HENRY FORD HEALTH®
Heart & Vascular

CardioBeat Spring/Summer 2022

TAVR: 10 miraculous years of saving lives

William W. O'Neill, M.D.

Twenty years ago, renowned Interventional Cardiologist Alain Cribier, M.D., was observed performing the first in the world TAVR (or TAVI) procedure at Charles Nicolle University Hospital in Rouen, France by Interventional Cardiologist William W. O'Neill, M.D. "I recall thinking it was a very complicated, intricate procedure where we went in backwards from the right atrium to the left atrium and around the mitral valve to the aortic valve. I wasn't sure it would even be possible to do," shared Dr. O'Neill, medical director of Henry Ford Health's Center for Structural Heart Disease.

In February of 2005, Dr. O'Neill performed the first successful TAVR procedure in North America at Beaumont Hospital. At that time there were only two other hospitals in the nation where TAVR was being attempted. Dr. O'Neill recalls of that early experience, "There were seven TAVR patients in the U.S., only three (ultimately) survived, including two of my patients."

Dr. O'Neill explained, "About a year and half later, Edwards Lifesciences led the redesign of TAVR using the femoral artery, making the device more flexible, much easier and safer to deliver the valve, aligning

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The Henry Ford Vein Center: a multispecialty, patient-centered approach

Paul Corcoran, M.D.

Patients with vein and vascular diseases will find many benefits due to an extraordinary effort to create a collaboration among the vascular specialists of The Henry Ford Vein Center. A multispecialty approach of vascular medicine, vascular surgery, plastic surgery, and interventional radiology ensures each patient will receive appropriate treatment for their condition or disease.

"It doesn't really matter where a patient enters the system for vein or vascular care, our goal is to ensure they see the expert who is specialty trained to care for their condition and follows the appropriateness protocols of care," explained Timothy J. Nypaver, M.D., chief of Vascular Surgery. "Often patients with vascular issues do not recognize a vascular condition or understand that treatment can relieve their symptoms, discomfort or pain."

Paul Corcoran, M.D., medical director of The Henry Ford Vein Center, explains that "The continuity of care provided by our team of experts within a multispecialty Vein Center is what ensures our patients will

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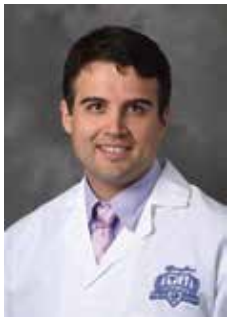
Inside

Research

LAVA-ECMO: effective in cardiogenic shock complicated by biventricular failure



Pedro Villablanca, M.D.

Waleed Al-Darzi, M.D.

Believed to be one of the only sites in the country performing **L**eft **A**trial **V**eno-**A**rterial **E**xtra**c**orporeal **M**embrane **O**xygenation (LAVA-ECMO), structural heart cardiologists conducted a retrospective analysis of hemodynamic changes and in-hospital outcomes for 25 consecutive patients treated at Henry Ford Hospital in Detroit between July 2020 and January 2022.

Cardiogenic shock (CS) complicated by biventricular heart failure remains associated with high mortality. Mechanical circulatory support (MCS) options include the use of two uni-ventricular MCS devices or VA-ECMO. VA-ECMO is commonly used in patients presenting with biventricular failure with cardiogenic shock as a bridge to myocardial recovery, durable left ventricular assist device, or cardiac transplantation. However, use of VA-ECMO in CS can result in increased afterload with observation data suggesting that such patients do better with left ventricular (LV) unloading.

Pedro A. Villablanca, M.D., director, Structural Heart Fellowship Interventional Cardiology explained, the LAVA-ECMO technique involves echo-guided transseptal entry into the left atrium, insertion of a stiff wire into the pulmonary vein or left atrium, followed by balloon dilatation of the septum as needed, and then over-the-wire implantation of a single 24-Fr venous cannula (VFEM024; Edwards Lifesciences) with a long fenestrated segment (15 cm). "It unloads, or vents, on both the left and right sides of the heart at the same time with a single cannula, rather than requiring an additional large-bore arterial access on top of the regular VA- ECMO configuration which is what happens when Impella® is added to help unload the LV."

LAVA-ECMO is a feasible option for patients in cardiogenic shock for whom Impella® offloading is contraindicated. Early data suggests use of LAVA-ECMO appears to be a safe and feasible means of support for patients with CS complicated by biventricular failure.

Through the LAVA FORD registry, 25 consecutive patients of several Henry Ford cardiologists, who underwent LAVA-ECMO for cardiogenic shock between July 2020 and January 2022 were identified. Of the population, the mean age was 64.6 (+2.5), 20 male, body mass index 32 (+7.2), comorbidities: smoking history 5 (20%), hypertension 16 (64%), diabetes mellitus 9 (36%), hemodialysis 5 (20%), prior myocardial infarction 5 (20%), and prior cerebrovascular accident 2 (8%). The baseline SCAI Shock class rendered: B-1 (4%), C-7 (28%), D-13(52%), and E-4 (16%).

Table 1 displays the baseline echocardiograph parameters:

Table 1: Baseline Echocardiographic Parameters

N=25	N (%)
Left ventricular ejection fraction %; mean (± SD)	36 (± 20)
Right ventricular dysfunctions	17 (68%)
Right ventricular systolic pressure mmHg; mean (± SD)	53 (± 13)
Severe aortic regurgitation	8 (32%)
Severe mitral regurgitation	7 (28%)
Severe tricuspid regurgitation	6 (24%)
Severe mitral stenosis	1 (4%)
Severe aortic stenosis	6 (24%)

Dr. Villablanca explained that the results of the limited, single site study indicated that LAVA-ECMO provides biventricular support with a single circuit and use of a single large bore access with low incidence of direct complications making it both safe and feasible in the hands of experienced structural heart cardiologists. The process is effective in both left arterial (LA) and LV unloading when utilized mostly in patients with severe valvular heart disease. Table 2 displays the LAVA-ECMO procedure characteristics and outcomes of use in the study participants.

In conclusion, Dr. Villablanca explained the study showed improved hemodynamics and that LAVA-ECMO is a successful bridge to therapy/decision, using a simplified configuration, yet prospective studies are still needed.

Table 2: LAVA-ECMO Procedural Characteristics and Outcomes	
N=25	N (%)
Number of days on LAVA-ECMO; Mean (SD)	7.25 (±6.3)
Ipsilateral Reperfusion Sheaths	22 (88%)
Intracardiac Echocardiography used as Imaging Modality	22 (88%)
Additional Left Ventricular Unloading used	2 (8%)
Decannulation	20 (80%)
Destination	
Durable LVAD	2 (8%)
Heart Transplant	3 (12%)
Percutaneous or Surgical Valve Replacement	11 (44%)
Coronary Artery Bypass Grafting	1 (4%)
Ventricular Septal Defect Surgical Repair	1 (4%)
Death on ECMO	4 (12%)
Bridge to decision	4 (16%)
In-Hospital Complications	
Stroke	3 (12%)
Limb Ischemia	2 (8%)
Access Site Hematoma	3 (12%)
Hemolysis	1 (4%)
Non-Access Site Bleeding	7 (28%)
Infection (Including cellulitis, line, pneumonia)	7 (28%)
New Renal Replacement Therapy	5 (20%)
Alive Status at Hospital Discharge	13 (52%)

The findings of this study were presented and well received at the Technology and Heart Failure Therapeutics (THT) 2022 meeting in New York by Henry Ford Fellow Waleed Al-Darzi, MBBCh.

For more information, visit: https://www.tctmd.com/news/lava-ecmo-early-data-point-hemodynamic-benefits-safety

Doctor

CTO-Complex PCI Live Aid 2022 to Support Hospitals in Ukraine

Khaldoon Alaswad, M.D., a world-renowned Henry Ford interventional cardiologist who specializes in catheter-based treatment of heart blockages, was one of only two U.S. doctors to perform a live procedure during a 15-hour marathon of cases that took place around the world on June 9, 2022. Each of the cardiologists who participate are specialists in Chronic Total Occlusion (CTO) and Complex Coronary Artery Disease catheter-based therapies.

CTO Live Aid is a fundraiser designed to help international Medical Non-Governmental Organizations. Proceeds raised this year will benefit Support Hospitals in Ukraine.

Conceived by cardiologists in Milan, Italy, 26 international renowned interventional cardiologists at 24 medical centers were invited to participate in the event. Through livestreamed sessions, medical professionals from around the world joined to watch CTO cases performed one after another.

"This is a unique opportunity to teach and learn from the best interventional cardiologists around the world as we all continue to learn from each other to save and improve the lives of our patients," said

Khaldoon Alaswad, M.D., during PCI Live Aid 2022

Dr. Alaswad, director of the Catheterization Laboratory. "It is an honor to once again be asked to participate in such an important event. It is our opportunity to showcase the advanced work being done at Henry Ford Hospital."

All patients have generously given permission for their case to be shared during the live event.

Donations can be made to Support Hospitals in Ukraine, an international humanitarian project, at https://www.cto-liveaid.com/.

TAVR: 10 miraculous years of saving lives

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with the natural blood flow rather than against it which is how it's being done today."

On March 20, 2012, Mayra Guerrero, M.D., who had been one of Dr. O'Neill's fellows at Beaumont Hospital and now was part of the Henry Ford Medical Group, invited Dr. O'Neill to proctor her, Adam Greenbaum, M.D., and Gaetano Paone, M.D., in their first TAVR procedure at Henry Ford Hospital in Detroit. Today's team is quick to credit Dr. Guerrero for recognizing the importance of TAVR in the treatment of aortic valve disease and opening the door for Dr. O'Neill to make Henry Ford Hospital in Detroit his home where he built the Structural Heart Disease program and advanced TAVR as a procedure and its accessibility.

"Over several years, the valve devices were also improved to reduce leaking and expanding the sizing of devices to allow for smaller and larger valves. This meant TAVR was possible for half the women who otherwise would not have been candidates for the larger devices, and larger to provide a better fit for larger men. The catheters that deliver the valves were also improved. They became smaller in diameter, allowing us to enter the large femoral artery without using a surgical cutdown. Because the catheter just slides in, about 90 percent of patients can have the procedure through the femoral artery rather than surgery," explained Dr. O'Neill.

In 2015, interventional cardiologists at Henry Ford were the first in the world to use the Transcaval approach, a unique procedure, which accesses the heart for valve replacement by temporarily connecting major blood vessels in the abdomen. This procedure is used when scar tissue, small arteries or other medical issues prevent traditional access to the heart going through the vein and a parallel artery in the abdomen. A smaller catheter is moved through the vein, across the bridge and up through the artery into the heart to implant a new artificial aortic heart valve.

The early days

Prior to Dr. O'Neill's arrival as medical director of the Henry Ford Hospital in Detroit Structural Heart Disease program, Helen Constan, R.N., lead nurse, Structural Heart Catheterization Lab remembers, "Dr. Guerrero and Dr. Greenbaum, then director of the Cath Lab, prepared the team by explaining we would be doing something fascinating and new. They told us we would need to think outside the box to help patients who had no other options medically or surgically. We were both excited and scared."

Janet Wyman, DNP, ACNS-BC, RN-CS, FACC, administrative director, Structural Heart Disease Clinical Services, said,

TAVR Research Pathway and FDA Approval Timeline

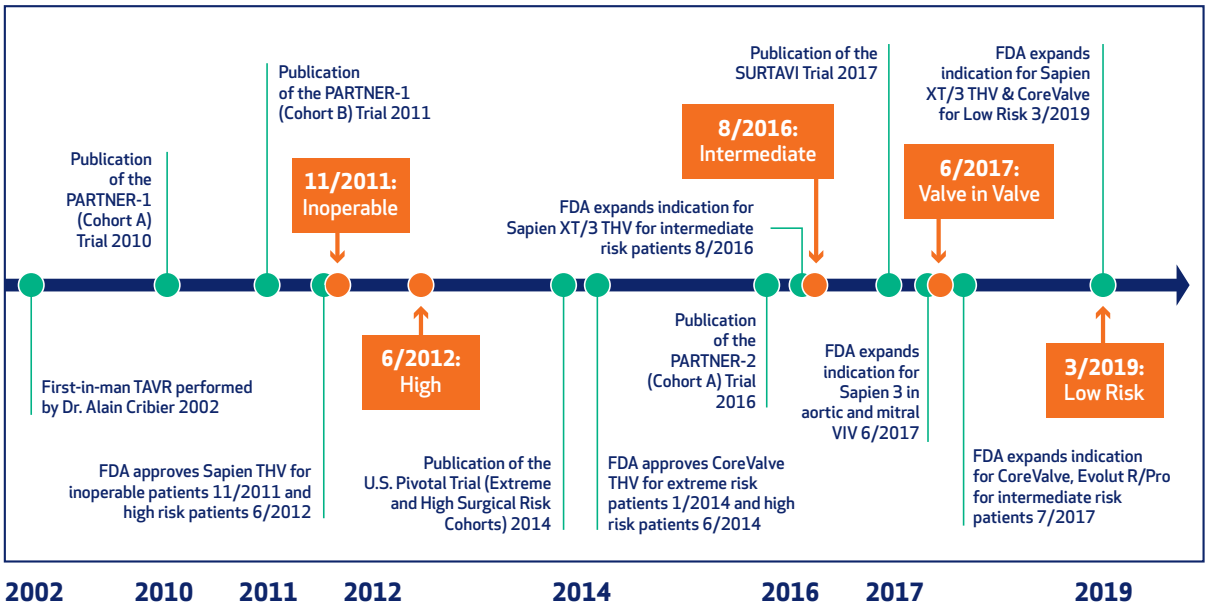

Figure 1: FDA/Research Timeline

"We recognized we were in the midst of a paradigm shift, it was happening right before our eyes. It was a total philosophical change for us and looking back we made the transition well." Dr. Wyman shared, "Because the FDA had only approved TAVR for the sickest of patients, we had to acknowledge some patients would not survive, but for many their lives would be saved." Dr. O'Neill reflected, "To me it was miraculous that we would be able to save the lives of so many patients who otherwise would have died."

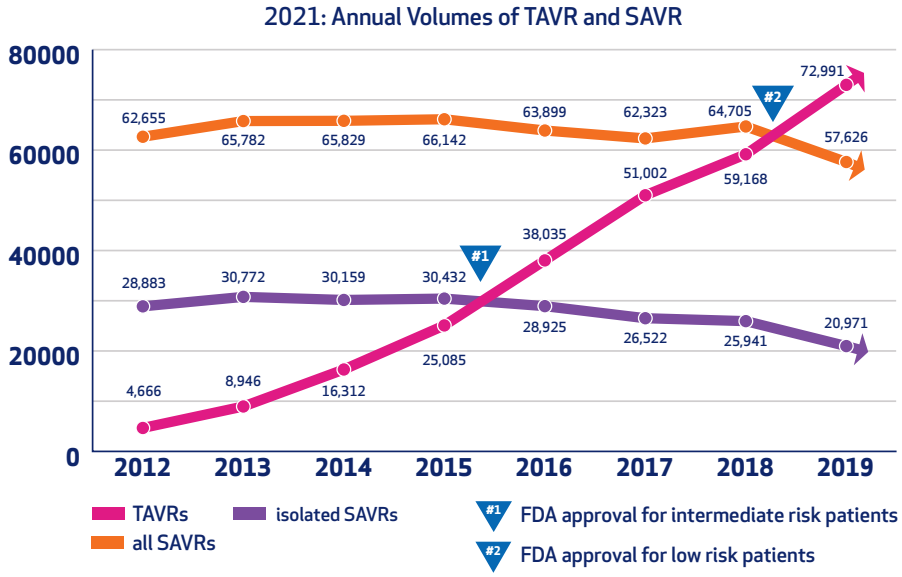

Figure 2: Impact FDA Approvals Made On Patient Volume

Carroll JD, et.al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. Ann Thorac Surg. 2021 Feb;111(2):701-722. doi: 10.1016/j.athoracsur.2020.09.002. Epub 2020 Nov 16. PMID: 33213826.

Earliest TAVR patient shares her experience

As an 8 year-old, Madge Renius of Rochester Hills had Rheumatic fever, then again at 34 being hospitalized this time at Henry Ford. "I'm pretty sure that caused my life-long heart valve issues," Madge explained. Today 92 year-old, Madge can share a thing or two about how heart valve replacement and repair has evolved over the decades.

She was in her early 60s when she first met Dr. O'Neill. He performed a mitral valvuloplasty in 1990. Needing a mitral valve replacement eight years later, she was disappointed to learn Dr. O'Neill had left the area. "I went to an out-of-state hospital which was not a great experience," Madge explained. While pointing to her back, chest and under her ribcage to show all the surgical entries she explained in 2010 she had second mitral valve replacement at the University of Michigan.

"My husband Otto was a scientist and always believed in going to doctors who were on the cutting edge," she said. So in 2015, when Madge met up with Dr. O'Neill again at Henry Ford and "he explained to me that TAVR was a new procedure and they would go through my artery to insert this new heart valve, I said yes," she shared. Dr. O'Neill performed a TAVR aortic valve replacement and a TMVR mitral valve replacement on Madge. "She was one of our first patients to receive TAVR at the age of 86," Dr. O'Neill explained. "She may be my longest surviving patient."

Henry Ford Health patient Madge Renius

In April 2022, at 92 years-of-age Madge had another TAVR procedure. This time Madge agreed to be part of the annual American College of Cardiology (ACC) conference. Her recent TAVR procedure was seen live from Henry Ford by thousands of cardiovascular professionals around the world who gathered to learn from Dr. O'Neill and TAVR team.

Recovering well, she is eager to get back to mowing her own lawn and is excitedly awaiting the arrival of two great grandchildren over the summer, "one of each and I can't wait," she beamed.

"I'm so thankful for Dr. O'Neill, he's saved my life over and over again and I love his hugs every time I see him," Madge said with a big grin.

The entire TAVR team agrees, the bravery of all those patients who were willing to participate in the journey to improve the care of people with valve disease are always remembered, recognized and appreciated. They are the true heroes in this innovation. Each patient contributed to the science of bringing TAVR into the mainstream of structural heart treatment in the future whether they survived or not.

Philosophical and facility change

Much had to change, from the mindset and philosophy to the facility that needed updates to accommodate the anticipated volume and an entirely different procedure choreography.

Creation of a new program has a multitude of activities that must occur behind the scenes. For the emerging Structural Heart team, it meant developing a research lab, training, research, funding, and facility enhancements. Dr. Wyman recalled a tour she conducted with the Edwards Lifesciences team to gain inclusion in the first PARTNER (**P**lacement of **A**o**RT**ic tra**N**scathet**ER** valves) trial for TAVR which began nationally in February 2011.

Janet Wyman, DNP, RN-CS

"For Henry Ford to be part of the PARTNER trial, a research lab was required. We called the visit of the Edwards team and the trial sponsors, 'shock and awe'. Our goal was to exceed their expectations with the resources available at Henry Ford to convince them we were qualified to be included in the PARTNER trial and a commercial site. And we did, becoming the first commercial Edwards site in Michigan on March 20, 2012. Our first PARTNER trial patient was July 10, 2012."

Both the facility and the staffing changes evolved to accommodate TAVR procedures. Henry Ford Hospital in Detroit opened its first hybrid cath lab on March 28, 2013. Staffing of the hybrid cath lab/OR required a specialized team to perform TAVR and emergency surgery, if necessary. The assembled team included an interventional cardiologist or two, a cardiac surgeon, a cardiology fellow, two RNs and two registered cardiovascular intensive specialists, an anesthesiologist and CRNA, and a structural heart interventional imaging specialist and in most cases a clinical device representative is in the Cath Lab to assist in preparing the valve device for insertion.

PARTNER research study

"The national PARTNER research study was conducted in three phases and looked at new avenues to fix the aortic valve and decrease the risks," explained Dr. O'Neill.

From 2010-2011 the PARTNER 1 trial studied high risk and inoperable patients that were very ill and older patients who were very high risk for open heart surgery. In November 2011, the FDA approved TAVR for these patients who were otherwise inoperable. In June 2012, the FDA approved patients for TAVR who were considered high risk.

There were only 25 programs in the United States at that time, yet in 2013 Dr. O'Neill acknowledged that TAVR had the potential to help 25,000 to 50,000 patients a year in the U.S.

The results of the PARTNER 2 trial were released in 2016, and in August 2016 the FDA approved intermediate risk patients for TAVR. In June 2017 the FDA had approved valve in valve via TAVR, offering people with a failing bioprosthetic aortic valve, who had already gone through open heart surgery, a non-surgical valve replacement.

PARTNER 3 studied TAVR in lower risk patients. "The study was very successful, showing it is actually less risky for patients who are lower risk to receive TAVR valve replacement than open heart surgery. As a result of the study, the FDA approved TAVR for low-risk patients in March 2019," shared Dr. O'Neill. Figure 1 also shows the TAVR research pathway and FDA milestones achieved.

Henry Ford participated in several studies related to TAVR between 2010 and 2019, including Sapien XT/3 THV, CoreValue THV, Sapien 3 in aortic and mitral valves, and Evolut R. Figure 1 shows the timing of these important studies. Figure 2 shows the impact risk-related FDA approvals had for patients to receive TAVR.

Outcomes

TAVR outcomes at each phase of the PARTNER 1, 2 and 3 trials indicated significant improvements in all cause death and major stroke from 2012 through 2019. While the highest risk patients were in PARTNER 1 trials, these outcomes were predictive as TAVR was the last option for these patients.

Figure 3 shows the 30-day outcomes of TAVR through the three phases of the PARTNER trials. As the FDA approved TAVR for intermediate and low-risk patients, the overall deaths and stroke were significantly lower than surgery as these patients benefited from TAVR over surgical interventions. "This also comes from having more experienced operators with expertise in preparation and handling complications," said Dr. O'Neill.

First transcaval TAVR patient was out of options

Another critical point in the history of TAVR occurred on July 3, 2013 when the first transcaval TAVR was performed on 79-year-old Viola Waller of Charlevoix when it became evident that no other means would work. That's when interventional cardiologists at Henry Ford Hospital created a new route to the heart to implant an artificial heart valve by temporarily connecting major blood vessels that do not normally intersect. "We knew of an experimental technique that had not yet been done in humans, and I had a patient with no other options who was failing rapidly," said William O'Neill, M.D. "The transcaval approach is a direct result of our work with TAVR."

William O'Neill, M.D., and Henry Ford Health patient Viola Waller

Another aspect in reducing complications comes from the expertise of Dee Dee Wang, M.D., director of Structural Heart Imaging and her partner James Lee, M.D. Drs. Wang and Lee create 3-D heart structure modeling to support interventional cardiologists in TAVR. Using these heart models, interventional cardiologists are guided through the TAVR procedure and determine the valve device that best fits the patient's heart structure. Dr. O'Neill shared, "The expertise of Dr. Wang and Dr. Lee provides an inside view of a patient's heart and vascular structure which is needed for some patients. Their expertise helps all of us to collectively have better outcomes for the patient."

Dr. O'Neill shared, "TAVR really led the way for treating valve disease with catheters rather than surgery. Our experience with TAVR has allowed us to access all four of the heart valves. Not only can the left side heart valves be repaired or replaced, but we are now able to repair severe abnormalities of the mitral valve on the left and the tricuspid valve on the right side — an additional outcome of our experience with TAVR."

"We continue to be involved in research programs as we advance the field of aortic, mitral and tricuspid valve problems," explained Dr. O'Neill. Much of the success of the program has been driven by research

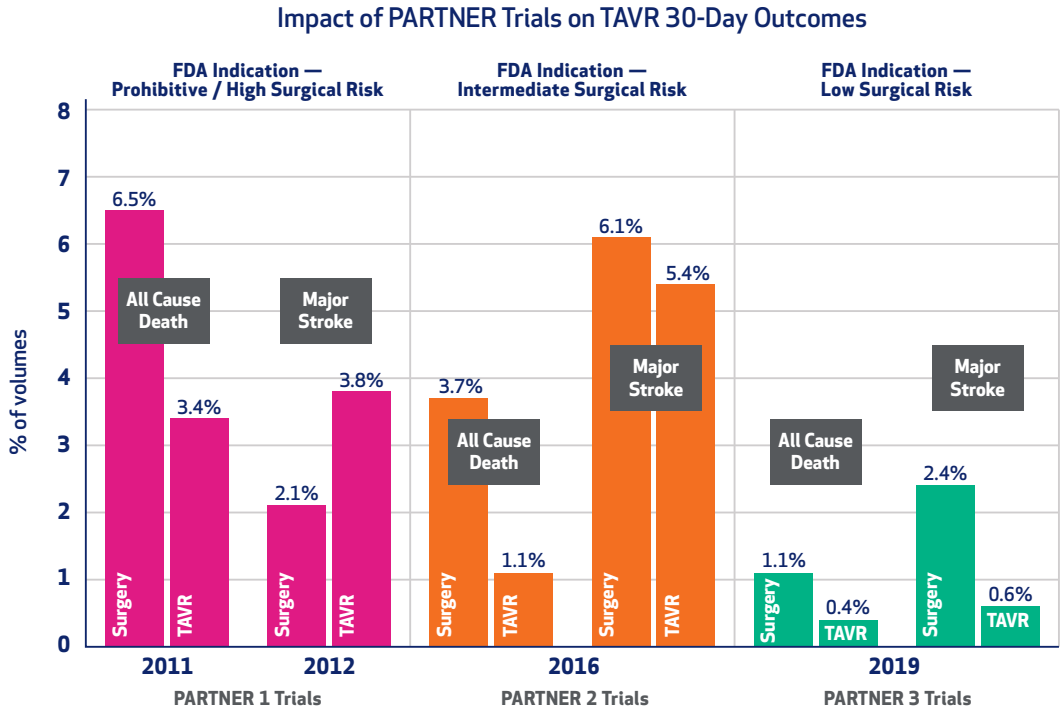

Figure 3: Impact of PARTNER Trials On TAVR 30-Day Outcomes

trials the team leads or are participants. This research program became so large and complex that in April 2020 Brian O'Neill, M.D., was recruited and joined the team to lead the research effort. Currently the Structural Heart Research team has 60 sponsored research studies with 13 FTE staff. The program now leads three national research trials.

Expansion of TAVR program

Long before approval for low-risk patients, Dr. O'Neill recognized that expansion of the Center for Structural Heart Disease into its other regions was necessary to meet the needs of the neighboring communities, allow patients to receive TAVR closer to their homes and utilize all the system's medical resources. "We made this a very successful and collaborative effort among Henry Ford Medical Group physicians and community cardiologists. It was a win for the physicians, a win for the patients, and a win for our communities," said Dr. O'Neill. "We knew that hundreds of patients would benefit from a TAVR procedure, we expanded to meet that need in Michigan, Indiana and Ohio."

The first TAVR performed at Henry Ford Jackson Hospital was guided by lead operator Tiberio Frisoli, M.D., to train and support Interventional Cardiologists Matthew Jonovich, M.D., Usman Khokhar, M.D., and Cardiac Surgeon Vincent Simonetti, M.D.

William O'Neill, M.D., was the lead operator at Henry Ford Macomb Hospital to guide Interventional Cardiologists, Samer Kazziha, M.D., Subhi Sabhi, M.D., Luay Syed, M.D., and Cardiothoracic Surgeon Raed Alnajjar, M.D., in the development of their TAVR services.

Beginning in 2019, armed with experience, knowledge and highly skilled, Center for Structural Heart Disease interventional cardiologists expanded TAVR to Henry Ford Jackson Hospital and Henry Ford Macomb Hospital. To achieve excellent outcomes in two new programs, sharing the best practices from a very experienced program and having highly experienced operators lead every case while proctoring the new operators with every case was the strategy. Tiberio Frisoli, M.D., became the lead operator at Henry Ford Jackson Hospital, to train and support the new operators — Interventional Cardiologists Matthew Jonovich, M.D., Usman Khokhar, M.D., and Cardiac Surgeon Vincent Simonetti, M.D.

Dr. William O'Neill and Brian O'Neill, M.D., supported Henry Ford Macomb Hospital as the lead operators to guide Interventional Cardiologists, Samer Kazziha, M.D., Subhi Sabahi, M.D., Nikhil Ambulgekar, M.D., Luay Sayed, M.D., and Cardiothoracic Surgeon Raed Alnajjar, M.D., in the development of their TAVR services.

On June 26, 2019 the first TAVR case was performed at Henry Ford Jackson Hospital and the first on August 7, 2019 at Henry Ford Macomb Hospital. "Each case was flawless," explained Dr. O'Neill. "We have a far better mortality rate then the rest of state for TAVR and we want to maintain that rate."

Figure 4 represents the growth of TAVR between 2012 and 2019 at Henry Ford Hospital and expansion in the fall of 2019 as Henry Ford Jackson Hospital and Henry Ford Macomb Hospital initiated TAVR procedures. Also in 2019, two Valve Clinics were started at Henry Ford West Bloomfield Hospital and Henry Ford Wyandotte Hospital who are led by Pedro Villablanca, M.D., to provide patient

evaluation and initial testing. During COVID-19 restrictions in 2020, TAVR was considered an essential procedure and patients continued to be treated safely.

In this 10th year of the TAVR program, the team has grown to include five interventional cardiologists, two interventional imagers, two surgeons, four acute care nurse practitioners, one physician assistant, six registered nurses and a research staff of two research nurse coordinators, three research coordinators and one research assistant and many others supporting the program across the system.

Dr. O'Neill believes the success of this program would not have been possible without the active, enthusiastic support of surgical partners, Hassan Nemeh, M.D., Dimitri Apostolou, M.D., Raed Alnajjar, M.D., and Vincent Simonetti, M.D.

Dr. O'Neill concluded by encouraging physicians to consider contacting the team to discuss their very symptomatic patients with valvular heart disease who might not be good candidates for surgery. He explained, "There are a lot of new technologies to treat previously untreatable patients and improve their quality of life."

A milestone 100th TAVR was performed at Henry Ford Health in Macomb and celebrated by Raed Alnajjar, M.D., Nikhil Ambulgekar, M.D., William O'Neill, M.D., Samer Kazziha, M.D., Subhi Sbahi, M.D., Kenneth Warner, M.D., and Brian O'Neill, M.D.

To refer a patient in your region, call: Henry Ford Macomb Structural Heart Disease Program: (586) 263-2221; Henry Ford Health Jackson Cardiology: (517) 205-1234; Henry Ford Health Detroit, Center for Structural Heart Disease: 855-518-5100.

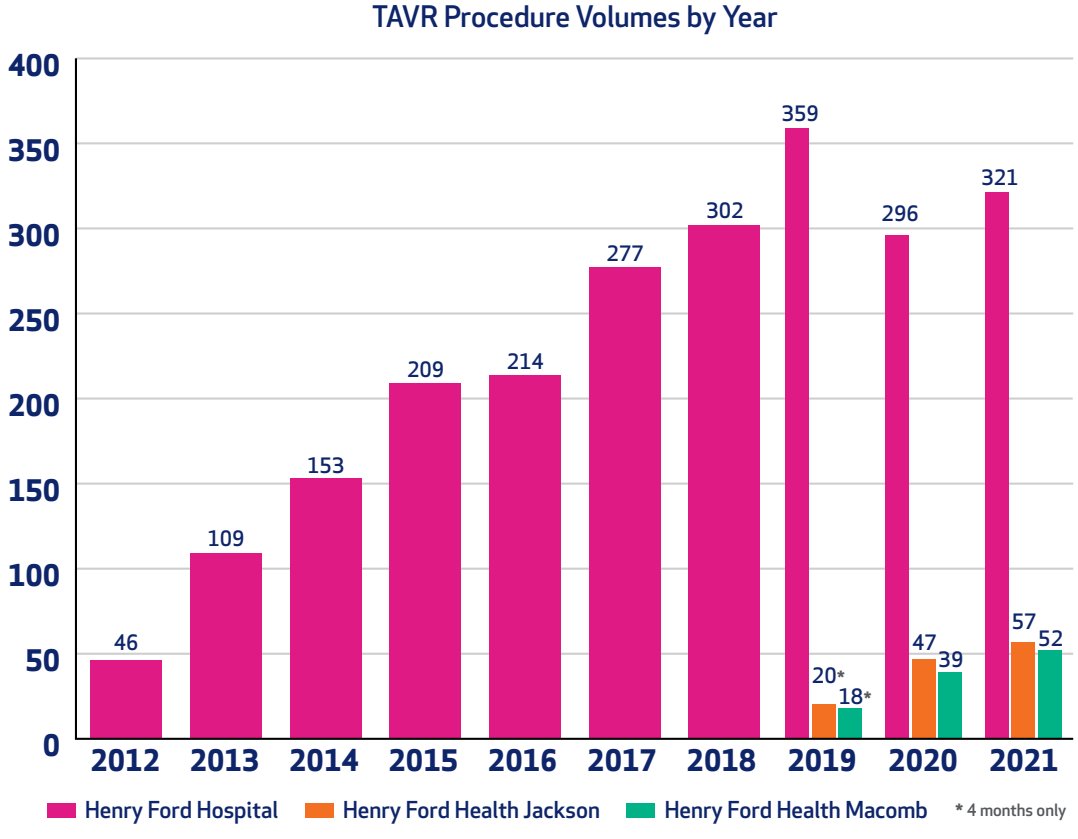

Figure 4: Expansion of TAVR at HFH

Research

Henry Ford study finds low risk of myocarditis in college athletes who recover from mild COVID-19 symptoms

Neo Poyiadji, M.D.

In a small study of college athletes who tested positive for COVID-19, researchers at Henry Ford Hospital in Detroit have found they were at low risk of developing myocarditis, an inflammation of the heart muscle. Researchers retrospectively evaluated cardiac MRI images of 39 athletes and discovered there was no evidence they developed the heart condition after a COVID-19 infection between June 2020 and January 2021.

The findings were presented at the annual meeting of the Radiological Society of North America. While the findings have not yet been peer reviewed, they do mirror more recent research that has shown the risk of college athletes developing myocarditis from COVID-19 infections ranges from 0 to 3 percent.

"If athletes have COVID-19 and develop mild or no symptoms and their initial cardiac testing is negative, it's very unlikely they'll have myocarditis," said Neo Poyiadji, M.D., a fourth-year radiology resident at Henry Ford Hospital in Detroit and the study's lead author.

Dr. Poyiadji and his research colleagues urged caution, though, because the true incidence of COVID-19 related cardiovascular disease like myocarditis in college athletes, especially those who are asymptomatic or display mild symptoms, remains unclear. Dr. Poyiadji says that further study is needed.

The 39 athletes studied ranged in age from 18 to 23 years old and all but two were male. The college students participated in a cross section of sports, but the majority played football. Each athlete underwent a cardiac MRI, using gadolinium contrast injected intravenously into the body to enhance the quality of the images being taken to diagnose a broad range of heart abnormalities like congenital heart defects, tumors, defective valves and myocarditis. The imaging scans were interpreted by cardiothoracic fellowship trained radiologists in collaboration with Henry Ford cardiologists.

Dr. Poyiadji emphasized, "Performing a cardiac MRI on every college athlete who tests positive for COVID-19 is an unnecessary use of medical testing resources and we should limit their exposure to gadolinium." Cardiac MRI is only recommended on those who have cardiac abnormalities on an echocardiogram and have persistent symptoms or heart rhythm problems despite initial negative testing.

To read the study visit:
Poyiadji N., Sennot J., Vummidi D., Ananthasubramaniam K., Song T. Cardiac Magnetic Resonance Imaging Findings in College Athletes with Recent COVID-19 Infection: Not All Doom and Gloom. Presented at RSNA. November 2021. Chicago, Illinois.
https://dailybulletin.rsna.org/db21/index.cfm?pg=21mon10

Innovation

New device for left atrial appendage closure

Marc Lahiri, M.D.

Brian O'Neill, M.D.

Henry Ford Health's Electrophysiology team was the first in the Midwest to use the WATCHMAN FXD Curve™ Access System. The new delivery system deploys the WATCHMAN FLX™ and offers smoother deployment and successful placement to the delivery of the most studied and implanted left arterial appendage closure (LAAC) device in the world.

Marc K. Lahiri, M.D., FACC, director, Cardiac Electrophysiology Fellowship Training Program and Section of Cardiac Electrophysiology explains, "WATCHMAN FXD Curve™ offers advanced control in delivery of the device with the ability to recapture and reposition the FLX™ device and redeploy to ensure a complete seal." The device has a proven safety rate, with a 0.5% complication rate and at 12 months the device has shown a 100% closure in these procedures.

"The WATCHMAN FLX™ also is available in five sizes from the smallest at 20mm to 35mm and an allowable compression of 10–30% allows us to offer treatment to more patients who may have many different anatomies," said Brian P. O'Neill, M.D., Structural Heart Interventionalist and director of Interventional Cardiology Research.

Another benefit of the FLX™ in treating LAAC is the reduction in average procedure time between WATCHMAN FLX™ and Legacy WATCHMAN. Dr. O'Neill shared, "Reducing the fluoro, contrast and general anesthesia by approximately 20 minutes is better for the patient and the cardiologist."

Designed to have quicker, complete seal for better long-term outcomes, the device has 98.8% implant success, supported by reduced metal exposure (77%) promotes healing.

To refer a patient to Henry Ford Heart & Vascular, call 1-877-434-7470.

New device

Amplatzer™ Amulet™ LAA occluder offers freedom from oral anticoagulants

A new device for patients for Left Atrial Appendage Occlusion (LAAO) is now FDA approved and available and being used by Henry Ford Health interventional cardiologists. The Amplatzer™ Amulet™ is the first and only FDA approved LAA occluder that offers immediate freedom from oral anticoagulants (OACs).

Brian P. O'Neill, M.D., Structural Heart Interventionalist and director of Interventional Cardiology Research explains, "Amulet™ makes closure an option for those with non-valvular atrial fibrillation (AF) and who are at risk of ischemic stroke. The device uses unique dual seal technology to ensure immediate and complete closure and offers an additional option to help reduce the risk of stroke in eligible patients."

Brian O'Neill, M.D.

To refer a patient to Henry Ford Heart & Vascular, call 1-877-434-7470.

Innovation

The Henry Ford Vein Center: a multispecialty, patient-centered approach

continued from page 1

receive the best treatment, from the right specialist to treat their condition," said Dr. Corcoran. "We have found that most patients arrive for what they believe to be a cosmetic procedure and Plastic Surgeon Dr. Donna Tepper recognizes the patient has a venous disease or lymphedema and quickly engages Dr. Syed Ahsan, vascular medicine, to treat and follow the same patient."

The goal is to be patient-centered in the care of each patient. Donna Tepper, M.D., shared, "It may be fixing simple spider veins that makes the patient feel better, but when I see an underlying vascular condition that the patient would not recognize, I become the intermediary so the condition can be treated by the right vascular expert."

The same is true for referring physicians. "If a physician has a patient with a vascular condition and they are not sure which specialist to refer to, just get them to us and we will guide the patient to the right vascular specialist for their condition and keep them in the loop," said Dr. Corcoran.

Syed Ahsan, M.D., said, "We know patients who need tests who are physically challenged and find it difficult to complete testing at more than one location. When possible, we offer patients all of their diagnostic testing in one same-day visit, rather than multiple visits to several locations."

Further Dr. Ahsan added, "I often see patients who have had a vascular procedure at a local vein center that does not have the capacity or a follow up treatment plan for their patients. Our Center is different. Patients who have a procedure in our Center will have a vascular expert who follows their care. This is especially important if there are complications." Dr. Ahsan explained, "Treating a patient with a vascular condition early can improve the patient's quality of life, and in some cases even prevent limb amputation from untreated vascular conditions."

Nik Kolicaj, M.D., vascular interventional radiologist, explained, "We take cases other centers do not or cases that have failed — we treat every aspect of vein disease and malformations. From the least to the most complex cases. Sometimes our skills overlap, sometimes we perform procedures together but most importantly we work collaboratively to bring each patient the best care possible."

Being aware of the services of The Vein Center also offers support to community primary care and internal medicine physicians who treat patients with vascular conditions resulting from diabetes, hypertension, and smoking. "We have many options," explained Dr. Corcoran. "When patients come to us, they may be enrolled in current research or have access to medications or procedures not available elsewhere."

To refer a patient to the The Vein Center at Henry Ford Health for vascular evaluation or treatment, call Vein Center Nurse Vernita Anderson, at (248) 325-3181.

Or visit https://www.henryford.com/services/vascular-disease/veins to learn more about the specialists of The Henry Ford Vein Center.

Timothy Nypaver, M.D.

Syed Ahsan, M.D.

Donna Tepper, M.D.

Nik Kolicaj, M.D.

Research

SAVVE study: new treatment for chronic venous insufficiency

Paul Corcoran, M.D.

Vascular Surgeon Paul Corcoran, M.D., is the primary investigator at Henry Ford Health in a new clinical trial called **S**urgical **A**nti-reflux **V**enous **V**alve **E**ndoprosthesis or SAVVE to determine whether the VenoValve® is a safe and effective treatment for patients with severe, deep venous Chronic Venous Insufficiency (CVI).

The only site in Michigan, Henry Ford Health vascular surgeons can provide this new treatment option to adult patients with active or healed venous stasis ulcers who have failed at least three months of standard care, including compression therapy. Dr. Corcoran said, "It is exciting to participate in a study of a new device that fixes the underlying condition of the malfunctioning valves with the potential to solve the problem of CVI, reduce patients' leg pain and suffering and get them back into an active lifestyle."

The SAVVE clinical trial is a pivotal, prospective, non-blinded, single arm, multi-center study of 75 CVI patients enrolled at up to 20 U.S. medical centers. The VenoValve® was developed to reduce the venous hypertension and provide relief to the patient. In the first-in-human study for the device, 10 out of 11 patients went from having severe CVI, to a much milder form of the disease, or no disease at all.

Surgical intervention

VenoValve® device

In a one-hour procedure, under general or regional anesthesia, The VenoValve® is surgically implanted via a 5-to-6-inch incision in the upper thigh to access the femoral vein. After the vein is clamped off, a 2-to-3-inch incision called a venotomy is made. The VenoValve® is inserted and the stabilization ring on the VenoValve® frame is tacked to the femoral vein wall before closing the femoral vein and incision. To see an animation of how the device operates and the procedure visit: Venovalve.com.

"What we will look at is the effectiveness of the device to restore the proper directional flow of blood within the veins, how it decreases elevated venous pressure within the deep veins of the leg and allows the blood to return from the lower leg to the heart and lungs," explained Dr. Corcoran.

After the VenoValve® procedure, the patient will stay in the hospital for one night for patient comfort. The study requires that the patient see their doctor 7 days, 30 days, 90 days, 180 days and 365 days after the VenoValve® procedure. The VenoValve® is designed to be a permanent implant and the patient should continue to see their doctor once a year for at least the next four years.

What is CVI?

More than two million people in the U.S. suffer a debilitating condition that involves leg pain, leg swelling, enlarged veins, skin discoloration, and open sores on the lower leg, called Chronic Venous Insufficiency (CVI). This leads to increased pressure within the veins in the lower legs, which causes leg swelling and pain. In severe cases, the skin breaks down, resulting in open sores or ulcers on the leg. CVI occurs when the valves inside the veins the leg do not function properly, causing blood to flow backwards or regurgitate and pool in the lower leg, leading to elevated venous pressure inside the leg veins.

Henry Ford Health is currently enrolling patients from the community for this study. Patients who have failed three months of prior treatment for CVI yet continue to experience symptoms including leg swelling, discoloration, heaviness, itchiness, pain, and open sores that are difficult to heal are candidates. Please contact Winnie Cheung, (313) 916-1074, wcheung1@hfhs.org, or Alexander Driessche, (313) 916-4477, adriessche1@hfhs.org.

Association between socioeconomic status in acute limb ischemia outcomes

Acute limb ischemia (ALI) represents the most common of vascular surgical emergencies and can lead to major complications including limb loss and death. The Henry Ford Division of Vascular Surgery, with extensive experience in ALI, investigated the association between socioeconomic status (SES) and outcomes of lower extremity ALI and presented their results at the Midwestern Vascular Surgical Society in Chicago, IL.

ALI is defined as those patients presenting with new onset of arterial occlusion resulting in an immediate threat to the patient's limb and represents a surgical and medical emergency. This retrospective study identified 278 Henry Ford ALI patients who were treated between April 2016 and October 2020 and represents one of the largest series ever presented. The mean age of patients was 64 years, with 55% male, and a racial breakdown as follows: 59% white, 39% African American.

In addition to the type of treatment rendered and the classification scheme of the severity of their ischemia (Rutherford ALI Classification), other variables which were studied to determine their effect upon outcome included smoking ($p = 0.81\%$); diabetes ($p = 0.32$); HTN ($p = 0.08$); CAD ($p = 0.44$); PAD ($p = 0.02$); HLD ($p = 0.06$); CHF ($p = 0.11$); CKD ($p = 0.11$); and Cancer ($p = 0.52$). The SES was quantified using the neighborhood deprivation index (NDI) which is a standardized and reproducible index used in research that summarizes eight domains of socioeconomic deprivation. The patients were categorized as follows: NDI category 1 had 80 patients (42%); category 2 had 77 patients (36%); and category 3 had 47 patients (22%). Severity of ALI using the Rutherford Classification of limb viability was: Class I included 13 patients (6%); IIa 113 patients (53%); IIb 64 patients (30%); and III 23 patients (11%).

There was a statistically higher 30-day readmission ($p = 0.04$) in patients with lower SES. However, 30-day limb loss ($p = 0.16$) and 1-year limb loss ($p = 0.18$) did not differ based upon the NDI. This association persisted on a multivariate analysis ($p = 0.02$); 30-day mortality ($p = 0.64$); and 1-year mortality ($p = 0.68$). Type of repair (endovascular or open) or SES did not influence the outcome.

Loay Kabbani, M.D.

Abdul Kader Natour, M.D.

Timothy Nypaver, M.D.

Abdul Kader Natour, M.D., research fellow for the Division of Vascular Surgery presented the results of this study at the 45th meeting of the Midwestern Vascular Surgical Society. Loay Kabbani, M.D., lead researcher for the study noted, "Socioeconomic status was not associated with the severity of ALI on presentation. Although low SES was associated with a presence of PAD at presentation and higher readmission rates in ALI patients, it was not a predictor of short-term or 1-year limb loss." Timothy J. Nypaver, M.D., head, division of Vascular Surgery noted, "In this specific disease process SES was not a predictor of outcome." He further explained, "For acute limb ischemia, socioeconomic status has no impact upon presentation or outcomes, what takes priority is the severity of ischemia and the emergent intervention necessary to restore perfusion to the leg. There are a variety of methods and techniques both with standard surgical, as well as, newer thrombectomy devices which have helped facilitate care of in this tough disease process. Acute limb ischemia is a process that can, if unrecognized, lead to limb loss and multiple systemic complications. What is important is prompt recognition and management in a center that has the capabilities of taking care of this high-risk patient population."

To refer a patient to Henry Ford Vascular Surgery call 1-877-434-7470.

GALACTIC-HF study shows new drug efficacious in Black heart failure patients

David Lanfear, M.D.

The purpose of the **G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure (GALACTIC-HF) pivotal trial was to evaluate the impact of omecamtiv mecarbil when compared with placebo in subjects with chronic heart failure (HF) with reduced ejection fraction (EF) who received standard of care therapy. This randomized study included 8,256 patients at 944 sites in 35 countries.

David Lanfear, M.D., MS, FHFSA, advanced heart failure specialist and section chief of Advanced Heart Failure and Transplant Cardiology at Henry Ford Hospital in Detroit, and one of the primary investigators explained, "Omecamtiv mecarbil is a novel drug in a completely new class of agents. It boosts systolic function and in GALACTIC-HF was shown to reduce the risk of cardiovascular death or adverse HF events, mostly reducing hospitalizations. This is a completely different pathway than anything else for heart failure. It is the only medication that acts on the sarcomere. Every other therapy is in the neurohormonal pathway." Dr. Lanfear believes this new drug might be most useful in patients with severe HF despite maximal standard medication, and as emerging evidence suggests, it appears to be as effective in Black patients as in White patients."

This new analysis of the GALACTIC-HF results, which Dr. Lanfear led and presented as a late breaking trial at the 2021 Heart Failure Society of America meeting, provided a unique opportunity for researchers to evaluate the effect of omecamtiv mecarbil across race groups. "Black patients are clearly at higher risk of developing heart failure. They often seem to have worse outcomes. This is a group of patients that need new therapies, yet we don't always get as much data as we would like in pivotal clinical trials because Black patients are often underrepresented in clinical trials. This leaves an uncertainty about whether there is a consistent effect across race groups," explained Dr. Lanfear.

Dr. Lanfear shared key details of the GALACTIC-HF cohort which included one of the largest groups of self-identified Black patients in recent HF clinical trials, "It included 562 Black patients (mean age, 58 years; 34% women), 95% of whom were from the U.S., Brazil or South Africa. Black patients were younger, more likely to be women, less likely to have an ischemic etiology of HF, more likely to have hypertension and less likely to have atrial fibrillation compared with White patients." He added, "Both Black and White patients trended toward having less risk for the primary outcome if assigned omecamtiv mecarbil compared with placebo and did not show any significant differences in effect by race." In Black patients, there was a strong trend towards reduced risk of the primary outcome in the omecamtiv mecarbil group compared to placebo with an estimated 18% reduction in risk (HR = 0.82; 95% CI, 0.64-1.04; P = 0.1) which accounted for nearly 8 less events per 100 patient-years; or number-needed-to-treat of 13, which by most standards is deemed very favorable.

Dr. Lanfear explained that despite the fact that Black participation was better than comparable studies, the Black patient group alone was still not large enough to expect a statistically significant result in the clinical outcomes tested. "Yet, the effect estimate trending protective, being statistically no different than in White patients, and having an impressive 18% magnitude in the reduction in the primary endpoint is very reassuring regarding the potential use of this agent in Black patients."

Other measures of effect such as vital signs and biomarkers were statistically significant within race subgroups and again was consistent across race. Treatment with omecamtiv mecarbil lowered heart rate (P = .05) and N-terminal pro-B-type natriuretic peptide levels (P = .04) and slightly increased troponin I levels (P = .04) at 24 weeks. Among Black patients only omecamtiv mecarbil increased systolic BP compared to the placebo group (P = .031). There were no differences between the groups in safety events.

The overall results are very consistent with omecamtiv mecarbil being protective in Black patients. Dr. Lanfear explained. "I would have a lot of confidence in Black patients using it, if it comes for FDA approval."

The full study can be reviewed at: Teerlink, J.R.; Diaz, R.; Felker, G.M.; McMurray, J.J.V.; Metra, M.; Solomon, S.D.; Biering-Sørensen, T.; Böhm, M.; Bonderman, D.; Fang, J.C.; Lanfear, D.E.; Lund, M.; Momomura, S.; O'Meara, E.; Ponikowski, P.; Spinar, J.; Flores-Arredondo, J.H.; Claggett, B.L.; Heitner, S.B.; Kupfer, S.; (et al); GALACTIC-HF Investigators; *Journal of the American College of Cardiology (JACC)*, Jul2021; 78(2): 97-108. 12p. https://doi.org/10.1016/j.jacc.2021.04.065

To connect with a Henry Ford physician, call:

Henry Ford Health Heart & Vascular

1-877-434-7470

henryford.com

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In the news

Herbert Aronow, M.D.

Herbert Aronow, M.D., M.P.H., joined Henry Ford Health on May 2, 2022, as the Medical Director for Heart & Vascular. He was chosen for this role by physicians and leaders of the Henry Ford Heart & Vascular across all the operating units. In this role, Dr. Aronow will provide executive leadership of Cardiovascular Medicine, Cardiac Surgery and Vascular Surgery across the system. In collaboration with heart and vascular physicians and leaders across the Operating Units, Dr. Aronow will develop and implement strategies to advance clinical services accelerating growth, standardization and innovation. At the same time, he will continue to move forward the successful transformation of health care from volume-based to value-based care across all markets. Working with the department chairs and division chiefs in Heart & Vascular, Dr. Aronow will also ensure progress of the academic activities across the service line.

Henry Kim, M.D., will continue to serve as the Division Head of Cardiology for Henry Ford Hospital and Medical Group and will play a pivotal role in the future of the service line.

More on Dr. Aronow to come in the next edition.

Babar Basir, D.O.

Babar Basir, D.O., was named as assistant co-chair at the SCAI® Shock meeting to be held October 13-15, 2022 in Minneapolis, MN. In 2023 he will serve as associate co-chair and chair of the event in 2024. This event is held by the Society for Cardiovascular Angiography and Interventions.

Dr. Basir served as the primary investigator of the national Cardiogenic Shock Initiative which began at Henry Ford Hospital in Detroit, along with William O'Neill, M.D.

CORRECTION:
In the last edition of CardioBeat, Dr. Elizabeth Pielsticker shared that Henry Ford Jackson Hospital had teamed up with Henry Ford Hospital in Detroit to deliver heart failure care to patients in the Jackson community.

To refer a heart failure patient to the Heart Failure Clinic at Henry Ford Jackson Hospital, the correct number to call is 517-205-2163.