

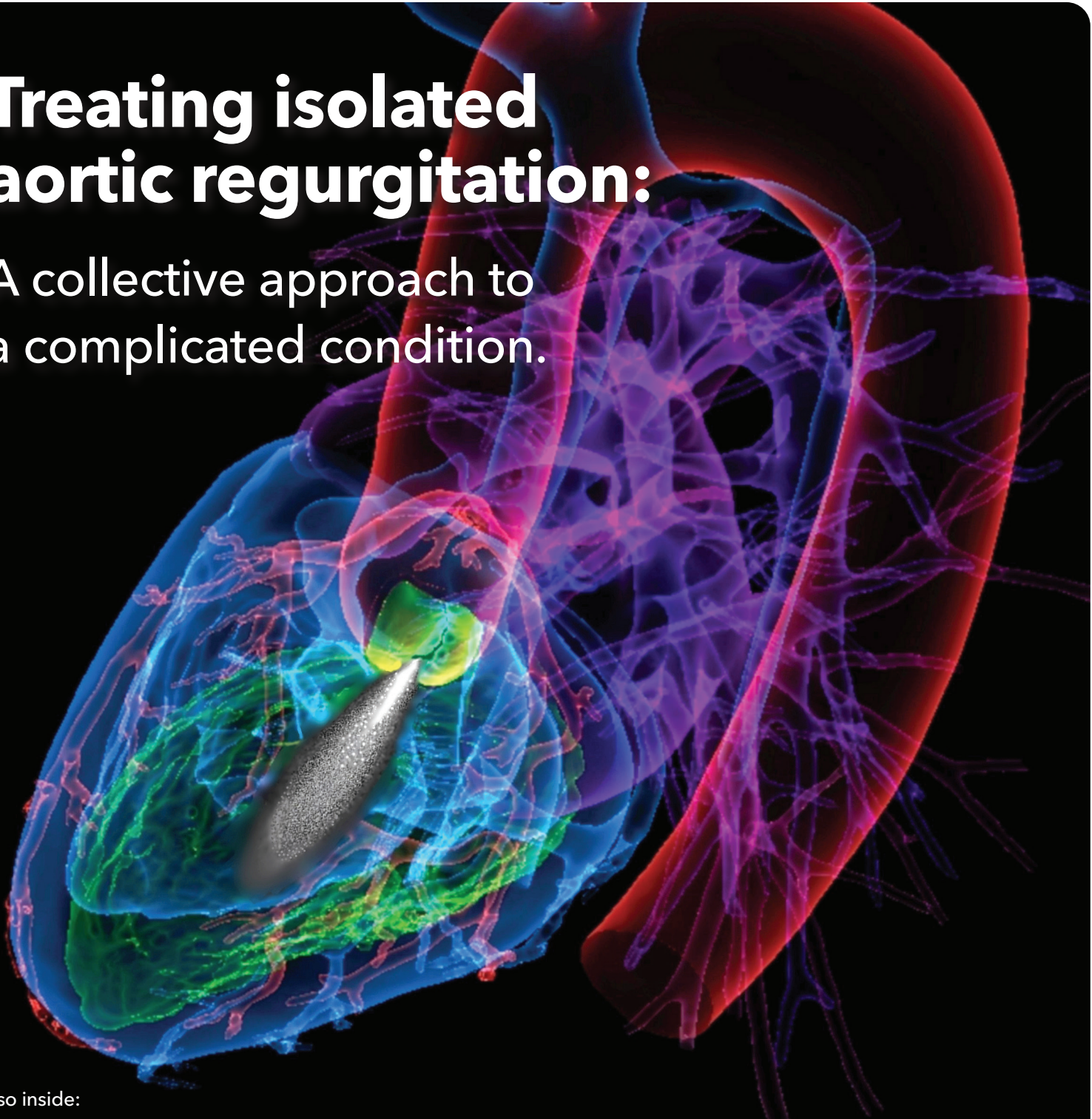
Cardiovascular **Physician**

A clinical practice and research publication.

VOLUME 20 | NO 1 | WINTER 2024

Treating isolated aortic regurgitation:

A collective approach to a complicated condition.



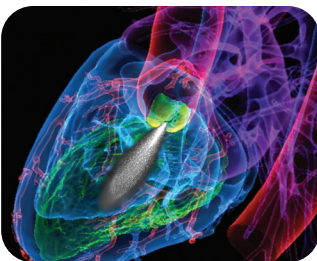
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Emerging alternatives for challenging cases of coronary disease.

Unique epicardial approach resolves complex heart rhythm disorder.

Making TAVR safer: Clinical trial studies new stroke-reduction technology.

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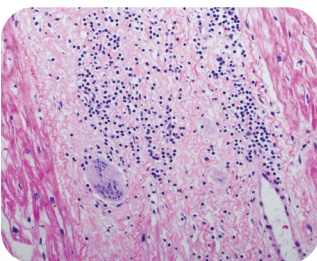
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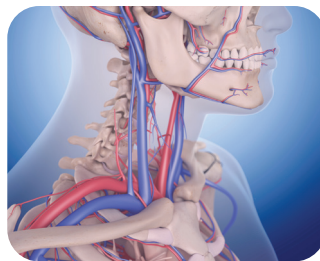
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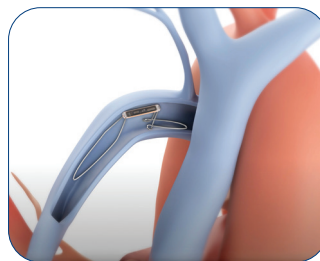
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Strategy for the new year: Addressing emerging needs, creating better access, and practicing in partnerships.

Inspired by the impending start of a new year, the leadership team of MedStar Heart & Vascular Institute (MHVI) recently spent time reflecting and strategizing around the concepts of 'where we are' and 'where we are going'. Organized by Thomas MacGillivray, MD, physician executive director of Cardiac Surgery, and Zayd Eldadah, MD, director of Cardiac Electrophysiology and MHVI chief strategy officer, the clinical and administrative leaders from each unit across our system's geography recently gathered for a vigorous, productive, and energizing in-person discussion. I am eager to share with you a few takeaways from this summit—many of which are reflected in the articles in this issue of *Cardiovascular Physician*.

As always, the current and anticipated needs of our patients took center stage. As ongoing research better informs us about underlying pathophysiology, and as technologies consequently evolve, we must assess the role of new diagnostic and therapeutic options, and ensure access for our patients. Take, for example, our feature story on treating isolated aortic regurgitation (page 4). As surgical techniques are refined and TAVR options explored, we are committed to staying on the forefront—particularly given the nuanced nature of the anatomy in each individual. This is further demonstrated in our ongoing investigations of how to best manage challenging variants of coronary artery disease (page 10), as well as our comprehensive range of options for stenting and plaque removal in the carotid circulation (page 16).

As the knowledge base rapidly evolves, we count on our system's extensive network of specialized and subspecialized expertise. This interdependency enables us to treat the most complex cases, such as the patient presented on page 12—a man with recurrent ventricular tachycardia, an LV aneurysm, and hypertrophic cardiomyopathy. His care team, comprised of a cardiac electrophysiologist, interventional cardiologist, and an advanced heart failure specialist, established an integrated and coordinated care plan to manage his immediate and long-term needs.

To effectively address individual needs, we seek to provide seamless access to care for our community. For example, MedStar Health is now a Center of Excellence in the treatment of sarcoidosis, ensuring that patients in our region do not need to travel to receive their specialized care



(page 14). Community access, as well as improved clinical outcomes, are enhanced by use of novel technology, as demonstrated by our lead participation in the expanded use of remote pulmonary artery pressure sensors (page 18).

The challenges facing healthcare systems—specifically workforce and economic obstacles—continue to push us to prioritize resources and work together to make ourselves the most efficient, productive, service-oriented unit possible. We are pleased to have welcomed new specialists onto the clinical team during the last quarter (page 17) and continue to prioritize making MedStar Health a desirable, meaningful, and fulfilling environment in which to practice medicine.

As we move forward, I am grateful for your partnership in the care of our collective patients. I wish you a happy, productive year, and I look forward to our continued collaboration.

Treating isolated aortic regurgitation:

A collective approach to a complicated condition.



The current conversation surrounding the treatment of pure aortic insufficiency—that is, aortic regurgitation (AR) without any stenosis or calcification—continues to build. With the anticipation of the first transcatheter aortic valve replacement for AR, as well as the growing number of patients in whom AR is identified, it is an appropriate time to review the full landscape of the condition and evaluate each approach available for treatment.

As with any cardiovascular condition, our physicians approach treatment plans as a multidisciplinary team equipped with a number of options. This is particularly important when managing AR, as it can present more of a challenge than aortic stenosis (AS). AR in the context of aneurysm, coarctation, root damage, anomalous coronaries, or bicuspid anatomy can all complicate the course of treatment. The condition may also be exacerbated by a left ventricle that is dilated or permanently damaged—which limits treatment options. Careful consideration must also be given to potential risks such as a stroke, pacemaker rates, and acute heart failure.

"There is quite a bit of nuance in the treatment of AR," explains Thomas MacGillivray, MD, physician executive director of Cardiac Surgery. "We believe that appropriate and successful treatment requires us to carefully weigh the risks and benefits for each individual patient. We need to balance effectiveness and durability, and determine how the treatment fits into the lifetime management of the patient. Ultimately, this is up to the patient to decide—our job is to offer expertise in each approach and have the conversation to help them fully understand their options."

Our team has decades of experience in both the traditional and novel approaches to treating pure AR. Our substantial volumes and excellent outcomes in traditional and niche surgical repairs and replacements, as well as our leading position in TAVR research, offer patients and their cardiologists a high level of confidence that every option is on the table.



Cardiac Surgeon Christian Shults, MD, performing a valve-sparing root procedure.

A suite of customizable surgical options.

"When feasible, and especially in the context of surrounding aortic disease, we prioritize repair," explains Christian Shults, MD, co-director of the Complex Aortic Center in Washington, D.C. "In the right context and if done well, repairs can be more durable than a tissue valve and do not require the lifelong anticoagulants that a mechanical valve does."

While more technically complex, surgeries such as valve-sparing root replacement, leaflet plication, subvalvular ring application, and other repair methods, offer the potential to preserve the patient's native valve. High-volume centers, such as ours, offer all options.

In isolated cases, surgeons can also offer niche approaches such as the Ross Procedure where the patient's pulmonic valve is moved to the aortic position, increasing the probability of a lasting solution while obviating long-term anticoagulation. To achieve good outcomes, these surgeries should be done only in high-volume centers with specific expertise, since a surgeon must have a broad and deep understanding of all alternative approaches and of the surrounding anatomy, should a change be needed mid-procedure.

Contemporary surgical options.

Our surgeons offer a number of repair and replacement options customized to the unique characteristics of each patient.



Repair techniques including valve-sparing root replacement, leaflet plication, and subvalvular ring application, among others.



Ross Procedure: the diseased aortic valve is replaced with the patient's pulmonic valve.



Tissue valve replacement (INSPIRIS RESILIA® valve pictured).



Mechanical valve replacement (On-X® valve pictured).

"In the right scenario, these may be excellent options," says Dr. Shults. "But just because we can do something, doesn't mean we should. The choice in treatment must be a durable solution for the individual patient. We are very realistic and honest in these decision-making discussions with our patients and their families."

When a replacement operation is selected, patients can be assured that they are receiving state-of-the-art valves. The On-X® valve, for example, represents a new generation of mechanical valves that is less thrombogenic thereby decreasing the amount of anticoagulation and associated risk of bleeding.

"We also select strategies to minimize future operations," shares Jeffrey Cohen, MD, surgical director of the Structural Heart Program in Washington, D.C. "For instance, if a valve replacement is required, techniques such as aortic root enlargement should be employed to optimize the patient's suitability for a future valve-in-valve TAVR. This can enable a patient to still undergo only one open operation and avoid the challenges of lifelong anticoagulation."

—Continued on next page



(l to r) Interventional Cardiologists Ron Waksman, MD, and Lowell Satler, MD, with Cardiac Surgeon Jeffrey Cohen, MD

“Initial outcome data presented at the Cardiovascular Research Foundation Clinical Trials Center (CRF CTC) this past fall showed safety and efficacy outcomes were achieved,” he explains. “The JenaValve system appears well positioned to become a viable option for the studied population.”

In addition, MedStar Washington has joined other leading TAVR sites in enrolling patients in the early feasibility study for the J-Valve™ Transfemoral System. The J-Valve presents an expansion on previously established concepts with a valve designed to accommodate patients with larger valve annulae.

At this point, TAVR is only appropriate for a small subset—those who have severe, symptomatic AR, have a high surgical risk of mortality/morbidity, and meet certain anatomical criteria. In the future, the studies may expand to those at intermediate risk.

“This approach isn’t right for everyone, but it offers a very promising opportunity for certain subsets of patients,” says Dr. Waksman.

“Along with high risk populations, TAVR has some interesting potential indications and uses to explore in the future. Consider a woman of child-bearing age who wants to avoid anticoagulants. She may elect to have a TAVR to buy her some time, understanding that eventually she will need another valve. Or for those with an LVAD who are at greater risk of developing AR, mechanical valve replacement is not advisable, so TAVR could be a solution. Finally, for those whose native leaflets are at risk for obstructing the coronary arteries, rather than an open intervention, TAVR may be protective.”

As with all treatments of the aortic valve, experience is key to optimal outcomes.

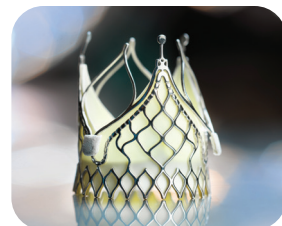
“AR is much less common than AS,” says Lowell Satler, MD, director of Interventional Cardiology in the Washington, D.C. region. “Whereas many sites have experience in TAVR for AS, the same cannot be said about treatment of AR. So you really need to go to an experienced center that has every option available, and doesn’t need to compromise on a treatment plan, such as using a suboptimal conventional valve.”

Investigational transcatheter valves.

Clinical trials are investigating use of the TAVR approach for pure aortic regurgitation.



JenaValve Trilogy™ Heart Valve System has recently completed its pivotal trial. Initial data showed safety and efficacy outcomes were achieved.



J-Valve™ Transfemoral System is in its early feasibility study, currently enrolling patients.

Two trials for transcatheter valves.

Transcatheter aortic valve replacement (TAVR) has long been used as a safe and effective treatment for aortic stenosis. Even mixed aortic valve disease, explains John Wang, MD, director of Interventional Cardiology in the Baltimore region, can be replaced via transcatheter methods. “As long as there is some amount of calcification, a standard TAVR may be an option. But for those with pure aortic regurgitation, surgical aortic valve replacement (SAVR) has been the gold standard.”

Unfortunately, SAVR is not an option for some high risk surgical patients, and left untreated, severe, symptomatic AR is associated with high mortality. Historically, there have been few treatment options available for this population.

“There is a relatively lengthy history of using conventional transcatheter methods off-label to treat AR, but it is generally not appropriate and not advisable,” explains Ron Waksman, MD, director of Cardiovascular Research and Advanced Education. “We’ve seen high mortality and morbidity, such as pacemaker need and repeat surgery, even with some of the newer generation valves.”

Now, some progress is being made to explore safer, more durable TAVR solutions.

The JenaValve Trilogy™ Heart Valve System, initiated seven years ago, has recently completed its pivotal trial, ALIGN-AR, for which MedStar Washington Hospital Center was one of the top enrollers. Dr. Waksman served as principal investigator for the study.



(l to r, standing) Interventional Cardiologists Ron Waksman, MD; Toby Rogers, MD; Itsik Ben-Dor, MD; Cardiac Surgeons Christian Shults, MD; Jeffrey Cohen, MD; Yuji Kawano, MD; (l to r, seated) Interventional Cardiologist Lowell Satler, MD; Cardiac Surgeon Thomas MacGillivray, MD

Robotic approach combines benefits of SAVR and TAVR.

New this year, our robotic cardiac surgery team is offering aortic valve replacement. This approach provides a minimally invasive alternative to open sternotomy—essentially combining the benefits of SAVR and TAVR.

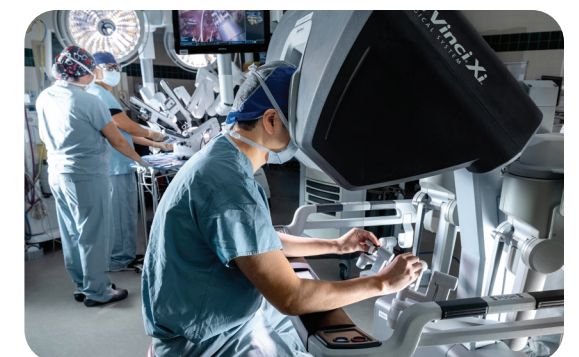
MedStar Washington is one of the few centers in the country offering robotic aortic valve replacement (RAVR), and Yuji Kawano, MD, director of robotic cardiac surgery, has performed hundreds of robotic heart procedures.

“RAVR can be truly beneficial to patients needing aortic valve surgery, thanks to its minimally invasive approach,” he explains. “The latest data available show that, when performed at an experienced center, RAVR offers significantly low paravalvular leak and pacemaker rates, and generally low risk of other morbidities.”

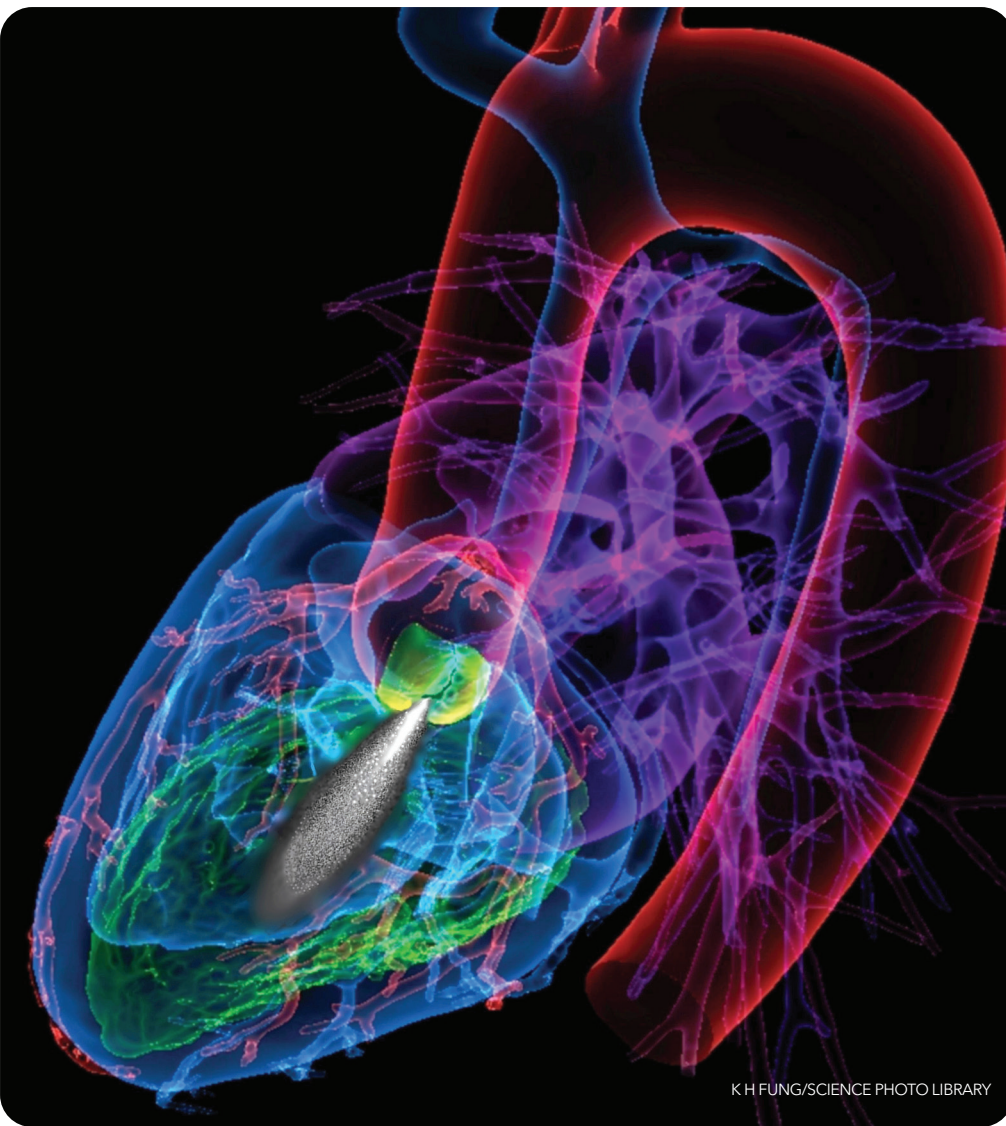
Any prosthetic valve can be implanted and there tend to be fewer limiting criteria than for TAVR at this point. If a patient can undergo SAVR, then they are likely to be a candidate for a robotic approach. Contraindications do exist, however, particularly if the patient has difficult access due to previous surgeries.

“RAVR is an exciting addition to the comprehensive range of options we offer our patients,” says Dr. Kawano. “As one team, my colleagues and I have the benefit of reviewing cases together, carefully determining which options to recommend to our patients and their families.”

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Yuji Kawano, MD, during a robotic cardiac surgery



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(Cover and top image) Illustration based on a 3D CT scan of a bicuspid aortic valve showing blood leaking backwards into the heart, known as aortic regurgitation (shown in grey);

(Bottom image) Physician Executive Director of Cardiac Surgery Thomas MacGillivray, MD

Looking ahead.

To continue advancing progress in the treatment of AR, our cardiologists agree that the focus should be on earlier diagnosis, regular monitoring, and timely intervention.

"Historically, guidelines say wait until significant symptoms appear or until the left ventricle begins to change—but why not intervene earlier?" suggests Dr. Shults. "We've seen updates to the intervention guidelines for aneurysm size and cardiac transplants. Presuming a careful risk/benefit balance, we should continue to consider the compelling data for earlier intervention."

Earlier patient presentation in the disease process combined with expert subspecialist physician management is how optimal results are achieved.

"One thing we have learned over the years is that the aortic valve is more complex than previously understood, and the surrounding structures must be carefully approached by someone who is deeply familiar with the entire area," says Dr. MacGillivray. "Just as important is that there be a team approach to all decision making and treatment planning. What makes MedStar Health a good choice for AR patients is our large heart team that is intentional about working together for the good of each patient."

Our multidisciplinary team is honored to partner with you in the care of your patients. To arrange a consultation, please call the Cardiac Surgery department at 202-877-7464. For information about the TAVR trials, please contact Erin Collins at 202-877-6622.

Making TAVR safer: Clinical trial studies new stroke-reduction technology.

In just a few years, transcatheter aortic valve replacement (TAVR) has become an established approach for treating many patients with severe aortic stenosis, not just those considered too high risk for open-heart procedures. Despite its wide acceptance, however, TAVR still carries the risk of embolization of calcium fragments, blood clots, or other embolic debris traveling through arteries toward the brain, increasing the potential for stroke or another ischemic event.

Since improving patient safety is an ongoing effort, medical technology manufacturers continue to look for ways to further minimize that risk. At present, only the Sentinel™ cerebral protection system has received FDA approval for use in attempting to reduce TAVR-related stroke.

One promising solution under study is the Emboliner® Total Embolic Protection Catheter, a new TAVR device designed to provide not only greater cerebral protection but safeguard other organs as well.

"The Emboliner's design is like a windsock that protects all four of the major arteries supplying the brain, unlike the Sentinel system that covers only three of the four," explains Toby Rogers, MD, scientific lead for MedStar Heart & Vascular Institute's Structural Heart Disease program. "Deployed just prior to a TAVR procedure, it also prevents embolic debris from traveling to additional organs in the body, such as the kidneys and other abdominal organs."

MedStar Health is currently participating in the Protect the Head-to-Head study (PROTECT H2H) a clinical trial to validate the Emboliner's safety and effectiveness. The randomized, open label, two-arm study will compare the Emboliner with the Sentinel system, with researchers assessing 30-day major adverse cardiac and cerebrovascular events and acute embolic debris captured during the procedure.

Nearly 20 hospital systems worldwide are participating in PROTECT H2H, which aims to enroll approximately 500 patients. Four procedures have been performed at MedStar Washington Hospital Center since the trial began.

"The study is just getting started, and it may be up to two years before we have final results," says Dr. Rogers. "The trial is open to any patient undergoing a TAVR. There may be rare instances where patient anatomy may preclude participation, but we've yet to have any exclusions."

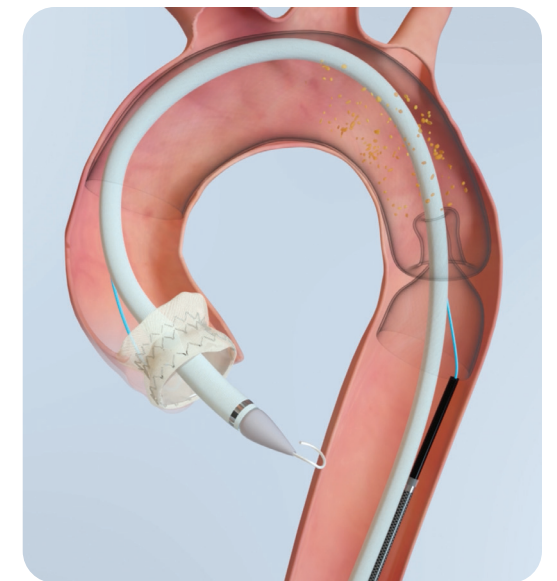
Dr. Rogers adds that having helped pioneer TAVR in the U.S., MedStar Health is well-suited to be involved in efforts to make an already sound procedure even safer.

"We've seen TAVR devices get smaller, easier, and safer to use, and the rate of stroke has come down," Dr. Rogers says. "If there are opportunities that can bring that risk as close to zero as possible, we're keen to do whatever we can to help. Being part of this trial is just one of the ways we can help bring these valuable innovations to patients not only in our region, but across the country and around the world."

To learn more about the Emboliner trial, please call 202-877-5976.



Interventional Cardiologist Toby Rogers, MD



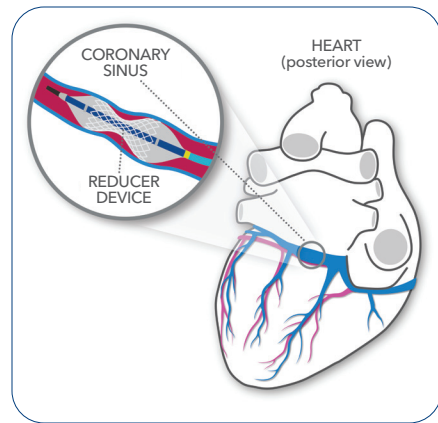
Deployed just prior to a TAVR procedure, the Emboliner® Total Embolic Protection Catheter prevents embolic debris from traveling not only to the brain but to additional organs in the body, as well, such as the kidneys and other abdominal organs.

Emerging alternatives for challenging cases of coronary disease.

Today, more than 18.5 million Americans live with coronary artery disease, and many survive for years thanks to cardiac interventions such as angioplasty and coronary bypass surgery. However, a subset of patients require further treatment to control their disease, and for these patients, standard interventions may not be viable. New clinical trials are underway at MedStar Washington Hospital Center to study options for treatment in such circumstances.



Interventional Cardiologist Hayder Hashim, MD



The Neovasc Reducer™ device is implanted into the coronary sinus via the right internal jugular vein, similar to right heart catheterization. The device is intended to modulate blood flow, restoring it to ischemic areas.

Tackling refractory angina.

Refractory angina is a painful chronic condition not controlled by the maximum guideline-directed medical therapy or interventions such as angioplasty or bypass surgery. For these patients who have already exhausted conventional options and are not candidates for further revascularization, their quality of life can be severely reduced.

The new COSIRA II clinical trial is studying whether the Neovasc Reducer™ device provides a safe and effective treatment. The proposed intervention implants a small, stainless-steel, mesh stent shaped like an hourglass into the coronary sinus via the right internal jugular vein, a procedure similar to right heart catheterization. The device modulates blood flow, toward restoring it to ischemic areas.

The procedure is minimally invasive and done under local anesthesia, allowing most patients to be discharged within 24 hours. The Reducer is a permanent implant and requires anticoagulation for one month post-procedure. Patients may feel a difference in their symptoms within 4 to 6 weeks.

"This is the first time that patients in the U.S. who are struggling and without other options will have access to this new device," states Interventional Cardiologist Hayder Hashim, MD, who is leading the trial. "We are enthusiastic about this option to advance treatment and improve quality of life for a growing patient population once deemed to have no effective options."

The first patient at MedStar Washington Hospital Center received their implant in the fall. A total of 350 patients are expected to enroll in the U.S. trial, and MedStar Washington is currently the only participating site in the region. The device has been commercially available in Europe since 2015.

Latest generation of drug-coated balloon technology offers new treatments.

Restenosis in coronary stents occurs in approximately two-to-five percent of patients who undergo coronary intervention in the first year, and one-to-two percent a year for the next five years. Drug-coated balloons offer a therapeutic advantage for these patients who have an occluded or narrowed stent. Currently, a study to examine the safety and efficacy of drug-coated balloons for the treatment of in-stent restenosis versus standard of care is ongoing and we anticipate full enrollment this spring. Most recently, the same drug-coated balloons were suggested as an alternative to drug-eluting stents (DES) for the treatment of de novo lesions.

Ron Waksman, MD, associate director of the Division of Cardiology and director of Cardiovascular Research and Advanced Education, is leading two national clinical trials evaluating the safety and efficacy of the SELUTION SLR™ drug-coated balloon technology for the treatment of in-stent restenosis and SELUTION De Novo for the prevention of restenosis in patients undergoing coronary intervention without a stent.

"Stents are used today in over 90 percent of coronary interventions, but some patients do not want a permanent implant," says Dr. Waksman. "Drug-coated balloons not only dilate the vessel and open the blockage but also elute an anti-restenosis drug without the need for a permanent implant. This novel approach leaves nothing behind after the intervention with no future worry about developing inflammation, thrombosis, or restenosis within a stent. It's a revascularization breakthrough."

The procedure uses the drug-coated balloon to open the blockage; if there is no recoil or tear of the vessel, the procedure is complete. The balloon provides a controlled and sustained release of the drug (sirolimus) for over 90 days. In the case of an unsatisfactory result with the balloon, a drug-eluting stent can be placed to improve the procedure's outcome.

The greatest opportunity for device use is with de novo lesions, especially in patients and vessels where drug-eluting stents are less successful, such as for diabetic patients, lesions in small vessels, and long or bifurcated lesions. Unlike with stents, patients undergoing the balloon-only procedure do not require prolonged administration of blood thinners, which could be attractive for patients at high risk of bleeding, up to 40 percent of all DES patients.

The ongoing SELUTION De Novo trial will compare this new sirolimus drug-coated balloon against a limus drug-eluting stent treatment. At least 60 U.S. sites will enroll 1,000 patients, with recruitment taking up to a year. Enrolled subjects will be followed clinically for one year, with results anticipated to be reported in 2026.



Interventional Cardiologist Ron Waksman, MD



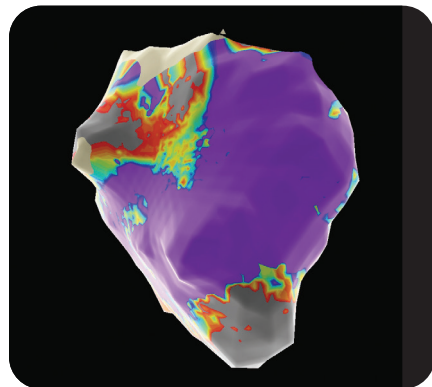
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There are two national clinical trials evaluating the safety and efficacy of the SELUTION SLR™ drug-coated balloon technology for the treatment of in-stent restenosis and SELUTION De Novo for the prevention of restenosis in patients undergoing coronary intervention without a stent.

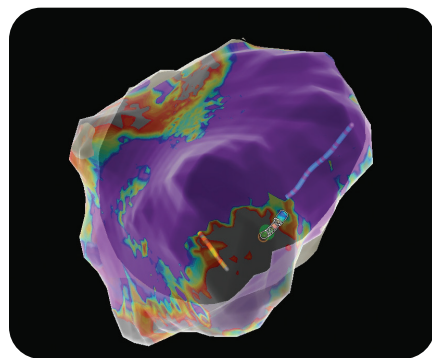
For more information on these studies, please call Caroline Jackman at 202-877-0572.

Case study:

Unique epicardial ablation resolves recurrent VT complicated by LV aneurysm and hypertrophic cardiomyopathy.



Epicardial voltage map demonstrating scar at the site of the left ventricular apical aneurysm.



Epicardial voltage map with ablation catheter at site of VT termination corresponding with lateral aspect of apical aneurysm.

In the fall of 2022, 67-year-old Mark Burgess was working in his yard when he suddenly felt extremely dizzy. "I wasn't in any pain," he says. "I just felt off and I'd been having spells like that for a while. I told a friend who was with me that I needed to go to the hospital."

Burgess was taken to MedStar Franklin Square Medical Center where his heart rate upon arrival was over 200 beats per minute. He was diagnosed with ventricular tachycardia (VT), a rapid and dangerous heart rhythm.

"VT prevents the heart from beating effectively," says Sunjeet Sidhu, MD, a cardiac electrophysiologist. "This can result in a loss of blood flow to the vital organs including the brain, and can cause lightheadedness, dizziness, the sudden loss of consciousness, or even cardiac arrest."

Prior to this issue, Burgess was unaware of any cardiac problems. He was referred to the heart failure specialists at MedStar Union Memorial Hospital, where he saw Erika Feller, MD, director of Heart Failure Outreach for MedStar Health's Baltimore region. There, further testing revealed he had hypertrophic cardiomyopathy (HCM), an inherited heart condition that causes the heart muscle to thicken.

"HCM is a complex disease that presents in a variety of ways. When the heart muscle thickens, it shrinks the blood's path through the heart. This forces it to work harder to pump blood, which can result in abnormal rhythms, shortness of breath, chest pain, cardiac arrest, or heart failure," explains Dr. Feller. "With such a range of potential symptoms, it's not a simple condition to manage."

To detect and control Burgess' irregular heartbeats, his cardiac team recommended the insertion of an implantable cardioverter defibrillator (ICD), which he initially declined. So, he was fitted with a LifeVest® (an apparatus applied to "shock" the patient should cardiac arrest occur), and was started on medications to try to suppress the VT. However, when a recurrent episode of VT caused readmission to the hospital a few weeks later, he agreed to the ICD.

It was then discovered that he had an aneurysm in the ventricular wall. In addition, there was a thrombus in the aneurysm, further complicating the condition.

"In patients with recurrent VT despite medications, we would normally perform an ablation, a procedure where we identify the source of the VT and cauterize the diseased tissue typically from the inside of the heart using a catheter introduced

from the leg," Dr. Sidhu explains. "But because of the location of the blood clot, inserting a catheter into the heart would likely disrupt the blood clot, significantly increasing the risk of stroke from the procedure. So, Mr. Burgess was treated with blood thinners and several different antiarrhythmic medications while we waited for the clot to dissolve."

Unfortunately, Burgess continued to experience recurrent VT, resulting in several more hospital admissions. While his heart rate was better controlled on medication, the VT continued and sometimes sustained for hours. Not only was it very symptomatic, it was life threatening.

"Given his residual blood clot and his recurrent frequent VT, we offered him an alternative approach to ablation, targeting the scar from the outside of the heart," Dr. Sidhu says. This unique procedure, performed in collaboration with John Wang, MD, chief of the Cardiac Catheterization Laboratory at MedStar Union Memorial, is called an epicardial VT ablation.

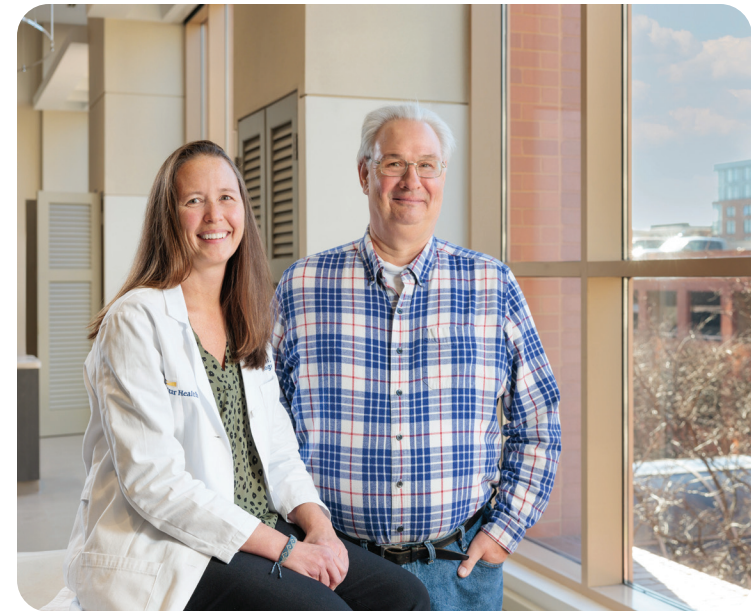
During the procedure, Dr. Wang and Dr. Sidhu inserted a special needle just under Burgess' sternum, creating an opening to the pericardial space. Once access was obtained, the ablation catheter could be safely inserted into the pericardial space, making it possible to identify and map the exact source of the arrhythmia. It also obviated disruption of the thrombus, lowering the risk of stroke.

"Gaining access safely to the pericardial space is the most difficult part of the process. It's a technically demanding procedure," says Dr. Wang. "Too much and you're inside the heart, too little and you're not where you need to be. This procedure is not performed in many heart centers because of its complexity but our multidisciplinary approach makes procedures like this possible on a regular basis."

The procedure went smoothly, and Burgess was discharged without any further VT. He has had no more arrhythmias and has been able to come off most of the medications that he was previously on for his VT. He continues to see Dr. Feller regularly for management of his HCM.

"The treatment of heart rhythm disorders continues to evolve and that's important because of the growing population with heart disease," Dr. Sidhu notes. "Today, our program spans the spectrum of arrhythmia management, offering physicians and their patients state-of-the-art medical, catheter-based, device, and surgical therapies. Plus, recognizing that sometimes the therapies needed require the expertise of multiple cardiac specialists, we regularly collaborate with the many talented interventional cardiologists and cardiothoracic surgeons here. We are able to provide the most comprehensive care for the most complex cardiac arrhythmia problems."

To contact the Cardiac Electrophysiology program at MedStar Union Memorial Hospital, please call 410-554-6727.



Advanced Heart Failure Specialist Erika Feller, MD, with patient Mark Burgess



Cardiac Electrophysiologist Sunjeet Sidhu, MD, and Interventional Cardiologist John Wang, MD

MedStar Health now a Center of Excellence in the treatment of sarcoidosis.



Farooq Sheikh, MD, medical director of Advanced Heart Failure, Washington, D.C. region

MedStar Health has been recognized as a Center of Excellence in the treatment of sarcoidosis by the World Association of Sarcoidosis and Other Granulomatous Disorders (WASOG), a leading organization in the field. The MedStar Health Multidisciplinary Sarcoidosis Program is also a founding member of the Foundation of Sarcoidosis Research's Global Sarcoidosis Clinic Alliance.

"This recognition represents the hard work of a number of dedicated clinicians across multiple campuses in the MedStar Health system," says Farooq Sheikh, MD, medical director of Advanced Heart Failure in MedStar Health's Washington, D.C. region, and director of the new Center of Excellence. "This recognition provides important validation of the national reputation this program has garnered in only a few years."

To effectively manage sarcoidosis—a progressive, multi-organ disease—patients should be seen at a site with the infrastructure built around their unique needs. At our Center of Excellence, patients have access to the full complement of technologies and a multidisciplinary team of experts, including:

- Heart failure physicians and Advanced Practice Providers (APPs), specialized in infiltrative cardiomyopathy.
- Nurse navigators.
- Advanced imaging specialists and technology.
- Experienced cardiac electrophysiologists.
- Interventional cardiologists on the forefront of all major research.
- Cardiac surgeons with high-volume expertise in LVAD therapy and transplantation.



- A genetic counselor.
- Clinical pharmacists and financial counselors to expedite insurance coverage of new drugs.
- Palliative care specialists.
- Other specialists assembled according to the disease state, to include rheumatology, pulmonology, neurology, infectious disease, pathology, hematology/ oncology, and radiology.

To refer a patient to the clinic, call 202-877-4698.



Trial finds aspirin may not be required as part of antithrombotic therapy for patients with a HeartMate 3™ LVAD.

Results of the ARIES-HM3 trial (Aspirin and Hemocompatibility Events with a Left Ventricular Assist Device in Advanced Heart Failure) show that the optimal antithrombotic regimen for advanced heart failure patients implanted with a HeartMate 3™ LVAD need not include aspirin.

MedStar Washington Hospital Center was a leading enroller in the trial, with Farooq Sheikh, MD, medical director of Advanced Heart Failure in MedStar Health's Washington, D.C. region, serving as principal investigator.

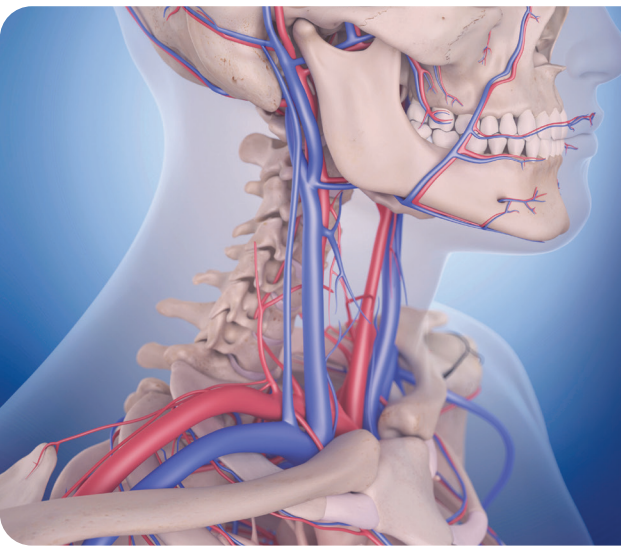
"Adverse events following LVAD implantation include occurrences of bleeding and thromboembolism," explains Dr. Sheikh. "As one of the highest-volume LVAD centers in the country, it is critical for us to determine the appropriate antithrombotic therapy for these patients."

To test the need for aspirin as part of an optimal regimen, researchers at 51 centers across nine countries studied 589 HM3 LVAD patients for a median period of 12-to-14 months.

Randomized patients received either aspirin (100 mg/day) or placebo with their prescribed anticoagulation therapy, a vitamin K antagonist (warfarin). Results showed that those patients not receiving aspirin were less likely to experience a major bleeding event without any increased risk for thrombotic events (such as LVAD pump thrombosis or stroke) when compared to patients receiving aspirin. Aspirin avoidance was associated with a 47 percent reduction in days spent in hospital as a result of the reduction in bleeding events.

Subsequent analyses are expected to come from this pivotal trial where MedStar Health clinicians will continue to contribute to this body of research.

"This study helps us refine the medical management of LVAD patients which further augments our ultimate goal of improving the lives of our patients," says Dr. Sheikh.



Broader, balanced options for carotid artery stenosis, and what the recent CMS coverage change means for patients.

Carotid artery stenting is receiving renewed attention after the recent change in coverage determination by the Centers for Medicare & Medicaid Services. The decision effectively expands eligibility for the procedure by removing some prior limitations for candidacy.

Background.

While some cases of carotid artery stenosis may be managed through lifestyle changes and medications, intervention may be recommended in some instances. The existing interventions for carotid artery stenosis are:

- **Surgical carotid endarterectomy (CEA):**
An open surgical procedure to directly remove plaque from within the carotid artery to prevent stroke.
- **Transfemoral carotid artery stenting (TF-CAS):**
An endovascular technique for stent placement, via femoral artery access utilizing a temporary filter for distal embolic protection, that permanently traps carotid artery plaque behind a stent.
- **Transradial carotid artery stenting (TR-CAS):**
CAS via access through the radial artery utilizing a temporary filter for distal embolic protection.
- **Transcarotid artery revascularization (TCAR):**
CAS via exposure of the common carotid artery that temporarily redirects blood flow to reduce risk of embolization.

In 2005, CMS determined that CEA had a higher rate of procedural safety than CAS—primarily due to stroke risk—so strict criteria were established to make CAS available only to those who were deemed high risk for open surgery. Since then, CAS has been used only in specific situations at certain sites, including MedStar Health, largely in clinical trials. Many of the elective stenosis interventions have thus been CEAs or TCARs. Our vascular surgeons have performed more than 500 TCAR procedures.

To consult with our multidisciplinary team, please contact Interventional Cardiology at 202-877-5975 or Vascular Surgery at 202-877-0275 (Washington, D.C.) or 410-554-2950 (Baltimore).

CMS changes and what they mean for patients.

The new CMS rules now allow for the expansion of CAS for a broader population of patients—not just those labeled high risk or those who are part of a clinical trial. Following certain requirements for imaging, diagnostics, and embolic protection device use, patients may be eligible if they have symptomatic CAS with greater than 50 percent occlusion or are asymptomatic with greater than 70 percent occlusion.

Our specialists are in the unique position to help this newly eligible population of patients, as CAS is most successful when performed by highly experienced providers who use appropriate imaging and advanced technology and are committed to superior quality and safety standards.

“Through our continuous involvement in carotid clinical trials, our teams have been able to consistently perform the procedure, even while the eligible population was more limited,” explains Interventional Cardiologist Nelson Bernardo, MD. “We remain at the forefront of carotid artery care, offering longstanding expertise in all options for patients who are best served through an intervention.”

The multidisciplinary review of carotid cases by vascular surgeons, interventional cardiologists, neurologists, vascular neurologists, and stroke specialists ensures that each patient receives the best possible recommendation, whether that be CAS, TCAR, or CEA.

“We tailor each approach to the patient’s individual risk factors, care needs, and anatomy,” explains Steven Abramowitz, MD, chair of the Vascular Surgery program. “The new ruling allows us to have a comprehensive conversation about all the available options, along with the risks and benefits of each, and how they pertain to the unique individual. Through this process of shared decision-making, we can ensure that best care plan is selected.”

Our providers remain on the forefront of new device and technique development, and are committed to quality review and improvement, including JCAHO audits, The LeapFrog Group Hospital Surveys, and SVS Vascular Quality Initiative (VQI) registries.

Welcome **new medical staff.**



Ricardo Nieves, MD, is a cardiologist at MedStar Washington Hospital Center and MedStar Georgetown University Hospital. He is board certified in echocardiography, cardiac MRI, cardiovascular disease, and internal medicine. Dr. Nieves specializes in using cardiac MRI imaging technology to better diagnose, treat, and understand heart diseases such

as infiltrative cardiomyopathies and hypertrophic cardiomyopathy, among other processes. He also has special interest in the potential of 4D cardiac MRI imaging. His treatment approach is patient-centered and holistic, as he is passionate about helping people improve their health while considering their lifestyle and the social determinants that influence their access to care. Dr. Nieves is fluent in Spanish.

Education and training:

- **Fellowships:**
 - Advanced Cardiac Imaging, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
 - Cardiovascular Disease, University of Pittsburgh Medical Center
- **Residency:** University of Pittsburgh Medical Center
- **Medical School:** University of Pittsburgh School of Medicine



Apostolos Tsimploulis, MD, is a clinical cardiac electrophysiologist at MedStar Washington Hospital Center, MedStar Georgetown University Hospital, and in Waldorf, Md. He specializes in the management of the full spectrum of heart rhythm conditions, especially complex atrial and ventricular arrhythmias. He is board certified in clinical cardiac electrophysiology, echocardiography, cardiovascular disease, and internal medicine. Dr. Tsimploulis performs a broad range of procedures, including catheter ablation, implantation of defibrillators (traditional and subcutaneous), pacemakers (traditional and leadless), cardiac resynchronization as well as conduction system devices, and cardiac monitors. He also has specialized expertise in lead extraction.

passionate about medical education and the use of imaging to help better diagnose, monitor, and guide treatment for patients. Dr. Waheed uses an individualized approach to patient care, incorporating each person's unique risk factors, as well as social and demographic factors. She believes in a physician-patient partnership with clear communication and shared decision making.

Education and training:

- **Fellowships:**
 - Electrophysiology, MedStar Georgetown University Hospital/MedStar Washington Hospital Center, Washington, D.C.
 - Cardiovascular Disease, State University of New York (SUNY) at Stony Brook, Stony Brook, New York
- **Residency:** MedStar Georgetown University Hospital/ MedStar Washington Hospital Center
- **Medical School:** Aristotle University of Thessaloniki School of Medicine, Greece



Anam Waheed, MD, is a cardiologist at MedStar Washington Hospital Center and MedStar Georgetown University Hospital. Dr. Waheed has extensive training in advanced multi-modality cardiology imaging, and is board certified in nuclear cardiology, echocardiography, cardiac CT, cardiac MRI, cardiovascular disease, and internal medicine. She is

passionate about medical education and the use of imaging to help better diagnose, monitor, and guide treatment for patients. Dr. Waheed uses an individualized approach to patient care, incorporating each person's unique risk factors, as well as social and demographic factors. She believes in a physician-patient partnership with clear communication and shared decision making.

Education and training:

- **Fellowships:**
 - Advanced Cardiac Imaging, Brigham and Women’s Hospital/Harvard Medical School, Boston, Massachusetts
 - Cardiovascular Disease, Boston University Medical Center, Boston, Massachusetts
- **Residency:** University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
- **Medical School:** Aga Khan University, Pakistan

MedStar Washington ranks in top 5 percent of nation's cardiac care hospitals.



In the 2024 Healthgrades rankings of the country's best hospitals for overall cardiac care, MedStar Washington Hospital Center was selected as one of only 48 programs that met the criteria. This is the third year in a row that MedStar Washington has received this recognition.

MedStar Washington and MedStar Southern Maryland Hospital Center also achieved superior grades for excellence, receiving recognition as one of America's 100 Best Hospitals for Coronary Intervention.

Healthgrades reviews outcomes from approximately 4,500 U.S. hospitals using Medicare Provider Analysis and Review data.

MedStar Union Memorial Hospital enrolls world's first patient in new trial of the Cordella™ PA Pressure Sensor.

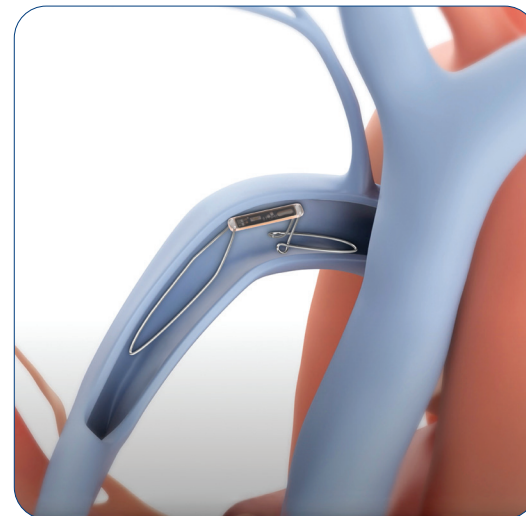
An 82-year-old woman with advanced heart failure (HF) left the MedStar Union Memorial Hospital cardiac catheterization lab on Dec. 5th, with the unique distinction of being the world's first patient enrolled in the global PROACTIVE HF 2 trial, to further evaluate the Cordella™ PA Pressure Sensor, designed to remotely transmit pulmonary artery pressure readings to her providers via a wireless microelectromechanical sensor. With this real-time data, the care team can proactively adjust medications with the goal of reducing HF hospitalizations.

The team at MedStar Union Memorial participated in previous investigations of the device's performance, and is now expanding the option to NYHA II patients through this trial launch.

"We are very excited to be the first to advance this study," said Erika Feller, MD, principal investigator in the clinical trial and an advanced heart failure specialist at MedStar Union Memorial. "It puts MedStar Health on the forefront of heart failure treatment technology with goals to reduce symptoms that compromise a patient's life. Proactive treatment means the possibility of greater independence for the patient, and fewer visits to the hospital."

Chief of the cardiac catheterization lab, John Wang, MD, and his team implanted the Cordella sensor in the pulmonary artery through femoral access in a procedure that took less than 30 minutes. The patient was discharged the same day.

For more information on the Cordella sensor, or the PROACTIVE HF 2 trial, call 443-278-9170, ext. 2.



Breaking news and best practices: 6th annual Advanced Heart Failure Summit offers updates from the front lines.



The MedStar Health Advanced Heart Failure Summit was held on October 21, 2023, at the Washington Hilton in Washington, D.C. Now in its sixth year, this symposium focused on recent updates, trials, best practices, and research in the field. Treating cardiogenic shock, expanding patient access to cardiac transplantation, and the evolving use of mechanical circulatory support devices were among some of the highlights.

Attendees received updates on the recently published heart failure guidelines, a review of the best practices in pharmacology, and an overview of modalities for treating end-stage heart failure. Tracks included highly specialized topics such as structural heart disease, pulmonary hypertension, infiltrative cardiomyopathies, heart failure with preserved ejection fraction, and cardio-oncology.

Mandeep Mehra, MD, medical director of the Brigham and Women's Hospital Heart & Vascular Center, gave the keynote address, providing his perspective on how prevention strategies, as well as artificial intelligence, gene editing, and other technology may impact the future of heart failure care.

Clinicians from across the heart failure spectrum were in attendance, including cardiac surgeons, critical care specialists, hospice and palliative care specialists, internal medicine specialists, medical oncologists, transplant specialists, physician assistants, nurse practitioners, nurses, social workers, and other members of the healthcare team interested in the management of heart failure patients.

Course Director Mark Hofmeyer, MD, shares, "It was wonderful to be back in person this year, after being virtual for the past three. We were delighted to welcome attendees from all facets of the care team, including physicians, APPs, nurses, and ancillary staff. It was an exciting day from start to finish, with a fantastic panel of speakers covering all topics in heart failure. It was thrilling to see a packed house—even until the end of the very last lecture."



Course Directors Mark Hofmeyer, MD, Advanced Heart Failure and Transplant Cardiologist (top image); and Ferooz Sheikh, MD, Medical Director of the Advanced Heart Failure Program in Washington, D.C. (bottom image)



Mandeep Mehra, MD, Keynote speaker and Medical Director of the Brigham and Women's Hospital Heart & Vascular Center



(l to r) Regional Chief of Cardiology in Baltimore Samer Najjar, MD; AHF Cardiologist Phillip Lam, MD; and Medical Director of Heart Transplantation Maria Rodrigo, MD



(l to r) Cindy Bither, ACNP-BC; AHF Cardiologist Ahmed Khan, MD; and Tiffany McKenzie, AGACNP-BC



Cardiovascular Physician is a publication of MedStar Health. It is a forum to share clinical, research, and teaching information in cardiology, cardiac surgery, and vascular care.



Please submit any comments to Managing Editor Karoline Hutson, at karoline.m.hutson@medstar.net.

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CRT 2024

March 9 - 12, 2024

Washington Hilton Hotel
Washington, DC

This annual conference will focus on five tracks—coronary, valve and structural, endovascular and stroke intervention, health disparities, and nurses and technologists. The concurrent meetings are designed to impact practice with focused sessions that discuss new trial data, explore evidence-based research, and demonstrate cutting-edge techniques that can be directly applied to the learners' clinical and academic practice.

CRTmeeting.org

CRTvirtual

Saturdays, April 13 to May 4

Each session will include a deep dive into devices, clinical techniques, and research data, as well as the opportunity to review interesting cases and challenging complications.

Registration opens on March 11 at CRTvirtual.org.

Regularly scheduled series—AMA PRA Category 1 Credit(s)[™]

Cardiac Catheterization Conference

Weekly, Wednesdays, 7:30 a.m.

1 AMA PRA Category 1 Credit[™]

202-877-7808

Cardiac Surgery Grand Rounds

Weekly, Tuesdays, 7:15 a.m.

2 AMA PRA Category 1 Credits[™]

202-877-3510

Cardiology Grand Rounds

Weekly, Tuesdays, 12:30 p.m.

1 AMA PRA Category 1 Credit[™]

202-877-9090

Cardiac Ultrasound and Advanced Imaging Conference

Weekly, Thursdays, 7:30 a.m.

1.25 AMA PRA Category 1 Credits[™]

202-877-6264

Electrophysiology Core Curriculum Conference

Weekly, Tuesdays, 7 a.m.

1 AMA PRA Category 1 Credit[™]

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