

HEART & VASCULAR INNOVATIONS



**Percutaneous
mitral valve repair
comes to UH Case
Medical Center**

page 4

2

Controversies
in cardiology:
DAPT duration

3

When to refer
for complex
cardiac surgery

5

Image challenge:
What is the
diagnosis?

CONTROVERSIES IN CARDIOLOGY: DAPT DURATION



University Hospitals
Harrington Heart & Vascular Institute



SOON J. PARK, MD

Chief, Division of Cardiac Surgery, UH Case Medical Center;
Co-Chair, Clinical Executive Committee, UH Harrington Heart &
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DR. MARCO COSTA: Dr. Simon, today we are sitting down to talk as interventional cardiologists with high-volume, complex PCI practices. One of the most common questions we are asked by referral physicians after all these years is still, “How long should we continue dual anti-platelet therapy (DAPT)?” Is this question still unsettled today?

DR. DANIEL SIMON: Marco, it is amazing that after all these years there is still controversy around DAPT duration. U.S. guidelines recommend 12 months of uninterrupted DAPT and European guidelines six to 12 months. However, there are emerging data possibly supporting shorter duration of DAPT.

DR. COSTA: Dan, it sounds like you’re hedging. Not very decisive for an interventional cardiologist!

DR. SIMON: Marco, you’re right. The data are simply conflicting. We started down this path in 2006 with the first reports of very late stent thrombosis in first generation drug-eluting stents (DES) occurring at a rate of 0.6 percent per year with no plateau. The simple thought was that prolonging DAPT would prevent stent thrombosis.

DR. COSTA: But as you know, Dan, simple thoughts are often wrong!

DR. SIMON: Indeed, Marco. Observational data from registries for the most part teach us that the protective effect of DAPT on stent thrombosis is observed only within the first six months after drug-eluting stenting (DES). Furthermore, we are not using first-generation DES in our procedures anymore. Third-generation, thin-strut, cobalt chromium DES have very late stent thrombosis rates less than ~0.1 percent per year. This raises the key question as to whether prolonged DAPT is needed. In other words, are we preventing ischemic events or only exposing our patients to increased risk of bleeding?

DR. COSTA: I thought new randomized trials have addressed this important clinical question.

DR. SIMON: Yes, Marco. There are multiple clinical trials examining shorter courses of DAPT. These trials include EXCELLENT, DES-LATE, PRODIGY, OPTIMIZE, SECURITY and others that compared six vs. 12 months, three vs. 12 months, and six to 12 vs. 24 months. To date, the results of these trials suggest that prolonging DAPT increases bleeding without reducing MI or stent thrombosis.

DR. COSTA: Dr. Simon, I am disappointed by your interpretation of these trial results. As a clinical trialist, we all recognize that these trials are grossly underpowered to make this conclusion. I am also not convinced by meta-analysis of the trials that we really know the answer. What’s next?

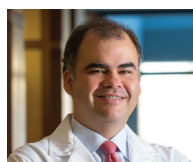
DR. SIMON: Marco, as usual you are spot-on here. Two large trials will be presented at the upcoming AHA meeting in Chicago this November. The FDA and industry co-sponsored DAPT trial randomized nearly 12,000 patients to 12 vs. 30 months of DAPT. The ISAR-SAFE trial randomized another 6,000 patients to six vs. 12 months. The DAPT trial is powered to look at stent thrombosis and bleeding events. We participated in this trial and, as you know, I am serving as the National Co-PI for the Cordis/Johnson & Johnson cohort of this trial.

DR. COSTA: Sounds like we better go to the AHA meeting this year.

DR. SIMON: Yes, I think we will learn a lot from these two trials.

DR. COSTA: I like devices more than drugs, but even I am looking forward to evidence-based data to guide my clinical practice.

View the full discussion online at UHhospitals.org/DAPTduration



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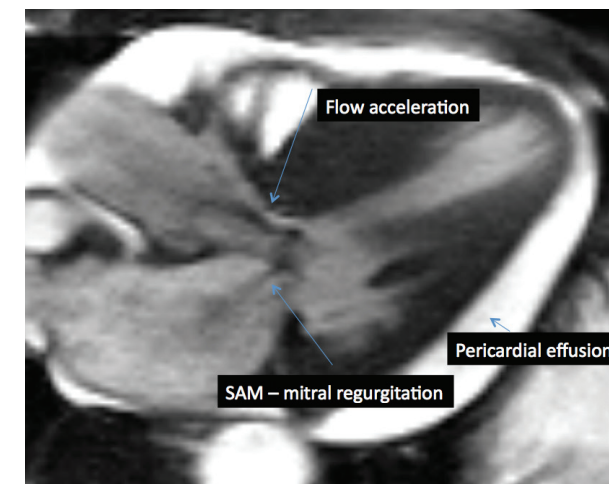


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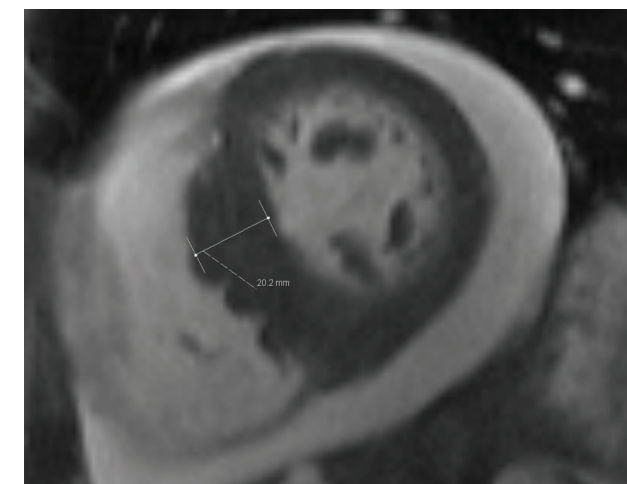


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The commitment to exceptional patient care begins with revolutionary discovery. University Hospitals Case Medical Center is the primary affiliate of Case Western Reserve University School of Medicine, a national leader in medical research and education and consistently ranked among the top research medical schools in the country by U.S. News & World Report. Through their faculty appointments at Case Western Reserve University School of Medicine, physicians at UH Case Medical Center are advancing medical care through innovative research and discovery that bring the latest treatment options to patients.



SSFP cine at LVOT view reveals flow acceleration in the LVOT and systolic anterior motion of the mitral valve with mitral regurgitation



Short axis view at mid cavity level reveals hypertrophic septum 20.2 mm



Complex Cardiac Surgery

WHEN TO REFER YOUR PATIENT FOR LEADING-EDGE SURGICAL THERAPIES

As physicians manage symptoms of patients with complex conditions, advanced surgical therapy should be considered. University Hospitals Harrington Heart & Vascular Institute has created a multidisciplinary team to care for such patients, with every patient receiving the most appropriate and personalized care.

“Our surgical expertise is truly comprehensive and among the best in the country,” says Soon Park, MD, Division Chief of Cardiac Surgery at University Hospitals Case Medical Center and Professor of Surgery at Case Western Reserve University School of Medicine, who joined UH from the Mayo Clinic.



Delayed enhancement sequence reveals gadolinium uptake in a patchy pattern, predominantly mid cavity

HYPERTROPHIC CARDIOMYOPATHY

An underacknowledged pathology, hypertrophic cardiomyopathy (HCM) is an inherited condition characterized by shortness of breath, chest discomfort and exercise intolerance. The abnormal thickening of the heart muscle impedes blood flow and can even lead to sudden death. While not preventable, hypertrophic cardiomyopathy can be treated.

"The most proven and effective therapy is surgical resection of the abnormal tissue, known as a septal myectomy," says Dr. Park, who has many years of experience in treating such specialized patient populations. In this open-heart procedure, a portion of the thickened septum is removed to restore blood flow path and reduce mitral regurgitation.

As noted by the Journal of the American College of Cardiology in 2014, "HCM has emerged from an era of misunderstanding, stigma and pessimism, experiencing vast changes in its clinical profile, and acquiring an effective and diverse management armamentarium. These advances have changed its natural history, with prevention of sudden death and reversal of HF, thereby restoring quality of life with extended (if not normal) longevity for most patients, and transforming HCM into a contemporary treatable cardiovascular disease."

For more information about complex cardiac surgery at UH or to refer a patient, call 216-844-3800.



PERICARDIAL DISEASE

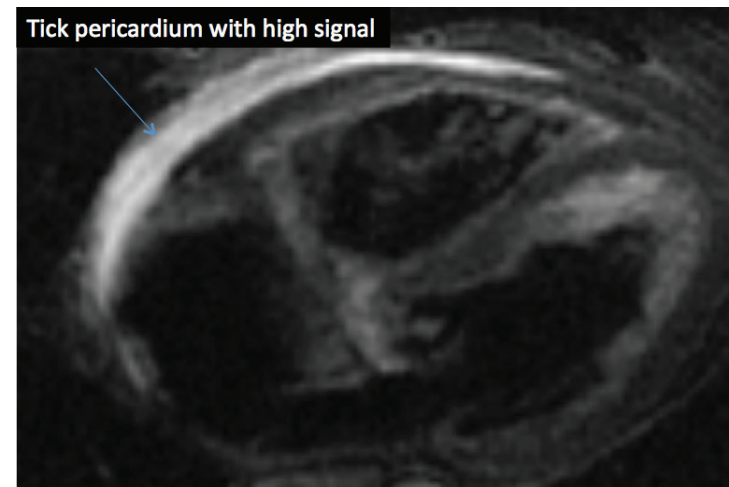
Advances in imaging have improved the diagnosis of pericardial disease, or inflammation and/or thickening of the tissue sac enveloping the heart.

With constrictive pericarditis, patients often experience profound fatigue, exertional intolerance, lower extremity edema and ascites, says Dr. Park. Echocardiography and/or hemodynamic studies with right heart catheterization can confirm the diagnosis, while the demonstration of thickened pericardium on cardiac CT or MRI can provide supportive evidence. While not immediately life-threatening, pericarditis seriously impairs patient quality of life. Pericardiectomy should be considered when patients fail to respond to medical management.

"A pericardiectomy for this under-recognized disease process provides remarkable success in relieving symptoms," says Dr. Park, who has performed many of these surgical procedures.

PULMONARY HYPERTENSION

"The definitive therapy for chronic thromboembolic pulmonary hypertension is surgery. These patients should be evaluated by a team with medical and surgical expertise. We have a multidisciplinary team of medical cardiologists, pulmonologists, radiologists and heart surgeons who work together seamlessly to diagnose and treat these complex patients," says Dr. Park. For those deemed appropriate, surgical removal of obstructive scars in the pulmonary arteries could dramatically lower their pulmonary hypertension and alleviate their right-sided heart failure.

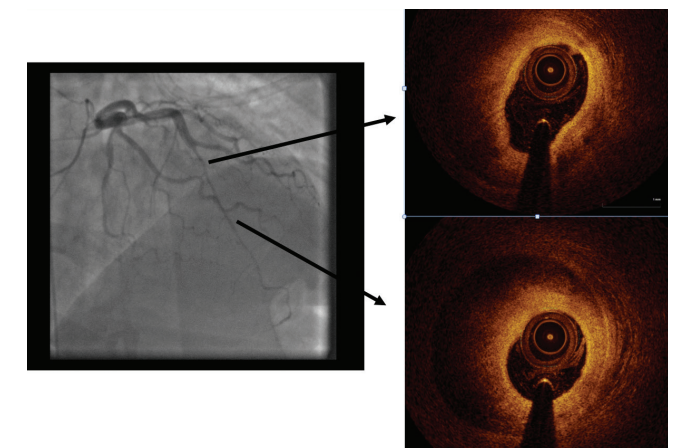


STIR image with tick and high signal pericardium

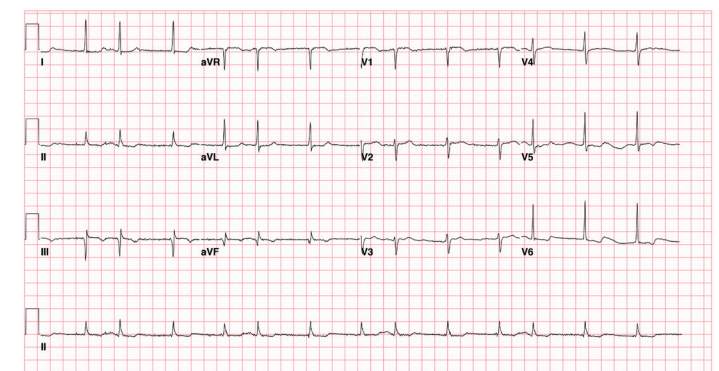
HEART, LUNG AND HEART-LUNG TRANSPLANTS

The heart, lung and heart-lung transplantation programs at UH Case Medical Center have been reactivated under the leadership of Soon Park, MD, Robert Schilz, DO, and Guilherme Oliveira, MD. As part of University Hospitals Harrington Heart & Vascular Institute, the comprehensive Advanced Heart Failure & Transplant Center is designed to successfully tailor highly specialized, advanced medical and surgical therapies to the unique needs of patients with advanced heart or lung disease. "We are committed to improving their quality of life and longevity with thoracic organ transplantation," says Dr. Park.

IMAGE CHALLENGE: WHAT IS THE DIAGNOSIS?



A 52-year-old woman with hypertension and tobacco use presents to the emergency department with chest pain and dyspnea. She ran out of her blood pressure medications one week prior to presentation. Her initial blood pressure was 243/132, and she was started on a nitroprusside drip and admitted to the cardiac intensive care unit. Her initial troponin was 0.7 ng/mL. Her EKG reveals ST segment depression in leads V1 – V3. Shown is a still frame from her coronary angiogram, as well as two cross-sectional optical coherence tomography images of her mid and distal left anterior descending coronary artery. What is the diagnosis?



79-year-old woman admitted with acute coronary syndrome. What is the diagnosis of the rhythm shown in this ECG tracing?

To view larger images, submit your interpretations and see the answers, visit UHhospitals.org/imageFall14

All correct answers will be entered into a drawing for the chance to win one iPad™ 64GB.



GUILHERME F. ATTIZZANI, MD

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School of Medicine

MitralMINIMALISM

Percutaneous mitral valve repair now available at UH Case Medical Center

When interventional cardiologist Guilherme Attizzani, MD, performed his first percutaneous mitral valve repair in January 2013, he came away impressed. ***"I was excited by the possibility of offering high-risk patients who cannot undergo surgical mitral valve repair or replacement a safe and effective minimally invasive procedure,"*** he recalls.

Dr. Attizzani, who specializes in structural heart disease interventions, joined University Hospitals Harrington Heart & Vascular Institute in August 2014 and is now spearheading UH's percutaneous mitral valve repair program using the MitraClip® device. The device, manufactured by Abbott Laboratories, was approved by the FDA in October 2013 for patients with moderate-to-severe (grade 3) or severe (grade 4) degenerative mitral regurgitation (DMR) who are considered to be at prohibitively high risk for mitral valve surgery. Dr. Attizzani comes to UH from Ferrarotto Hospital in Catania, Italy, which has extensive experience with the MitraClip device. The device has been used in Europe since 2008, when it received CE mark approval.

The design of the MitraClip device is based on the Alfieri edge-to-edge mitral valve repair technique, in which a cardiac surgeon uses sutures to approximate the regurgitant mitral valve leaflets and creates a double orifice in the mitral valve. With the MitraClip procedure, the device itself is permanently attached to the mitral valve leaflets, creating the double orifice. The device is inserted via a catheter placed in the femoral vein and threaded into the heart using transesophageal echocardiogram (TEE) guidance.

"The TEE is the eyes of the interventionalist," Dr. Attizzani says. "It shows you step-by-step where you are when you're crossing the septum, when you point the clip toward the mitral valve, when you open the arms of the clip and when you grasp the two leaflets. We also use angiography and fluoroscopy, but TEE is essential."

According to Dr. Attizzani, one advantage of the MitraClip device is the ability to assess the results of the deployment in real time. "If we are not happy with the result, we can open the clip again and regrasp the leaflets as many times as we need until we are satisfied," he says. "Then we do the final deployment of the clip."

Researchers have studied the safety and efficacy of MitraClip in reducing mitral regurgitation (MR) when compared with surgery, most notably in the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) II trial, reported in The New England Journal of Medicine in April 2011. Its findings highlighted the increased safety of the percutaneous procedure. In addition, data from the four-year follow-up of the EVEREST II study showed that both mitral valve surgery and percutaneous mitral valve repair led to similar reductions in MR magnitude and mortality. Moreover, the study showed that patients treated with the novel percutaneous therapy experienced reduced left ventricular (LV) volumes, improved New York Heart Association (NYHA) functional class and overall hemodynamic improvement. A July 2014 study, published in the Journal of the American College of Cardiology, reported on MitraClip's success among very high-risk patients with MR of grade 3+ or 4+. It found that treatment with the percutaneous device led to early, significant reduction in MR, improved clinical symptoms and decreased LV volumes one year after the procedure.

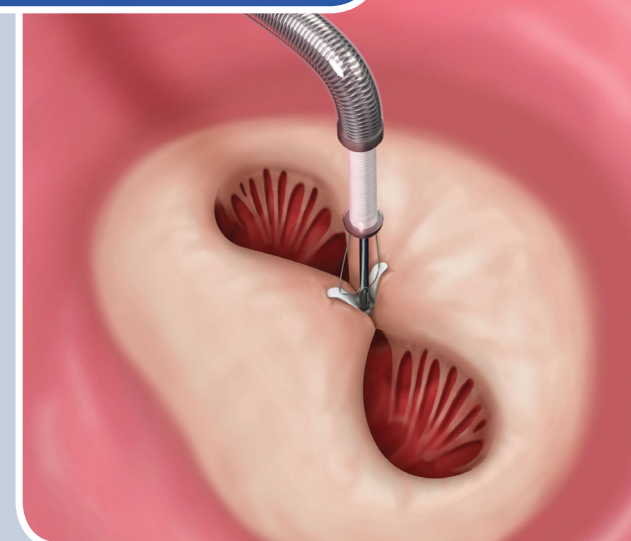


For Dr. Attizzani, these results confirm what he's seen in his practice. "At 30 days, we already see a marked benefit of the procedure, and these results are generally sustained at one year and in the following years," he says. "We are able to reduce MR from severe and moderate-to-severe to mild or none in most patients. Patients also have left ventricle reverse remodeling, and ejection fraction increases."

Research conducted by Dr. Attizzani and colleagues in Italy, to be published soon in the Journal of the American College of Cardiology Cardiovascular Interventions, suggests that indications for MitraClip could eventually expand to more complex mitral valve anatomy. In addition, their research suggests that percutaneous mitral valve repair may be an option after a failed mitral valve surgical annuloplasty. The researchers reported in the Journal of the American College of Cardiology in March 2014 on the initial experience of six patients who received a MitraClip device after a failed mitral valve annuloplasty. All six patients had MR of grade 2 (moderate) or lower after the procedure, without an important increase in the transmitral gradients. "This is another potentially important application of the device, when other options have failed. Nonetheless, these findings require further investigation and are currently considered an off-label indication," Dr. Attizzani says.

Indications for MitraClip are likely to expand in coming years, Dr. Attizzani says – especially among patients with functional mitral regurgitation (FMR). "It's been shown that 90 percent of MR patients who are denied surgery are FMR patients," he says. "It's an area of unmet need."

For now, however, Dr. Attizzani's take-home message is clear: ***"If you have a patient with severe mitral regurgitation and that patient is inoperable due to prohibitive surgical risk, today you have an option. And that option is MitraClip."***



For more information about percutaneous mitral valve repair at UH Case Medical Center or to refer a patient, call 216-844-3800.



University Hospitals
Harrington Heart & Vascular Institute



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DEVICE DUO

STUDIES OF GROUNDBREAKING NEW ELECTROPHYSIOLOGY DEVICES UNDER WAY AT UH CASE MEDICAL CENTER

Physician-scientists at University Hospitals
 Harrington Heart & Vascular Institute are
 investigating two potentially game-changing
 electrophysiology devices in national studies:
 the leadless pacemaker and the subcutaneous
 implantable cardioverter-defibrillator (S-ICD).

Judith A. Mackall, MD, Section Chief
 of Electrophysiology at UH Case
 Medical Center, and UH cardiac
 electrophysiologist Harish Manyam,
 MD, are enrolling patients in the
 national LEADLESS II Study, a safety
 and effectiveness trial of St. Jude
 Medical's investigational leadless
 pacemaker. They're implanting the
 tiny device, which is less than 10
 percent the size of a conventional
 pacemaker, in select patients and
 collecting data about complications,
 pacing thresholds and R-wave
 amplitudes, at implant, predischarge
 and at prescribed follow-up intervals.

"When you implant a lead
 transvenously, there is the risk of
 pneumothorax, hemothorax, lead
 dislodgment, infection and bleeding,"
 says Dr. Mackall. "Those complications
 occur in about 3 percent of pacemaker
 implantations. We hope the leadless
 pacemaker will cut that rate down."

The leadless pacemaker is indicated
 only for patients who need single-
 chamber pacing. It is implanted via
 a catheter delivery system through
 the right femoral vein into the right
 ventricular apex.

Initial results from studies of the
 leadless pacemaker are encouraging.
 LEADLESS investigators writing in
 Circulation in March 2014 reported
 an implant success rate of 97 percent
 and an overall complication-free rate
 of 94 percent.

S-ICD

Dr. Mackall and Dr. Manyam are also
 enrolling UH patients in a national,
 post-approval study of the "sub-Q,"
 or S-ICD, manufactured by Boston
 Scientific. The S-ICD received FDA
 approval in September 2012, giving
 some patients at risk of sudden cardiac
 arrest a less-invasive treatment option.

"This device is a huge advance,"
 says Dr. Mackall. "It is an entirely
 subcutaneous device that does not
 require a lead or leads to be placed in
 the heart."

In the post-approval study, Dr. Mackall
 and Dr. Manyam are implanting the
 device in select patients and collecting
 data on patient complications and the
 effectiveness of the S-ICD in converting
 spontaneous, discrete episodes of
 ventricular tachycardia/ventricular
 fibrillation, among other measures.
 This study will run for five years.

In a review of the literature on the
 S-ICD, published in the Journal of the
 American College of Cardiology in
 April 2014, investigators wrote that the
 device appears to be best for younger
 patients, those at increased risk for
 bacteremia, those with in-dwelling
 intravascular hardware at risk for
 endovascular infection and those with
 compromised venous access.

"One example of this would be
 congenital heart disease," Dr. Mackall
 says. "If you have CHD and you don't
 have an easy way for leads to go into
 the heart, the S-ICD would be ideal."

"The advantage is that it is not in the
 vasculature, so there's a lower risk of
 severe infection," adds Dr. Manyam.
 "If there is an infection, the device is
 easily removed."

The S-ICD is indicated for patients who
 need a defibrillator but who do not
 have a pacing indication.

For more information about the leadless
 pacemaker or S-ICD or to refer a
 patient to UH, call 216-844-3800.

LASER LEAD EXTRACTION AT UH

Leads for electrophysiology
 devices have a failure rate of
 about 20 percent. If the lead
 has failed and the patient
 has had it longer than a year,
 laser lead extraction is nearly
 always required.

To perform laser lead extraction,
 cardiac electrophysiologists at
 UH Case Medical Center put a
 small sheath or tube over the
 lead and use a laser to cut or
 burn away the surrounding
 tissue, freeing it up from the
 vessel wall and heart muscle.

Safety is paramount for this
 high-risk procedure. "We do
 it in the OR with cardiac
 surgery backup, with
 perfusionists on standby
 and an OR team scrubbed
 with us," says Dr. Manyam.

Laser lead extraction has
 typically been discouraged
 for older patients because
 of its risks, but Dr. Mackall
 and colleagues at UH have
 conducted research suggesting
 this needn't always be the case.
 In a study of 139 patients who
 underwent transvenous lead
 extraction (TLE), presented
 at the Heart Rhythm Society,
 the researchers found that
 patients older than age 75
 have similar success with TLE
 and no increased mortality,
 when compared with
 younger patients.

For more information on laser
 lead extraction at UH or to refer
 a patient, call 216-844-3800.





VIKRAM S. KASHYAP, MD

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TEVAR FOR TYPE B AORTIC DISSECTION

AB is a 62-year-old man with a type B aortic dissection. The aorta has degenerated and he has developed aneurysmal expansion. He has severe hypertension, diabetes and hyperlipidemia. His blood pressure is under reasonable control, but the dissected segment has continued to expand.

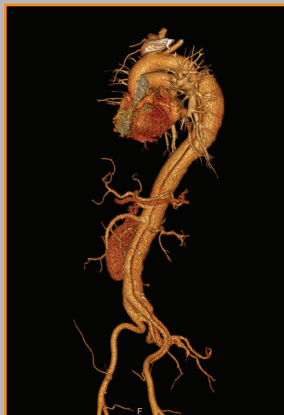


FIGURE 1. CTA with 3-D reconstruction of the aorta. This image shows the dissection extending from the descending thoracic aorta to the iliac arteries. The entry tear is in the proximal descending thoracic aorta.

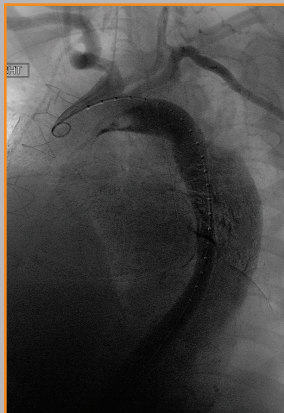


FIGURE 2. Angiogram preceding TEVAR. A marker pigtail catheter is in the aortic arch and is in the true lumen. This was confirmed via intravascular ultrasound (IVUS) prior to stent placement. The catheter abuts the dissected intima. The false lumen fills laterally (right on image, patient's left).



FIGURE 3. CTA with 3-D reconstruction of the aorta after TEVAR. This CT was obtained six months after the procedure and shows remodeling of the aorta. The true lumen fills preferentially and the false lumen has shrunk. Over time, the dissection should "heal" with remodeling and obliteration of the false lumen.

Vascular surgeons typically perform thoracic endovascular aortic repair (TEVAR) to repair aortic aneurysms. However, according to Vikram S. Kashyap, MD, Chief of Vascular Surgery and Endovascular Therapy at University Hospitals Harrington Heart & Vascular Institute, the minimally invasive TEVAR procedure has also emerged as the treatment of choice for patients with dissections of the descending aorta (type B).

"TEVAR is especially indicated when the acute type B dissection is complicated – when it is compromising the renal, iliac or superior mesenteric arteries and the patient is experiencing malperfusion," Dr. Kashyap says. Other complicating factors that indicate TEVAR include rupture, persistent pain and intractable hypertension.

In some cases of type B dissection, TEVAR can result in remodeling of the aorta. "With the radial force of the stent, eventually the false lumen of the dissection collapses," Dr. Kashyap says. "We don't see that all the time, but when we do, it's very impressive."

Patients undergoing TEVAR have a CT scan about a month after the procedure and then every six months for life. "These patients often have other medical issues, especially hypertension and sometimes coronary artery disease, so they also need lifelong surveillance by a cardiologist and internist as well," Dr. Kashyap says.

Although medical therapy is still the treatment of choice for most uncomplicated type B dissections, new research suggests that TEVAR may play an increasingly important role in these cases, where five-year mortality rates are 50 percent. "In the data from the IRAD registry, there are hints that TEVAR may be more beneficial than medical therapy," Dr. Kashyap says. "The hope is that for all patients with type B dissections, we'll ultimately be able to treat them with TEVAR, leading to aortic healing and better long-term outcomes."

For more information about TEVAR for type B dissection at UH or to refer a patient, call 216-844-3800.

LOW-DENSITY LIPOPROTEIN (LDL) APHERESIS FOR DYSLIPIDEMIA

For some patients with abnormal cholesterol levels, the standard trio of diet, exercise and medications doesn't always lower cholesterol into the optimal range. At University Hospitals Harrington Heart & Vascular Institute, these patients have the option of LDL apheresis. During three-hour sessions that occur about every two weeks,

For more information on the LDL apheresis program at UH or to refer a patient, call 216-844-3800.

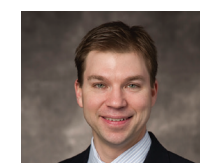
patients with treatment-resistant dyslipidemia have bad cholesterol selectively filtered out of their blood.

"This treatment typically reduces LDL cholesterol by somewhere between 50 – 80 percent and has been associated with improved outcomes in those at highest risk," says David A. Zidar, MD, PhD, an interventional cardiologist who

directs the LDL apheresis program at UH, along with co-director Trevor Jenkins, MD.

LDL apheresis is generally indicated for select patients with existing heart disease whose LDL cholesterol remains over 200 mg/dL (or non-HDL cholesterol above 230 mg/dL) and for those with no history of heart disease whose LDL remains over 300 mg/dL (or non-HDL cholesterol above 330 mg/dL), despite six months of diet, exercise and medical therapy.

The LDL apheresis program at UH is the only one in northern Ohio, providing hope for patients who have dwindling options. "People typically come to us after recurrent heart attacks or strokes, feeling vulnerable with the knowledge that their cholesterol levels remain high," Dr. Zidar says. "For these patients, LDL apheresis can be a lifeline. These patients typically stabilize and do very well on therapy. This is a testament to the expertise of nurses Lisa Swope, RN, and John Smith, RN, who administer the treatment sessions, and Vikram Kashyap, MD, Chief of Vascular Surgery at UH, who is an integral member of this multidisciplinary team."



DAVID A. ZIDAR, MD, PHD

Director, LDL Apheresis Program, UH Harrington Heart & Vascular Institute; Assistant Professor of Medicine, Case Western Reserve University School of Medicine



University Hospitals
Harrington Heart & Vascular Institute



CS is a 67-year-old woman with a history of mixed hyperlipidemia, hypertension and a significant family history of coronary artery disease. She was first diagnosed with mixed lipidemia in 2007. She underwent CABG in January 2008 and coronary stenting in October 2008. She was intolerant of statin therapy and was unsuccessful with diet management, with LDL greater than 210 mg/dL. CS began LDL apheresis in September 2012. CS's pretreatment LDL values typically fall between 160 – 180 mg/dL. Post-treatment LDL values range from 35 – 45 mg/dL, resulting in an overall reduction of 75 to 79 percent. Values typically return to baseline levels within one to two weeks.

ATTIZZANI AND SPARANO JOIN UH

Interventional cardiologist Guilherme F. Attizzani, MD, and cardiac electrophysiologist Dina M. Sparano, MD, recently joined University Hospitals Harrington Heart & Vascular Institute.



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Dr. Attizzani completed his internal medicine residency at Brazil's Sao Vicente Hospital and completed cardiology and interventional cardiology fellowships at the University of Sao Paulo's Dante Pazzanese Institute of Cardiology. He has also served as a research associate with UH's Cardiovascular Imaging Core Laboratory (CICL) and a structural heart disease clinical fellow with Ferrarotto Hospital in Catania, Italy. Dr. Attizzani, who has also been named Co-Director of the UH CICL, is a reviewer for such medical journals as *Circulation* and the *American Journal of Cardiology* and is the author of more than 40 scientific papers.

Dr. Sparano completed her internal medicine residency at Northwestern University and completed cardiology and electrophysiology fellowships at the University of Chicago, where she was chief cardiology fellow. Dr. Sparano is board-certified in internal medicine and cardiovascular disease and has conducted research on gender differences in sudden cardiac death and infections and extractions of cardiac implantable electronic devices. She is the author of nearly 20 scientific papers and has presented widely at scientific meetings, including an invited lecture as an emerging leader to Women in Electrophysiology.



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