits the patient's heart unique anatomy, making the procedure safer and more effective. William W. O'Neill, M.D., director of the Henry Ford Center for Structural Disease further explained, "CT imaging allows us to take any guesswork out of device implantation. We know that we can safely close the appendage and have a success of 98% when imaging is available."

In a minimally invasive procedure, the left atrial appendage is closed in the heart via a small catheter using the FDA approved WATCHMAN™ device. The device permanently seals off that heart muscle sac, preventing clot formation and dramatically decreasing the patient's risk of stroke.

Research

RADIANCE-CAP: study of ultrasound renal denervation therapy

The RADIANCE CAP (Continued Access Protocol) study will evaluate the safety and effectiveness of ultrasound renal denervation therapy via the Paradise™ System in patients with uncontrolled hypertension. The Paradise™ Ultrasound Renal Denervation (uRDN) system, is a new approach using ultrasound energy to decrease the activity of the nerves traveling to the kidneys, which may lower blood pressure and reduce the need for blood pressure medications. Individuals with high blood pressure typically have overactive renal (kidney) nerves, and it has been shown that calming these overactive nerves can help reduce blood pressure.

Gerald Koenig, M.D., Ph.D.

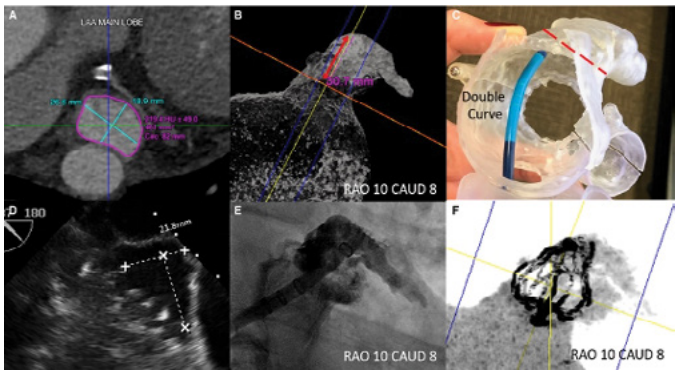
Through a minimally invasive procedure via the femoral artery, a small flexible catheter is inserted, and then placed in the artery supplying the kidney. Ultrasound energy (sound waves) is delivered to the tissue surrounding the artery for several seconds. The ultrasound energy generates heat at a depth of 1-6 mm beyond the kidney artery to interrupt renal nerve signaling and not affect the artery. Both kidneys are treated. Following treatment, the device is removed.

In this study, researchers retrospectively reviewed all LAAO procedures using the WATCHMAN™ performed at a single center, Henry Ford Hospital – Detroit, from May 2015 to December 2019. During this time, a total of 485 LAAOs were performed using the WATCHMAN™ device, including 328 (67.6%) cases who underwent additional CT for preprocedural planning and 157 (32.4%) cases using stand-alone TEE for guidance.

The new FDA-approved left atrial appendage occlusion devices available to patients implanted by Henry Ford structural heart cardiovascular medicine specialists is the WATCHMAN FLX that replaced the original WATCHMAN and the Amulet Left Atrial Appendage Occluder, made by Abbott Vascular.

Dr. O'Neill explains, "The study clearly indicates patients who had additive CT for preprocedural planning had a significantly higher rate of successful device implantation with <5 mm peri-device leak than using stand-alone TEE (98.5% versus 94.9%). Total procedural time was shorter in the additive CT group than the stand-alone TEE group (median, 45.5 minutes versus 51.0 minutes). It was also less common to change device size after initial deployment in the additive CT group than the stand-alone TEE group (5.6% versus 12.1%) with significantly more device upsizing in the stand-alone TEE group (4% versus 9.4%)."

To review the full manuscript, visit the *Journal of the American Heart Association*. To learn more about LAAO at Henry Ford Health, visit henryford.com/services/structural-heart.



Case example of Watchman™ implantation using computed tomography (CT) for preprocedural planning.

***A,** Left atrial appendage (LAA) landing zone dimensions measured by CT. **B,** The depth measured perpendicular to the LAA landing zone and the optimal fluoroscopic deployment projection determined by CT. **C,** In vitro testing to select the curvature of the delivery sheath, which achieved coaxiality to the LAA landing zone for optimal deployment. **D,** The landing zone size measured by intraprocedural TEE, which was consistently smaller than that by preprocedural CT. **E,** LAA angiogram at predetermined fluoroscopic projection. **F,** Postimplantation CT 3-dimensional reconstruction of patient's successful device implant.*

To view the complete article, scan the QR code.

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So, C., Kang, G., Villablanca, P.A., Ignatius, A., Asghar, S., Dhillon, D., Lee, J.C., Khan, A., Singh, G., Frisoli, T.M., O'Neill, B.P., Eng, M.H., Song,T., Pantelic, M., O'Neill, W.W. and Wang, D.D. *Journal of the American Heart Association*. Aug. 16 2021;10:e020615

https://doi.org/10.1161/JAHA.120.020615

Cardiovascular Medicine Specialist Gerald Koenig, M.D., Ph.D., is the primary investigator at Henry Ford Health. He explained, "Earlier studies have shown that patients with moderate and severe high blood pressure treated with renal denervation have resulted in significant decreases in blood pressure. The decreases seen by renal denervation are equivalent to at least one blood pressure medication and persist for at least 6 to 12 months after the procedure."

We hope to extend prior study results to allow for continued access to the ultrasound renal denervation therapy via the Paradise Renal Denervation System to our patients, and to allow for the on-going collection of safety and effectiveness data in subjects with uncontrolled hypertension despite the prescription of antihypertensive medications.

To enroll a patient in the study, contact Gerald Koenig, M.D., Ph.D., Henry Ford Health principal investigator, at (313) 627-1735 or email gkoenig1@hfhs.org and/or Melanee Schimmel, RN, Henry Ford Health research coordinator, at (313) 932-0382 or email mschimm2@hfhs.org.

To learn more about the procedure, scan the QR code.

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Cardio-Obstetrics Program: heart healthy moms

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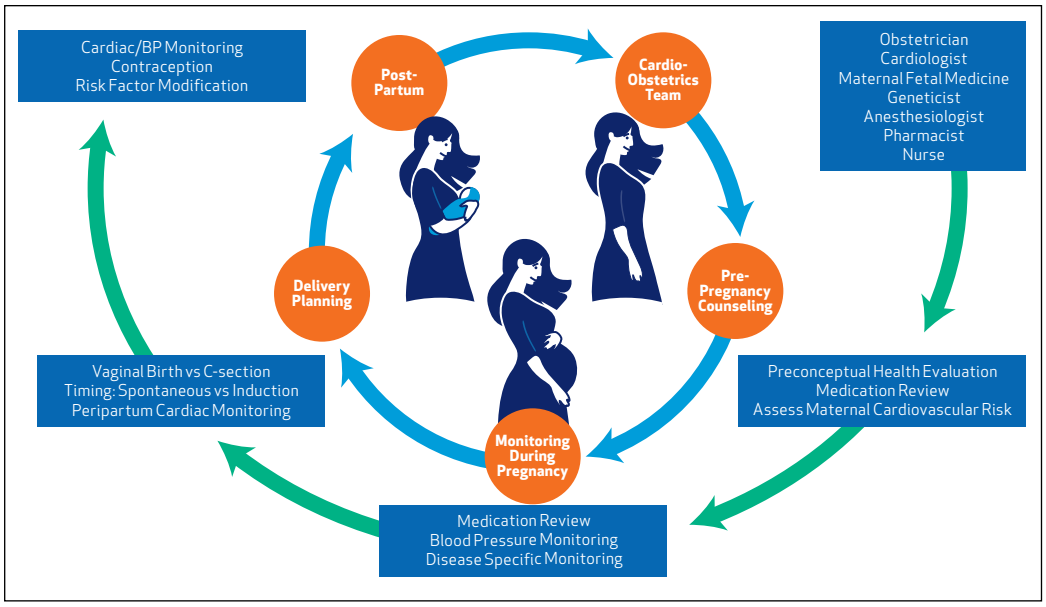

Figure 1: Cardio-obstertrics team in the management of women before pregnancy, during pregnancy, and postpartum. BP indicates blood pressure. Mehta et al, CV considerations in caring for pregnant patients, Circulation 2020;141:00–00. DOI: 10.1161/CIR.0000000000000772

cardio-obstetrics. "We hope to increase awareness about modifiable risk factors, help our patients maintain healthy blood pressure after pregnancy, improve follow up and early recognition of heart disease, and provide high quality care to eventually improve maternal outcomes for women with cardiovascular risk factors," said Dr. Radjef.

Henry Ford Health's Cardio-Obstetrics Program will provide an evaluation by a cardiovascular medicine specialist to women with known cardiovascular disease. The evaluation will provide baseline assessment of potential risks to the woman. This exam should ideally happen before pregnancy or as early as possible during the pregnancy, to go over the effect pregnancy will have on the underlying cardiovascular disease and provide close monitoring when deemed appropriate.

The Pregnancy Heart Team

"We know that hypertensive disorders during pregnancy are the leading cause of maternal mortality in the U.S. and can be associated with higher risks of cardiovascular disease in the future, including heart attacks and stroke. Managing patients with moderate and high-risk cardiovascular disease during pregnancy, delivery, and the postpartum period in medical centers with our multidisciplinary Pregnancy Heart Team, has the potential to make a significant impact," explained Dr. Radjef. The Henry Ford Pregnancy Heart Team includes obstetric providers, maternal–fetal medicine subspecialists, cardiovascular medicine specialists including cardio-obstetrics, anesthesiologists including cardiac anesthesia, and often other subspecialties such as gastroenterology, hematology, infectious disease, nephrology, and pulmonology.

A step-by-step methodology for treatment and monitoring the woman during pregnancy and post-partum are shown in Figure 1. "We believe these steps will help women better understand their own conditions and through our support, will be able to avoid heart failure," Dr. Radjef explained.

Risk factors

Health status, ethnicity, and social factors are shown to contribute to heart failure in the first-year post-partum. The World Health Organization reports that in the U.S. 52% of pregnancy-related deaths occur in the first year postpartum, with 19% between days 1-6, 21% between days 7-42, and 12% between days 43-365. "Two years ago, the CDC released data on maternal mortality in the U.S. and unfortunately we are the country with the highest rate of maternal mortality in all developed nations," said Dr. Radjef, referencing the 2021 CDC report.

Although any woman can have a cardiac event during pregnancy and post-partum, ethnicity does play a role, as the majority of deaths are among Black women and the numbers are continuing to climb. Michigan ranks 23rd in the country for maternal mortality.

Cardio-Obstetrics Program: heart healthy moms

"We've engaged with many of our colleagues and spent the time to truly get this program right, to address the obstetrical and cardiac needs, and using the best methods to identify and bring the women most likely to be effected to the clinic," explained Dr. Radjef. The innovative clinic also aims to focus on disparities in health care for women at high risk of cardiovascular morbidity and mortality that exist in the community. *Heart Healthy Moms* is made possible in part by a Michigan Health Endowment Fund $100,000 grant, with more funding resources expected in the future.

The main clinic is located inside the state-of-the-art, preventive cardiology facility at the Henry Ford Medical Center – Second Avenue in Detroit, the clinic tele-monitors blood pressure and other clinical parameters in at-risk, post-partum patients from Detroit and surrounding communities. A second clinic is located at Henry Ford Medical Center – Sterling Heights.

Referrals and appointments for preconception counseling, high-risk pregnancy or post-partum program are available through Henry Ford Cardio-Obstetrics.

Call to make an appointment with a cardio-obstetrics specialist at one of our locations:

Henry Ford Medical Center - Second Avenue
6525 Second Ave.
Detroit, MI 48202
(313) 876-4540

Henry Ford Medical Center - Sterling Heights
3500 15 Mile Road
Sterling Heights, MI 48310
(586) 977-6216

According to the World Health Organization:

- The population in the city of Detroit is 78% Black with a poverty rate of approximately 35% (U.S. Census, 2019).
- Pregnant Black women are 4.5 times more likely to die than White women.
- A Black woman is 22% more likely to die from heart disease than a White woman.
- Black expectant and new mothers in the U.S. die at about the same rate as women in countries such as Mexico and Uzbekistan.

Why the focus on Black women:

- Black women have higher rates of C-section.
- More than twice as likely to be readmitted to the hospital in the month following the surgery.
- Twice as likely to have preeclampsia, eclampsia, and embolism.
- More likely to have postpartum depression.
- Much less likely to receive mental health treatment.
- Social determinants of health such as food insecurity, lack of transportation, environmental injustice, and access to healthcare.
- But also…Black women with at least a college degree had higher severe complication rates than women of other races and ethnicities who never graduated high school, raising the possible contribution of chronic stressors.

Stipulated causes for increased maternal mortality in the U.S. compared to other industrialized countries: U.S. women have:

- Highest rate of chronic disease burden
- High rates of caesarean sections
- Highest rates of medical bills problems
- High out-of-pocket costs
- Highest rate of skipping care
- Highest rate of emotional distress

Patient Highlight

Iwan: A patient's experience with the Henry Ford Aortic Center

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As they arrived at their local hospital on March 1, 2022, Iwan was experiencing an aortic dissection. The doctors at the community hospital did not have the capability to treat the aortic dissection, so Iwan was flown out. "I don't remember any of that," said Iwan. "I woke up at Henry Ford Hospital in Detroit where I meet Dr. Kabbani and learned what happened."

Loay Kabbani, M.D., a co-director of the Henry Ford Aortic Center, said, "We used a team approach to treat Iwan, the Henry Ford Aortic Center includes a team of experienced vascular surgeons, cardiovascular medicine specialists,, cardiac surgeons, vascular medicine specialists, radiologists, pathologists, and rheumatologists." These health care providers have a special interest in the diseases of the aorta and work together to integrate medical, surgical, radiologic and research expertise to benefit the people who seek them out for effective and innovative care. Khaled Nour, M.D., lead cardiovascular medicine specialist in the Aortic Center, oversees the multidisciplinary monthly aortic conferences, said that "Henry Ford's multidisciplinary aortic team has been in place for more than a decade and is considered one of the region's premier Aortic Centers."

Treating Iwan

Dr. Kabbani recalled that Iwan's case, like many others, required the care and expertise of several physicians. He said, "When Iwan arrived at Henry Ford Hospital we realized not only was he suffering from an acute aortic dissection, but he was also having a heart attack. Our multi-disciplinary team allowed for Iwan to quickly be treated by the experts in both aortic and cardiac diseases."

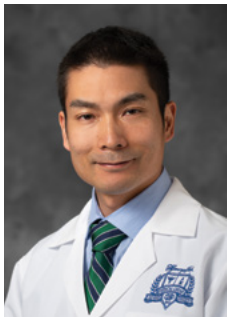
Dr. Kabbani explained, "Iwan was pretty critical by the time he got to Henry Ford." First, he had an aortic dissection, an entity where the artery tears and splits the artery wall layers. Cardiothoracic Surgeon Daizo Tanaka, M.D., said, "I believe the severe pain from dissection induced stress and demand ischemia of the heart exposed his underlying severe coronary artery disease."

Iwan was found to have elevated troponin which prompted a cardiac catheterization revealing severe coronary artery disease. Iwan needed open heart surgery to treat his heart and a stent graft to treat his aortic dissection. During Iwan's initial episode, "we also found out that Iwan had a complex asymptomatic abdominal aortic aneurysm that was at risk of rupturing," said Dr. Kabbani.

"We started by treating Iwan's aortic dissection by placing a stent graft to stabilize the thoracic aorta," Dr. Kabbani explained. "We usually proceed with bypass surgery relatively urgently when the patient has critical disease such as Iwan had," Dr. Tanaka explained. "However, a serious condition immediately after an acute dissection can increase the risk in a major open-heart surgery.

Loay Kabbani, M.D.

Khaled Nour, M.D.



Daizo Tanaka, M.D.

Sayed Ahsan, M.D.

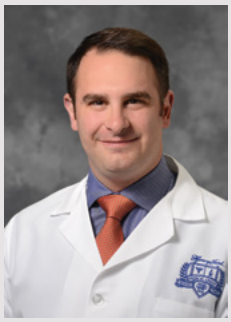
Michael Hudson, M.D.

Henry Ford Health Multidisciplinary Aorta Program uses team approach to aortic disease diagnosis and management

New guidelines published by the American College of Cardiology (ACC) and the American Heart Association (AHA) emphasized the importance of a multidisciplinary team approach to effectively diagnose and manage aortic disease. Loay Kabbani, M.D., a co-director of the aortic center, emphasized that in their top 10 recommendations the AHA stated that "Shared decision-making involving the patient and a multidisciplinary team is highly encouraged to determine the optimal medical, endovascular, and open surgical therapies."

The new guidelines include focusing on surgical intervention considerations. Kyle Miletic, M.D., lead cardiac surgeon in the Aortic Center, said that the ACC/AHA recommendation emphasized the better outcomes at high volume centers with multidisciplinary aortic teams and experienced surgeons. The ACC/AHA guidelines now recommend that the threshold for surgical intervention at these centers for sporadic aortic root and ascending aortic aneurysms be lowered from 5.5 cm to 5.0 cm, and even lower in specific scenarios among patients with heritable thoracic aortic aneurysms.

Loay Kabbani, M.D.



Kyle Miletic, M.D.

Khaled Nour, M.D.

Henry Ford Health's Multidisciplinary Aorta Program is a premier center for diagnosing and treating people with serious and complex aortic disease. The program offers a multi-disciplinary team and treat aortic diseases, including thoracic, abdominal and peripheral aortic aneurysms, aortic dissections, and aortic coarctations.

The program's team includes experienced surgeons who offer both open and endovascular treatments, cardiovascular medicine specialists, vascular medicine specialists, radiologists, pathologists and rheumatologists. These health care providers have a special interest in the diseases of the aorta and work together to integrate medical, surgical, radiologic and research expertise to benefit the people who seek them out for effective and innovative care.

Khaled Nour, M.D., lead cardiovascular medicine specialist in the aortic center, oversees the multidisciplinary monthly aortic conferences, said that "Henry Ford's multidisciplinary aortic team has been in place for more than a decade and is considered one of the region's premier aortic centers."

To refer a patient to the Henry Ford Aortic Center, please call 1-877-434-7470.

Inserting the stent graft was very beneficial in stabilizing the aorta and minimizing the risk of surgery. Two weeks later, we performed a 6-vessel coronary artery bypass surgery."

Iwan's recovery was uneventful and by mid-July he was strong enough for Dr. Kabbani to perform the AAA repair. "This aneurysm was complex and required the insertion of a specialized fenestrated graft that would cover his abdominal aorta to a level above his kidney arteries but still be able to perfuse the kidney arteries through small fenestrations in the graft," explained Dr. Kabbani.

"Iwan's been through a lot, but his prognosis is excellent, and he will continue to be followed by my colleagues Vascular Medicine Specialist Dr. Sayed Ahsan and Cardiovascular Medicine Specialist Dr. Michael Hudson. Both of whom will continue to monitor Iwan's progress," said Dr. Kabbani. "I trust them with my life," Iwan shared.

"It's been a lifestyle change for sure, I eat differently and exercise more. I've even reduced my workload and am more conscience of what's important in life, like my grandkids," Iwan concluded.

Research

Structural heart studies

Aortic Valve

ALIGN AR

Principal Investigator: Tiberio Frisoli, M.D.
Official Title: The JenaValve ALIGN-AR Pivotal Trial
Description: This study will examine the use of TAVR (Transcatheter Aortic Valve Replacement), which is a minimally invasive procedure designed to replace the aortic valve inside the heart. In this study, TAVR will be performed using the JenaValve Pericardial TAVR System, which is intended to help treat symptomatic severe aortic regurgitation.
Expected Completion: August 2023
Enrollment: Not Actively Enrolling

Mitral Valve

CLASP IID/IIF

Principal Investigator: William O'Neill, M.D.
Official Title: Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP IID/IIF): A Prospective, Multicenter, Randomized, Controlled Pivotal Trial to Evaluate the Safety and Effectiveness of Transcatheter Mitral Valve Repair With the Edwards PASCAL Transcatheter Valve Repair System Compared to Abbott MitraClip in Patients With Mitral Regurgitation
Description: To establish the safety and effectiveness of the Edwards PASCAL Transcatheter Valve Repair System in patients with degenerative mitral regurgitation (DMR) who have been determined to be at prohibitive risk for mitral valve surgery by the Heart Team, and in patients with functional mitral regurgitation (FMR) on guideline directed medical therapy (GDMT)
Expected Completion: December 31, 2023
Enrollment: IIF arm is actively enrolling

ENCIRCLE Trial

Principal Investigator: William O'Neill, M.D.
Official Title: SAPIEN M3 System Transcatheter Mitral Valve Replacement Via Transseptal Access
Description: This study will establish the safety and effectiveness of the SAPIEN M3 System in subjects with symptomatic, at least 3+ mitral regurgitation (MR) for whom commercially available surgical or transcatheter treatment options are deemed unsuitable.
Expected Completion: February 2028
Enrollment: Recruiting

MitralClip REPAIR MR

Principal Investigator: Brian O'Neill, M.D.
Official Title: Percutaneous MitraClip Device or Surgical Mitral Valve REpair in PAtients With PrImaRy MItral Regurgitation Who Are Candidates for Surgery (REPAIR MR)
Description: The objective of this randomized controlled trial (RCT) is to compare the clinical outcome of MitraClip™ device versus surgical repair in patients with severe primary MR who are at moderate surgical risk and whose mitral valve has been determined to be suitable for correction by MV repair surgery by the cardiac surgeon on the local site heart team.
Expected Completion: April 2034
Enrollment: Recruiting

SUMMIT

Principal Investigator: Tiberio Frisoli, M.D.
Official Title: Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Transcatheter Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation
Description: This randomized controlled trial will provide the opportunity to evaluate the safety and clinical benefits of the Tendyne Transcatheter Mitral Valve System compared to the MitraClip System in patients with symptomatic, moderate-to-severe or severe mitral regurgitation, within approved MitraClip indications. In addition, the safety and effectiveness of the Tendyne Transcatheter Mitral Valve System will be evaluated in patients with severe mitral annular calcification who are at prohibitive risk for mitral valve surgery. Patients who are not suitable for mitral valve surgery for reasons other than severe mitral annular calcification and are also not suitable for transcatheter repair with MitraClip, will be enrolled in the non-repairable cohort.
Expected Completion: June 2027
Enrollment: Recruiting

Staff update

Kevin T. Onofrey, M.D.
Vascular Surgery

Medical school education
Wayne State University School of Medicine, Detroit, MI

Fellowship
Henry Ford Hospital, Vascular Surgery, Detroit, MI

Residencies & internships
University of Illinois, Chicago, Metropolitan Group Hospitals, Chicago, IL

Research interests
Dr. Onofrey's research interests include management of acute and chronic limb-threatening ischemia as well as variables influencing the outcome in addition to various aortic pathologies.

Kevin T. Onofrey, M.D.
Henry Ford Hospital
Henry Ford West Bloomfield Hospital

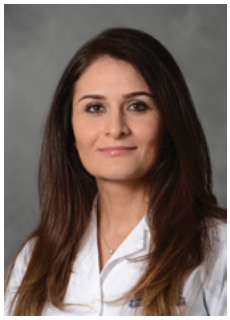
Yasaman Kavousi, M.D.
Vascular Surgery

Medical school education
University of Washington School of Medicine, Seattle, WA

Fellowship
John Hopkins University, Vascular Surgery, Baltimore, MD

Residencies & internships
Henry Ford Hospital, General Surgery, Detroit, MI

Research interests
Dr. Kavousi's special interests include management and treatment of lower extremity occlusive disease, particularly as it relates to the diabetic population.



Yasaman Kavousi, M.D.
Henry Ford Hospital

Tamer Boules, M.D.
Vascular Surgery

Medical school education
University of Michigan, MI, 1998

Fellowship
University of Pittsburgh Medical Center, Vascular Surgery, Pittsburgh, PA

Residencies & internships
University of Michigan, General Surgery, Ann Arbor, MI

Board certifications
American Board of Surgery General and Vascular Surgery

Practice interests
Dr. Boules practices the full spectrum of vascular and endovascular surgery, with a special interest in aortic, carotid, and lower extremity arterial disease. In addition to offering standard open surgical therapies for vascular disease (such as open aortic aneurysm repair, carotid endarterectomy, and lower extremity bypass), he has extensive training and experience in minimally invasive procedures, now available as an alternative to open surgery for most patients. These include Carotid Stenting/TCAR, lower extremity arterial angioplasty and stenting, venous thrombectomy and stenting for iliofemoral DVT, endovascular aortic aneurysm repair (EVAR/FEVAR/TEVAR), and endovenous laser ablation therapy (EVLT) for varicose veins and venous insufficiency.

Tamer Boules, M.D.
Henry Ford West Bloomfield Hospital
Henry Ford Hospital

Miles Jackson, M.D.
Vascular Surgery

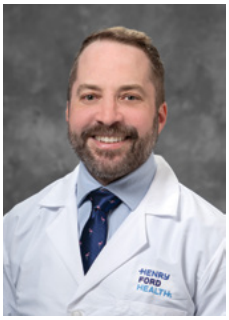
Medical school education
University College of Cork Faculty of Medicine, Cork, Ireland

Fellowships
ProMedica Toledo Hospital, Vascular Surgery, Toledo, OH

Residencies & internships
St. Joseph Mercy Hospital, General Surgery, Ann Arbor, MI

Research interests
Dr. Jackson's special interests include: minimally invasive aortic repair and endograft selection, optimal timing for carotid intervention, and hemodialysis access creation approaches.

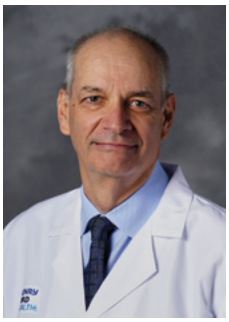
Dr. Jackson speaks fluent French and Canadian English



Miles Jackson, M.D.
Henry Ford Allegiance Vascular Health, Jackson, MI

Trial Results: BEST CLI study

The Best Endovascular versus Best Surgical Therapy for Patients with Critical Limb Ischemia (BEST-CLI) study was a groundbreaking trial performed worldwide, which evaluated the two major accepted and performed treatment options in the management of critical limb threatening ischemia (CLTI). Critical limb threatening ischemia (CLTI) is an advanced stage of peripheral artery disease where an established and high risk of limb amputation is involved. Patients with CLTI present with significant foot pain or may have wounds that fail to heal or even gangrene, all of which put them at risk for amputation.



Timothy Nypaver, M.D.

Risk factors for CLTI include tobacco use, diabetes, hypertension, hypercholesterolemia, family history, stroke, and coronary artery disease. Henry Ford Hospital served as a major contributor to the BEST-CLI trial nationally as well as led the way in the State of Michigan as the highest recruitment center in the state. Timothy Nypaver, M.D., chief of the Division of Vascular Surgery and the principal site investigator for the BEST-CLI trial, hosted the initial Michigan-wide BEST-CLI recruitment with a case presentation series/update at the first Detroit Critical Limb Ischemia Consortium.

Presently, CLTI care has been marked by a lack of high reliable data, substantial treatment variability, and heavy reliance on the treatment bias of individual providers. The Best Endovascular versus Best Surgical Therapy for Patients with Critical Limb Ischemia (BEST-CLI) trial was designed to guide therapeutic decision making for the treatment of CLTI who are candidates for either open surgical bypass or endovascular therapy.

Dr. Nypaver noted that "peripheral artery disease affects over 200 million patients globally and approximately 11% of these have the advanced form of the disease which necessitates vascular or endovascular intervention. "This study was particularly appealing to us as we are engaged in the treatment of many patients with critical limb ischemia and have instituted an aggressive approach toward limb savage, avoidance of amputation, and reestablishment of the patient's functional capacity and independence," explained Dr. Nypaver. "This study sought to answer a critical question: when these patients present with their CLTI symptoms what is the appropriate first-line treatment for the patient?

The answer, Dr. Nypaver explained may be, "an endovascular approach with the performance of intraluminal procedures inclusive of angioplasty, atherectomy, or stent or stent graft placement, versus our patients are better served with an open bypass utilizing the saphenous vein." Dr. Nypaver also indicated that "last year, we performed 518 lower extremity patient interventions on patients with peripheral artery disease, the majority of which were performed for CLTI."

The results from the BEST- trial were recently published in *The New England Journal of Medicine* and presented at the American Heart Association 2022 Scientific Sessions. The study involved 1,830 international patients who were divided into cohorts determined by the status of an available good quality single segment greater saphenous vein, the optimal conduit for bypass. If the patient did not have a good vein, they were assigned to the second cohort which included those patients with alterative conduit options, including segments of vein or prosthetic material. The patients in both cohorts were randomized to receive either a bypass procedure or an endovascular procedure as a treatment for CLTI and were followed for an average of 2.8 and 1.9 years, respectively.

The study revealed that patients with available greater saphenous vein who received the open bypass had a 32% reduction in major adverse limb events (MALE) or death compared to those who received the endovascular approach. A major adverse limb event was defined as an above ankle amputation of the index limb or a major index limb reintervention. In addition, bypass patients required 65% fewer major reinterventions and 27% fewer amputations.

For the second cohort of patients (those without an available quality greater saphenous vein), no difference in any of the outcome measures was noted. Another important finding was that both open bypass and endovascular revascularization reduced pain and led to clinically meaningful improvements in quality of life. Also, in terms of outcomes, the number of heart attacks, strokes,

or deaths associated with the procedure were similar irrespective of the treatment utilized. The BESTCLI study in the largest randomized controlled trial comparing revascularization treatment strategies in patient with CLTI and will continue to provide important information about study participant's care going forward.

Dr. Nypaver emphasized the important aspects of the study: "First of all, many of our patients due to their significant co-morbidities, cannot undergo an open operation and thus a less invasive endovascular approach can offer a real and viable option for limb salvage and reduction in pain and major improvement in quality of life. However, for those patients who are candidates for either procedure and who have a good quality useable saphenous vein, it is apparent that the bypass procedure offers significant advantages. But, critically important, there is no standardized approach for these challenging patients, and that to provide these patients with the maximal care and benefit, the full armamentariums of options in developing an individualized approach for each CLTI patient needs to be offered."

Editor's Note: BASIL-2, a second randomized trial examining this question, was recently published in the Lancet. BASIL-2 enrolled 345 patients with CLTI at 41 vascular surgery centers in the UK, Sweden and Denmark and compared best endovascular therapy to surgical bypass in patients who were candidates for either revascularization strategy. During a median follow up of 40 months, BASIL-2 found that the likelihood of amputation-free survival was 35% lower and the likelihood of death 37% higher among those who underwent surgical bypass than endovascular therapy. Vascular thought leaders are working actively to reconcile the discrepant results from these two landmark studies.

To read the full article, scan the QR code.

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Arfaat Khan, M.D. and William O'Neill, M.D. celebrate the 1000th case with the Henry Ford Hospital team with (from left) Brandon Bulmer, RN, APP student, James Lee, M.D., Joshua Greenberg, M.D., Brian O'Neill, Dee Dee Wang, M.D., Laura King, APP, and Kyle Fater, Watchman representative.

Achieving 1,000 LAAO procedures

The Electrophysiology and Structural Heart Disease teams throughout Henry Ford Health have performed over 1,000 Left Atrial Appendage Occlusion (LAAO) implants using the Watchman FLX TM system. LAAO devices implanted in the heart reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation. A precise, 3D model of the heart is created to help determine the device that best fits heart's unique anatomy, making each procedure safer and more effective.

Cardiovascular medicine study recruits participants

The Division of Cardiology seeks participants for a study to determine if bromocriptine therapy improves myocardial recovery and overall event-free survival for women with peripartum cardiomyopathy (PPCM). Eligible participants are ages 18 and older who have been diagnosed with post-delivery PPCM and are within 5 months of post-partum. The study dubbed REBIRTH is a prospective multi-center placebo-controlled double-blind randomized trial to determine efficacy of bromocriptine, a dopamine receptor agonist, during myocardial recovery in 200 women newly diagnosed with PPCM.

Contact Study Coordinator Jodi Baxter at jcarte23@hfhs.org or (313) 590-2407.

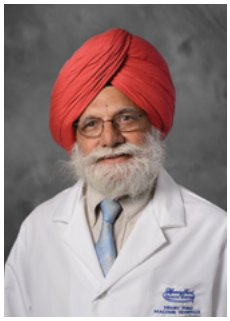
Patient Highlight

Tried and true: TCAR

Experiencing a lack of energy, Paul Wywierowski of Harrison Township thought he might soon have another myocardial infarction. His Cardiovascular Medicine Specialist Natesh Lingam, M.D., sent Paul to Vascular Surgeon Sachinder Hans, M.D. for an ultrasound. The diagnosis was bilateral severe carotid artery stenosis. Dr. Hans brought in his colleague Vascular Surgeon Kaitlyn Rountree, D.O., at Henry Ford Macomb Hospital, for further testing. "A 3D CT showed both my carotid arteries were blocked and I needed stents on both sides," explains Paul.

Paul Wywierowski

Kaitlyn Rountree, D.O.



Sachinder Hans, M.D.

Natesh Lingam, M.D.

For some, plaque buildup in the carotid arteries may only bring mild symptoms like Paul experienced or may go unnoticed. For others the plaque causes arteries to harden and narrow, blocking the blood flow and restricting perfusion to the brain creating a more urgent situation such as stroke or TIA. Transcarotid artery revascularization (TCAR) treats carotid artery disease and provides great benefit to patients and especially for those who might be too sick or high risk for open surgical interventions.

Luckily for Paul, Dr. Rountree had recently returned to Henry Ford Macomb Hospital following a vascular fellowship in Missouri. "TCAR is a hybrid procedure that combines the less invasive benefits of placing a stent with the low stroke risk of traditional carotid surgery," she says. "I learned the procedure during my fellowship and am happy to bring these skills and experience back to my patients at Henry Ford."

Dr. Rountree explains, "TCAR is a minimally invasive vascular procedure that combines the benefits of using a stent with the safety of an open surgical exposure. To perform the procedure, I make a small incision on the base on the neck to expose the common carotid artery and place a puncture in the groin to access the femoral vein. This allows me to use the specialized TCAR system to place a stent across the affected artery while staying away from the diseased portion of the artery until it's safe to manipulate it."

Dr. Roundtree further explained, "TCAR is less invasive than other carotid artery treatment options like traditional open surgery and transfemoral stenting. TCAR usually requires a shorter hospital stay and has a faster recovery time, with less risk of injury to nerves, muscles, and lower stroke risk than transfemoral stenting. The most significant benefit is the lower risk of stroke."

Paul recalled, "Dr. Lingam, Dr. Hans, and Dr. Rountree worked together on my case, they talked to each other and decided what was the best option for me. Dr. Rountree was patient and kind as she explained everything to me and together we decided that TCAR was the right procedure to fix my problem. In November, the left carotid artery was opened and in December the right, which was a little more challenging, but Dr. Rountree didn't give up on me. There's no doubt Dr. Rountree saved my life."

Dr. Rountree said, "Some of our patients travel a long distance, and I want to ensure they receive top-notch care here at Henry Ford Macomb Hospital without having to travel all the way to Detroit. I'm proud to be able to offer newer procedures and technologies right here. TCAR is a great option for well-selected patients and can be life changing for them."

Dr. Rountree joined vascular surgeon Sachinder Hans, M.D. in serving the patients and community of Henry Ford Macomb Hospital in September 2022. Since reopening the TCAR program she has expanded the surgical options for patients with carotid artery disease, especially for those with high anatomical lesions, patients at higher risk for surgery and those with recurrent narrowing, and all have done well.

JETi™ thrombectomy device features a dual-action design for efficient clot removal

Kevin Onofrey, M.D.

Henry Ford Hospital is one of the leading centers in the United States in the use of the JETi™ hydrodynamic thrombectomy system. The device uses high-pressure saline jet in a 360-degree motion to aspirate and fragment thrombus. Henry Ford Hospital vascular surgeons have made "Henry Ford Hospital one the longest and most frequent users of the device in the region," explained Vascular Surgeon Kevin Onofrey, M.D.

Dr. Onofrey explained, "I began using the JETi™ clot removal device during fellowship at Henry Ford Hospital and found it to be very efficacious in rapid removal of acute acute and subacute arterial thrombus. Over time all our vascular surgeons at Henry Ford Hospital recognized the benefits and began to use the JETi™ when it was appropriate for the case. It is highly unusual for a significant number of surgeons to choose to use the same device at one hospital, but we now all agree that it's our first line device in minimally invasive arterial thrombectomy."

Used within the peripheral and mesenteric vessels in a minimally invasive procedure, a catheter is inserted percutaneously in the peripheral artery and advanced to the clot. Engaging the JETI™ device causes the uniquely positioned saline jet to safely break up the thrombus as it is suctioned away. With minimized risk of embolization and hemolysis, low profile 6F and 8F catheters help to avoid large-bore access site complications. High single-session treatment success rates help to reduce costly ICU length of stays to get the patient home sooner.

In the June 2022 interactive poster session of the *Journal of Vascular Surgery*, Dr. Onofrey presented the Henry Ford Hospital single-center experience with JETi™—a study of the aspiration thrombectomy for acute and subacute lower limb ischemia. The results showed success of the JETi™ to remove the targeted clot was 85%. The authors included, Dr. Onofrey, Abdul Kader Natour, M.D., Chaitu Dandu, M.D., Mitchell Weaver, M.D., Alexander Shepard, M.D., Timothy Nypaver, M.D., Omar Kafri, M.D., Adam Chalek, M.D., Saurabh Gupta, M.D., Alice Lee, D.O., Farah Mohammad, M.D., and Loay Kabbani, M.D.

JETi™ Hydrodynamic Thrombectomy System

To view the complete article, scan the QR code.

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Dr. Onofrey explained, "JETi™ was purchased by Abbott in September 2021 and some modifications were made to the original instrument we had been using. As a result, Abbott began a Registry to monitor results which are confirming our experience. As a higher user of the device, Henry Ford Hospital vascular surgeons are part of the Registry."

To learn more about the procedure and this device, scan the QR code.

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Patient Highlight

EKOS program implemented at Henry Ford Wyandotte

For retired Nurse Practitioner Kathryn Cosgrove, becoming short of breath and tachycardic with a significant change in her blood pressure was not on her radar while enjoying a relaxed hike. "Other than some arthritic hips, I was in great shape, taking no medications," said Kathryn. "I had no symptoms of what was to come other than labored breathing."

As discovered in her visit to Henry Ford Wyandotte Hospital's emergency department, Kathryn had a DVT in her right leg, with a pulmonary embolism (PE), a large saddle on both sides of her lungs that needed to be removed immediately. She recalls being in the ER at 10 a.m., and by 3 p.m. she was in the cardiac cath lab.

Qaiser Shafiq, M.D.

Unknowingly, Kathryn had become the third patient to be treated by Interventional Cardiologist Qaiser Shafiq, M.D., an expert in catheter-directed therapies for PE, which includes use of the EkoSonic endovascular thrombolytic system (EKOS) ultrasound guided catheter, a minimally invasive procedure that would dissolve the PEs she was experiencing.

Kathryn Cosgorove is back walking and hiking.

Kathryn Cosgrove

Following diagnosis of a PE through symptom confirmation, laboratory tests, and a CT scan, patients are given a clotbusting drug. Dr. Shafiq explained, "In the cardiac cath lab, the two-part catheter, the infusion catheter, and ultrasonic core, are inserted and remain for up to eight hours. The ultrasonic core generates an acoustic field to drive the clotbusting drug deeper into the clot. This unwinds the fibrin, exposing plasminogen receptor sites." The PE dissolves faster without damaging vessels, valves, or wall. When the catheter is removed the patient either passes the clot material or the body absorbs it.

Dr. Shafiq believes that Kathryn had the perfect storm of issues that caused the DVT to form. "Kathryn was experiencing ilio tibial ligament syndrome, inflammation that further irritated the hip cartilage which caused her pain and stiffness, so she was more sedentary prior to having the DVT." Kathryn explains, "I'll be on medications to reduce the possibility of further clots." At 72, Kathryn shares following two hip replacements and PEs safely removed, she is enjoying a much-deserved retirement.

To learn more about Kathryn's story, visit: https://henryford.com/kathryn

Technology Supports for Heart Failure Monitoring

The Heart Failure Society of America reports 6.5 million people over the age of 20 have heart failure. And 8.5% of heart disease deaths in the United States are attributed to heart failure. Excessive resources are expended as heart failure remains the number one cause of hospitalization among the Medicare population. Yet, despite these figures those with heart failure can lead normal active lives as they learn how to manage the disease through the combination medications and technology.

Qaiser Shafiq, M.D.

One such technology that helps to keep patients out of the hospital is CardioMEMS™ Heart Failure System which monitors patients for changes in pulmonary artery pressure in real-time. "Patients eligible for monitoring are in Class III heart failure and have been hospitalized within the past year with either preserved ejection fraction (HFpEF) or reduced ejection fraction (HFrEF)," explained Dr. Qaiser Shafiq, Cardiac Catheterization Lab director at Henry Ford Wyandotte Hospital.

In an outpatient procedure, the sensor device is inserted into the pulmonary artery typically through the femoral vein, up to and through the right side of the heart and into the pulmonary artery," said Dr. Shafiq. The sensor, once deployed, is 15 mm x 10 mm, or smaller than a paper clip-sized monitoring device.

Mari Kostelee of Dearborn Heights, explained she's had heart failure for some time, with 6 stents, used a loop recorder, and patch for 90 days. "It's easy" says Mari, "I just lay on a pillow for 2 minutes each day and it sends all my measurements to Dr. Shafiq."

Dr. Shafiq explains, "Patients believe they are simply laying on the pillow, but the pillow activates the WIFI-enabled CardioMEMS™ device which transmits real-time data for monitoring, as the sensors activate a database linked to and monitored by my heart failure team. If there's any deviation, we contact the patient right away."

Monitoring provides "an early warning of changes in pulmonary artery pressure which tends to be an early indicator the patient is going into heart failure. If pressure in the pulmonary artery changes, we can adjust and tailor a patient's medications without delay preventing hospitalization." Dr. Shafiq explained. "Adding this device to a patient's treatment can help to prevent acute exacerbations of heart failure and/or dehydration which can result in a decrease of hospital admissions."

The ability for physicians to individually set thresholds personalizes and optimizes care and medical management for each patient. Traditionally, clinicians focused on patient weight, blood pressure, etc. to detect worsening heart failure. These markers appear late in the time course of decompensation allowing little time to respond before hospitalization is necessary.

Mari said, "The device really gives me peace of mind. It's one less thing to worry about. I know someone is looking out for me and it's not inconvenient to lay on the pillow. If they call me, I can adjust my medication without leaving my house."

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To learn more about Dr. Shafiq, visit: https://www.henryford.com/physician-directory/s/shafiq-qaiser

To connect with a Henry Ford physician, call:

Henry Ford Health Heart & Vascular

1-877-434-7470

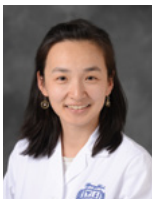
henryford.com

HENRY FORD HEALTH®
Heart & Vascular

Heart & Vascular Institute
Henry Ford Hospital
2799 West Grand Blvd.
Detroit, MI 48202

In the news

Moving Medicine Forward



Dee Dee Wang, M.D.

Congratulations to Dee Dee Wang, M.D., director of structural heart imaging at Henry Ford Health, who was featured in 2022 *Hour Detroit* Top Docs Magazine for her work with 3D imaging and printing. She said, "It's such a new technology. Even though we've been doing everything for over nine years, very few hospitals have the capability to perform in-house 3D printing or in-house computer-aided-design virtual twin 3D printing." Dr. Wang works side-by-side with structural heart interventionalists to build 3D heart models to help educate their patients while the doctors use the models to understand the patient's unique heart anatomy to perfect procedures.

To read the entire article, scan the QR code and scroll to page 65.
http://bit.ly/41fFizP

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Raed M. Alnajjar Joins the MISHC Leadership Team

Raed M. Alnajjar, M.D., Henry Ford Health has joined Drs. Stanley Chetcuti, P. Michael Grossman, and Himanshu Patel as a Michigan Structural Heart Consortium (MISHC) Co-Program Director. "He brings a wealth of experience in cardiac surgery, with a focus on surgical and percutaneous management of mitral valve disease," said Dr. Grossman.

Raed M. Alnajjar, M.D.

As MISHC has grown to include both mitral valve procedures and TAVR procedures, it is an ideal time to expand leadership, particularly from a surgical perspective.

"MISHC's mission of improving quality, safety, and patient outcomes motivates me," said Dr. Alnajjar. "I look forward to being available to our structural heart sites as a resource."

It is important to Dr. Alnajjar to continue fostering the collaboration between cardiovascular medicine specialists and CT surgeons, working to recruit more cardiac surgeons to the field of structural heart care. He is eager to develop best practice guidelines for structural heart procedures and share MISHC's work and experience at the national level.