

# CARDIOVASCULAR Physician



## Infiltrative Cardiomyopathy Program *Earlier Diagnosis and Treatment*

*Farooq Sheikh, MD, Director of MedStar Heart & Vascular Institute's  
Infiltrative Cardiomyopathy Program*

From the desk of Stuart F. Seides, MD  
Physician Executive Director  
MedStar Heart & Vascular Institute



## Drilling Down, Branching Out

In the not-too-distant past, a well-trained cardiologist could handle most patient diagnoses and treatment, and have a fairly complete understanding of the field. But the knowledge base has expanded exponentially in the last few decades, exceeding the absorption capacity of any one (even brilliant!) cardiologist.

The growth of the field has been organic, rooted in a strong core of information—the trunk from which branches and leaves have sprouted at an astonishing pace. Sub-specialties and sub-subspecialties have emerged and cardiology practice—as well as cardiac surgical practice—continues to be reshaped for the benefit of patients. The generalist, often acting as the “quarterback” in an increasingly complex system of care, must have a broad understanding of the field along with its growing sub-specialties and, critically, must have ready access to the necessary advanced expertise.

This subspecialty expertise is the result of the research enterprise: It’s the engine that fuels knowledge expansion. I’m proud to say that MedStar Heart & Vascular Institute (MHVI), through our Research Network (MCRN), has played an important role in this remarkable evolution in cardiovascular medicine and surgery.

### COMMUNICATION, DISSEMINATION

Perhaps nothing more dramatically demonstrates the growth of research and the increasing specialization of cardiovascular medicine than our annual Cardiovascular Research Technologies (CRT) conference. This year’s conference celebrated 40 years of percutaneous treatment options for heart disease. The CRT meeting has become

one of the world’s largest conferences of its kind, attracting an international audience of more than 3,000.

During four days of diverse programming, the meeting promotes the rapid dissemination of cutting-edge research and technology, which will have an immediate impact on the practice of cardiology globally.

The development of percutaneous treatment options for structural heart defects is one of the most rapidly growing areas of interventional cardiology and was a featured section of the meeting’s curriculum. You can read about one of the most exciting of these new treatments in this issue of *Cardiovascular Physician*. The BASILICA interventional procedure uses an off-the-shelf technology in an innovative way to treat failing surgical bio-prosthetic aortic valves with TAVR, while avoiding the devastating consequences of an “old” valve leaflet blocking off a coronary artery. The technique was developed in part by MHVI’s Toby Rogers, MD, PhD, in collaboration with the National Institutes of Health, and is helping to transform treatment for patients with this often fatal complication.

The treatment of advanced heart failure is another area in which research has exploded. Where we could offer only generalized therapeutic interventions, we now are drilling down into sub-categories of this once devastating diagnosis and developing alternative treatments. Farooq Sheikh, MD, is spearheading the development of a specialized program for one of these sub-categories—the diagnosis and treatment of infiltrative cardiomyopathies—which disproportionately affects minority populations (pages 4-5).

### FINDING A NICHE

With the growth of sub-specialization and concurrent specialized training, cardiovascular physicians are finding their unique practice niches. At MedStar Union Memorial Hospital, Ankit Shah, MD, represents this growing cadre of specialized MHVI experts. He is a fellowship-trained sports cardiologist and, as director of MedStar Sports & Performance Cardiology, offers comprehensive cardiovascular care and physiologic testing for active individuals and athletes (pages 8-9).

Increased fellowship training has become necessary to developing expertise in these specially focused areas, and new board certifications have followed suit. Leading medical centers such as MHVI have responded with increased training opportunities for physicians and other providers to bring the most sophisticated care to patients and our communities.



Venkatesh Raman, MD

Some cardiologists are scratching their heads when patients present them with their Fitbit® data, assuming their doctors can use the information to help diagnose and treat their conditions. The good news and the bad news is that fitness trackers and smart phones collect huge amounts of information about us every day—how much we move, how fast our hearts beat, and in some instances, how much and how well we sleep. So could all of that information help a patient’s healthcare team? Venkatesh Raman, MD, and colleagues in the MedStar Heart & Vascular Institute’s Electrophysiology Program hope to find out.

*“The challenge is how the data can be analyzed, curated and delivered to the healthcare team in actionable form and within a manageable workflow.”*

—Venkatesh Raman, MD

Dr. Raman, assistant professor at Georgetown University School of Medicine, and researchers at the fitness tracker giant would like to identify cases of atrial fibrillation (AFib) before health problems arise. While AFib occurs in fewer than 2 percent of people younger than 65, the risk rises to 10 percent in people older than 80. The most feared consequence is stroke; 20 to 25 percent of all non-bleeding strokes are attributed to AFib. However, “one-quarter of stroke patients have no clearly identifiable cause,” says Dr. Raman. “A significant portion of these strokes may be due to AFib, but detection is often challenging without the use of a loop recorder device implanted in the chest.” He and the Fitbit team have completed a study protocol to accelerate development of an AFib detection algorithm using data from the wristband sensor, which would avoid issues associated with a permanent implant and allow screening to be applied more broadly.

## Can Smart Phones and Fitness Trackers Assist Cardiologists?

The early results are very promising.

AFib is only one health target Fitbit and other companies are exploring. Trackers and smart phones might monitor other cardiac, pulmonary and endocrine conditions. For example, and already available, continuous glucose monitoring systems for diabetes could send data to a patient’s smart phone and relay that information to the provider team. This kind of active technological engagement can minimize office visits and lab tests, shortening potential delays in treatment to make useful changes faster and easier for the patient.

One of the biggest challenges is the deluge of data our devices generate. The human heart can beat well more than 100,000 times each day, and not all of those heartbeats are helpful to a patient or doctor. “It can be difficult for doctors to know what to do with all of the information,” says Dr. Raman. “The challenge is how the data can be analyzed, curated and delivered to the healthcare team in actionable form and within a manageable workflow.”

Rising to that challenge is what will turn these personal wellness gadgets into true digital health tools.





Farooq Sheikh, MD, director of MedStar Heart & Vascular Institute's Infiltrative Cardiomyopathy Program

# Infiltrative Cardiomyopathies

## New MHVI Program Improves Diagnosis and Management

Specialists at MedStar Heart & Vascular Institute (MHVI) have launched a new program to help diagnose and treat infiltrative cardiomyopathies earlier, in hopes of giving patients a greater chance for a longer, and improved, quality of life.

Infiltrative cardiomyopathies (CM) represent a group of acquired and inherited diseases characterized by the deposition of abnormal biological substances within the heart that ultimately lead to cardiac dysfunction.

These diseases result in symptoms of heart failure (breathlessness, lower extremity swelling, exercise intolerance, fatigue) as well as symptoms related to electrical disturbances (lightheadedness, palpitations, syncope), such as ventricular/atrial arrhythmias and even sudden cardiac death. Recognizing the disease in its early stages is essential to improve outcomes.

Designed to improve the diagnosis and treatment of all forms of infiltrative heart diseases, the new program—the first of its kind in the area—is directed by Farooq Sheikh, MD, FACC, a heart failure specialist in the Advanced Heart Failure (AHF) Program, and Selma

Mohammed, MD, PhD, director of Heart Failure Research, both at MedStar Washington Hospital Center. Reflecting the systemic nature of these diseases, these two doctors work with colleagues in advanced heart failure, as well as specialists in cardiac electrophysiology, rheumatology, radiology, hematology/oncology, pulmonary medicine, genetic medicine, neurology, pathology, and more.

Two of the most common and challenging forms of infiltrative cardiomyopathies are cardiac sarcoidosis (CS) and cardiac amyloidosis (CA). Recent progress in imaging tools and technology has made identifying these diseases much easier and more accurate than before, often meaning the difference between life and death.

### CARDIAC SARCOIDOSIS

Sarcoidosis is a multisystem disease characterized by the accumulation of inflammatory cells within various organs, resulting in the pathologic finding of non-caseating granulomas. Increasingly, specialists are recognizing that cardiac involvement is a major cause of morbidity and mortality with sarcoidosis and much more prevalent than

previously realized. In fact, the first international guidelines for the diagnosis and treatment of CS were only released in 2014.

“The annual incidence of sarcoidosis in the United States is estimated at 10 to 40 per 100,000 individuals, with a three-fold higher risk in African-Americans,” explains Dr. Sheikh.

“Approximately 30 percent of all sarcoidosis patients will experience cardiac involvement; however, clinically overt cardiac disease may only manifest in approximately 5 percent of cases. That means that the majority of CS patients have silent or asymptomatic disease, which has traditionally led to late or absent diagnoses and treatment.”

Over the last few years, however, cardiac MRI (CMR) and cardiac Positron Emission Tomography (PET) have emerged as the most effective and reliable imaging modalities for detecting CS. Cardiac PET imaging has also been shown to be useful in assessing the CS patient's response to immunosuppressive therapy.

“On their own, neither ECGs nor echocardiograms are specific enough to pick up the presence of cardiac sarcoidosis,” says Dr. Sheikh. “Even endomyocardial biopsy has a detection rate of less than 25 percent. By contrast, CMR and PET imaging have proven to be much more sensitive in detecting CS. These tests also serve as prognostic tools, predicting which patient is most likely to develop adverse cardiac events in the future, including heart failure, electrical conduction disease, ventricular tachycardia, and even death.”

While steroids remain the cornerstone immunosuppressive treatment, newer immunosuppressive therapies have been evaluated as steroid-sparing treatments, including biologic agents targeting TNF-alpha (Tumor Necrosis Factor). For patients with Stages B to D heart failure, medical management remains an essential treatment approach. Finally, advanced CS care includes implantable cardiac defibrillators, monitoring for conduction disease and, in the most severe cases, mechanical circulatory support such as left ventricular assist device (LVAD) therapy and cardiac transplantation.

### CARDIAC AMYLOIDOSIS

Amyloidosis is a systemic disease in which abnormal and even seemingly normal proteins deposit in organs and tissues, disrupting their function. Once considered rare, cardiac amyloidosis (CA) is now recognized as an under-appreciated cause of heart failure. Just like cardiac sarcoidosis, the diagnosis of cardiac amyloidosis requires biopsy evidence of amyloid deposits in the heart.

Two forms of amyloid generally infiltrate the heart: AL (immunoglobulin light chain, previously known as primary amyloidosis) and transthyretin (ATTR). Transthyretin (ATTR) amyloidosis further encompasses two distinct disease states: hereditary or familial amyloidosis (ATTR-mutant), which is due to a mutation in the transthyretin gene, and a non-genetic form seen in elderly individuals (ATTR-wild type, formerly known as senile systemic amyloidosis).

The incidence of AL cardiac amyloidosis remains relatively stable at around 3,000 new cases per year. However, recent data demonstrates that transthyretin CA is a frequent yet largely unnoticed cause of several cardiovascular diseases, including heart failure with preserved ejection fraction (HFpEF), atrial fibrillation, and aortic stenosis. It is particularly more widespread than previously expected among those individuals older than 70 and African Americans.

The past decade has seen a revolution in the diagnostic and treatment strategies for cardiac amyloidosis. The MHVI Infiltrative Cardiomyopathy Program has adopted a systematic approach to evaluate patients with suspected CA, which harnesses state-of-the-art tools for the diagnosis and treatment of the disease. This has included involvement in the Patisiran EAP Study, a phase 3 clinical trial assessing the utility of RNA interference in the treatment of hereditary amyloidosis.

### OUTLOOK FOR THE FUTURE

Through the MHVI Infiltrative Cardiomyopathy Program, Drs. Sheikh and Mohammed anticipate developing a nationally recognized center of excellence on both the clinical and research fronts that hopefully will yield new knowledge that can lead to disease-specific therapies for infiltrative CM patients. Meanwhile, they are focused on capturing more patients with suspected infiltrative heart disease early in the process when treatments can help manage disease progression. Dr. Sheikh will begin to see patients at our MedStar Union Memorial Hospital site this fall, as part of our continuing effort to expand access to the MHVI network.

“Infiltrative cardiomyopathies and related heart diseases are a group of conditions in which the heart is basically an innocent bystander, struck down by an out-of-control systemic illness,” Dr. Sheikh says. “Throughout the MHVI network, we have the full complement of tools, technologies, and talent at our fingertips to identify infiltrative cardiomyopathies, assess the threat, and intervene accordingly, giving patients their best hope for enhanced longevity and an improved quality of life.”



Selma Mohammed, MD, PhD, director of Heart Failure Research, is assisting the Infiltrative Cardiomyopathy Program with her research.

For more information on the Infiltrative Cardiomyopathy Program, please call Farooq Sheikh, MD, FACC, or Selma Mohammed, MD, PhD, at 202-877-8085. To schedule an appointment at MedStar Washington Hospital Center, call 202-877-4698. At MedStar Union Memorial Hospital, call 410-554-6550.

# CTO CHRONIC TOTAL OCCLUSION

Conquering the Last Frontier in Coronary Intervention



(L to R) Nelson Bernardo, MD, and Robert Gallino, MD

Despite dramatic improvement in outcomes over the past decade, the percentage of Chronic Total Occlusions (CTOs) treated by percutaneous coronary intervention (PCI) remains stubbornly low nationwide, at about 5 percent. But Nelson Bernardo, MD, and Robert Gallino, MD, both experienced masters of the intricate and demanding technique at MedStar Heart & Vascular Institute, want to change those statistics—and help more patients with CTO feel better and live longer, without open heart surgery.

One part of their strategy is correcting out-of-date, but still lingering misperceptions among the medical community about the safety and effectiveness of PCI for CTO. The other is training select interventional cardiologists in the procedure's subtleties to expand the numbers of skilled operators and make the benefits of CTO PCI more widely available.

"In the past, the ability to treat CTO successfully with PCI was pretty low, only about 70 percent, with a significant risk of cardiac perforation and other complications," says Dr. Bernardo, medical director of the Peripheral Vascular Laboratory and co-chair for cardiac peripheral vascular disease.

"But today, high volume centers like ours typically report success rates for CTO PCI of around 90 percent. Actually, in 2017, we performed 53 CTO PCIs and totally opened up the occlusion in all but one of the patients. That translates into a success rate of 98 percent."

Such progress is the result of continuing innovations that now allow interventional cardiologists to treat a disease that was once only amenable to open heart surgery. Chief among them are the development and improvement of specialized tools, with dedicated guide-wires, microcatheters, and other supportive devices, making even the most complex lesions and anatomies easier and safer to navigate and cross. The advent of drug-eluting coronary stents further enhanced outcomes, by improving long-term patency of the revascularized vessel.

But as in so many complex procedures, the key determinant to an optimal outcome is the individual operator's experience and skills, based upon volume. A sophisticated infrastructure with an accomplished cardiac catheterization lab is also a necessity.

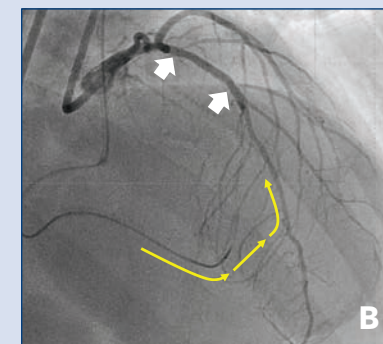
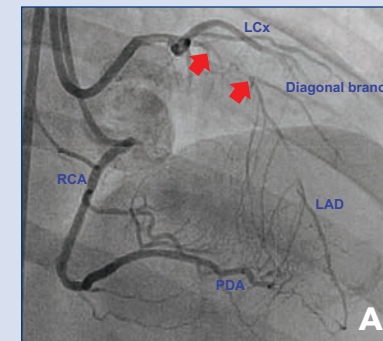
Since launching the program in 2015, MedStar Washington Hospital Center has emerged as one of only a very few hospitals in the U.S. termed high-volume CTO PCI centers—those doing 50 or more of the procedures each year. To date, Drs. Bernardo and Gallino have performed 174 CTO PCIs.

CTOs can affect one or all of the coronary arteries and are a fairly frequent occurrence. In fact, out of every 100 patients undergoing non-urgent coronary angiography, around 20 will be diagnosed with CTO.

"Unfortunately, many cardiologists still believe CTOs cannot be opened, or that opening the CTO will not lead to a significant clinical improvement," says Dr. Gallino. "Yet our personal experience, particularly with PCI, continues to illustrate the benefits of opening a total occlusion, even those that have been closed for 10 years or longer."

Recent studies corroborate their observations. One clinical trial demonstrated that using PCI to open totally blocked coronary arteries can offer symptomatic relief for patients with angina, helping them feel better [<https://www.tctmd.com/news/eurocto-revascularization-bests-medical-therapy-quality-life-cto-lesions>]. Two other clinical trials also showed a marked improvement in the quality of life for patients post-CTO PCI related to relief of lifestyle-limiting fatigue and shortness of breath [Am J Cardiol. 2013;111(4):521-5 and J Am Coll Cardiol. 2014;64(3):235-43].

A successful PCI depends upon thorough evaluation and pre-planning to examine each potential candidate's individual coronary anatomy and morphology. Factors include lesion length, the size and location of the distal target vessel, the existence of significant bifurcation, and the anomalies of the collateral vessels, including size and tortuosity. The specialist then devises the best strategy for achieving complete revascularization using the antegrade or retrograde approach, along with a series of back-up plans to address unforeseen difficulties that may arise.



(Left image, L to R) Robert Gallino, MD, and Nelson Bernardo, MD, perform a revascularization of complex chronic coronary total occlusion (CTO); Image A: Simultaneous angiography of both the left coronary artery and right coronary artery delineates the LAD CTO segment (red arrows); Image B: Successful CTO PCI of chronically occluded mid-LAD with successful DES stenting (white arrows). The CTO segment was crossed using a retrograde approach from the RCA through the septal perforators and into the distal LAD segment (yellow arrows).

Key: DES - Drug-Eluting Stent; LAD - Left Anterior Descending Artery; LCx - Left Circumflex Artery; PDA - Posterior Descending Artery; RCA - Right Coronary Artery

Once the plan is in place, the procedure gets underway. While CTO PCI is more difficult for physicians—the American College of Cardiology still called it "highly challenging" as recently as 2015—it is fairly straightforward for patients.

"After we perform CTO PCI, the patient is usually able to go home the next day and can resume regular activities a few days later," says Dr. Gallino. "By contrast, patients who have had open heart surgery typically spend between seven and 10 days in the hospital, followed by six weeks of recovery."

CTO PCI is still relatively new, but Drs. Bernardo and Gallino believe the outlook for the procedure is promising.

"In those cases where only one artery is totally occluded, we already know it's simply not worth the risk to perform open heart surgery when a minimally invasive PCI may be able to fix the problem," Dr. Bernardo says. "Theoretically, PCI can help the CTO patient live longer, as well, by potentially avoiding a myocardial infarction or contributing to an improved left ventricular function. If on-going and future studies continue to show significant positive impact on health and mortality, PCI could clearly change the treatment arc for coronary CTOs in the future."

Until that day, both doctors are happy with what PCI can offer patients now. "The improvement in the patient's lifestyle is the most rewarding aspect of why we do the procedure," concludes Dr. Gallino.

## SPREADING THE WORD... AND THE SKILLS

As leading specialists in percutaneous coronary intervention for CTOs, Drs. Nelson Bernardo and Robert Gallino are sharing their knowledge and experience with select cardiac interventionalists to raise awareness of the procedure and train others.

They have been working since 2014 to develop an animal model to represent the condition and its vagaries. Using a pig model to replicate CTO in a human, they offered their first day-long course earlier this year to train practitioners in the art and skill of crossing CTOs.

"We want to provide a venue for interventional cardiologists to hone their expertise in CTO PCI," explains Dr. Bernardo. "This model could also serve as a testing platform for guidewires and devices developed to cross CTOs as well as for evaluating different therapeutic options."

To schedule a consultation with Drs. Bernardo or Gallino, call 202-877-5975.

# SPORTS *Cardiology*

## Sports and Performance Cardiologist Ankit Shah, MD, Joins MedStar Union Memorial Hospital



MedStar Heart & Vascular Institute is pleased to announce the addition of Ankit B. Shah, MD, MPH, FACC, as director of the newly created MedStar Sports & Performance Cardiology Program at MedStar Union Memorial Hospital. Sports cardiology is an emerging subspecialty of cardiology that fills a previously undetected void in athletes' care, both recreational and professional, and active individuals with cardiovascular disease or symptoms.

A graduate of Tufts University School of Medicine, Dr. Shah completed his internal medicine training at Cedars-Sinai Medical Center in Los Angeles and cardiovascular disease training at Lenox Hill Hospital in New York City before completing a dedicated fellowship in sports cardiology at Massachusetts General Hospital—the only fellowship of its kind in the country.

"It is vital for those caring for athletes and active individuals to have a sound understanding of the cardiovascular

demands of exercise and the ability to differentiate healthy physiologic cardiac adaptations from pathologic changes," says Dr. Shah.

Sports cardiologists provide comprehensive cardiovascular care for athletes and active individuals, including assessment of cardiovascular symptoms such as chest pain, palpitations, dyspnea, syncope and decreased exercise tolerance. "Additionally," he says, "we work to provide safe return to play recommendations for athletic individuals that have coronary artery disease, history of myocardial infarction, cardiomyopathy, arrhythmias or valvular heart disease."

According to Dr. Shah, evaluation of symptoms is done in the context of the individual's age, risk factors and sport with the aim of reproducing symptoms through tailored exercise testing or ambulatory monitoring. All exercise testing is performed to maximal volitional effort, and cardiopulmonary exercise testing is used to perform complex exercise testing. This diagnostic tool helps clinicians distinguish the cause of exercise intolerance or dyspnea.

"It's important to recognize that athletes or active individuals may not

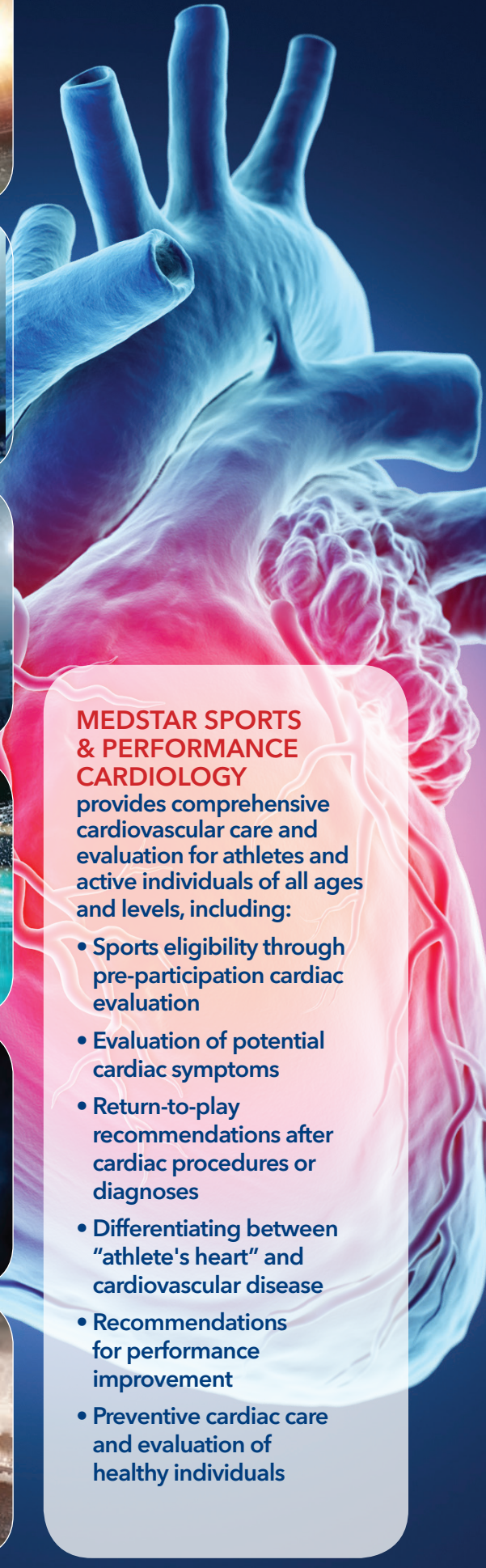
present the same way as their sedentary counterparts," notes Dr. Shah. "Active individuals may only experience symptoms or limitations at peak exercise, they may be more reluctant to voice concerns, and symptoms may be subtle, such as an inability to maintain prior race paces."

Likewise, he adds, interpretation of ECGs and cardiac imaging in athletes must be carefully considered, noting that what may look different or abnormal in a non-athlete might not be a concern in the athletic individual. Medications also play an important role and a careful review and customization of prescribed medications can have a significant impact on regaining or preserving athletic endurance.

During his fellowship at Massachusetts General Hospital, Dr. Shah participated in the cardiovascular care of the Boston Bruins, New England Patriots and Harvard University athletes. Since arriving in Baltimore in September of 2017, he has worked closely with MedStar Sports Medicine to provide cardiovascular care for local collegiate and professional athletes. He is also collaborating with Sports Medicine researchers to evaluate best methods for cardiac screening in athletes and the cardiovascular impact of long-term endurance exercise.

"We treat athletic individuals of all ages and athletic aspirations," says Dr. Shah. "We offer customized treatment plans and exercise prescriptions to allow patients to safely continue in their athletic endeavors. We work with our patients to try to get them back to their sport or activity of choice. Our ultimate goal is keeping our patients safe and active."

**For more information on MedStar Sports & Performance Cardiology at MedStar Heart & Vascular Institute or to make an appointment with Ankit Shah, MD, please call 410-366-5600.**



### MEDSTAR SPORTS & PERFORMANCE CARDIOLOGY

provides comprehensive cardiovascular care and evaluation for athletes and active individuals of all ages and levels, including:

- Sports eligibility through pre-participation cardiac evaluation
- Evaluation of potential cardiac symptoms
- Return-to-play recommendations after cardiac procedures or diagnoses
- Differentiating between "athlete's heart" and cardiovascular disease
- Recommendations for performance improvement
- Preventive cardiac care and evaluation of healthy individuals

# New Technique Expands Life Saving Use of TAVR



BIOPROSTHETIC AORTIC SCALLOP INTENTIONAL LACERATION TO PREVENT IATROGENIC CORONARY ARTERY OBSTRUCTION

# BASILICA

patients will die. With BASILICA, we now have a reliable percutaneous treatment option to offer," he says.

Before the development of BASILICA, the only alternative for these patients was deploying a stent in the ostium of the threatened artery to hold the leaflet away as the TAVR valve was deployed. "But this was a short-term solution with a number of complications," Dr. Rogers adds.

Dr. Rogers was part of the team at the National Heart, Lung and Blood Institute (NHLBI) that conducted the animal research leading to the BASILICA procedure. The first-in-man BASILICA procedure was performed at the University of Washington in the summer of 2017 with Dr. Rogers in attendance. To date, more than 25 BASILICA procedures have been performed worldwide.

### CRITICAL CLINICAL TRIAL AT MHVI

Late last year, Dr. Rogers performed the BASILICA procedure on a patient at MedStar Washington Hospital Center with excellent results. "The

patient we treated was very sick with a failing surgical bioprosthetic aortic valve that was leaking severely and causing heart failure," Dr. Rogers says. "Another surgery was not an option as she was just too unwell. Her CT scan showed that she was at risk of coronary artery obstruction. We performed the BASILICA procedure, which was a success, and the patient was discharged just a few days later."

"We believe we can predict fairly well through multimodality imaging who is at risk for this potentially fatal complication," he says. "But we would like to gather additional data from a larger patient population. This is why we initiated the BASILICA clinical trial, an FDA-approved Early Feasibility Study sponsored by the NHLBI. The Hospital Center is one of just five medical centers in the U.S. participating."

"The BASILICA procedure is part of a family of transcatheter electro-surgery techniques we developed at NHLBI," Dr. Rogers says. "These techniques are being applied to other



structural heart interventions, including as a way to prevent left ventricular outflow tract obstruction during transcatheter mitral valve replacement, and for transcaval access in patients uneligible for transfemoral access by TAVR due to peripheral artery disease. Our objective is to develop solutions for patients unable to have standard treatments due to their complex anatomy and comorbidities."

### Early Feasibility Study FIRST-IN-MAN TRANSCAVAL TAVR PROCEDURE USING NEW CLOSURE DEVICE

Transcaval access has become the preferred alternate access approach at MedStar Washington Hospital Center for patients who are ineligible for transfemoral TAVR due to small or diseased iliofemoral arteries. Until now, closure of the transcaval access was performed using cardiac occluder devices that were not designed for this purpose. The Hospital Center is participating in the first FDA-approved Early Feasibility Study (EFS) of a new dedicated closure device for transcaval TAVR, sponsored by the National Heart, Lung and Blood Institute. Toby Rogers, MD, performed the first-in-man transcaval TAVR procedure using this new device in February 2018. The hospital has enrolled seven patients into the study thus far, and early results have been very promising. The full results of the EFS will be presented later this year.

### CORONARY OBSTRUCTION AND PREVENTION BY BASILICA

After valve-in-valve TAVR in patients with large aortic root, blood can flow around the old valve to reach the coronary arteries. In some patients with small aortic root and low-lying coronary arteries, the leaflets of the failing surgical bioprosthetic valve can obstruct blood flow to the coronary arteries. BASILICA enables coronary blood flow in these patients by splitting the leaflet of the failing bioprosthetic valve immediately before TAVR.

An innovative catheter technique is helping to transform treatment for patients whose bioprosthetic aortic valve is failing. The BASILICA procedure, developed in part by MedStar Heart & Vascular Institute's Toby Rogers, MD, PhD, prevents one of the most feared, and often fatal, complications of valve-in-valve TAVR—coronary artery obstruction caused by mechanical displacement of the old valve's leaflets.

BASILICA (Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery) obstruction employs an electrified guide-wire threaded through a catheter to slice the leaflet of the patient's failing bio-prosthetic valve. Cutting the leaflet before TAVR allows blood to flow into the coronary artery through the split leaflet when the new valve is deployed.

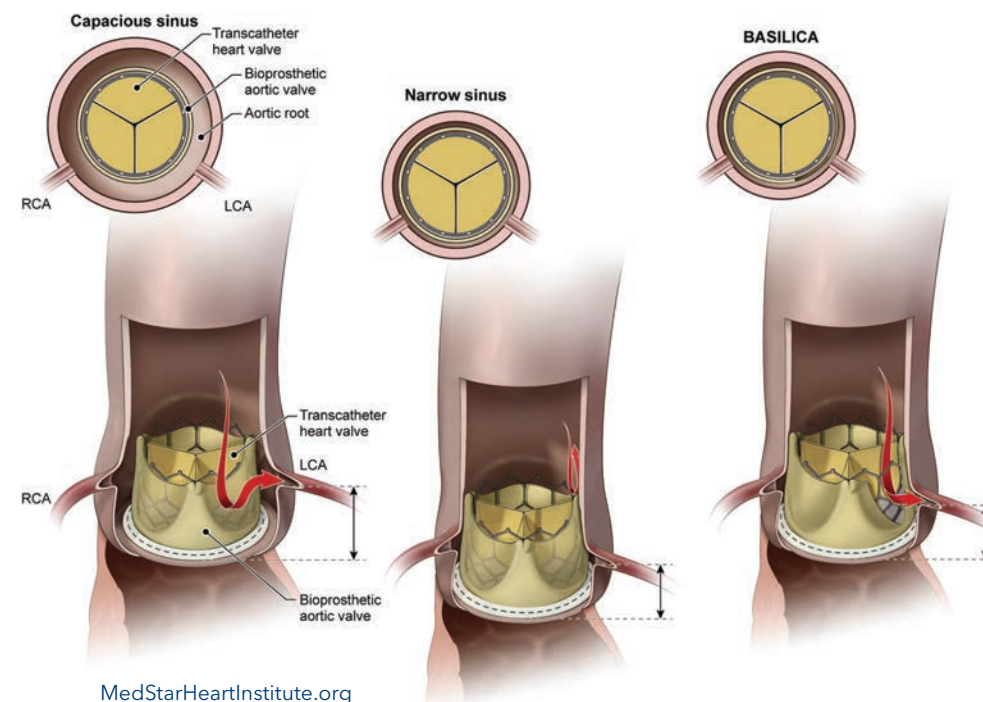
### DECREASING RISK OF A FATAL COMPLICATION

"Surgical tissue heart valves can become narrowed and

leaky over time," explains Dr. Rogers. "A second surgery to replace a failing valve is usually much higher risk for patients than their original surgery. For many patients, TAVR is a lower-risk alternative. But as a community we have learned the hard way that in some patients, displacing the leaflets of the original valve to make room for the new valve can block off a coronary artery," he says.

"As younger and younger patients receive bioprosthetic rather than mechanical surgical valves, and with bioprosthetic valves expected to last 10 to 15 years, many patients in the future will require a re-do procedure," Dr. Rogers explains. "They may want to have TAVR, but we have found that a small but significant minority are at high risk of coronary artery obstruction due to the type of surgical valve they have, and their own anatomy."

"We know from large registries that if coronary artery occlusion occurs, more than 50 percent of these



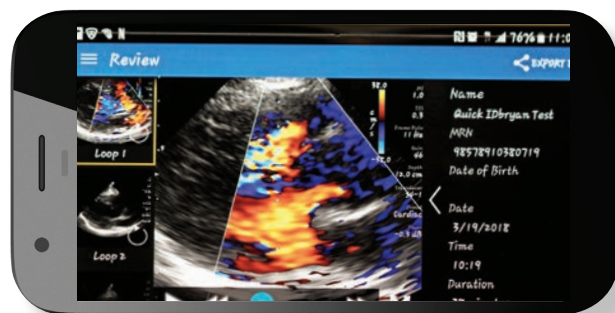
# Answers in the Palm of Your Hand

## How Handheld Ultrasound Is Changing Clinical Cardiology



(Above, L to R) Barbara Srichai, MD, and Carolina Valdiviezo, MD, are studying the efficacy of using handheld ultrasound devices in the cardiac clinic at MedStar Georgetown University Hospital.

(Below) The ultrasound device is small enough to fit in a lab coat pocket.



The patient had a history of heart failure, and came to the clinic complaining of a see-sawing heart rate. There was no possibility of getting an immediate echocardiogram to help with diagnosis.

So Barbara Srichai, MD., a cardiologist at MedStar Georgetown University Hospital, used the new handheld ultrasound device that was in trial at the Heart Clinic. "I saw that the issue was not that bad, and was able to pursue a therapeutic course that otherwise I might have had to wait several days to prescribe," she recalls.

Welcome to the new world of outpatient cardiac care, where the portability and miniaturization of diagnostic technology is transforming the patient care experience.

"Slowly, all the devices are getting smaller and smaller," says Dr. Srichai. "Echocardiographic devices are now more like laptop-type machines. These handheld devices, which have dual-sided transducers that optimize images of the heart, bring ultrasound down to something you can put into your pocket. It becomes an adjunct to the physical exam, allowing the clinician to refine the diagnosis and provide the patient more immediate feedback without having to schedule a separate appointment."

Both Dr. Srichai and her colleague, Carolina Valdiviezo, MD, note the devices at this point do not replace the detail of an echocardiogram. "This is for big issues," says Dr. Valdiviezo. "You can tell if heart function is normal or abnormal, if the valve is thickened, if someone in the cancer population has fluid around the heart. You can get an idea of stenosis, but you can't tell if it's moderate or severe. So in many cases you will still require a full cardiac study."

The handheld ultrasound devices went into use at the hospital this spring, and Drs. Srichai and Valdiviezo will be studying the efficacy of the device as they begin to implement it in the cardiac clinic. "Is it difficult to train clinicians to use this?" asks Dr. Srichai. "We'll look at cardiologists and internists who have no echocardiographic capture experience—if you can't capture the pictures, or if you don't know what you're looking at, then this may not be that useful in their exam."

While the technology is still prohibitively expensive for widespread use in community clinics, Dr. Valdiviezo says many physicians are interested in the potential of handheld ultrasound. "We've been reading about this in the literature for years," she notes. "It could be used to provide access in remote locations. It has the potential to reduce costs. Patients certainly appreciate not having to return for a separate appointment and reduced uncertainty. This is just the beginning, but it's a very exciting place to be."

## New Version of CodeHeart Debuts

In 2011, MedStar Washington Hospital Center unveiled CodeHeart, a secure mobile app, which provided a real-time video stream for Emergency Departments to discuss ECGs with interventional cardiologists in the hospital's Cath Lab. The app, conceptualized by Lowell F. Satler, MD, director of Cardiac Catheterization Laboratory at MedStar Washington Hospital Center in partnership with Vigilant Medical, proved to be a vast improvement over faxing ECGs, which could be missed.

*Cardiovascular Revascularization Medicine*, a study published in 2015, found that the application allowed heart attack patients to be treated more quickly—some an average of 30 percent faster—reducing potential heart damage.

This spring, the third iteration of CodeHeart is making its way into area EDs, allowing for secure texting of ECGs.

"We've used the CodeHeart app successfully for years," says Eileen Searson, manager, Transformational Technology. "Texting is the preferred method of communication, and cell phone cameras are so good now that you can zoom in, manipulate the images, and send multiple ECGs, for comparison."

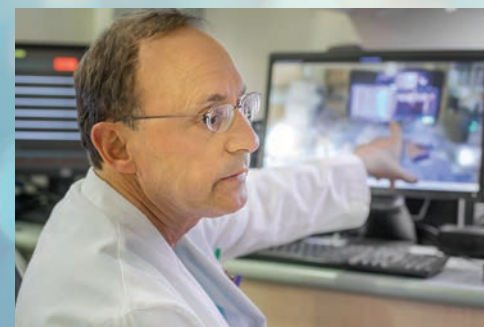
"This is how it works," she says. "You open the application and take the picture within the app. The picture resides in the secure app and not on your phone. It's easy to use!"



Eileen Searson, manager, Transformational Technology, says that the new iteration of CodeHeart allows for secure texting of ECGs.

***"When it comes to treating a patient who appears to be suffering from chest pain or other heart attack symptoms, every second counts. CodeHeart helps us provide optimal care as quickly as possible and effectively treat every heart patient who comes to our facility. As the technology continues to advance, we are able to save more lives and achieve faster treatment times than we could have imagined five or ten years ago."***

—Lowell F. Satler, MD



For more information about the CodeHeart app, please call 202-877-2704

# case study

## A Minimally Invasive Approach to Treating Carotid Artery Stenosis Transcarotid Artery Revascularization (TCAR)



Raghuveer Vallabhaneni, MD

### Abstract

During a routine scan, a 75-year-old male was found to be experiencing a rapid recurrence of carotid artery stenosis. As the patient had previously undergone a carotid endarterectomy on that side, a minimally invasive Transcarotid Artery Revascularization (TCAR) was performed to reduce risks of stroke and nerve damage. The procedure successfully cleared the blockage, with intraoperative imaging indicating no evidence of recurrence.

### Patient Presentation

- A 75-year-old male who had undergone a successful carotid endarterectomy for carotid artery stenosis nine years earlier was discovered during a routine follow-up scan to be experiencing a rapid recurrence of the condition.
- The patient had no other significant health issues.

### Assessment

- The patient was referred to MedStar Heart & Vascular Institute (MHVI) for further evaluation and treatment.
- A second conventional open carotid artery endarterectomy would have put the patient at greater risk for nerve damage and stroke, given the likely presence of scar tissue from the earlier procedure.
- Carotid stenting would be the most appropriate means of treatment.
- A minimally invasive transcarotid artery revascularization (TCAR) procedure was considered a more suitable option for the patient's condition than a typical transfemoral approach. A TCAR also offered the advantage of reversing blood flow away from the brain, thereby protecting it from embolic debris that might be created during the procedure.

### Diagnosis

- A CT scan confirmed that the patient was a good candidate for the TCAR stent procedure.
- The patient was advised of the procedure's benefits and risks, and gave his consent.

### Treatment

- The TCAR was performed during a short procedure under general anesthetic through a 2 cm incision above the patient's clavicle.
- No problems or unexpected conditions were encountered.

### Outcome

- The patient was discharged the day after surgery.
- A follow-up scan verified that the stent is performing as expected, with no recurrence of stenosis.
- The patient will continue to undergo routine monitoring.

### Conclusion

Transcarotid Artery Revascularization (TCAR) is an attractive option for treating carotid artery stenosis in patients instead of carotid endarterectomy or the transfemoral approach.

### About Dr. Vallabhaneni

Dr. Vallabhaneni is the director of Vascular Surgery-Baltimore Region for the MedStar Heart & Vascular Institute. Fellowship-trained in vascular surgery, he is experienced in all forms of minimally invasive and open vascular surgery techniques, and is well versed in the medical management of vascular issues. Dr. Vallabhaneni is one of a few physicians in Maryland certified with expertise to perform the TCAR procedure.

"By combining surgical principles of neuroprotection with minimally invasive endovascular techniques," says Dr. Vallabhaneni, "Transcarotid Artery Revascularization (TCAR) offers tremendous potential for the treatment of carotid artery stenosis as an alternative to conventional carotid endarterectomy and stenting procedures. Indeed, it has the potential to become the primary therapy for carotid artery stenosis, a trend that will benefit both patients and surgeons."

*Individuals with all forms of carotid artery stenosis may benefit from minimally invasive treatment options such as TCAR. If you would like to discuss a patient, Dr. Vallabhaneni may be reached at 412-215-7123. Or, call 410-554-2950 to refer a patient.*

*To learn more, visit [MedStarHeartInstitute.org](http://MedStarHeartInstitute.org).*

## Record Numbers Attend CRT 2018

### Latest Research in Structural Abnormalities Highlighted

More than 3,000 people gathered in Washington, D.C., for the 21st annual Cardiovascular Research Technology (CRT) meeting in early March. The conference once again featured a diverse, boutique-style curriculum with live-case presentations, breaking research trial results, and a trio of keynote speakers that attracted large, appreciative audiences.

### KEYNOTERS: MOTIVATIONAL, THOUGHTFUL AND COMPELLING

Former President Barack Obama topped the list of popular keynoters, drawing a crowd that exceeded the capacity of the hotel, and was moved to the DAR Constitution Hall. The lively discussion between the former president and Ron Waksman, MD, CRT course chairman and director of MedStar Heart Cardiovascular Research, was a freewheeling, amusing, thoughtful conversation that drew applause and hoots from the audience.

Keynote Dolvett Quince of *The Biggest Loser* fame talked about the importance of consistency in adopting a healthy lifestyle and urged cardiologists to practice what they preach.

Donna Edwards, former U.S. representative from Maryland, discussed the continued disparities that exist in health care, drawing on her own experiences and those of the predominantly African-American county she represented in Congress.

### AN EMPHASIS ON WOMEN

Among the most popular presentations was the first-ever, all-women live case. The case, directed by Annapoorna S. Kini, MD, director of the cardiac catheterization lab at Mount Sinai Hospital in New York City, was a "milestone that would help change the future participation of female cardiologists in live-case presentations and in the field," Dr. Waksman noted.

### LATEST TRIAL RESULTS

- The meeting highlighted the latest research in the growing use of interventional techniques for treatment of structural abnormalities. Dr. Waksman presented an interim analysis of the Low-Risk TAVR multicenter research trial, which shows positive results for using transcatheter aortic valve replacement (TAVR) with commercially available valves in low-surgical-risk patients with symptomatic severe aortic stenosis. Currently, TAVR is reserved for both high and intermediate surgical-risk patients.
- Preliminary results from the ongoing LIBERTY 360 study show the use of endovascular device interventions in patients with symptomatic lower-extremity peripheral artery disease continues to show freedom from major adverse events and improvements in quality of life.

# CRT18

CARDIOVASCULAR RESEARCH TECHNOLOGIES

- In a first-in-man study, the sirolimus-coated balloon was safe and feasible.
- Use of radial access in patients with acute coronary syndrome undergoing invasive management is associated with lower risk of death, myocardial infarction or major bleeding at 180 days compared with femoral access.
- Another study indicates using paclitaxel-coated balloons in treating de novo lesions in small coronary vessels is as safe and effective as zotarolimus-eluting stents.

### RECOGNIZING INNOVATION IN INTERVENTIONAL CARDIOLOGY TECHNOLOGY

Philippe Genereux, MD, co-director of the Structural Heart Program at Morristown Medical Center in New Jersey, was awarded first place for his presentation, "A Novel Transcatheter MR Treatment Technology." Dr. Genereux was also awarded second place for the Saranas™ Early Bird Bleed Monitoring System.

Third place went to Ronald J. Shebuski, PhD, president and CEO of Symmatrix Pharmaceuticals, who introduced a localized sirolimus delivery system for vascular grafts.



*To learn more about CRT 2018 and to get a look ahead to CRT 2019, visit [CRTonline.org](http://CRTonline.org).*



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Please submit editorial comments to Norma Babington, at [norma.babington@medstar.net](mailto:norma.babington@medstar.net), or 202-877-0201.

Visit our website, at [MedStarHeartInstitute.org](http://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

### 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](http://cme.medstarhealth.org/AHF)

### CARDIOVASCULAR RESEARCH TECHNOLOGIES 2019

**March 2 - 5, 2019**

The Omni Shoreham, Washington, D.C.  
Course Director: Ron Waksman, MD  
[www.crtmeeting.org](http://www.crtmeeting.org)

## REGULARLY SCHEDULED SERIES—AMA PRA Category 1 Credit(s)<sup>TM</sup>

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#### Cardiac Catheterization Conference

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CTEC Conference Theater  
1 AMA PRA Category 1 Credit<sup>TM</sup>  
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#### Cardiac Surgery Grand Rounds

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#### Cardiology Grand Rounds

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1 AMA PRA Category 1 Credit<sup>TM</sup>  
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#### Echocardiography Conference

Weekly, Thursdays, 7:45 a.m.  
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#### Electrophysiology Core Curriculum Conference

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First, second and third Tuesdays: Room 5B3  
Fourth Tuesdays: CTEC Conference Theater  
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