



## Transfemoral tricuspid valve replacement: TRISCEND study 30-day results

## Vascular medicine intervention prevented amputation

The objective of the TRISCEND study (Edwards EVOQUE Tricuspid Valve Replacement: Investigation of Safety and Clinical Efficacy after Replacement of Tricuspid Valve with Transcatheter Device) is to evaluate the safety and performance of transfemoral transcatheter tricuspid valve replacement in patients with clinically significant tricuspid regurgitation (TR) and elevated surgical risk.



Brian P. O'Neill, M.D.



William W. O'Neill, M.D.

Often referred to as the forgotten heart valve, TR occurs when the tricuspid heart valve is dilated or stretched and its leaflets no longer close tightly, allowing blood to flow backwards within the heart. The patient will experience shortness of breath with activity, swelling in the abdomen, legs or veins in the neck. "We've made significant progress in the transcatheter treatment of left sided heart

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Char Litvin thought there was a real possibility her toes might be amputated. "I've had a lot of medical issues that I've had to manage for years and years, some may have affected my vascular system," Char, a 67-year-old Farmington Hills resident, explained. "It was my podiatrist who recognized that I needed a physician who could improve circulation in my legs and feet."



*Char Litvin can wear shoes again*

Char was referred to Syed Ahsan, M.D., a vascular medicine specialist, Henry Ford Health. Dr. Ahsan explained when he first met Char in August 2020 she had bilateral toe cyanosis, she had no circulation in either leg. "I had black lesions on my toes and had very little circulation. That's when amputation became a real possibility," she said.

"We discovered that Char had Lupus, an autoimmune disease, which likely was the cause of small vessel vasculitis. Finding a way to dilate those

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### Inside



**Vascular medicine: save limbs and save lives**



**remedē® system for central sleep apnea**



**First specialty ICU dedicated to cardiovascular at Henry Ford Macomb Hospital**



From the desk of Herbert D. Aronow, M.D.



*Herbert D. Aronow, M.D., M.P.H., Medical Director, Heart & Vascular Service Line*

Dear Colleagues:

It is an honor to return to Michigan and join the renowned team of heart and vascular specialists at Henry Ford Health. Although I am six months into my new role as Medical Director for the Heart & Vascular Service Line, I continue to be impressed by the innovative solutions our experts bring to bear for our patients and share with our colleagues around the globe.

One thing is certain. I could not envision a path forward without the outstanding contributions from my predecessors Henry Kim, M.D., and Doug Weaver, M.D. As I build on their legacy and work toward our collective vision, I see our future manifest in three equally important pillars: care alignment, innovation, and market growth:

**Care Alignment** – In most health systems, cardiovascular care can be siloed and unidimensional. As we look out toward the horizon and develop a common vision for the heart and vascular service line, we will create a cardiovascular care model that is coordinated, collaborative, team-based — comprised of multiple specialties and disciplines — and one that emphasizes the importance of shared decision making between patient

and provider. Doing so will allow us to align care across specialties, disciplines, and locales and across employed and private practice members of our care team. This unique approach will provide our patients with the exceptional care they deserve.

**Innovation** – Henry Ford Health has long been known for its innovative diagnostic and treatment approaches. Heart and vascular care is no exception. Many of the techniques employed around the world in cardiac and vascular surgery and in structural heart and coronary intervention were first pioneered within our four walls. Our innovative culture lends itself well to everything we do, whether it be clinical care, quality, research, or education. We will continue to push the care envelope, creating options for patients who were told they had none, restoring life, and improving quality of life.

In partnership with Henry Ford Innovations, we will create new ways to address old problems. With the help of our transformation specialists, we will redesign the way in which we deliver care, optimize efficiency, minimize cost, and maximize value. Likewise, from the bird's eye view that our service line provides, we will identify and share best practices and standardize care where appropriate



## Staff update

### Herbert D. Aronow, M.D., M.P.H.

Interventional Cardiology  
Medical Director for the Heart & Vascular Service Line



#### Medical school education

University of Michigan,  
Ann Arbor, MI

#### Residencies & internships

University of Michigan, Ann  
Arbor, MI, Internal Medicine

American Board of  
Vascular Medicine (ABVM) –  
Vascular Medicine

#### Fellowships

Cleveland Clinic  
Foundation, Cleveland, OH  
Interventional Cardiology

#### Board certifications

American Board of  
Internal Medicine (ABIM) –  
Cardiovascular Disease

American Board of  
Vascular Medicine (ABVM) –  
Endovascular Medicine

Cleveland Clinic  
Foundation, Cleveland, OH  
Cardiovascular Disease

American Board of  
Internal Medicine (ABIM) –  
Interventional Cardiology

#### Research interests

Dr. Aronow's research  
centers on the comparative  
safety and effectiveness  
of endovascular procedures.

#### Herbert D. Aronow, M.D., M.P.H.

Dr. Aronow practices at:  
Henry Ford Hospital and  
Henry Ford West Bloomfield  
Hospital

With privileges at:  
Henry Ford Jackson Hospital  
Henry Ford Macomb Hospital -  
Clinton Township  
Henry Ford Wyandotte Hospital

in the name of enhanced quality. We hope you take advantage of our faculty, some of the most sought out educators in virtual and face-to-face teaching venues. Through simulation, interactive live case transmission, and expanded didactic opportunities we will continue to mentor and inculcate tomorrow's clinical leaders within and outside of our institution.

**Market Growth** – Our footprint extends across southeastern Michigan, but our imprint is much larger. We are the referral site for many of our state's sickest patients and we excel when patients have no further treatment options available. By bolstering our capabilities, providing optimally aligned care and employing an innovative, patient-centered approach, I believe we will continue to lead cardiovascular care in our region.

In this and future editions of *CardioBeat*, we will continue to highlight our efforts in care alignment, innovation, and market growth. The current issue features articles about our ground-breaking research in catheter-based tricuspid valve replacement, patient stories about life-restoring care, our participation in a virtual PCI course, where we broadcast a live complex PCI procedure to a worldwide audience, and expanded programs and services

at Henry Ford Macomb Hospital. We also showcase two of our Vascular Medicine specialists: Dr. Syed Ahsan and Dr. Olusegun Osinbowale, who support the Henry Ford Health Vein Center, Vascular Service and physicians throughout our community.

I am certain that we are embarking upon a journey where the whole is greater than the sum of its parts, and am eager to witness everything we'll accomplish together. Thank you to our superb team for all you've achieved and for the exemplary care you provide each and every day. And to those who entrust us to care for mutual patients, thank you for your support not only of the patients, but of our team!

#### Herbert D. Aronow, M.D., M.P.H., FACC, FSCAI, FSVM

President, Society for Vascular Medicine  
Professor, Michigan State University  
College of Human Medicine  
Medical Director, Heart & Vascular Service Line  
Benson Ford Chair in Cardiology  
Henry Ford Health

# Vascular medicine: save limbs and save lives

The expertise of a vascular medicine specialist is to improve vascular disease outcomes and reduce the rate of interventions. Medical management provides an accurate and thorough diagnosis of the circulatory system, including arterial or venous disorders and supports identification of the cause of the condition, which is often complex. Vascular medicine specialists treat the entire vascular system, except vasculature in the heart.

Henry Ford Health Vascular Medicine Specialist Olusegun Osinbowale, M.D., explained “We work closely with our colleagues in vascular surgery, cardiology and interventional radiology. We also encourage our colleagues in internal medicine, family practice orthopedics, nephrology, hematology, endocrinology, rheumatology and podiatry to tap into our expertise when their patients experience vascular conditions. Patients from these specialty areas are often at higher risk for circulatory disorders, have a blood clot, have vein damage or experience venous insufficiency.” Other factors include: smoking, being overweight, diabetic and having high cholesterol. Most often the patients are older, but younger patients are now experiencing these contributing factors and subsequent vascular issues too, especially since COVID-19 has also affected this age group.

Syed Ahsan, M.D., vascular medicine, explained that by collaborating early with referring physicians we improve quality of life and frequently prevent amputation to preserve limb function. He encouraged, “early referrals mean a disease process is diagnosed before damage is too severe to the vessels. We use medical management and early interventions in order to prevent or delay amputation.”

Dr. Osinbowale added, “early intervention should begin when physicians ask their patients if they function well, then look at their feet. Those at higher risk for peripheral vascular disease will often indicate a specific area that swells or hurts, they likely will mention shortness of breath or that they don’t get around well. Leg cramping when walking is another symptom that suggests vascular disease. That’s a patient who should see a vascular medicine specialist.”

Both Dr. Ahsan and Dr. Osinbowale advocate to “Save limbs and thereby save lives.”

## The specialty of vascular medicine

There are very few vascular medicine specialists in the United States. Dr. Osinbowale attributes that to fewer available training programs than other specialties, although programs have grown to 25 worldwide, yet it is still a young specialty. The Society of Vascular Medicine which was established in 1989, currently headed by Henry Ford’s Interventional Cardiologist Herbert Aronow, M.D., medical director for Heart & Vascular Service Line, is its president.

As a vascular medicine specialist, Dr. Osinbowale explained he was drawn to this “specialty to care for patients who are often at risk for advanced vascular disease to provide earlier detection, optimize medical management and educate them to help prevent amputation and mortality.”

## Vein center approach

Dr. Ahsan explained, “We’ve created a Vein Center so we can care for all aspects of vascular diseases. Some patients do not require surgery or might fit better with medical management of their case. We work closely with our vascular surgery and interventional radiology colleagues to ensure our patients’ needs are addressed by the right specialty. Our approach is to first provide medical management to get the maximum benefit. Surgery is the last option because there’s no way to undo a surgical procedure. Vascular medicine becomes the quintessential portion of the larger picture to provide the best comprehensive care to our patients and the problem, rather than just procedures first. This is patient centric care.”



Syed Ahsan, M.D.



Olusegun Osinbowale, M.D.

**Call (248) 661-7022 to refer your patients to a Vascular Medicine specialist.**

## Most common disorders treated by vascular medicine:

- Thrombosis (arterial and venous), hypercoagulable disorders
- Aneurysms
- Vasculitis
- Genetic connective tissue disorders resulting in vascular disease
- Lymphedema and lipedema
- Upper and lower extremity venous and arterial disease
- Non-atherosclerotic disorders (e.g. fibromuscular dysplasia and others)
- Thermal disorders (e.g. Raynaud syndrome, erythromelalgia, others)



## The Henry Ford Vein Center highlights

- **Expertise in vein disease:** The Vein Center team includes board-certified vascular specialists with years of experience and advanced training. Using a team approach to treat patients, doctors from several specialties work together to manage all types of vein disease.
- **Nationally recognized vascular testing:** Specialized vascular labs have received accreditation from the Intersocietal Accreditation Commission. This recognition means the highest standards for technologies used to diagnose vascular disease have been met.
- **Full range of care:** Whether it's help with unsightly veins or relief from painful symptoms, the specialists provide expert diagnosis to treatment tailored for each patient in a warm, professional environment.
- **Advanced techniques:** Utilizing all the skills and resources to perform every type of procedure, including injections, laser therapy and minimally invasive procedures. Many treatments are same day outpatient procedures with little or no downtime for recovery.

## Vein conditions treated include:

- Chronic venous insufficiency
- Deep vein thrombosis
- Pelvic congestion syndrome, chronic pelvic pain caused by pooled blood in pelvic veins
- Spider veins
- Superficial thrombophlebitis, a blood clot in a vein near the skin's surface, which causes inflammation
- Varicose veins
- Venous ulcers, open skin sores caused by poor blood flow in leg veins

## Venous compression syndromes treated include:

- Klippel-Trenaunay-Weber syndrome, a congenital disorder that causes red birthmarks and abnormal development of certain veins, tissues and bones
- May-Thurner syndrome, compression of the iliac vein that returns blood from the left leg to the heart
- Nutcracker syndrome, compression of the left kidney vein
- Paget-Schroetter syndrome, a type of thoracic outlet syndrome, with compression of veins in the armpit or shoulder



Patient

## Vascular medicine intervention prevented amputation

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vessels would support healing, so we had to think outside-the-box," Dr. Ahsan explained. "Char was prescribed blood thinner Eliquis and aspirin and off-label Sildenafil (Viagra) to dilate the vessels to improve circulation." This treatment strategy worked and by January 2021 Char was healed. Dr. Ahsan emphasized how important it is to consider the entire patient, so in systematic diseases we don't miss anything, like in Char's case.

Char returned to Dr. Ahsan in November 2021 when ulcers re-emerged on three toes. While Char had remained on Eliquis and aspirin, she was again placed back on Sildenafil with exercise. This time, Dr. Ahsan added ArtAssist®, a pump device to increase blood flow in her legs. "It's outside of our protocol and I wasn't certain it would help, but I knew we needed to try something more if we were going to save her

toes," he said. Within five months Char saw progress as her toes began to heal. By May 2022 the ulcers had resolved.

"I am so pleased that Dr. Ahsan was determined and really thought out-of-the box so that I wouldn't lose my toes and knew what medications could restore my circulation. When I first came to Dr. Ahsan, I thought I'd lose my toes, today I am 100% recovered – two times. Dr. Ahsan is just the best!"



scan with phone

Dr. Ahsan and Char share how treatment prevented amputation of her toes at: <https://bit.ly/VascularMed-Char>

To refer a patient with vasculitis to the Vein Center at Henry Ford Health, call (248) 661-7022.

# Lymphedema is a treatable condition

Robert Cooper, 39, of Southfield, doesn't really know what caused his legs to swell some seven years ago, except it might have been standing for 10–12 hours every day at work. The swelling kept getting worse, with ulcers, discoloration, and varicose veins; he realized in June 2018 it was time to find out what was causing this discomfort.

"I chalked all that up to working long hours and not taking care of myself," said Rob. But now faced with many diagnosed conditions, he knew it was time to address his health.

A visit with his primary care doctor revealed some endocrinology issues were the cause of his extreme fatigue, high blood pressure, low potassium and maybe his sleep apnea. "Of course, it didn't help that I was overweight," Rob chuckled. "That was something I knew needed to be addressed." He underwent numerous tests and learned his thyroid was not working properly.

Rob's endocrinologist referred him to Syed Ahsan, M.D., vascular medicine specialist, Henry Ford Health, who diagnosed Rob with untreated lymphedema. "Rob's condition was so severe he couldn't get his shoes on — he had massive leg swelling and weighed 480 pounds. "Within six weeks Rob lost 40 pounds, then I didn't see Rob until October 2021. He had continued to lose weight by following a healthy diet and lifestyle and the swelling in his legs lessened. It was at this point that we added physical therapy to his treatment plan. Dr. Ahsan explained that "sending a patient with extreme lymphedema to physical therapy too early might move the fluid out but it comes right back because there's nowhere for the fluid to go, so the patient gets discouraged."

There are a lot of treatments we could use, but "I believe conservative management along with our physical therapy team is much more successful; 99% of my patients with lymphedema never need surgery." Each time Dr. Ahsan saw Rob he continued to lose weight, and by April 2022, Rob had lost 146 pounds and the swelling in his legs.

By June 2022 Rob shared, "I've lost over 200 pounds. My life is a whole lot better over these last two or three years, because I had good doctors. I should have seen Dr. Ahsan five years earlier!" Rob's prognosis is "pretty impressive," Dr. Ahsan has determined, and remarks his



Robert Cooper lost over 200 pounds and addressed the lymphedema

patients almost always say they should have come to him sooner.

Dr. Ahsan offers the following to physicians treating patients with lymphedema in their offices:



Syed Ahsan, M.D.

1. Lymphedema is a treatable condition. It is not permanent, and patients don't just have to live with it, they can improve over time with effort.
2. Always focus on intrinsic factors of diet modification, lifestyle improvements, exercise and skin conditions, and not on extrinsic with use of wraps, compression dressing or physical therapy.
3. Water pills and diuretics are always the wrong choice, except in rare cases.
4. Do not ask the patient to lose weight, focus on the swelling. That is what the patient sees as the condition to be treated and support the patient in their challenge to eat well and exercise. This is patient-centered care.



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Dr. Ahsan and Rob share how treatment changed his life trajectory at: <https://bit.ly/VascularMed-Robert>

To refer a patient with lymphedema to the Henry Ford Vein Center, call (248) 661-7022.



# remedē<sup>®</sup> system for central sleep apnea

A new option for Central Sleep Apnea (CSA), which occurs when the brain does not send proper signals to the muscles that control breathing, was recently approved by the Food and Drug Administration (FDA). The implantable **remedē<sup>®</sup>** System stimulates the phrenic nerve to signal the large muscle that controls the diaphragm.

Tom Julian of Warren knew he wasn't getting adequate sleep because an over-the-counter device called Oura Biometric Ring measured his sleep. "The device showed I was getting about 40 minutes of deep sleep a night. I would have 7, 8, 9 episodes where I would stop breathing and that interrupted my sleep cycle."

After several sleep studies resulting in conflicting results and a failed attempt at using a CPAP machine, Tom was sent to Henry Ford Hospital where he was diagnosed with CSA by Sleep Medicine specialist Maria Tovar, M.D., director of the Advance Treatment of Sleep Apnea Clinic.

Dr. Tovar explained, "CSA is different than obstructive sleep apnea (OSA) and is more uncommon. During sleep when the brain does not signal the breathing muscles, and a regular breathing pattern cannot be established, then the patient stops breathing for brief periods."

Tom tried using a CPAP "but it didn't work for me," he said. "That's when Dr. Tovar presented a newer treatment option that was only for patients like me."

Dr. Tovar referred Tom to Arfaat Khan, M.D., section chief of Cardiac Electrophysiology, to be evaluated for a new sleep apnea device. Tom explained, "So after a conversation with Dr. Khan, I thought the **remedē<sup>®</sup>** System was the right solution for me. Dr. Khan explained that it was relatively new, it could be inserted with a minimally invasive procedure, and I could finally get some sleep." Tom further added,



Courtesy of Zoll<sup>®</sup>



remedē<sup>®</sup> System

"I already have an ICD so I imagined it to be very similar."

Dr. Khan explained, "The device is comprised of a battery generator very similar to implantable cardioverter defibrillator. Like an ICD it is placed in the upper chest area, but usually on the right side. The leads are then placed near the phrenic nerve which stimulates breathing to restore normal breathing while the patient sleeps."

Tom gave Dr. Khan an added challenge, "I had to insert the lead in the superior vena cava adjacent to the phrenic nerve instead of the pericardiophrenic nerve on the on left because Tom's anatomy was different. With the ICD leads already in the venous system, the leads were inserted side-by-side with the ICD leads."

One of the first in Michigan to offer the **remedē<sup>®</sup>** System as a treatment option, "we have implanted four and all of the patients indicate significant improvements in their sleep with resolution of more than 90% of central sleep apnea," explained Dr. Khan.

The criteria for use includes patients with moderate to severe CSA only or a mixed CSA and OSA, which many cardiac patients with heart failure or atrial fibrillation experience.

The next step according to Tom, "Once the lead was placed on the diaphragm and healed in place, the electrodes were activated and adjusted to work as I slept on the right or left side or on my back." With the **remedē<sup>®</sup>** System, Tom no longer feels tired or needs to nap four or five times a day. "After the device was activated, I average about 1.3 hours per night of deep sleep and I'm feeling better — it was a life changer."

**If you have a patient experiencing or diagnosed with Central Sleep Apnea, they may be a candidate for remedē<sup>®</sup> System. For a consultation, please contact Henry Ford Cardiac Electrophysiology Dr. Khan, at [akhan2@hfhs.org](mailto:akhan2@hfhs.org).**



Arfaat Khan, M.D.



Maria Tovar, M.D.

## Novel clinical trial with virtual patient participation

Henry Ford Health was part of a multi-institutional heart failure study that was launched and executed completely virtual during the early phase of the COVID-19 pandemic. This novel study design lays the groundwork to be a model for future research.

Researchers in this study engaged directly with more than 400 patients through a mobile app and secure website to collect participants' data and other information. Patients received study medication delivered to their home, used the mobile app and Fitbit to monitor their physical activity and completed online symptom surveys. Enrollment was about five times faster than the average in-person heart failure clinical trials.

David Lanfear, M.D., M.S., a Henry Ford advanced heart failure specialist and researcher, said the virtual study is believed to be the first randomized drug study of its kind in cardiology. He was among the eight co-authors on the study published in *Nature Medicine*.

"This study demonstrated that you can execute a virtual clinical trial with greater efficiency than a traditional, in-person trial," Dr. Lanfear said. "This could lead to more people getting involved in medical research because of the convenience of participating from home and the potential for lower costs and faster results."

With the help of Dr. Lanfear, Zack Malouf, M.D., lead clinical study coordinator at Henry Ford enrolled 62 patients in the study, second highest among the 18 U.S. participating health systems. A total of 476 patients were enrolled between March 2020 and February 2021 ranging in age from 20 to 94 years old. The aim of the study was to test the impact of a heart failure drug on system severity and quality of life in heart failure patients.

The study drug was canagliflozin, a sodium-glucose co-transporter 2 inhibitor (SGLT2i) that had not been tested in heart failure. This class of drugs is relatively newer as a heart failure treatment but has shown improved clinical outcomes in patients in large randomized traditional clinical trials. The study was also unique in the way it focused on how patients feel and live, which is sometimes referred to as patient reported outcomes.

Dr. Lanfear said the study results showed improved symptoms and health status in patients, adding to the growing body of evidence on the benefits of this class of medications. "Improving symptom burden is one of our main goals for managing heart failure patients," Dr. Lanfear said. "Clearly, what this study showed is that these agents have meaningful impact on patients within just weeks of starting treatment, which we were able to prove using a completely virtual research approach."



David Lanfear, M.D.



Zack Malouf, M.D.



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To read the complete study,  
visit <https://go.nature.com/3RgF71k>



# TRISCEND study 30-day results

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valve disease. It is our hope that as this national study concludes the outcomes from this transcatheter valve replacement could lead to a paradigm shift in treating TR and improving patient quality of life," explained Brian P. O'Neill, M.D., structural heart research director at Henry Ford Health.

The Edwards EVOQUE system is an investigational device designed to replace the native tricuspid valve in a minimally invasive transcatheter procedure. Using a transcatheter approach, the sheath is advanced through the femoral vein to the heart. The device is then positioned and deployed to function as the tricuspid heart valve.



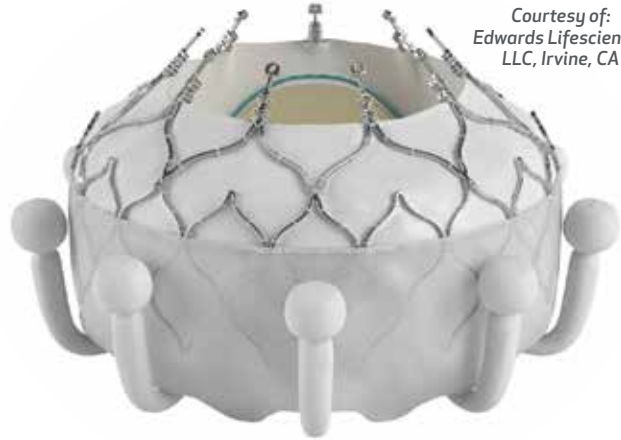
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To see the process visit:  
<https://bit.ly/TRISCENDII>

In this prospective, single-arm, multicenter TRISCEND study, patients with symptomatic moderate or greater TR, who despite medical therapy, underwent percutaneous transcatheter tricuspid valve replacement with the EVOQUE system. To date, "Henry Ford has been one of the highest enrolling sites in the trial," said Dr. O'Neill.

"We are encouraged by the 30-day results," said William W. O'Neill, M.D., medical director of Henry Ford Health's Center for Structural Heart Disease. It included 56 patients (mean age of 79.3 years, 76.8% female, 91.1% TR severe or greater, 91.1% atrial fibrillation, and 87.5% New York Heart Association (NYHA) functional class III or IV) were treated. At 30 days, TR was reduced to mild or less in 98% of the patients. The composite major adverse events rate were 26.8% at 30 days caused by one cardiovascular death in a patient with a failed procedure, two reinterventions after device embolization, one major access site or vascular complication, and 15 severe bleeds, of which none were life-threatening or fatal. No myocardial infarction, stroke, renal failure, major cardiac structural complications, or device-related pulmonary embolism were observed. NYHA significantly improved to functional class I or II (78.8%;  $P < 0.001$ ), 6-minute walk distance improved 49.8 m ( $P < 0.001$ ), and Kansas City Cardiomyopathy Questionnaire score improved 19 points ( $P < 0.001$ ).

Courtesy of:  
Edwards Lifesciences  
LLC, Irvine, CA



EVOQUE Device

Dr. William O'Neill explained, "From this early experience indications with the transfemoral EVOQUE system in patients with clinically significant TR demonstrated technical feasibility, acceptable safety, TR reduction, and symptomatic improvement at 30 days."

The TRISCEND II randomized controlled pivotal clinical trial to evaluate the safety and effectiveness of the EVOQUE System with optimal medical therapy (OMT) compared to OMT alone in the treatment of patients with at least severe tricuspid regurgitation is underway.



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To read the complete article: Kodali, S., Hahn, R., George, I, et.al., 2022 Mar 14;15(5):471-480. JACC Cardiovasc Interv. doi: 10.1016/j.jcin.2022.01.016. <https://bit.ly/JACCTRISCEND>

**Enrollment for the TRISCEND II Pivotal study is open. To determine if a patient might qualify for this study, please contact Research Coordinator Alyson Erving at [aerving1@hfhs.org](mailto:aerving1@hfhs.org).**



Research

# Tricuspid valve studies

The following Tricuspid Valve studies are currently enrolling patients. To learn more about the study and enrollment criteria visit the Clinical.gov site listed.

## CLASP II TR

**Principal Investigator:** William O’Neill, M.D.

**Official Title:** A prospective, multicenter, randomized, controlled pivotal trial to evaluate the safety and effectiveness of transcatheter tricuspid valve repair with the Edwards PASCAL Transcatheter Valve Repair System and optimal medical therapy (OMT) compared to OMT alone in patients with tricuspid regurgitation.

**Description:** To establish the safety and effectiveness of the Edwards PASCAL Transcatheter Repair System in patients with symptomatic severe tricuspid regurgitation who have been determined to be at an intermediate or greater estimated risk of mortality with tricuspid valve surgery by the cardiac surgeon with concurrence by the local Heart Team.

**Expected Completion:** December 2024

**Link:** <https://bit.ly/CLASPSTUDY>



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## TRISCEND II Pivotal

**Principal Investigator:** William O’Neill, M.D.

**Official Title:** Edwards EVOQUE tricuspid valve replacement: investigation of safety and clinical efficacy after replacement of tricuspid valve with transcatheter device.

**Description:** Early feasibility study to assess safety and performance of the Edwards EVOQUE Tricuspid Valve Replacement System.

**Expected Completion:** 2025

**Link:** <https://bit.ly/TRISCENDII>



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Innovation

# PCI case presented live at TCT

Khaldoon Alaswad, M.D., Henry Ford Health interventional cardiologist, performed a complex PCI with heart support live from Henry Ford Hospital’s catheterization lab to an international and national audience during the annual TCT conference. Mr. Dufault, a 57-year-old male patient, was initially evaluated for CABG however poor left ventricular function made the patient too high risk for surgery. He was told, “there is nothing we can do for you” and “you might qualify for a heart transplant but you have to wait for the appropriate heart to come.”

The patient had severe three vessel coronary artery disease with ischemic cardiomyopathy with an ejection fraction of 15–20%. Dr. Alaswad shared, “Mr. Dufault did very well, agreed to help us educate our colleagues nationally and around the world to learn Henry Ford’s protocols and innovative techniques.” He will return to be followed by our Advanced Heart Failure team.



Photos courtesy of VAS BioMedical Communications



# First specialty ICU dedicated to cardiovascular at Henry Ford Macomb Hospital

To meet the expanding cardiac services provided at Henry Ford Macomb Hospital, the 24-bed SICU Unit (2500) was reconfigured into two separate and distinct units: dedicated 12-bed cardiovascular ICU and 12-bed surgical ICU, both with separate operations. Each unit has dedicated staff who specialize in adult cardiac surgery, thoracic surgery and cardiology and vascular care. Cardiac ICU Medical Director Jelena Arnautovic, D.O., explained, "This is a transitional phase as we await the completion of the new tower in the summer (2023) which will house a 20-bed dedicated cardiovascular intensive care."

Barbara Rossmann, president and CEO said, "We're excited to have the CVICU as our first specialty ICU at Henry Ford Macomb. It will serve as the blueprint for future specialty units as we prepare to transition into the new patient tower, expanding from the current 48 ICU beds to a total of 60 ICU beds."

Raed Alnajjar, M.D., director, division of cardiothoracic and cardiovascular intensive care unit medical director explained, "Due to the increased volume and complexity of our cardiovascular cases at Henry Ford Macomb Hospital, and in line with our expansion of services, a dedicated CVICU is essential to our strategic growth."

Dr. Arnautovic adds, "We have excellent services in the catheterization lab and surgery, but care does not stop at those doors. These patients with more severe disease or illness require the complex care and monitoring we provide. By expanding our ICU services, we look forward to partnerships with other Henry Ford facilities to provide care for more complex cases like cardiogenic shock, thrombotic complications, and complex structural heart disease."

The mission of the CVICU is to provide the highest level of evidence-based medicine, compassion, and education in caring for our Henry Ford Macomb patients. The unit will provide a respectful, team-oriented environment for patients and families with focus on safety and high-quality care of our patients, families, and team members.

"With my cardiovascular expertise and earlier background as a CICU nurse as well, I know what goes into building a successful program," said Dr. Arnautovic. "There is unlimited growth potential for a CVICU at Macomb with proper education and training for staff and the right protocols in place. This means we can provide advanced cardiovascular care in our own hospital and serve patients who come to us from outlying areas."

Dr. Arnautovic and Dr. Alnajjar serve as the physician leaders for the project. Jill Murphy, R.N., serves as clinical nurse manager and Amanda Tiseo, R.N., as clinical educator. The CVICU will provide medical education opportunities for fellows, residents, and advanced practice providers with priority for Henry Ford Health and MSU affiliated programs.

**For career opportunities in the CVICU, please reach out to Jill Murphy, R.N., nurse manager, at (586) 263-2525 or [jmurphy4@hfhs.org](mailto:jmurphy4@hfhs.org).**



Raed Alnajjar, M.D.



Jelena Arnautovic, D.O.



Jill Murphy, R.N.

## TAVR outcomes: Henry Ford Macomb Hospital

In just under two years, Henry Ford Macomb Hospital's structural heart program has performed over 150 successful TAVR cases, with no mortalities. The expansion of the TAVR program began in late 2019 when William W. O'Neill, M.D., medical director for Structural Heart Disease and Interventional Cardiologist Brian O'Neill, M.D., joined forces as lead operators to support their interventional cardiology colleagues at Henry Ford Macomb Hospital to become TAVR operators.

Nikhil Ambulgekar, M.D., interventional cardiologist, explained, "With this level of support we have learned from the best, those who have been performing TAVR from the start. They continue to share their experiences and we can all only get better at what we do as we expand services to our community. This collaboration has saved lives and given our patients access to care closer to home."

Dr. Ambulgekar shared that Henry Ford Macomb Hospital has achieved milestones of success above the national average because, "In addition to the patient's primary cardiologist assessing the patient, we have a vigorous review process to determine what options are best for each patient. We review CT scans, echocardiograms and cardiac catheterizations using a multidisciplinary team approach with our other interventional cardiologists here and at Henry Ford Hospital."

The CT imaging is done at Henry Ford Macomb Hospital, and through a collaborative effort Dee Dee Wang, M.D., director of Structural Heart Imaging and James Lee, M.D., Structural Heart Imaging, read them and "create 3-D heart structural models from the CT images. These 3D heart models provide valuable information to help us choose the correct device and guide us through the TAVR procedure for each patient. We look at access points and look for potential pitfalls that we might encounter with each patient so we can plan in advance how to prevent or manage the situation," said Dr. Ambulgekar. In addition, "To reduce the potential for stroke, we are now using the Sentinal™ embolic device in the patients whose anatomy allow it, if not we use carotid compression to minimize stroke risk." He stated, "Our outcomes indicate success with this approach."

In part, said Samer Kazziha, M.D., interventional cardiologist at Henry Ford Macomb Hospital, "We developed this very strategic and considered process to guide our team to make the best decision for and with each patient. It might be a transfemoral, transapical, subclavian or transaortic approach or surgery, whichever is the best option. If the patient is a better candidate for carotid approach and one of our colleagues at Henry Ford Hospital has performed this more complicated procedure or if there is a potential the patient might need ECMO or an Impella® heart pump, we do what is best for the patient."

Dr. Ambulgekar, just five years out of his fellowship, finds this "the most exciting program I have been in with the level of mentorship and tutoring from pioneers in the field who only want to offer patients in our community a procedure that is needed — there's no sense in gamesmanship. We are all just trying to do what's best for the patient. Kudos to the Structural Heart team at Henry Ford Hospital for their support to bring this procedure to our community," he concluded.

**To refer a patient to a Heart & Vascular physician at Henry Ford Macomb Hospital, call 586-263-2030.**



Nikhil Ambulgekar, M.D.



Samer Kazziha, M.D.



William W. O'Neill, M.D.





## Staff update

### Waleed K. Al-Darzi, M.D.

Cardiologist



#### Medical school education

Ain Shams University Faculty of Medicine, Cairo, Egypt

#### Fellowships

Henry Ford Hospital, Detroit, MI, Cardiovascular Disease

Henry Ford Hospital, Detroit, MI, Advanced Heart Failure

#### Residencies & internships

Henry Ford Hospital, Detroit, MI, Internal Medicine

#### Board certifications

American Board of Internal Medicine (ABIM) – Cardiovascular Disease

American Board of Internal Medicine (ABIM) – Internal Medicine

#### Research interests

Dr. Al-Darzi's research interests include cardiogenic shock, mechanical circulatory support devices, and cardiorenal syndrome.

Dr. Al-Darzi also speaks Arabic.



Waleed K. Al-Darzi, M.D.  
Henry Ford Health Center – Brownstown  
Henry Ford Hospital  
Henry Ford Wyandotte Hospital

### Matthew W. Ebinger, D.O.

Electrophysiology, Cardiology



#### Medical school education

Michigan State University Office of the Registrar, Ann Arbor, MI, Internal Medicine

#### Fellowships

Henry Ford Hospital, Detroit, MI, Electrophysiology

Wayne State University School of Medicine, Detroit, MI, Cardiovascular

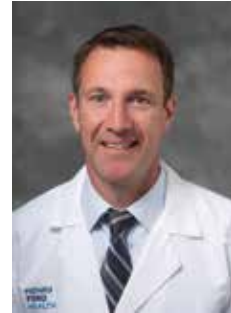
#### Residencies & internships

Detroit Medical Center/ Sinai Grace Hospital, Detroit, MI, Internal Medicine

#### Board certifications

American Board of Internal Medicine (ABIM) – Cardiovascular Disease

American Board of Internal Medicine (ABIM) – Clinical Cardiac Electrophysiology



Matthew W. Ebinger, D.O.  
Henry Ford Hospital  
Henry Ford West  
Bloomfield Hospital

### Pedro A. Engel, M.D.

Interventional Cardiology



#### Medical school education

Northwestern University, Feinberg School of Medicine, Chicago, IL

#### Fellowships

Henry Ford Hospital, Detroit, MI, Structural Heart Disease Interventional Fellowship

University of Texas Southwestern Medical Center, Dallas, TX Interventional Cardiology Fellowship

University of Texas Southwestern Medical Center, Dallas, TX Cardiovascular Disease Fellowship

#### Residencies & internships

McGaw Medical Center of Northwestern University, Chicago, IL, Internship and Residency in Internal Medicine

#### Board certifications

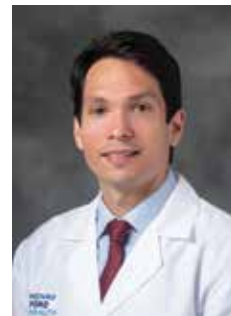
American Board of Internal Medicine (ABIM) – Cardiovascular Disease

American Board of Internal Medicine (ABIM) – Interventional Cardiology

#### Research interests

Dr. Engel's research interests are developing and utilizing patient registries to evaluate outcomes related to minimally-invasive interventions for structural heart disease.

Dr. Engel is fluent in Spanish with a working knowledge of Portuguese.



Pedro A. Engel, M.D.  
Henry Ford Hospital  
Henry Ford West  
Henry Ford Wyandotte Hospital



## Staff update

### Karl J. Ilg, M.D.

Cardiology, Electrophysiology



#### Medical school education

Wayne State University  
School of Medicine,  
Detroit, MI

#### Fellowships

University of Michigan,  
Electrophysiology,  
Ann Arbor, MI

University of Michigan,  
Cardiovascular Disease,  
Ann Arbor, MI

#### Residencies & internships

University of Michigan,  
Internal Medicine,  
Ann Arbor, MI

#### Board certifications

American Board  
of Internal Medicine (ABIM) –  
Cardiovascular Disease



Karl J. Ilg, M.D.  
Henry Ford Hospital  
Henry Ford Medical  
Center – Fairlane  
Henry Ford Medical  
Center – Royal Oak

### Kellsey Peterson, M.D.

Cardiology



#### Medical school education

State University of New York  
(SUNY), Syracuse, NY

#### Fellowships

Albany Medical Center,  
Albany, NY, Cardiology

#### Residencies & internships

Albany Medical Center,  
Albany NY, Internal Medicine

University of Rochester,  
Rochester, NY  
Internal Medicine

#### Board certifications

American Board of  
Internal Medicine (ABIM) –  
Internal Medicine

Certification Board of  
Nuclear Cardiology (CBNC),  
Board of Nuclear Cardiology

Examination of Special  
Competence in Adult  
Echocardiography, National  
Board of Echocardiography

American Board of  
Internal Medicine (ABIM) –  
Cardiovascular Disease  
(pending Oct. 2023)

#### Research interests

Dr. Peterson's research  
interests include women's  
cardiovascular health and  
the challenges regarding  
optimizing lipid management.  
She has presented at  
numerous national  
conferences on her research  
in echocardiographic  
measurements related to  
heart failure readmission.  
She has also published in  
the field of stable coronary  
artery disease.



Kellsey Peterson, M.D.  
Henry Ford West  
Bloomfield Hospital



## Staff update

### Kaitlyn M. Rountree, D.O.

Vascular Surgery



#### Medical school education

A.T. Still University,  
Kirksville, MO

#### Fellowships

University of Missouri,  
Columbia, MO, Vascular  
Surgery

#### Residencies & internships

Henry Ford Macomb Hospital,  
Clinton Township, MI  
General Surgery

#### Board certifications

American Board of Surgery –  
General Surgery

#### Research interests

Dr. Rountree's research  
interests include tissue  
coverage following  
vascular reconstruction  
and limb salvage.



Kaitlyn M. Rountree, D.O.  
Henry Ford Vascular  
Surgery – Clinton Township

### Minh Quan Vu, M.D., FRSCS

Cardiothoracic Surgery



#### Medical school education

Université de Montréal,  
Faculty of Medicine,  
Montréal, Canada

#### Fellowships

Cleveland Clinic, Cleveland,  
OH, Department of Thoracic  
and Cardiovascular Surgery,  
Robotic and Minimally  
Invasive Clinical Associate

Mount Sinai Morningside,  
New York City, NY  
Advanced Coronary Surgery

#### Residencies & internships

Université de Montréal,  
Faculty of Medicine,  
Montréal, Canada,  
Cardiac Surgery

#### Board certifications

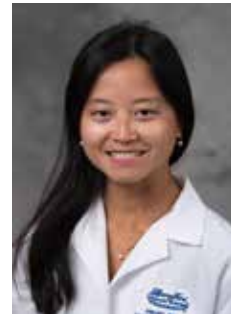
Postgraduate Medical  
Training License,  
College of Physicians  
of Quebec

Medical Council of Canada

#### Research interests

Dr. Vu's research has  
covered stem cell therapy  
in ischemic heart failure at  
the experimental level  
as well as pharmacological  
endothelial preservation.

Dr. Vu also speaks fluent  
French and Vietnamese.



Minh Quan Vu, M.D., FRSCS  
Henry Ford Jackson  
Hospital



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  
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Detroit, MI 48202

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## In the news

### ACC announces Henry Ford Cardiologist to 2023 slate of officers and board of trustees

Congratulations to Interventional Cardiologist Akshay K. Khandelwal, M.D., FACC, who was appointed chair elect for the Finance Committee for the American College of Cardiology. Starting March 2024, he will serve a three-year term as Chair of the Finance Committee; Treasurer, American College of Cardiology; and member, ACC Board of Trustees.

Dr. Khandelwal says of the appointment, "It is an honor to be nominated and confirmed by the Board of Trustees for these very important leadership roles as we collectively seek to improve heart health for patients through education and innovation."



Akshay K. Khandelwal, M.D.

### Center of Excellence robotic surgery accreditation

Henry Ford Macomb Hospital has been accredited by the Surgical Review Corporation (SRC) as a Center of Excellence in Robotic Surgery. Raed Alnajjar, M.D., and Ryan Nelson, D.O., are accredited as Surgeons of Excellence in Robotic Surgery. SRC is an internationally recognized, nonprofit, patient safety organization dedicated to recognizing and refining surgical care. SRC's accreditation recognizes robotic surgery programs that demonstrate an unparalleled commitment and ability to consistently deliver safe, effective, evidence-based care.

