Henry Ford Health System

CARDIO BEAT

henryford.com
1-877-434-7470

PUBLISHED BY HENRY FORD HEART & VASCULAR INSTITUTE SUMMER 2021

EKOS Clot-busting Therapy Treats Pulmonary Embolism: Gives A Second Chance At Life

Assistant Coach Matthew Godfrey quickly goes back to work.

With a history of blood clots, Matthew Godfrey didn't waste any time getting to the emergency room at Henry Ford Wyandotte Hospital when he awoke with excruciating pain above his knee one December 2020 morning. He previously had been diagnosed with deep vein thrombosis (DVT) on his right leg and immediately knew this latest pain could be deadly serious.

"They got me right in after I told them I was a previous DVT patient," he said. "Immediately they found that a clot had traveled to my groin area." A CT scan then revealed pulmonary embolisms in both of his lungs.

Interventional Cardiologist Qaiser Shafiq, M.D. told the 50-year-old father of three boys that he needed an immediate procedure. "He told me I was in bad shape, and I started to realize how serious this was," Matthew said. "At that point, I was kind of in a panic, but Dr. Shafiq was very relaxed and calm. That made me feel better."

Continued on page 13

NCSI Results Demonstrate Significant Increase in Cardiogenic Shock Survival

The National Cardiogenic Shock Initiative (NCSI) has concluded its five-year study and demonstrates an improved survival compared to historic controls. The shock protocol, first established during a pilot study in Detroit to treat heart attack patients in cardiogenic shock, was implemented in 80 hospitals nation-wide to determine the effectiveness and reproducibility of using a shock protocol in cardiogenic shock.

"The National Cardiogenic Shock Initiative is the largest prospective study of therapy for acute myocardial infarction cardiogenic shock conducted in the United States in the past 20 years," said William O'Neill, M.D., medical director of Henry Ford's Center for Structural Heart Disease and principal investigator of the study.

"The protocol emphasizes the importance of medical personnel recognizing and treating cardiogenic shock as soon as possible," said Babar Basir, D.O., director

Continued on page 10

INSIDE

BRACHYTHERAPY USED TO TREAT RECURRENT BLOCKAGE IN THE HEART

NEW DEVICE TO TREAT HEART FAILURE, IMPROVE KIDNEY FUNCTION

POPLITEAL ARTERY ENTRAPMENT SYNDROME IN YOUNGER ATHLETES

INNOVATION

Brachytherapy Used To Treat Recurrent Blockage in the Heart

Interventional cardiologists at Henry Ford Health System began offering brachytherapy in March 2021, using radiation to prevent restenosis in a stent that has been implanted in the coronary arteries of the heart. The health system's first cases were performed by Mohamed Elshaikh, M.D., senior staff physician and director of Brachytherapy at Henry Ford Cancer Institute, Khaldoon Alaswad, M.D., director of the Catheterization Laboratory at Henry Ford Hospital, and Interventional Cardiologists Mohammad Alqarqaz, M.D. and Babar Basir, D.O.

Khaldoon Alaswad, M.D.

Babar Basir, D.O.

Mohamed Elshaikh, M.D.

Mohammad Alqarqaz, M.D.

Standard treatment options include minimally invasive, catheter-based procedures, such as the placement of drug eluting stent in the coronary artery, or angioplasty to open a blocked or partially blocked artery. While drug-eluting stents slowly release a drug to prevent restenosis, some patients may still experience recurrent blockage. This is where brachytherapy may be able to help.

"We are thrilled to offer brachytherapy as treatment option for our patients who are struggling with recurrent blockage," said Dr. Alaswad. "Using radiation prevents cells that cause scar tissue from rapidly dividing, leading to another blockage. This type of treatment has been shown to be effective for patients who have experienced recurrent blockage or narrowing of the artery after standard treatments."

The interventional cardiologist working with the radiation oncologist determine the exact amount of radiation needed for the procedure. Once determined, the interventional cardiologist will use a catheter to get to the blocked or narrowed artery in the heart using a small catheter-based balloon, and a small amount of contained radioactive material which is

STAFF UPDATE

Bipin K. Ravindran, M.D.

Cardiac Electrophysiology

MEDICAL SCHOOL EDUCATION
Thomas Jefferson University Hospital, PA

FELLOWSHIPS
University of Washington School of Medicine, WA, Electrophysiology

University of Washington School of Medicine, WA, Cardiovascular Disease

RESIDENCIES & INTERNSHIPS
Thomas Jefferson University Hospital, PA, Internal Medicine

Thomas Jefferson University Hospital, PA, Internal Medicine

BOARD CERTIFICATIONS
American Board of Internal Medicine - Cardiovascular Disease

American Board of Internal Medicine - Clinical Cardiac Electrophysiology

Bipin K. Ravindran, M.D.
Henry Ford Allegiance Health

introduced into the artery for a few minutes. Once the catheter and radioactive material are removed the artery remains open.

"This collaboration between our cardiology experts, radiation oncologists and medical physicists at Henry Ford Cancer Institute is a testament to the wonderful multidisciplinary approach and world class care that our patients receive," said Dr. Elshaikh. "This would not be possible without the dedicated work and support of our medical physicists, including Tony Doemer and the entire radiation oncology team. This expansion of our brachytherapy program will greatly benefit many patients who have struggled with coronary artery disease."

For Randall Westphal, 62, one of the first patients to receive brachytherapy at Henry Ford Hospital, this procedure gave hope for the future.

Randall Westphal

Randall's journey began at age 42 when he suddenly started experiencing symptoms of a heart attack and was rushed to a nearby hospital in Saginaw. At that time, he had three stents placed in his heart and participated in a research trial of a blood thinner medication, which for some time alleviated the symptoms he was experiencing. The drug-eluting stents put into his heart at that time were medicated to prevent restenosis, but Randall still experienced recurrent blockage.

At the age of 49, he suffered a massive heart attack and was rushed to Henry Ford West Bloomfield Hospital. He had additional stents placed in his heart through a catheter. He required 10 stents inside his heart over multiple episodes of heart attacks.

Over the past four years, Randall has been in the hospital for other heart-related procedures. Last year, he underwent angioplasty and in just over a year, the blood vessel had closed again.

Using radiation to prevent the growth of heart tissue inside the stent, brachytherapy is a treatment option that may prevent the restenosis Randall previously experienced.

"I'm feeling 100% now, much better than I was before," Randall said. "When the blood vessels were blocked up, I felt progressively slower and slower over time. I felt more fatigued and tired, and just didn't have the drive I need for everyday life. The improvement I feel now after brachytherapy is like night and day."

To refer a patient for brachytherapy at Henry Ford Hospital, call 1-877-434-7470.

Timothy Shinn, M.D.

Cardiac Electrophysiology

MEDICAL SCHOOL EDUCATION
University of Illinois College of Medicine, IL

FELLOWSHIP
Indiana University Medical Center, IN,
Cardiac Electrophysiology

University Medical Center, IN,
Cardiovascular Disease

RESIDENCIES & INTERNSHIPS
Loyola University Health System, IL,
Internal Medicine

Loyola University Health System, IL,
Internal Medicine

BOARD CERTIFICATIONS
American Board of Internal Medicine - Cardiovascular Disease

American Board of Internal Medicine - Clinical Cardiac Electrophysiology

RESEARCH INTERESTS
Dr. Shinn's research interests are in new technologies in the treatment of congestive heart failure and sudden cardiac death, including quality initiatives and investigations regarding their use and application.

Timothy Shinn, M.D.
Henry Ford
Allegiance Health

RESEARCH

Henry Ford Cardiologists Are First in U.S. to Implant New Device to Treat Heart Failure, Improve Kidney Function

Cardiologists at Henry Ford Hospital are first in the U.S. and second in the world to implant a circulatory support device that is being investigated in a clinical trial for patients hospitalized with acute decompensated heart failure (ADHF) and worsening kidney function, a condition known as cardiorenal syndrome. The first case was performed by interventional cardiologists Babar Basir, D.O., Gerald Koenig, M.D., Ph.D., and Mohammad Alqarqaz, M.D., at Henry Ford Hospital in May 2021.

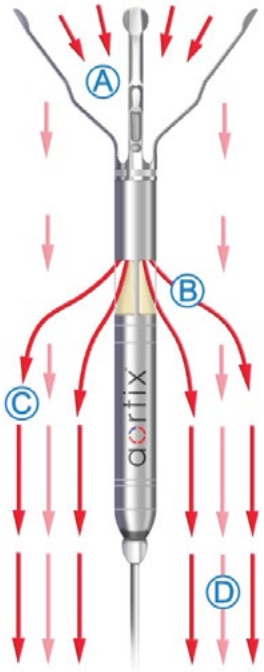
The Aortix™ System from Procyrion, Inc. is an intra-aortic axial flow pump, which is deployed via a femoral catheter to the descending aorta. This tiny pump, thinner than the size of a #2 pencil, is designed to relieve some of the heart's workload, allowing the heart to recover while more effectively pushing blood flow to the kidneys.

The heart pump is being evaluated in a multi-site clinical trial in the United States and Australia. Henry Ford is the only U.S. site involved in the trial.

"Cardiorenal syndrome is associated with twice the mortality of heart failure without renal dysfunction, as well as increased length of stay and rehospitalization rates."

–Cristina Tita, M.D.

"When a patient is suffering from ADHF, the amount of blood the heart pumps to the kidneys may be insufficient for the kidneys to work at full capacity," said Gillian Grafton, D.O., an advanced heart failure and critical care cardiologist, and co-principal investigator of the trial at Henry Ford. "The kidneys are responsible for maintaining the fluid balance that keeps heart failure congestion in check. Heart failure



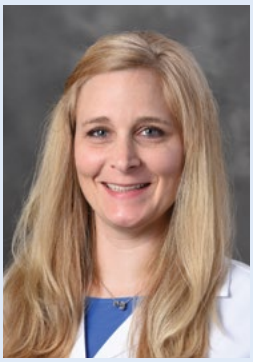
A — A portion of the native flow enters the pump at the inlet

B — The flow is accelerated in the pump and exits the device in high velocity jets directed downstream

C — The high velocity jets entrain the native flow, transferring momentum and energy to it

D — The result in a net increase in overall velocity and aortic flow

Caution: Investigational Device. Limited by federal law to investigational use only.



Gillian Grafton, D.O.

Cristina Tita, M.D.

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

Babar Basir, D.O.

Mohammad Alqarqaz, M.D.

by itself is a chronic and progressive condition, but the additional complication of reduced kidney function can significantly worsen a patient's condition."

When suffering from heart failure, the body may compensate for the heart's weakened state in several ways. These can include the narrowing of blood vessels to keep blood pressure up and diverting blood flow away from organs like the kidneys to supply more critical organs, such as the brain. Cardiorenal syndrome encompasses a spectrum of disorders involving both the heart and kidneys in which acute or chronic dysfunction in one organ may induce acute or chronic dysfunction in the other organ.

"Heart failure is a leading cause of morbidity, hospitalization and mortality in older adults," said Cristina Tita, M.D., an advanced heart failure and transplant cardiologist, and co-principal investigator of the trial at Henry Ford. "Cardiorenal syndrome is associated with twice the mortality of heart failure without renal dysfunction, as well as increased length of stay and rehospitalization rates."

Certain medical conditions can increase a person's risk for heart failure, including coronary artery disease, diabetes, high blood pressure, obesity, valvular heart disease, and other conditions related to heart disease. Heart failure risk can also be increased by unhealthy behaviors and lifestyle factors, such as smoking; regularly eating foods high in fat, cholesterol, and sodium; not getting enough physical activity; and excessive alcohol intake.

Inclusion Criteria for the clinical trial for those over 21 years of age includes:

1. Admitted to the hospital with a primary diagnosis of acute decompensated heart failure, either heart failure with reduced or preserved ejection fraction (HFrEF, HFpEF or HFmEF).
2. Worsening renal function (serum creatinine increase by ≥0.3 mg/dl [≥27 µmol/L]) despite 48 hours of intravenous diuretic therapy Increase can be compared to a baseline value taken within 90 days of hospitalization or during hospitalization.
3. Objective measure of congestion (Elevated PCWP [≥20 mmHg] OR Elevated CVP [≥12 mmHg]) obtained via catheter measurement.
4. Persistent clinical signs and/or symptoms of congestion despite diuretic therapy (one or more of the following):

    1. dyspnea at rest or with minimal exertion
    2. paroxysmal nocturnal dyspnea
    3. orthopnea
    4. lower extremity edema (≥2+)
    5. elevated jugular venous pressure
    6. pulmonary rales
    7. enlarged liver or ascites
    8. pulmonary vascular congestion on chest x-ray

Patients are enrolled in this study through their Henry Ford Health System cardiologist. To refer a patient to a Henry Ford Cardiologist, call 1-877-434-7470. To learn if your heart failure patient may qualify to be enrolled in this study, call (313) 829-3570.

INNOVATION

FlowTriever® System Extracts Large Clots Without Thrombolytic Drugs

Extraction of large emboli and thrombi from the peripheral vasculature without the use of thrombolytic drugs is the purpose of a new FDA cleared device called the FlowTriever® System by Inari Medical©. It is the first mechanical thrombectomy device to be awarded an FDA indication for treatment of pulmonary embolism (PE).

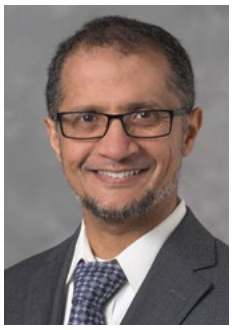
The large clot removed from John's left leg.

When John Lambrect, 60, of Riverview, arrived in the Emergency department at Henry Ford Wyandotte Hospital, his left leg was swollen and painful. His son had suggested his father may have a blood clot and encouraged him to seek immediate care. John was diagnosed with acute chronic femoral vein deep venous thrombosis. An intravascular ultrasound and venogram showed a complete long segment occlusion of the femoral vein and compression stenosis of the left common and external iliac veins, called May-Thurner syndrome.

Qaiser Shafiq, M.D.

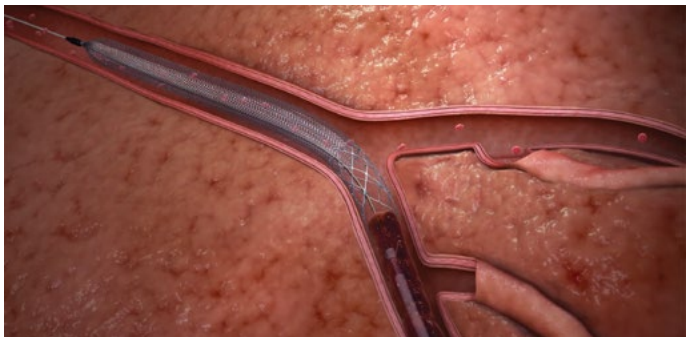
FlowTriever System® is an over-the-wire system used to capture and remove significantly larger clots. There are two components, the ClotTriever® catheter and ClotTriever® sheath. The catheter includes a coring element and a braided collection bag. The sheath has a self-expanding funnel at its tip. The system is completely self-contained and does not require capital equipment for use.

Qaiser Shafiq, M.D., interventional cardiologist, explains the procedure, "As venous access is gained, the guide wire is inserted, then the ClotTriever® sheath is introduced over the guide wire and positioned below the clot. The dilator is advanced from the sheath deploying the self-expanding funnel which helps ensure maximum clot capture. Next the ClotTriever® catheter is advanced beyond the clot and positioned for deployment. The catheter is then unsheathed and deploys the self-expanding coring element and collection bag and preparing for the collection bag for the thrombectomy. It is then slowly retracted toward the sheath, coring and separating the clot from the large vessel wall and capturing it within the collection bag. This provides embolic protection throughout the pull-back. The coring element and the basket are returned to the funnel of the sheath, collapsed and elongated then withdrawn along with the captured clot. We can capture any remaining clot fragments in the sheath via aspiration and deposit it into the clot reservoir."



Mustafa Hashem, M.D.

For John and nine other patients, the FlowTriever System® used by Dr. Shafiq, reduced potential blood loss and did not require an ICU stay of several days. Now John has better mobility and a quality of life, with no leg swelling or pain. His advice for others where blood clots may be a diagnosis, "get it before it gets you."

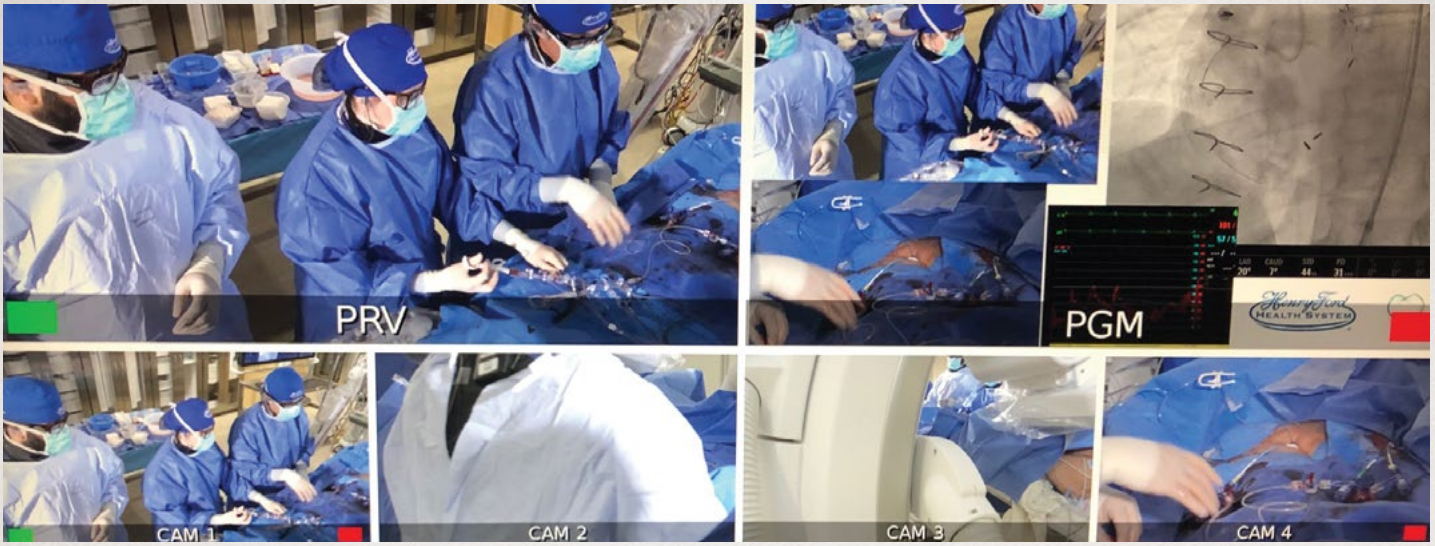


Mustafa Hashem, M.D., interventional cardiologist, explains that "Patients have been treated the same way for venous thrombosis for the last 50 years. By adapting to the newest technology like the Flowtriever System® to remove clots we can drastically improve the long-term prognosis for the patient."

To refer a patient to Interventional Cardiologists Dr. Shafiq or Dr. Hashem at Henry Ford Wyandotte Hospital, call 1-734-324-3500.

INNOVATION

Virtual CTO LIVE AID Fundraiser Educates Interventional Cardiologists Across the World



Cameras capture the PCI procedure performed by Dr. Alaswad, live to cardiologists across the world from Henry Ford Hospital.

A world-renowned interventional cardiologist at Henry Ford Hospital in Detroit performed a live Percutaneous Coronary Intervention (PCI) during a live-streamed event during a 16-hour marathon of cases that took place around the world on May 6.

Khaldoon Alaswad, M.D.

Khaldoon Alaswad, M.D., director of the Catheterization Laboratory at Henry Ford Hospital, performed the case as part of CTO LIVE AID, an event designed to fundraise for Doctors without Borders while providing invaluable training to cardiologists around the world.

Dr. Alaswad was the only U.S. cardiologist to perform a live case at the first CTO LIVE AID event in July 2020. While the July 2020 event focused exclusively on chronic total occlusion (CTO) cases, the 2021 CTO LIVE AID event also featured live bifurcation cases.

The event involved 26 expert interventional cardiologists in a unique "World Tour" featuring 10 CTO live cases from nine international centers and 16 bifurcation live cases from 16 international centers were performed in succession over the 16-hour timeframe. Cases were performed in East Asia, the Middle East, Europe, North and South America.

"The first CTO LIVE AID in July 2020 was an incredible success," Dr. Alaswad said. "It was an honor to be part of enhancing the education of cardiologists around the world while supporting the International Red Cross. I was thrilled to once again support this important event and demonstrate the advanced techniques offered at Henry Ford Hospital. By sharing knowledge among the international cardiology community, Henry Ford Hospital is ultimately saving lives and improving outcomes for patients around the world."

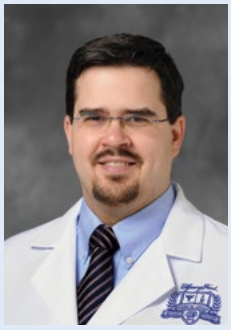
Before the COVID-19 era, live cases were traditionally part of these educational activities; however, the ongoing COVID-19 pandemic made safely traveling and congregating in person unrealistic. "The pandemic challenged how we could learn from each other, but we met and exceeded our learning opportunities and eliminated the risk of COVID-19 transmission," says Dr. Alaswad.

The CTO LIVE AID event was viewable online only by healthcare professionals. All patients gave permission for their case to be shared during the event. CTO LIVE AID is sponsored by Humanitas Research Hospital in Milan, Italy, one of the most advanced research hospitals in Europe, and a number of cardiology device and equipment manufacturers. The livestream from Henry Ford Hospital was sponsored by Boston Scientific.

Donations are still being collected for Doctors without Borders at the CTO LIVE AID webpage: https://www.cto-liveaid.com/.

Aortic Center to Provide Comprehensive Care and New Options for Patients with Abdominal and Thoracic Aortic Aneurysms

The Henry Ford Hospital Aortic Center vascular surgeons were the first in Michigan to perform Endovascular Aneurysm Repair (EVAR) and among the first to perform Fenestrated Endovascular Aneurysm Repair or FEVAR, minimally invasive procedures for aortic aneurysms. Patients who require repair of aortic aneurysms near the kidneys and other visceral blood vessels can receive the latest therapeutic option, a fenestrated endovascular procedure, where a custom graft is tailored to the patient's anatomy by creating the fenestrations in situ during performance of the procedure.



Loay Kabanni, M.D.

Loay Kabbani, M.D., senior vascular surgeon, explained "In approximately 10-20 % of patients with an abdominal aortic aneurysm, we find the aneurysm is too close to the arteries that branch off to the kidneys and other visceral organs to perform the traditional EVAR repair. This type of aneurysm is too complicated to treat endovascularly, and often requires open surgery to repair the aneurysm and prevent rupture." However, as pioneers in research on aneurysm repair, vascular surgeons at Henry Ford Hospital have increased options beyond major abdominal surgery with new methods to treat these type of aneurysms with endovascular means. Dr. Kabbani explains, "The new fenestrated procedure offers hope for patients with aortic damage near the critical intersection of the aorta and the kidneys or other visceral blood vessels when open surgery is not an option."

The unique feature of fenestrated endografts is that they can cover branch arteries of the aorta (such as the renal arteries) because the graft has fenestrations, or holes, that correspond to the position of these branching arteries within the aorta to allow for blood to flow through the graft into the branch vessel. These fenestrations are custom made for each patient, either by ordering a specific tailored graft, or by creating them in-situ using laser technology.

Fenestrated endovascular grafts were recently approved by the FDA. Using a computed tomography (CT) scan of the aorta, vascular surgeons create a custom-designed

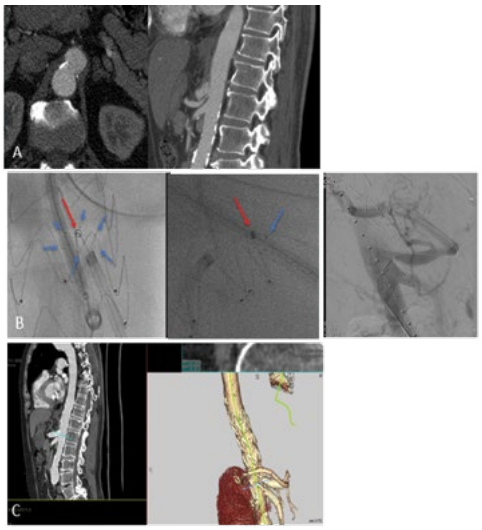
In-Situ Laser Fenestration Of Visceral Vessels In Endovascular Aortic Aneurysm Repair And Other Advanced Techniques

Henry Ford Hospital Vascular surgeons Timothy Nypaver, M.D., head, Division of Vascular Surgery and director of Endovascular Services, Mitchell Weaver, M.D., vascular surgeon and lead of the advanced vascular lab at Henry Ford Hospital and Loay Kabbani, M.D., senior vascular surgeon, recently presented a case series of abdominal aortic aneurysm (AAA) where a fenestrated endograft) could not be pre-fabricated, and therefore an in situ laser fenestration of the renal artery, celiac or superior mesenteric artery was performed.

Fenestrated and branched aortic stent grafts have increased the endovascular solutions for complex aortic aneurysms. However, these specialized grafts may be anatomically incompatible or unavailable on an urgent/emergent basis. Dr. Kabbani explained, "In our experience, In situ laser fenestration of visceral aortic branches is an alternative method to augment existing stent technologies allowing for extension of seal zones while maintaining anatomically aligned visceral vessel flow."

The presenters concluded some aortic pathologies posed unique challenges to advanced endovascular modalities. Fenestrated endovascular aneurysm repair (FEVAR) with in-situ laser fenestration is a feasible option for patients with unfavorable anatomy, and allows the use of "off the shelf" devices. Dr. Nypaver concluded by adding, "Using in-situ fenestration techniques, we can repair many aneurysms endovascularly on an urgent or emergent basis using grafts that are readily available."

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



A. Para visceral pseudo-aneurysms adjacent to the celiac artery.

B. Endovascular repair of pseudo aneurysm.

C. After covering the aneurysm and preforming an in-situ laser fenestration of the celiac artery

graft with fenestrations (holes). These fenestrations correspond to the unique positioning of the arteries that branch off from the aorta to the kidneys, small bowel, and liver. During the procedure, surgeons position the endograft in the aorta with the fenestration's openings at the level of the branched vessels to allow blood to flow to the kidneys and other organs. Then the graft is deployed, and the fenestration is supported by smaller covered stents, sealing the endograft and restoring blood flow to the kidneys.

Mitchell Weaver, M.D.

Patients may be candidates for this procedure if they have an aortic aneurysm, aortic dissection, or traumatic aortic injury that is located near or around the branch arteries to the kidneys or other visceral blood vessels. However, some patients may still require a more traditional open surgery using prosthetic grafts.

"Despite all the new technology some patients are better served by the traditional open repairs," said Mitchell Weaver, M.D., vascular surgeon and lead of the non-invasive vascular lab at Henry Ford Hospital. "Henry Ford is one of the few centers in the state that still performs a large number of open repairs due to a substantial referral network."

Timothy J. Nypaver, M.D.

Timothy Nypaver M.D., chief of the Division of Vascular Surgery explains, "We can offer what is best for the patient whether it be an endovascular repair or an open repair and eliminate the risk of rupture that these patients are subjected to."

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

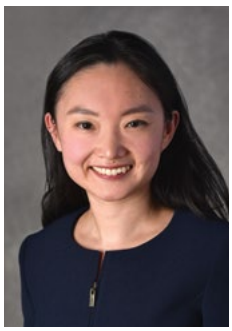
VASCULAR SURGERY

Popliteal Artery Entrapment Syndrome In Younger Athletes

Popliteal Artery Entrapment Syndrome (PAES) is a very uncommon condition that is most often diagnosed in both active men and women between the ages of 20 and 40 years old, average age is 30. "It is often called the jogging disease because it effects runners of marathons, track, and sports like soccer," explains Huiting Tina Chen, M.D., vascular surgeon at Henry Ford Allegiance Health in Jackson. The underlying anatomy causing PAES is congenital. Calf and foot pain is caused by compression and reduced blood flow through popliteal artery, which runs behind the knee, is the cause of paresthesia, cramping, and pain. It is usually recognized under exertion in those who are very active or are athletic.

"For coaches and athletic trainers, it is important to recognize these symptoms and consider PAES as the cause of leg or calf pain," says Dr. Chen. However, she points out, "It's not the type of leg pain we see in older adults with circulatory issues, it is not arteriosclerosis."

Dr. Chen shares upon physician examination, "Testing using a blood pressure cuff (ankle brachial index, or ABIs) may not show a decrease in pulse, but if the patient is younger, healthy, complaining of calf pain or numbness with exercise, evaluation with a vascular surgeon and further testing should be done."



Huiting Tina Chen, M.D.

To correctly diagnosis PAES, Dr. Chen includes ankle pressure measurements, an arterial duplex, and MRI of the legs to examine the soft-tissue or band causing the compression on the artery. If functional popliteal entrapment is suspected an angiogram and ultrasound of the popliteal artery with specific foot manipulation to provoke compression is performed. "Treatment for the syndrome is a popliteal entrapment release of the muscle or fibrous bands pressing on the artery. If the artery has deteriorated over years of compression a bypass of the artery may be required."

Dr. Chen explains, "Patients who get back to their sport after surgery experience immense relief from the pain they haven't had for years. They are able to get back into their sport without holding back."

To refer a patient to Henry Ford Allegiance Health Vascular Services and Dr. Chen, please call 517-205-1305.

RESEARCH

NCSI Results Demonstrate Significant Increase in Cardiogenic Shock Survival

Continued from page 1

of the acute mechanical circulatory support program at Henry Ford and principal investigator of the study. "If physicians need to use medications to support the patient's blood pressure, that's when they should also be thinking, 'We need to consider using a pump to support their heart.'"

Cardiogenic shock occurs when the heart is unable to pump enough blood to sustain the body's needs, damaging vital organs.

Led by a cardiology research team based at Henry Ford Hospital in Detroit, the NCSI results demonstrated a survival rate of 71% in patients whose heart attack was complicated by cardiogenic shock who were treated using the shock protocol. Researchers announced the trial results on April 28, 2021 at the Society for Cardiovascular Angiography and Interventions (SCAI) 2021 Scientific Sessions.

William O'Neill, M.D.

"We have found that the original observations of the Detroit Cardiogenic Shock Initiative have been reproduced in 80 hospitals throughout the U.S. If implemented across the country, the National Cardiogenic Shock Initiative protocol could save up to 20,000 lives a year. We strongly believe that our results will be validated in the upcoming Recover IV trial, which should commence enrollment late next year," explained Dr. O'Neill.

The 80 hospitals in 29 states that participated in NCSI all agreed to treat patients who presented with acute myocardial infarction and cardiogenic shock using a standard protocol, which involved rapid initiation of mechanical circulatory support (MCS) with an Impella® heart pump. Patients were enrolled between July 2016 and December 2020.

"More than 400 patients from across the country were enrolled in this study, including just under half of patients who had already suffered a cardiac arrest," said Dr. Basir. "The survival rate of 71% is significantly higher than any other previous study in cardiogenic shock. The protocol standardizes the process of care provided by nurses, technicians, interventional cardiologists and critical care physicians, providing predictable care in high risk and complex patients. Use of this protocol has already saved many lives and will continue to do so as more hospitals implement its principles."

In the early fall, Dr. Basir and Dr. O'Neill will begin a trial on Incorporating Supersaturated Oxygen in SHOCK (ISO-SHOCK) trial. The trial will incorporate treating patients using the NCSI shock protocol and then randomizing 60 patients in 20 sites in the U.S. to standard or care with supersaturated oxygen. The trial was given investigational device selection (IDE) by the FDA in April of 2021.

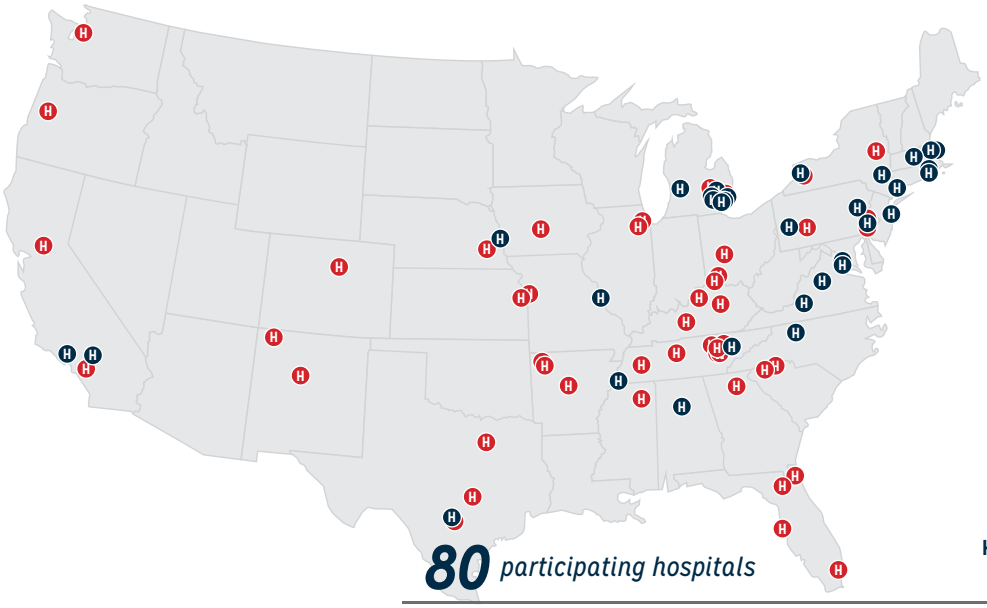
The primary safety endpoint will assess mortality at 30 days with the SSO2 Therapy group compared to the control group against the historical 32% mortality from the NCSI. The feasibility endpoints will measure completion of a 60-minute SSO2 infusion after successful PCI, and obtaining an MRI 3–7 days after PCI.

Babar Basir, D.O.

The treatment algorithm, available at henryford.com/cardiogenicshock, emphasizes quick recognition of the condition, then inserting a temporary straw-sized pump into the heart to keep blood flowing throughout the body. The Impella® heart pump, an FDA-approved device, is inserted through a catheter in the groin as soon as the patient arrives at the hospital. Doctors then treat the cause of the heart attack, either inserting a stent, removing a clot or taking other necessary action.

"The NCSI involved cardiologists at 48 community hospitals, where many patients with heart attack first present, and 32 academic centers" emphasized Michael Hacala, the NCSI study coordinator, who visited and started up all 80 sites. Of the more than 1,100 patients who were screened, 406 were enrolled into the study. The study also isolated predictive markers that indicate a patient's condition, an invaluable tool in determining treatment.

To learn more about the NCSI, visit henryford.com/cardiogenicshock.

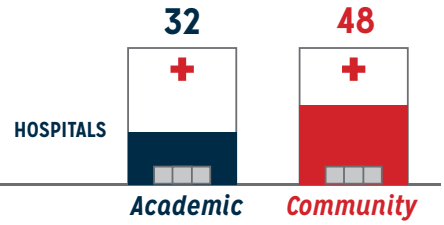


80 *participating hospitals*

NCSI: CLINICAL SITES

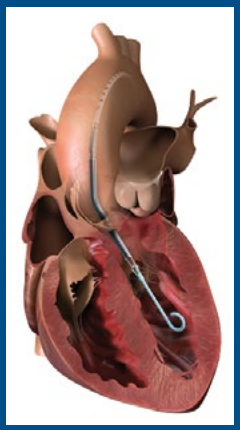
406 *patients enrolled nationally*

1,103 *total patients screened (with AMI + cardiogenic shock)*



David Johnson is the grateful recipient of the cardiogenic shock protocol. Sharing his experience David explained he had just returned home from working out at his local gym in metro Detroit when he had a sudden onset of extreme tiredness forcing him to sit down. He noted that it was unusual for him to want to sleep in the middle of the day which prompted him to call his brother. His brother advised him to call 911, take an aspirin and go outside his house to wait for help.

"All I remember is putting my foot up in the ambulance and then waking up four days later to the faces of relieved doctors who explained what had happened to me," shared David.



The Impella heart pump

Thankfully, Sarah Gorgis, M.D. and Mohammad Zaidan, M.D., were there to quickly recognize not only was David having a heart attack, but he was in cardiogenic shock. Following the protocol, David received an Impella CP® heart pump to support the blood flow to his major organs, allowing his heart to rest prior to further treatment.

"I had 36 physical therapy and rehabilitation visits and learned how to eat better, after spending 14 days in hospital," said David. "Then one day I realized I could run a half-mile, then a mile, then two and half miles, then three. I'm grateful to be back living a full life."

RESEARCH

Polygenic Score for β-Blocker Survival Benefit in European Ancestry Patients With Reduced Ejection Fraction Heart Failure

For patients experiencing heart failure with reduced ejection fraction, β-Blockers (BBs) are the main therapy, yet how each patient responds may vary. In a recent study, researchers explored how genetic variation could be the reason. The goal of the study was to derive and validate the first polygenic response predictor (PRP) for BB-associated survival benefit in heart failure with reduced ejection fraction patients (HFrEF) among patients with European ancestry.

David Lanfear, M.D.

David Lanfear, M.D., section head, Advanced Heart Failure and Transplant Cardiology, Henry Ford Hospital, explains, "Polygenic scores have been developed for several common diseases, such as coronary disease and many others, but similar analytic methods have not yet been successfully adapted to drug response." There are emerging examples published he added, but none that applied to the treatment of heart failure.

Methodologic challenges, such as lack of sufficiently detailed drug exposure data and complexities of analysis may limit adaptation of polygenic scores to drug response," explains Dr. Lanfear. "But this approach may help overcome the fact that single genetic alleles do not often contain enough predictive power to be actionable; by taking into account many genetic loci at the same time predictive power can be improved, which could have broad impact on precision medicine and drug development."

Only self-reported White patients were included in this analysis because polygenic score techniques can currently only really work within ancestral groups. Dr. Lanfear's team is actively working on a similar score for African Americans and scores that are robust to ancestry or genetic admixture.

First, a derivation group was randomly created, followed by testing in multiple independent datasets to test its performance. The study utilized data from the one cohort study, the Henry Ford Heart Failure Pharmacogenomic Registry (HFPGR) and two clinical trials, the Trial of Intensified Versus Standard Medical Therapy in Elderly Patients With Congestive Heart Failure (TIME-CHF) (n=431), and Heart Failure: a Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) (n=510).

PRP creation resulted in optimal prediction with a 44 single-nucleotide polymorphism score and treatment cutoff at the 30th percentile of that score. In validation testing (n=1,188), greater BB exposure was associated with reduced all-cause mortality in patients with low PRP score (n=251; hazard ratio, 0.19 [95% CI, 0.04–0.51]; *P*=0.0075) but not high PRP score (n=937; hazard ratio, 0.84 [95% CI, 0.53–1.3]; *P*=0.448)—a difference that was statistically significant (*P* interaction, 0.0235). Results were consistent regardless of atrial fibrillation, ejection fraction (≤40% versus 41%–50%), or when examining cardiovascular death.

Dr. Lanfear explained the study concluded that "Among patients of European ancestry with heart failure with reduced ejection fraction, a PRP distinguished the subset of patients who derive substantial survival benefit from BB exposure from a larger group that did not." Additional work is needed to prospectively test clinical utility and to develop PRPs for other population groups and other medications.

This study was originally published online and can be viewed at: *Heart Failure, Oct. 4, 2020,* Vol. 13, No. 12. doi.org/10.1161/CIRCHEARTFAILURE.119.007012.
Lanfear, D., Luzum, J., Ruicog, S., Gui, H., Donahue, M., O'Connor, C., Adams, K., Sanders-van Wijk, S., **Zeld, N.,** Maeder, M., **Sabbah, H.,** Kraus, W., Brunner-LaRocca, H., Li, J., and **Williams, L.K.** Polygenic Score for β-Blocker Survival Benefit in European Ancestry Patients With Reduced Ejection Fraction Heart Failure.

INTERVENTIONAL CARDIOLOGY

EKOS Clot-busting Therapy Treats Pulmonary Embolism: Gives A Second Chance At Life

Continued from page 1

New targeted therapy treats clots

Qaiser Shafiq, M.D.

Dr. Shafiq explains the EkoSonic endovascular thrombolytic system (EKOS), "is a two-part catheter. The infusion catheter and ultrasonic core are inserted and remain six to eight hours. The ultrasonic core generates an acoustic field to drive the clot-busting drug deeper into the clot. This unwinds the fibrin, exposing plasminogen receptor sites eliminating clots in hours instead of days using less than one-fourth the amount of medication." The procedure takes about 10 to 15 minutes after which the patient goes to the ICU for six to 10 hours.

Matthew was one of the first patients to undergo EKOS therapy at Henry Ford Wyandotte after two massive clots were discovered in his lungs. Between the fall of 2020 and April 2021, there were 21 other patients successfully treated by Dr. Shafiq and Mustafa Hashem, M.D., interventional cardiologist. "In our experience EKOS has significantly decreased our ICU length of stay and saved or changed the lives of these patients," said Christian Fisher, RN, BSN, MBA, nursing administrator Cardiovascular Services.

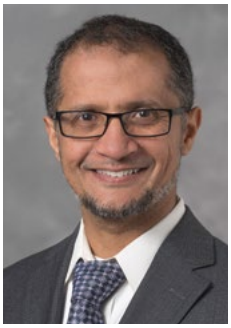
"I gained a sense of trust through Dr. Shafiq's calm explanation."

–Matthew Godfrey

Previously, the only option was to deliver clot-dissolving medication through an IV that not only went to the lungs but also other organs, increasing the risk of bleeding. EKOS delivers targeted therapy to the clots, avoiding other bleeding risks.

"They told me about the new EKOS procedure and I was very glad to be one of the first patients, especially when they said the other option was not as good," Matthew said. "I gained a sense of trust through Dr. Shafiq's calm explanation."

Less risk, quicker recovery



Mustafa Hashem, M.D.

"Between the Lord upstairs, the new technology and having the right doctor on call, it put me back to just about 100 percent really quick," Matthew said. "With more research I did after the fact, I realized I could've been in the ICU for a few weeks with a lot more risk if I had it done the old-fashioned way." He was home by mid-afternoon the following day.

Matthew also was diagnosed with May-Thurner syndrome, a rarely diagnosed condition occurs when the left iliac vein is compressed by the right iliac artery, increasing the risk of DVT in the left extremity. Dr. Shafiq performed a venous thrombectomy to remove clots from Matthew's knee to his pelvis and inserted a stent to improve blood flow.

Extremely grateful for the advanced, lifesaving care he received at Henry Ford Wyandotte Hospital Matthew said, "It's a partnership that I'll remember forever. I couldn't have had better care." He shared, "While I was in a bad condition, I would never have wanted it to be done anywhere else. Everyone from the people who gave me the tests to the nurses and doctors could not have been kinder and more compassionate."

Coach Matthew has returned to his assistant coaching role for the boys' varsity basketball team at Flat Rock High School.

"My lungs are markedly improved and clear," he said. "I've had a lot of people tell me that it was meant for me to still be here."

To refer a patient to Interventional Cardiologists Dr. Shafiq or Dr. Hashem at Henry Ford Wyandotte Hospital, call 1-734-324-3500.

To connect with a Henry Ford physician, call:

Heart & Vascular Institute

1-877-434-7470

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

IN THE NEWS

Providing Safe Heart Care During COVID-19 Pandemic

The Cardiology team at Henry Ford Wyandotte Hospital took extraordinary efforts to ensure their patients continued to receive care during a once-in-a-lifetime pandemic. Elsewhere in the hospital patients with COVID-19 filled the hospital. Other area hospitals restricted procedures and surgeries unless the need was urgent. Delays in care could have meant patient's conditions would worsen. Coming together to care for their patients, the Wyandotte team developed a way to keep their patients from hospital acquired COVID exposure by extending their own workdays, so their patients were treated and discharged the same day. "The results of a survey showed that 97% of the patients described their same day care being satisfactory," explained Christian Fisher, RN, BSN, MBA, nursing administrator Cardiovascular Services, "Our team really stepped up, that's what community is all about, caring for each other."

Henry Ford West Bloomfield Hospital Achieves Cardiovascular Accreditation

Corazon, Inc., a national leader in services for the cardiovascular specialty based in Pittsburgh, has granted accreditation to the Elective PCI program at Henry Ford West Bloomfield Hospital. Through a rigorous process, the accreditation proves that the program at Henry Ford West Bloomfield Hospital has once again met or exceeded the requirements established by the Michigan Department of Community Health in accordance with Certificate of Need Review Standards for Cardiac Catheterization Services effective September 14, 2015, such as providing 24-hour coverage for PCI emergencies, undergoing detailed quarterly quality reviews to ensure outcomes and practices meet or exceed national standards, and other such factors.

Henry Ford West Bloomfield Hospital has demonstrated through their accreditation survey that they are committed to providing the highest quality level of care to their patient community.