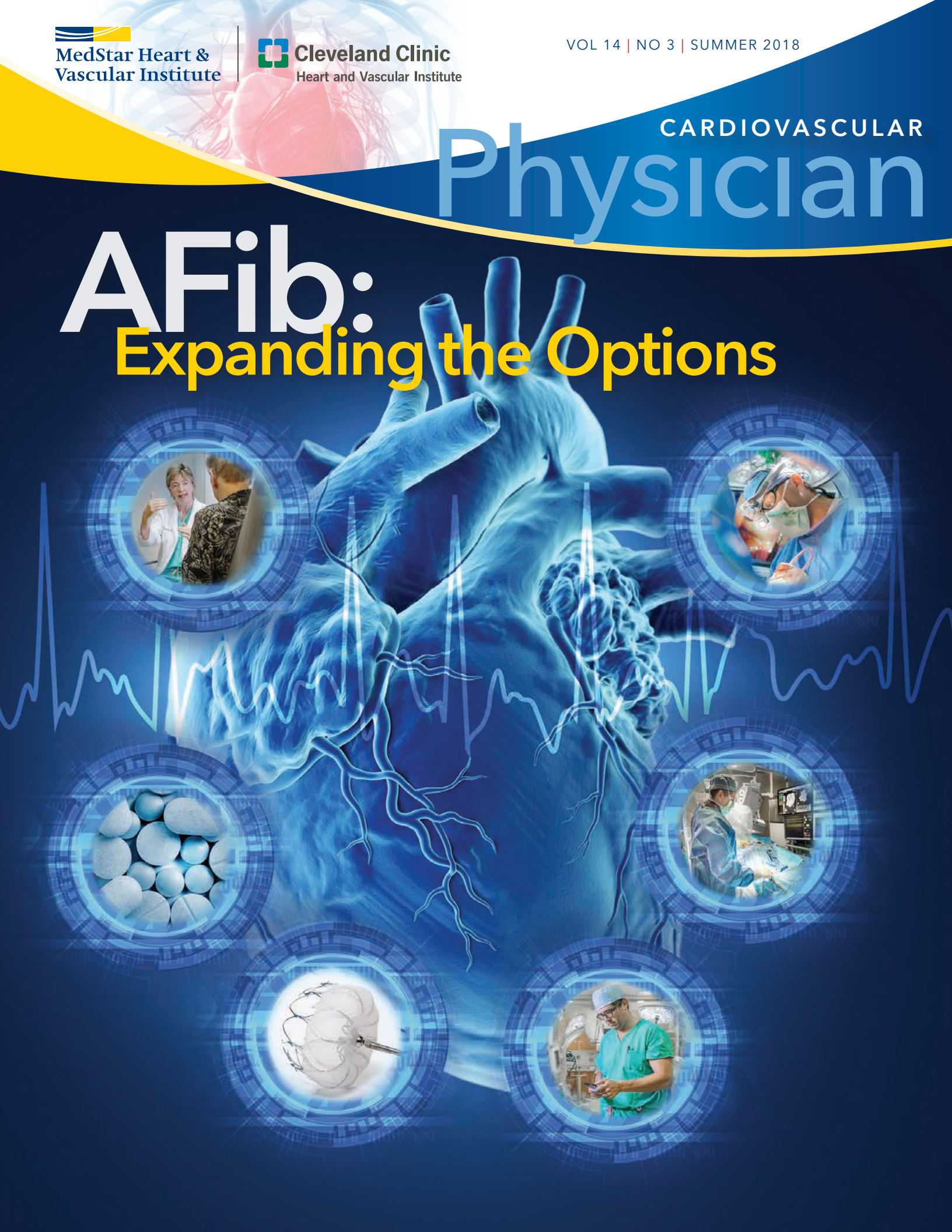


Physician

AFib: Expanding the Options



Thanks to the Dreamers

"Other people see things and say why? But I dream things that never were and I say, why not?"

This George Bernard Shaw quote is often repeated in many contexts. In medicine, Shaw's idea is always relevant. The people who say "why not" are the innovators—those pioneers who break rules and stretch convention to create something better, more effective—often lifesaving.

We recently lost one of these dreamers when James Bacos, MD, died earlier this year. Dr. Bacos was the first full-time chief of Cardiology at MedStar Washington Hospital Center.

In a relatively conservative Washington, Jim was the inventive leader who opened the metro area's and hospital's first CCU and catheterization lab. He was first to open the cath lab to qualified physicians who weren't full-time staff—ensuring the flow of patients to the hospital and creating an enduring relationship with the wider cardiology community. No other facility at the time offered this welcoming policy.

He encouraged a young Jorge Garcia, MD, to seek additional training at The Cleveland Clinic and return to ultimately build our world-class cardiac surgery program.

Jim's ability to see past conventional thinking made the present-day MHVI possible. And it's the litany of dreamers who are advancing cardiovascular care today. You will read about some of their out-of-the-box thinking in this issue of *Cardiovascular Physician*.

WHY NOT?

Atrial Fibrillation is the most common sustained cardiac arrhythmia, and an expanding portfolio of treatments can now be tailored to meet the specific needs and preferences of our patients. On pages 3-6, we showcase an impressive array of even newer potential treatment options that we are studying to further expand the possibilities.

When the first transcaval TAVR was performed, the notion of creating a fistula connecting vein to aorta seemed like risky business. Today the procedure is becoming an important option for a growing subset of patients. On page 7, we highlight Dr. Toby Rogers' research testing the first-ever dedicated occluder device used to facilitate this remarkable procedure.

Pushing the envelope is also Dr. Seth Worley's forte. With his pioneering techniques, he successfully implants intracardiac leads other experts won't attempt. Read his patient case highlighted on page 12.



Elsewhere we feature stories about how well-proven technologies are used in new ways to improve safety and effectiveness, how novel combinations of tools create cardiovascular breakthroughs, and how rethinking the old in new ways can revolutionize patient care.

Radial, femoral and pedal access. Veins functioning as arteries. TAVR for patients at low risk for surgical mortality. Second generation WATCHMAN™ technology. All of it is the result of dreamers who say, "why not."

BREAKING DOWN BARRIERS

Pushing boundaries also involves crossing geographic lines that can impede access to those innovations. MHVI has been doing this for the last decade. We are creating connectivity between Institute member hospitals in many ways, including exporting members of our expert medical team.

I am delighted that Dr. William Suddath has assumed chairmanship of Cardiology at MedStar Southern Maryland Hospital Center. Bill has been an important and well-respected member of the MedStar Washington Hospital Center medical staff for more than two decades—ties that make him an ideal leader as we further "systematize" our cardiovascular care.

I'm also happy to announce that Dr. Federico Asch, director of the MedStar Cardiovascular Research Network echocardiography core laboratory based on the Hospital Center campus, will be spending several days a week in Baltimore helping to further refine MedStar Union Memorial's echocardiography services.

I'd like to think that when Jim Bacos began to dream about the future of cardiovascular care in the region he might have imagined what the MedStar Heart & Vascular Institute has become. His vision is what jump-started all our achievements—and will continue to fuel our future.

AFib: Expanding the Options

"We now recognize that AFib is a progressive condition that requires thoughtful, comprehensive, long-term management, achieved best via effective collaboration among referring physicians, cardiac electrophysiologists, and even cardiac surgeons."

—Zayd Eldadah, MD, PhD



(L to R) Manish Shah, MD, Zayd Eldadah, MD, PhD, and Christian Shults, MD

An aging population—and rising tides of obesity, sleep apnea, and uncontrolled or undiagnosed high blood pressure—are forming the public health equivalent of the perfect storm: Atrial Fibrillation.

From the numbers affected (up to 10 million adults) to the related deaths (130,000) to the expense (\$6 billion)¹, atrial fibrillation exacts a considerable and growing national toll each year. Experts predict that arrhythmia management, especially for AFib, is on track to dominate cardiology care over the next decade.

"AFib today is a major clinical problem...one that keeps snowballing. We are seeing more and more cases each year, in adults of all ages, and we are increasingly appreciating how variable this arrhythmia's symptoms and danger can be," says Zayd Eldadah, MD, PhD, director of the MedStar Heart & Vascular Institute's Cardiac Electrophysiology Program, the region's largest cardiac electrophysiology center and a national leader in AFib research and care. "We now recognize that AFib is a progressive condition that requires thoughtful, comprehensive, long-term management, achieved best via effective collaboration among referring physicians, cardiac electrophysiologists, and even cardiac surgeons."

The good news is that MHVI is showing the way with more—and more effective—options than ever before, including multiple clinical trials (see chart, page 6). The key is finding the best solution for each patient, no matter where he or she falls along the spectrum.

¹Centers for Disease Control and Prevention

COMPREHENSIVE CARE FOR A COMPLEX CONDITION

"With atrial fibrillation, there's no one-size-fits-all approach," says Allen J. Taylor, MD, Cardiology chair. "That said, a common theme and major aim of our initial treatments target the risk of stroke—our #1 priority."

Someone with AFib is about five times more likely to suffer a stroke than the general populace, according to the American Heart Association®. Strokes in AFib patients also tend to be devastating, often with more severe deficits. First-line treatments typically include an anticoagulant, often with an antiarrhythmic to control AFib's hallmark irregular heart rate and rhythm. The combination works for many, often for years, and can be well-managed in the community setting.

But drug therapy is limited. That's when the expertise of an advanced arrhythmia management center like MVHI—which offers the full breadth and depth of AFib treatments—becomes essential to both a patient's quantity and quality of life.

BEYOND "BLOOD THINNERS"

Anticoagulation is an essential component of AFib management but, even with today's safer and more effective therapies, it's not without its problems.

"The long-term use of any type of blood thinner is complicated, especially in combination with other prescription and over-the-counter medications," says Dr. Taylor. "As more patients are diagnosed with AFib and put on anticoagulants at an earlier age, we increasingly and carefully consider the risk of bleeding problems."

²Kakkar AK, Mueller I, Bassand JP, et al. Risk profiles and antithrombotic treatment of patients newly diagnosed with atrial fibrillation at risk of stroke: perspectives from the international, observational, prospective GARFIELD registry. *PLoS One* 2013;8:e63479.

And with older, frailer patients, there is always the concern of falls and a serious bleed."

In fact, one out of 10 AFib patients on anticoagulation therapy will have a major hemorrhagic event at some point in their care, requiring transfusion and a termination of anticoagulation.

Additionally, around two out of 10 will experience smaller bleeding episodes that remain clinically relevant, such as nose bleeds. While many physicians view such bleeds as a minor consequence of care, many patients see them as a major problem, often reducing their dose on their own or simply stopping the medication altogether.

"Whether from non-compliance, sub-therapeutic dosage, or contraindications, up to 40 percent² of AFib patients today are inadequately protected," says Manish Shah, MD, director of MedStar Washington Hospital Center's Clinical Cardiac Electrophysiology Fellowship Training Program. "Yet it doesn't have to be like that."

STOPPING STROKES BEFORE THEY STRIKE

Over the past decade, a mechanical device that basically offers the same protection as anticoagulants but without the risk of bleeding has emerged as an important and successful alternative for certain patients. Called occluders, the mesh-like implantable devices physically trap clots where they originate in the Left Atrial Appendage (LAA), the small sub-chamber responsible for the majority of AFib-related strokes. This keeps them out of the bloodstream and away from the brain.

Starting with WATCHMAN™, the first commercially available LAA occluder, and continuing through subsequent iterations, MHVI has been at the national forefront in testing and adopting the potentially life-changing devices. To date, MedStar Washington Hospital Center and MedStar Union Memorial Hospital have implanted more than 200 WATCHMANs.

Now MHVI is part of the clinical trial for the device's next generation, WATCHMAN FLX™. Out of a total of 40 institutions, MHVI was only the third site in the nation to start enrolling patients.

"Our participation in this clinical trial is yet another example of how comprehensive the AFib program at MHVI really is," says Dr. Shah, principal investigator for the new trial and its predecessors, the leading implanter of WATCHMAN devices regionally, and a national course director for physician training. "Through these and other studies, we're providing patients with access to cutting-edge devices and treatments before they are widely available."

Dr. Shah is also PI for several other occluder trials, including Amulet™ and Coherex WaveCrest®. They are designed to evaluate variations in size, ease of placement, anticoagulation requirements and efficacy for FDA consideration in the hopes of making the option applicable to more patients. At MedStar Union Memorial Hospital, John Wang, MD, is PI for another trial, ASAP-TOO. This study evaluates the safety and effectiveness of the WATCHMAN device for non-valvular AFib patients deemed unsuitable for anti-coagulation therapy to reduce the risk of stroke. "Regardless of the therapy chosen," Dr. Shah states, "everyone with AFib needs to be evaluated for stroke protection."

RESTORING RHYTHMS

In addition to strokes, AFib can potentially cause heart failure, heart attack or even sudden cardiac death. When hearts beat too fast or too slow for too long—and medications cease to work—MHVI's specialists turn to the other advanced tools in their armamentarium.

"For a patient with newly recognized atrial fibrillation, we often start with cardioversion, a quick electrical fix to 'reset' the heart rhythm," says Dr. Eldadah. "This can be augmented by medical therapy to control heart rate and preserve normal heart rhythm. Catheter ablation was historically the next step when medical therapy was insufficient or not tolerated, but now, the increasing efficacy, safety, and simplicity of ablation may elevate it to be considered first-line therapy to suppress the arrhythmia."

When ablation is the answer, MHVI is the region's most experienced site. Its experts at the Hospital Center and Union Memorial successfully performed the procedure more than 600 times last year alone, using either radiofrequency or cryoablation.

And now the MHVI network is helping to advance understanding of the procedure and its efficacy even further.

"MHVI is the only site in the region to participate in a new trial evaluating the use of cardiac ablation as the first line of defense against AFib," says Glenn Meininger, MD, medical director of Cardiac Electrophysiology services for the institute's Baltimore region. "Called STOP AF First, the study will compare patient outcomes following cryoablation with those of patients on antiarrhythmic medication alone. The study will help us to understand if ablation should be initiated sooner."

Continued

Managing Atrial Fibrillation



REFERRAL TO AN EXPERT

Cardiac electrophysiologist Susan O'Donoghue, MD, crafts an individualized treatment plan to address her patient's specific presentation of atrial fibrillation.



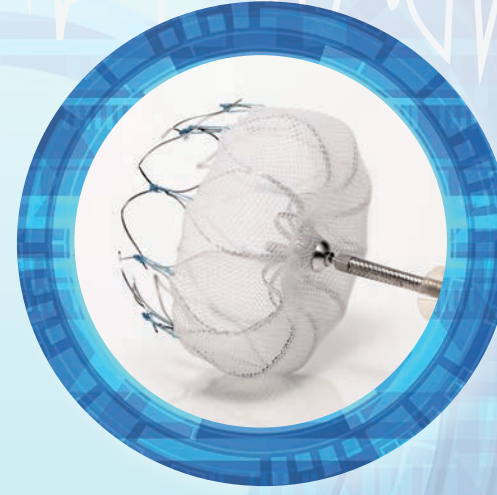
MEDICATION

Selecting the most appropriate blood thinner and potentially even a rhythm-restoring drug is often a necessary first step.



ELECTROPHYSIOLOGY PROCEDURES

Zayd Eldadah, MD, performs electrical cardioversion and catheter ablation, which augments medical therapy to restore normal heart rhythm.



DEVICES

MHVI is a world leader in the implantation of left atrial appendage occlusion devices to prevent stroke without the need for long-term anticoagulation medications.



HYBRID PROCEDURES

Convergent atrial fibrillation ablation and other cutting-edge EP/surgical procedures can permanently correct long-standing, refractory AFib as demonstrated by cardiac surgeon Christian Shults, MD.



LONG-TERM MANAGEMENT

After advanced care at MHVI, David Strouse, MD, contacts the AFib patient's referring physician, who will take over the longitudinal management of the patient.

WHEN ALL ELSE FAILS

When all other attempts at rhythm and rate control have failed, MHVI offers a variety of cutting-edge, hybrid treatments. While more invasive, they often succeed in returning patients to a quality of life they thought was forever out of reach.

The first is convergent atrial fibrillation ablation. Developed just recently, the procedure uses a combination of epicardial and endocardial approaches to block the errant electrical currents that cause atrial fibrillation, including the posterior left atrial wall. Convergent therapy can be performed with an EP specialist and cardiac surgeon working sequentially, or in two separate procedures. The convergent procedure is often combined with a thorascopic closure of the left atrial appendage to increase the effectiveness of the procedure as well as reduce the long-term risk of stroke.

“A surgeon can get to certain areas of the heart better than a cardiac electrophysiologist can and vice versa,” says Christian Shults, MD, an MHVI cardiac surgeon at the Hospital Center and proponent of the new technique. “By working together, we can reach more of the problem areas and produce very good, long-lasting results.”

Since the advent of the hybrid therapy, MHVI has emerged as the second highest volume center in the U.S., with 130 procedures performed at MedStar Washington Hospital Center and MedStar Union Memorial Hospital.

That distinction may have played a role in MHVI's selection as a site for the multi-center CONVERGE trial, which stopped enrolling patients at the end of August.

“We compared standard catheter ablation head-to-head with the convergent approach to see which works better for patients with long-standing, refractory, persistent

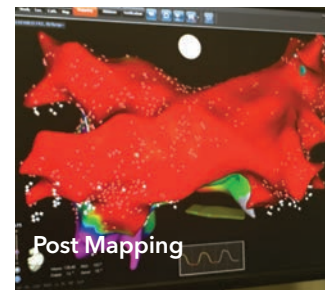
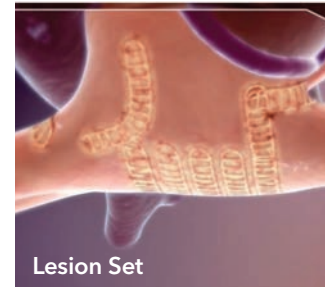
AFib,” explains Dr. Shults. “The goal was to determine if convergent therapy should be considered earlier in the disease process.”

For patients with atrial fibrillation already undergoing cardiac surgery, a Cox-Maze IV procedure is performed, which is the gold standard and most effective treatment for AFib. Because it requires arresting the heart and use of the heart lung machine, it is typically reserved for patients who otherwise require open heart surgery.

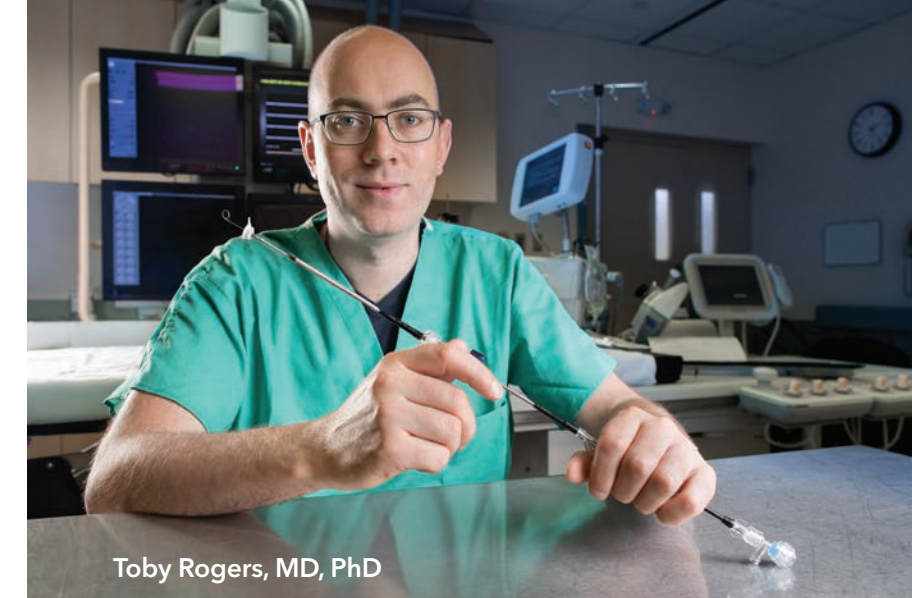
But regardless of where a patient is on the AFib severity spectrum, MedStar Heart & Vascular Institute has the complete arsenal of treatments and techniques to help.

“Our mission is to deliver the most appropriately tailored, state-of-the-art therapy for each individual. No patient should ever languish on outdated or ineffective care. Our aspiration as a multi-disciplinary team is not just to treat this global heart rhythm problem, but one day to eradicate it,” concludes Dr. Eldadah.

(Top) Posterior wall epicardial lesion set
(Center) Completion mapping showing electrical silence of the posterior wall [red areas silent]
(Bottom) Application of clip to left atrial appendage



MHVI Tests First-of-a-Kind Occluder Device for Transcaval TAVR



Toby Rogers, MD, PhD

The development of percutaneous treatment options for structural heart defects is one of the most fertile areas of innovation in cardiovascular care—with transcaval TAVR leading the pack. It offers a new treatment option to patients in need of aortic valve replacement who are too sick for open-heart surgery and whose iliofemoral artery anatomy prevents the use of more traditional percutaneous routes to the heart. It is also a less risky and less painful approach than either transapical or transaortic access to the aorta.

As in many such endeavors, work-arounds are often good enough until something better comes along. The “good enough” in transcaval TAVR has been the off-label use of nitinol cardiac occluders. Now MedStar Heart & Vascular Institute’s Toby Rogers, MD, PhD, is testing a newly designed, first-ever dedicated occluder device aimed at improving outcomes and reducing complications.

PLUGGING CRITICAL HOLES

The occluder plays a critical role in the transcaval technique. During transcaval valve replacement, an electrified guidewire is used to cross from the inferior vena cava to the abdominal aorta to create a connection between the two vessels. This allows the catheters to bypass the iliofemoral arteries that are diseased.

During the procedure the connection is widened so that a catheter can be advanced from the vein through to the aorta to allow TAVR to be performed. The fistula from the aorta to the inferior vena cava is closed with the occluder device. While the occluder device is being deployed, higher pressure in the surrounding tissue ensures that bleeding from the aorta spontaneously decompresses back into the vena cava.

A BETTER OCCLUDER DEVICE

“We are currently using an occluder device originally designed to plug holes in babies’ hearts,” explains Dr. Rogers. “While it gets the job done, it is not designed for transcaval closure. The new device has been designed to be easier to deploy and promote rapid hemostasis.”

The new device is shaped like a double umbrella. “When positioned inside the aorta, the umbrella opens on both sides of the wall of the aorta, and the catheter is withdrawn through the vein,” he says.

The FDA early feasibility study has enrolled 12 patients at MedStar Washington Hospital Center; Emory Hospital, Atlanta; and Henry Ford Hospital, Detroit. “The early results are promising, and we will have the full results from the study later this year,” Dr. Rogers adds.

Last year more than 100,000 TAVR procedures were performed in the United States and approximately 5 to 10 percent of these required non-transfemoral access. “As a high-volume TAVR center, MHVI is well positioned to test new innovations in this very quickly evolving field,” Dr. Rogers says.

If you have any additional questions or wish to discuss a patient case, please contact Dr. Rogers directly at 202-877-5975, or Toby.Rogers@MedStar.net.



Aortogram showing complete occlusion of the transcaval tract by the new closure device (white circle)

AFib Clinical Trials: Calling all Candidates

MHVI is currently enrolling potential candidates into several different AFib clinical trials. For eligibility requirements, or to see if your patient could benefit, please contact the individual shown.

TRIAL NAME	OBJECTIVE	LOCATION	CONTACT
WATCHMAN FLX (LAA occluder)	• Evaluate 2nd generation enhancements	MWHC*	Roshila Mohammed 202-877-0805
Amulet (LAA occluder)	• Stroke prevention	MWHC*	Roshila Mohammed 202-877-0805
CohereX WaveCrest (LAA occluder)	• Reduce short term anticoagulation requirements	MWHC*	Roshila Mohammed 202-877-0805
STOP AF First	• Revise treatment guidelines for paroxysmal atrial fibrillation patients	MWHC*; MUMH** MFSMC***; MSMHC****	Isac Kunnath 202-877-0140
ASAP TOO	• Reduce the risk of thrombo-embolic ischemic stroke and systemic embolism	MUMH**	Judith Raqueno 443-278-9170

*MedStar Washington Hospital Center **MedStar Union Memorial Hospital ***MedStar Franklin Square Medical Center
 ****MedStar Southern Maryland Hospital Center

Flexible Expertise



(L to R) MedStar Washington Hospital Center cardiologists Robert Lager, MD, Itsik Ben-Dor, MD, and Robert Gallino, MD, are increasingly using the radial approach in cardiac catheterization procedures but maintain expertise in the femoral approach, which is still vital for many cases.

Patients want the least invasive procedures. And for those who need cardiac catheterization, the transradial approach is fast becoming the procedure of choice. While they are increasingly turning to the radial approach, cardiologists at MedStar Heart & Vascular Institute (MHVI) at MedStar Washington Hospital Center say there are still legitimate reasons to maintain expertise in other techniques as well.

Instead of inserting the catheter through the larger femoral artery in the groin, cardiologists insert a small hydrophilic-coated sheath through the radial artery to access the coronary artery. There is less pain, less down time and less risk of post-procedural bleeding—and patients can often eat within an hour of the procedure. And at MHVI's MedStar Union Memorial Hospital, due to the majority of catheterizations done radially, a dedicated Radial Recovery Lounge was constructed. Modeled after a high-end waiting area, it

features a large, open space outfitted with recliners and amenities such as a cafe, internet, and TV.

"It's remarkable to see how quickly the radial approach has gained traction in just the last 10 years," says cardiologist Robert Lager, MD, who is based at the Hospital Center. "Now, up to 90 percent of the coronary procedures in other parts of the world, such as Europe, China and India, are performed transradially. It's more comfortable, and it's safer."

In fact, Dr. Lager uses the radial approach in almost 80 percent of the cardiac catheterizations he performs each day. One of the key advantages: patients don't have to lie flat for four-to-eight hours after the procedure to avoid bleeding, which is required with the transfemoral approach. "You can be up and walking within an hour," he notes.

Patients in the midst of a heart attack who have been aggressively anticoagulated are another group that benefits from the radial approach, says Dr. Lager. "Their risks are higher for bleeding, and we've been able to show in studies that the radial approach, with the better ability to control bleeding, results in lower mortality."

Yet Dr. Lager and his Hospital Center colleagues Robert Gallino, MD, and Itsik Ben-Dor, MD, also maintain their expertise in the femoral approach. "All the structural work in the heart is done with large catheters," says Dr. Ben-Dor. "At this point they don't fit through the radial artery. So you have to be adept at both procedures."

At the Hospital Center, patients scheduled for radial procedures are prepared pre-operatively for a femoral procedure in the groin as well, notes Lager. "About five percent of the time we run into some anatomic problem," he says. "If we need to immediately switch over, we are able to do so without any delay."

Dr. Lager notes that acceptance for new catheterization techniques change slowly. "In the 1960s and 1970s, a more common procedural approach was to use the brachial artery," he recalls. "Then the majority switched to the femoral technique, which was felt to be much safer."

When transradial catheterization was introduced, "there was a lot of resistance. It was viewed as unnecessarily complex and more time-consuming." After more than a decade of use, however, the radial approach has been documented to be safe and effective. Many patients specifically ask for the approach, says Dr. Ben-Dor, because they've heard that the recovery is so much easier.

Drs. Gallino and Lager teach the radial approach to new physicians. In fact, many new interventional cardiologists are likely more comfortable with the radial access than the femoral access. Having a balanced approach and an open mind, says Dr. Lager, is critical to effectively reduce bleeding risk and the associated risk of death and heart attack for these procedures.

"You can't be a zealot about your approach," he says. "The physician should do what is best, safest and most effective for each patient, and this will require that the choice for a route of access is tailored to the individual clinical situation."

ENDOVASCULAR REVASCULARIZATION:



CLI
CRITICAL
LIMB
ISCHEMIA

Tareq Massimi, MD, is one of several MHVI vascular surgeons taking part in the BEST-CLI clinical study comparing optimal endovascular procedures to optimal surgery therapy for patients who are eligible for both.

More Americans are living longer, and many develop multiple co-morbidities that preclude them from undergoing open surgeries. This has led to an explosion of endovascular treatments for cardiovascular disease. During the last decade, millions of patients with peripheral arterial disease (PAD) have benefited from these newer percutaneous approaches to treatment, including those with critical limb ischemia (CLI).

While open surgery still plays a vital role in limb salvage, a burgeoning variety of innovative endovascular techniques are proving to be quite successful in restoring blood flow for the most critically ill—and saving limbs.

WHAT'S BEST FOR WHOM?

"Open surgery in limb salvage is well established, and endovascular techniques are increasingly used. Both approaches have their clear indications. However, in some instances, both ways are acceptable, and that's what we need to clarify," says Tareq Massimi, MD, vascular surgeon at MedStar Washington Hospital Center.

This is the goal of the international BEST-CLI study now underway. MedStar Washington Hospital Center and several other MedStar facilities are part of the multicenter U.S. arm of the investigation comparing optimal endovascular therapy to optimal surgical therapy in patients with CLI who are eligible for either approach. The study began in 2016 and will enroll more than 2,000 patients nationwide.

"To qualify for the study, patients must have advanced disease—CLI with rest pain or tissue loss (ulcer or gangrene)," Dr. Massimi explains. "After a thorough evaluation, if we determine the patient could benefit from either intervention and they agree to participate, they are randomized and receive the best possible approach of their assigned treatment."

Throughout MHVI, 14 patients have been enrolled and are undergoing treatment. Dr. Massimi says, "We provide close, long-term follow-up to document complications, define which procedure provides the longest period of relief before the patient requires another intervention, and ultimately what produces the best outcome."

Continued



Suzanne Kool, MD

Dr. Massimi says the study also may help eliminate institutional biases that are common nationwide. "Everyone advocates for their own techniques—those they were taught during their training," he says. "Surgeons and interventionalists have their preferences, based on experience and historical data. This trial would clarify the right thing for the patient based on the outcomes."

FOSTERING COLLABORATION

The BEST-CLI study goals also include building a "multidisciplinary structure that fosters cooperation among interventional cardiologists, interventional radiologists, vascular surgeons and vascular medicine specialists," Dr. Massimi says.

Suzanne Kool, MD, a vascular surgeon in the Baltimore region of MedStar Heart & Vascular Institute (MHVI), says in her fellowship at Ohio State University she was involved in the BEST-CLI study and agrees that the goals of the study promote collaboration among vascular specialists. "In our practice in Baltimore," she says, "we also include specialists in podiatry, diabetes, and plastic surgery. We are looking at bringing in everyone who can help treat the whole person and restore their quality of life as much as possible."

RISK VS. BENEFIT

Dr. Kool says that just like other disciplines, as the technology has improved, so have the procedures. In her practice, she says, about 60 percent of her limb salvage surgeries are performed endovascularly. "Fifteen or 20 years ago, a shorter lesion would get a bypass. Those lesions are now being treated using endovascular techniques. These newer techniques are being used in

more and more complex cases. But we need to be careful. Just because we CAN do a surgery endovascularly, SHOULD we?"

The advantages of endovascular procedures, she says, are:

- less risk of complications
- most are done without general anesthesia and are outpatient
- most have low blood loss, are less painful and have no long incisions that need to heal

A disadvantage, however, is that the benefits of endovascular procedures don't typically last as long as those from open surgeries. "But longer term results may not always be needed," she says. "For someone who is otherwise healthy and has severe disease, and you want the intervention to last long, then open is probably the way to go. But if you're just hoping to improve flow long enough to heal a wound, then an endovascular procedure may be safer for someone who has comorbidities."

It all comes down to what's best for the patient. Dr. Kool says, "We look at all the factors—age, comorbidities, and overall function status. For a bedridden patient who will never walk again, amputation can be the quickest and safest option to heal a wound without quality of life being affected. But for someone who could walk again, we aim to save the limb. If that's not possible, the goal is to get them back to their baseline functionality. There is clearly still a need for both open and endovascular options."

GROWING ENDOVASCULAR ARSENAL

Today, numerous percutaneous approaches are being used to revascularize limbs in cases of CLI—with more in the pipeline. With CLI affecting about 1.4 million people in the United States and nearly 320,000 new cases every year, more widespread and targeted use of these techniques will no doubt save both limbs and lives.

"Which procedure we choose depends on the individual patient, the location of the obstruction, and the direction of the blood flow," says Dr. Massimi.

"Using endovascular techniques, we are employing balloon angioplasty, drug-coated balloons, stents, and atherectomy devices to open and debulk plaques and various blockages, and treat de novo or restenotic lesions, all of which helps restore the blood flow into the limb," he says. New and creative techniques also include retrograde pedal access for limb salvage in high-risk patients.

One trial at MHVI is looking at the variety of medications and doses for drug-coated balloons to determine what is most effective. Another trial is examining the use of shock waves to break up highly calcified plaques.

The well-established open bypass surgery also is performed with great results using natural grafts as well as synthetic materials bonded with heparin, Dr. Massimi says. "However, it will be a few more years until we know which is best for what patient."



Nelson Bernardo, MD, is leading a feasibility study of an investigational revascularization technique called LimFlow™. Shown here (L to R) are Dr. Bernardo and Toby Rogers, MD, PhD.

LIMFLOW: VEINS INTO ARTERIES

Nelson Bernardo, MD, medical director for Peripheral Vascular Intervention at MHVI and director for Peripheral Interventional Research Studies at MedStar Cardiovascular Research Network, is leading a feasibility study of an investigational revascularization technique called LimFlow™.

The LimFlow System is currently indicated as a treatment for patients with end-stage CLI who have no other revascularization option—and have failed either endovascular or surgical interventions, or even both. "The procedure is based on a concept devised some time ago for use in the heart to 'bypass' occluded coronary arteries," says Dr. Bernardo.

The LimFlow procedure entails the creation of a fistula from an artery in the leg to its accompanying vein. The latter carries the oxygenated blood flow into the critically ischemic foot via venous pedal arch acting as the arterial system. The vein is accessed distally at the level of the ankle while the artery is accessed at the groin area using the antegrade femoral approach. Catheters are advanced from both access points, and these meet at an area above the arterial obstruction. A connection is made across from the patent segment of the artery to the vein, guided by the LimFlow ultrasound system.

To ensure correct direction of blood flow distally to the foot, "push valvulotome" is used to disrupt the venous valves. This is followed by the implantation of LimFlow ePTFE-covered nitinol self-expanding stents from the arterio-venous crossing point down to the ankle. This ensures laminar flow through the arterialized vein and into the pedal arch to perfuse the ischemic foot.

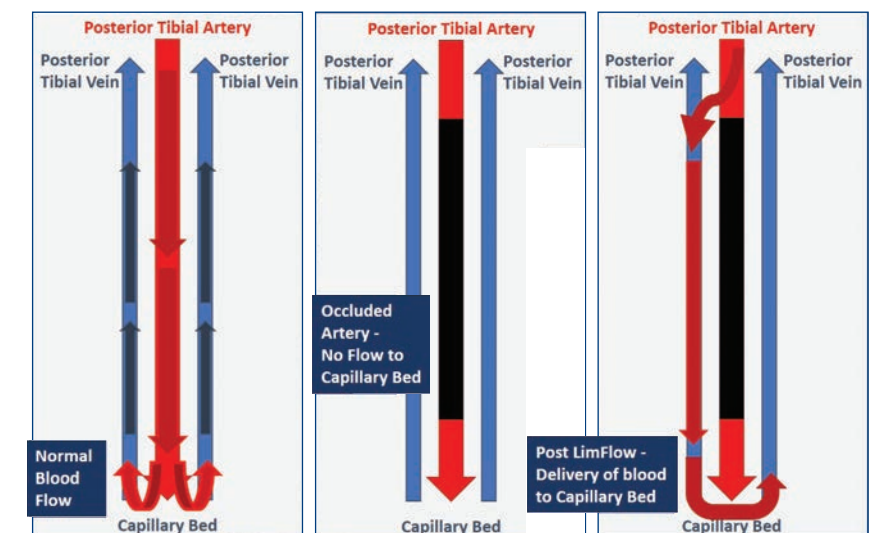
"Disappointing results in the heart led to its adaptation and use in the vascular bed of the legs. MedStar Washington Hospital Center is one of the few U.S. centers conducting the FDA-approved feasibility study," Dr. Bernardo explains.

"The goals of this pilot study are to investigate the safety, effectiveness and feasibility of the LimFlow procedure for the treatment of critical limb ischemia. We have treated five patients thus far, individuals who have been designated to have no hope, with no discernible blood flow to their foot. Limb loss/amputation is typically inevitable for these patients who present with complaints of resting foot pain, non-healing wounds/ulcers, and even gangrene."

"Wound healing is critical to the success of this procedure and all treatment for CLI," says Dr. Bernardo. "We have an entire expert team led by podiatric surgeon John S. Steinberg, DPM, and plastic surgeon Christopher Attinger, MD, who help ensure optimal recovery."

Dr. Bernardo says, "LimFlow is a simple but ingenious approach that shows great promise. Patients I've performed the procedure on feel relief from pain. What is very dramatic is the immediate relief of resting ischemic pain. At the end of the procedure, one is able to touch the affected limb without any complaint from the patient."

"It's one of a number of endovascular techniques with the potential to reduce amputation and agonizing pain in patients with CLI—and dramatically improve quality of life."



To reach one of our vascular specialists for a patient consult, call:

MedStar Washington Hospital Center:
202-877-0275

MedStar Union Memorial Hospital Center:
410-554-2950

MedStar Good Samaritan Hospital:
443-444-3431

An Effective Treatment for Challenging Congestive Heart Failure Cases

Cardiac Resynchronization Therapy (CRT) Using Antidromic Snare Technique and Venoplasty

Presentation

- A 71-year-old male with a long-standing cardiac condition had undergone four failed cardiac resynchronization therapy (CRT) procedures.
- Two of the failed procedures involved placement of the LV lead by vein using conventional implantation methods, while the other attempts were made with HIS-bundle pacing.
- The patient was referred to MedStar Heart & Vascular Institute to assess the feasibility of undergoing CRT using tools and techniques developed by Seth Worley, MD.
- The patient had also undergone previous bypass surgeries, and was being treated for diabetes mellitus.

Assessment and Diagnosis

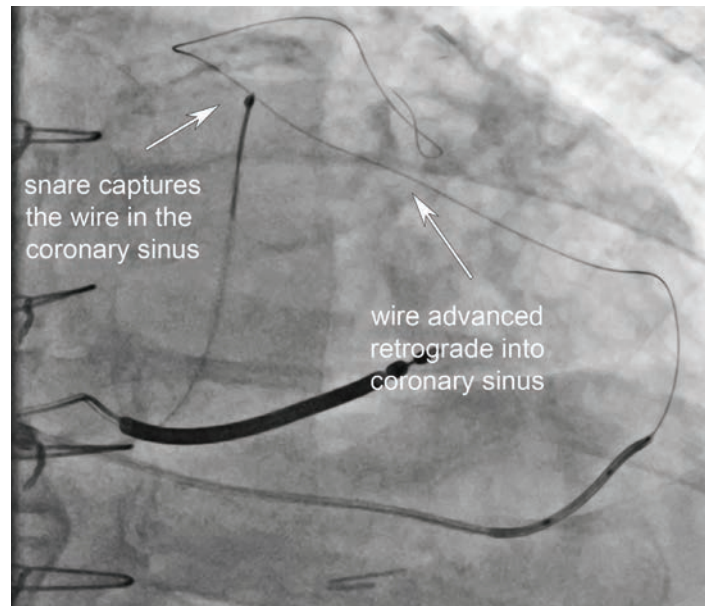
- The failed CRT procedures had resulted in refractory congestive heart failure.
- The patient's overall condition posed no obstacles to attempting another CRT procedure using Dr. Worley's tools and techniques. The only other option was open-heart surgery.
- After being advised of the surgical options and potential outcomes, the patient consented to the CRT procedure.

Treatment

- During the 1.5-hour procedure, a near-total occlusion in the patient's subclavian vein was dilated using venoplasty.
- At the heart, vessels used in previous lead placements were found to be damaged and blocked.
- Access to coronary sinus was achieved using an adjacent, undamaged vein. After widening using venoplasty, the vein was used to successfully place the LV lead using the antidromic snare technique.
- No problems were encountered during the procedure.

Outcome

- Upon awakening from anesthesia, the patient reported feeling immediate improvement.
- Post-operative tests confirmed proper blood flow and left ventricle function. The patient was discharged the day after surgery with no restrictions.
- Patient has continued to show marked progress in his overall health.



Conclusion

- While CRT is a proven treatment for congestive heart failure, the difficulty of placing leads may necessitate the use of alternative techniques.
- The antidromic snare technique is an attractive option in cases where conventional or HIS-bundle approaches are unsuccessful, or the LV lead fails to operate properly.
- The method can also be performed more quickly, reducing the patient's radiation exposure and anesthesia risks.
- Patients otherwise deemed "too sick" for surgery may nevertheless be candidates for antidromic snare technique procedures.

Dr. Worley says, "Any patient who has had an unsuccessful transvenous attempt at LV lead placement and is being considered for open-heart surgery should first be considered for advanced cardiac resynchronization therapy procedures. As precise placement of the LV lead is a critical factor, methods such as the antidromic snare technique may benefit patients whose congestive heart failure has not improved following CRT procedures that used conventional approaches."

If you have any additional questions about advanced cardiac resynchronization therapy (CRT) treatment methods, or wish to discuss a patient case, please contact Dr. Worley directly at 202-877-7685, or Seth.Worley@MedStar.net.

Suddath Named New Cardiology Chair and Medical Director of Cath Lab

Cardiac Services Elevated at MedStar Southern Maryland Hospital Center

MedStar Heart & Vascular Institute is pleased to announce that William O. Suddath, MD, has been named the new chairman of Cardiology and medical director of the cardiac catheterization laboratory at MedStar Southern Maryland Hospital Center. A highly experienced interventional cardiologist, Dr. Suddath spent the last 22 years as an integral member of the renowned interventional cardiology team at MedStar Washington Hospital Center.

Just three months into his new position, Dr. Suddath says plans are already underway to improve cardiology services for patients at MedStar Southern Maryland. These include streamlining services, rebuilding the Emergency Department, and increasing the number of beds in the Intensive Care Unit.

"My first goal is to streamline services in the cardiac catheterization lab so that patients are better managed, with few or no delays," says Dr. Suddath. This includes working hand-in-hand with both the Emergency Department and local Emergency Medical Services to more quickly activate Code STEMI. MedStar Southern Maryland maintains the current guidelines of the treatment of ST-segment elevation myocardial infarction of a door-to-balloon time of 90 minutes or less for patients undergoing primary percutaneous coronary intervention.

By meeting this guideline and other high quality standards, MedStar Southern Maryland was invited to join the MedStar Heart & Vascular Institute-Cleveland Clinic Heart and Vascular Alliance late last year. This alliance between two nationally recognized cardiac programs has accelerated improvements in heart care and research, and resulted in even better outcomes for the patients served by the participating healthcare organizations.

"Bill Suddath will be able to build on the outstanding work already underway by our MedStar Southern Maryland Hospital Center physicians, leadership and staff," says Stuart F. Seides, MD, physician executive director, MedStar Heart & Vascular Institute (MHVI). "His proven leadership skills and clinical expertise will be invaluable in his role as the new team leader for our cardiovascular colleagues practicing in this region."

During his time at the Hospital Center, Dr. Suddath was instrumental in the start-up and growth of CodeHeart, MHVI's regional program, which expedites the transport and treatment of heart attacks. He is also the program director for the interventional cardiology fellowship program, which trains physicians in advanced cardiac catheterization skills.

Looking ahead, Dr. Suddath hopes to expand other cardiovascular programs at MedStar Southern Maryland, such as peripheral vascular disease treatment and advanced heart failure management. He also hopes to increase patient volumes, while continuing to achieve excellent outcomes.

"MedStar Southern Maryland Hospital Center is rapidly growing," says Dr. Suddath. "We are looking to see more transfers and continue to be the 'go-to' cardiac and vascular center for the southern Maryland peninsula."



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—William Suddath, MD

MedStar Washington Hospital Center Cardiac Surgery Program Receives Top Quality Rating

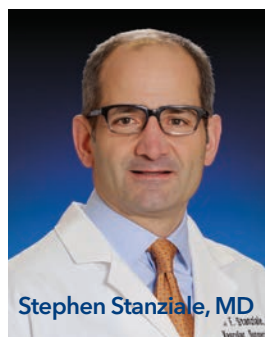
MedStar Washington Hospital Center received the highest rating possible (3 Stars) from the Society of Thoracic Surgeons in four areas: Coronary Artery Bypass Graft (CABG), Aortic Valve Replacement (AVR), AVR/CABG, and Mitral Valve Replacement/Repair (MVRR).

The Society developed this comprehensive rating system for measuring patient care and outcomes, using a series of performance measures endorsed by the National Quality Forum. This system is one of the most sophisticated and highly regarded overall measures of quality in health care, rating the benchmarked outcomes of cardiothoracic surgery programs in the United States and Canada.

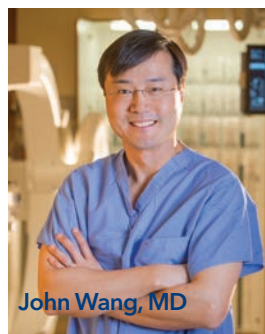
(L to R) Ezequiel Molina, MD; Jennifer Ellis, MD; Ammar Bafi, MD; Vinod Thourani, MD; Christian Shults, MD; Paul Corso, MD; Peter Hill, MD, Medical Director, Cardiac Surgery, MHVI



Allen J. Taylor, MD



Stephen Stanziale, MD



John Wang, MD

Physician Leaders Take New Positions

This spring, Allen Taylor, MD, Stephen Stanziale, MD, and John Wang, MD, were named to new positions within MHVI. MHVI Physician Executive Director Stuart F. Seides, MD, says, "These three physicians are outstanding clinicians and proven leaders whose increased scope of responsibility will further benefit MHVI and our patients."

Dr. Taylor, a member of the MedStar Washington Hospital Center Medical Staff since 2008 and chief of Cardiology at the Hospital Center since 2013, has been named inaugural chair of the newly approved Department of Cardiology at the Hospital Center. Cardiology was elevated to departmental status in 2018. He is also chief of the Division of Cardiology at MedStar Georgetown University Hospital, a position he has held since 2012. Dr. Taylor's major research accomplishments include defining the role of lipid lowering therapy on carotid atherosclerosis. He also has pioneered developments in the field of cardiac CT. He is a full Professor of Medicine at the Uniformed University of the Health Sciences, Bethesda, Md., and at Georgetown University, Washington, D.C.

Dr. Stanziale has been named head of the Vascular Surgery Service at MedStar Franklin Square Medical Center. A member of MedStar Cardiology Associates for 12 years where he was the vascular division lead physician, Dr. Stanziale specializes in minimally invasive endovascular therapies for carotid, renal, aortic aneurysm, lower extremity arterial and venous disorders. He is also skilled in traditional open surgery.

Dr. Wang has been appointed director, Interventional Cardiology and Structural Heart Disease, for the Baltimore region. An interventional cardiologist at MedStar Union Memorial Hospital since 2006, where he is chief of the Cardiac Cath Lab, he is also scientific director for Baltimore Cardiovascular Research. He has championed the use of the transradial approach to cardiac catheterizations at MedStar Union Memorial, and also has been principal investigator or sub-investigator on more than 40 studies relating to the safety and efficacy of new devices and technology in interventional cardiology. Currently, he is the national principal investigator of the OMEGA trial studying the latest generation of bare metal stents.

First ECHO-Guided Structural Heart Conference

The mitral valve took center stage at MedStar Heart & Vascular Institute's regional conference, Innovative Echo-Guided Treatment for Structural Heart Disease, on April 21, at the Hyatt Regency Bethesda in Bethesda, Md.

Lowell F. Satler, MD, FSCAI, director of Cardiac Catheterization Laboratories, kicked off the talk with an overview of mitral regurgitation (MR), including the dominant role of MitraClip in treating leaflet pathology. Vinod H. Thourani, MD, FACS, FACC, chair of Cardiac Surgery, spoke of the importance of having both surgical and transcatheter procedures as treatment options for MR. He added that echocardiographers play a key role in the treatment decision-making process. There were also sessions on the aortic and tricuspid valves.

Zuyue Wang, MD, director of Structural and Interventional Echocardiography, served as the course director, and Drs. Steven A. Goldstein, Satler, and Thourani were co-directors.



(L to R) Zuyue Wang, MD, Lowell Satler, MD, and Vinod Thourani, MD, at MHVI's regional conference

In Memoriam

Editor's Note: At press time, we learned of the death of **Dipin Gupta, MD**. A tribute to him will be published in the fall issue.

James Bacos, MD, 91, former chair of Cardiology, died Wednesday, June 6. Dr. Bacos was hired as the first and only full-time cardiologist at Washington Hospital Center in 1962. He served as chief of Cardiology from 1964-1981, and is shown at right at the opening of Washington Heart.

"Dr. Bacos had a visionary role in jump-starting this institution as a regional and national leader in cardiovascular care," said Stuart F. Seides, MD, physician executive director, MedStar Heart & Vascular Institute. During his tenure as chair, Dr. Bacos expanded the cardiology staff to include specialists and subspecialists, and opened the first Catheterization Lab, the first Coronary Care Unit and created the hospital's first Code Blue cart.

A native of Brooklyn, New York, Dr. Bacos attended Virginia Polytechnic Institute before being called to active service in World War II. In 1948, Dr. Bacos began medical studies at the Duke University School of Medicine. Upon graduation, he was called back to active service in the US Air Force. He was later assigned to Wilford Hall Air Force Hospital at Lackland Air Force Base, where he served as chief of the Cardiac Lab until his discharge from the service in 1963.



Ethan Haskel, MD, 60, died Saturday, May 26. He was a much beloved cardiologist at MedStar Franklin Square Medical Center for 26 years. A colleague, Dr. Jerry Fleishman, said, "I know that I speak for so many of our colleagues, friends, and patients that we are all better human beings because of having [Ethan] in our lives and we will forever be eternally grateful."

Dr. Haskel practiced cardiology at MHVI/MMG (MedStar Medical Group). A native of Huntington, New York, he was director of the Echocardiography Laboratory at MedStar Franklin Square Medical Center, and a clinical assistant professor of medicine at the University of Maryland School of Medicine in Baltimore.

New Medical Staff



Anil Pandit, MD, is a fellowship-trained cardiologist board certified in internal medicine, cardiovascular diseases, echocardiography

and nuclear cardiology. As part of the MedStar Heart & Vascular Institute, he sees patients at MedStar Franklin Square Medical Center and MedStar Health Bel Air Medical Campus.

A graduate of Manipal College of Medical Sciences, Pokhara, Nepal, Dr. Pandit did his internship at the University of Maryland Midtown

Medical Center, Baltimore, Md., and his residency at the University of Utah Medical Center, Salt Lake City, Utah. He completed a fellowship in Cardiovascular Diseases at the Mayo Clinic, Scottsdale, Ariz.

Dr. Pandit's clinical interests include:

- Cardiac imaging
- Preventive cardiology



CARDIOVASCULAR Physician



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

Please submit editorial comments to Norma Babington, at norma.babington@medstar.net, or 202-877-0201.

Visit our website, at MedStarHeartInstitute.org.

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UPCOMING CME CONFERENCES

CONTROVERSIES IN CARDIAC ARRHYTHMIAS 2018

September 28

The Cosmos Club, Washington, D.C.
Course Director: Edward V. Platia, MD

CARDIOVASCULAR RESEARCH TECHNOLOGIES 2019

March 2 - 5, 2019

The Omni Shoreham, Washington, D.C.
Course Director: Ron Waksman, MD
www.crtmeeting.org

ADVANCED HEART FAILURE SUMMIT: 30TH ANNIVERSARY CELEBRATION OF VENTRICULAR ASSIST DEVICE AND HEART TRANSPLANTATION

October 13

Martin's Crosswinds, Greenbelt, Md.
Course Co-Directors: Samer S. Najjar, MD;
Mark R. Hofmeyer, MD
cme.medstarhealth.org/AHF

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