The LV Parachute: An Exciting Treatment Option for Ischemic Heart Failure

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In the Spirit of Innovation

Delivering on our mission – To Heal. To Teach. To Discover. – inspires our ongoing commitment to advance clinical research and new treatment protocols. While advances in cardiovascular medicine mean we can save more lives today than ever before, we continue to dig deeper to further maximize our achievements. In this issue of Heart & Vascular Innovations, we share how the study and practice of cardiovascular medicine at the University Hospitals Harrington Heart & Vascular Institute at University Hospitals Case Medical Center means never being satisfied with success.

Thrombolysis therapy via anticoagulant medications revolutionized the treatment of deep vein thrombosis. But in “Research Connection,” John Chaw Wang, MD, FACS, and Vikram S. Kashyap, MD, FACS, describe how supplementation with pharmacomechanical thrombectomy may provide even more immediate and long-term relief for patients.

Similarly, ablation techniques for complex ventricular tachycardia have demonstrated notable outcomes, yet the procedure itself often places patients at risk for possible severe complications. This issue’s “Innovative Treatment” article describes a possible solution to this conundrum – the novel Impella pump – in which Mauricio Arruda, MD, notes how this left ventricular assist device appears to complement existing ablation procedures by increasing hemodynamic support, giving patients as well as clinicians the upper hand on these arrhythmias.

Congestive heart failure (HF) is one of the most burdensome diseases facing this country, and we have made great gains in helping patients live longer, better quality lives. In our cover story, James C. Fang, MD, FACC, FAHA, and Marco A. Costa, MD, PhD, discuss two methods for bolstering HF treatment: expanding the use of left ventricular assist devices beyond that of just bridge or destination therapy for heart transplant candidates, and the innovative Parachute Ventricular Partitioning Device.

Lastly, in “Case Study,” Alan Markowitz, MD, and Dr. Costa demonstrate how clinical research into severe aortic stenosis led to a revolutionary intervention for one patient in particular.

It is the constant drive for cutting-edge, innovative therapies that will continue leading us to better outcomes for the patients we serve. Indeed, innovation is at the core of our mission: To Heal. To Teach. To Discover.

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Deep vein thrombosis (DVT) acts as a double-edge sword, affecting the body both locally and systemically. Resulting limb swelling may produce pain, mobility problems and, in the long term, chronic post-thrombotic syndrome. But the more insidious and deadly consequence of DVT is pulmonary embolization occurs in about one-quarter of cases – approximately 25 percent of which can be fatal.

Consequently, vascular surgeons are increasingly relying on a different approach to DVT management that advances beyond older methods of invasive and potentially complicated surgery. Pharmacomechanical thrombectomy (PMT) not only means improving patients’ lives today, but, by possibly minimizing later complications, it also heralds a more promising future.

Old Problems…

Like any intervention for venous thrombosis, the goal of PMT is to remove the clot from within the vein. Its application has largely focused on DVT of the lower extremities, like veins in the thighs, pelvis and inferior vena cava. Although traditional treatment for DVT historically has centered on systemic anticoagulation, such as use of heparin or, in the long term, warfarin (Coumadin), Dr. John Chaw Wang, MD, FACS, attending Vascular Surgeon, UH Case Medical Center; and assistant Professor of Surgery, Case Western Reserve University School of Medicine, notes a changing tide.

“There is emerging evidence now that thrombolysis therapy combined with percutaneous mechanical thrombectomy improves immediate and long-term patient outcomes by reducing the clot burden that is present in the deep pelvic, thigh and leg veins. Blood thinners prevent more clots from forming, but do not melt the clots away,” he explains. “Your body’s endogenous fibrinolytic mechanisms are responsible for melting away a clot, and if the thrombus burden is high, the body may not be able to dissipate the entire clot. This is where we can help with PMT.”

…New Solutions

Until the 1970s, thrombectomy involved dissecting and opening a vein through an incision in the groin, allowing for clot extraction. But success came at a cost: high invasiveness, greater morbidity and excessive blood loss. “Most of these patients would re-clot,” adds Dr. Wang. “So the outcomes were really not so good.” By tapping the vein percutaneously, surgeons maintain direct access to the clot but with less risk than in open surgery. And when combined with pharmacological thrombolysis through catheter-directed tissue plasminogen activator and catheters to remove the clot, PMT has the additional benefit of dissolving occlusions altogether.

Dr. Wang, with colleague Vikram S. Kashyap, MD, FACS, Chief, Division of Vascular Surgery and Endovascular Therapy, UH Case Medical Center, Co-Director, UH Harrington Heart & Vascular Institute; and Professor of Surgery at the School of Medicine, promotes the use of PMT, largely because of favorable patient outcomes. Better clot clearance and reduced risk of post-thrombotic syndrome, swelling, varicose veins, venous ulcers and debilitation all appear to be associated with PMT. Dr. Wang cautions that much of the current data on the technique is drawn from case studies with relatively small sample sizes. But two randomized controlled trials – the completed TORPEDO Trial and the ATTRACTION Trial currently under way – will hopefully bring clarity to its effects within the coming year.

“It is becoming increasingly apparent that DVT is a treatable condition. If we can attack this early and provide a treatment that is fairly successful, we can prevent complications five, 10, even 15 years down the line,” he says. “We are doing more and more PMTs because we want to keep holding an aggressive stance in terms of using this treatment.”

Make a Referral

Patients can be referred to Vascular Surgery, Interventional Cardiology and Vascular Medicine by calling 216-844-3800.
Heart failure (HF) is one of the most pervasive cardiac diseases, affecting approximately 23 million individuals across the globe and nearly 6 million in the U.S. alone. Although many patients experience improvement through standard treatments with medications and special pacemakers, others experience a steady worsening of symptoms. There is a clear need for novel approaches to managing HF, and new device therapies are giving hope to patients as well as to physicians that such options are on the horizon.

Focusing on the Future
The use of a mechanical heart pump to take over the function of the heart – for example, left ventricular assist devices (LVADs) – is not novel to HF treatment. However, James C. Fang, MD, FACC, FAHA, Director, Advanced Heart Failure & Transplant Center; Chief Medical Officer, UH Harrington Heart & Vascular Institute at UH Case Medical Center; and Professor of Medicine, Case Western Reserve University School of Medicine, notes improvements in LVAD therapy for HF are evolving.

The use of LVADs as adjuvant therapy to allow the weakened heart to recover – known as bridge-to-recovery – continues to be an attractive strategy. “It is an active area of research because if you can do something to the heart to make it better, and you can temporarily support the human circulation until the heart can get better, you could then remove the LVAD,” he says. Although bridge-to-recovery is uncommon, incorporation of additional therapies, such as stem cells to regenerate human heart muscle while on an LVAD, holds significant promise for the use of LVADs as “platform” therapies (as opposed to permanent solutions) to treating heart failure.

Another area of research focus is reducing mortality and morbidity associated with LVAD implantation and chronic support. Future LVADs will be smaller, more durable, and less likely to cause infection or need blood thinners. The use of transcutaneous rather than percutaneous power lines, for instance, may help to reduce infection.

“The other evolving area is the use of these devices to support patients who are not currently heart transplant candidates but who continue to be symptomatic despite optimal medical treatment,” explains Dr. Fang. “This is what we call bridge-to-a-decision.” As a result, physicians can reassess transplant candidacy if LVAD therapy is successful in improving the patient’s overall health status.

UH Case Medical Center has been recognized with Joint Commission Advanced Certification in Ventricular Assist Device as well as Core Certification for the Management of Inpatient and Outpatient Heart Failure.

Parting Ways
Damaged heart muscle after a heart attack can lead to structural remodeling and decline in ventricular performance. The resulting enlargement of the heart may induce shortness of breath and fatigue, impinging on patients’ ability to function and maintain quality of life. In such cases, making the heart smaller with an alternative implantable device may improve symptoms and other outcomes. The novel Parachute™ Ventricular Partitioning Device, by CardioKinetix, is the first minimally invasive treatment for such populations.

The Parachute device partitions damaged heart muscle from normal muscle, allowing restoration of
cardiac output and functioning of the left ventricle in patients with ischemic HF secondary to myocardial infarction. Implantation is accomplished through catheter-based insertion through the femoral artery – an approach termed percutaneous ventricle restoration. Recent data on the first patients to receive the Parachute showed, three years after implant, recipients experienced improved cardiac output and symptoms. Cardiac death rate at two and three years post-implant remained stable, suggesting a lack of disease progression. Quality of life also improved.

“The Parachute presents an exciting new treatment option for patients suffering from ischemic heart failure,” says Marco A. Costa, MD, PhD, Director, Interventional Cardiovascular Center and Research & Innovation Center, UH Harrington Heart & Vascular Institute; Professor of Medicine, Case Western Reserve University School of Medicine; and Co-Principal Investigator in the PARACHUTE IV trial. “It offers patients a treatment option that does not involve the risks associated with surgical alternatives and in a short period of time.”

These findings suggest the safety and efficacy of the Parachute device, and further randomized controlled trials are being planned to assess outcomes in larger populations.
Catheter ablation is a potentially curative procedure designed to treat most types of arrhythmias, including complex VT.

The Impella system, along with the Stereotaxis Magnetic Navigation system that is part of the Center of Excellence for Stereotaxis for Complex Ablation, are among some novel approaches being utilized by Dr. Arruda at UH Case Medical Center. The Impella is a minimally-invasive percutaneous left ventricular assist device that provides hemodynamic support and appears to alleviate these problems. The Impella catheter is advanced into the heart and connected to an external pump. It then aspirates blood from the left ventricle and releases it into the aorta, aiding the weakened heart muscle by increasing cardiac output. The Impella not only improves the cardiac output, but also allows for adequate oxygen levels in the brain, despite low blood pressure.

“It seems that the Impella not only facilitates the ablation procedure but also decreases the commonly seen effects of worsening heart failure and long hospitalization that are typically observed following VT ablation,” Dr. Arruda summarizes.

**Adaptations for Pediatrics**

Ablation procedures in children largely mirror those in adults – with extra, added touches that help keep kids at ease. “The difference isn’t the age or the size of the patients; it’s the approach,” says Christopher Snyder, MD, Co-Director, Congenital Heart Disease Center, UH Harrington Heart & Vascular Institute; Chief of Pediatric Cardiology, University Hospitals Rainbow Babies & Children’s Hospital; and Clinical Associate Professor of Pediatrics, Case Western Reserve University School of Medicine.

Environmental modifications, such as cartoon drawings on the ceiling and DVD players in the rooms, are designed to keep children comfortable. Extra staffing, including two electrophysiologists in the lab at all times, ensures safety of the child and constant communication with parents. Just like their adult counterparts, pediatric patients enjoy impressive outcomes with ablation. “The beauty of it is, I get to tell the family, ‘We got it, and it isn’t coming back,’” says Dr. Snyder.
Leading-Edge Care

For one patient, clinical research provides a turning point for recovery

An 86-year-old male with congestive heart failure was referred to the Heart Valve Center of UH Harrington Heart & Vascular Institute at UH Case Medical Center with symptomatic severe aortic stenosis. Clinicians at an outside hospital indicated they could not supply a valve of sufficient size for the patient’s needs. Alan Markowitz, MD, Acting Chief, Division of Cardiac Surgery, UH Case Medical Center; Chief Surgical Officer, UH Harrington Heart & Vascular Institute, and Director of the Heart Valve Center; Marcella “Dolly” Haugh Chair in Valvular Surgery; and Clinical Assistant Professor of Surgery, Case Western Reserve University School of Medicine, assessed the patient to determine whether UH Case Medical Center could implant an appropriately sized valve and whether his symptoms warranted enrollment in a clinical trial for severe aortic stenosis.

Discussion

Risk stratification for aortic valve replacement considers the suitability of individuals to withstand and recover from the procedure, with older age and comorbidities indicating high risk. While standard aortic valve replacement through sternotomy may still be recommended, for many patients this is considered inadvisable.

“Mechanically, we can do almost anything, but the question is, should we,” says Dr. Markowitz. “You may have severe aortic stenosis in someone who is older and frail, and we know we can do something about the stenosis, but if there are problems in other major organ systems, like the kidneys or the liver, or there has been a previous stroke with significant neurological disturbance, those things can really get in the way of adequate recovery and resumption of quality of life.”

These patients may be appropriate candidates for transcatheter aortic valve replacement (TAVR), a nonsurgical alternative for aortic valve replacement, because of their severe aortic stenosis and high frailty (e.g., reduced mobility, inability to function independently). Further, risk of stroke and mortality is a primary concern, although current clinical trials (see sidebar “Looking to the Future”) are assessing how these complications compare with those of standard surgery.

Evaluation

After a failed balloon valvuloplasty at another hospital, the patient was referred for TAVR with a large (31-millimeter) prosthesis, which was not available in the U.S. at the time. The patient was experiencing shortness of breath at rest and, on minimal exertion, multiple fainting episodes and repeat hospitalizations.

“It took a little courage and lots of discussion with our multidisciplinary team, patient and family to conclude that he had no other chance to live if we did not try to restore the normal function of his aortic valve,” says Dr. Costa.

Therefore, he was enrolled in Medtronic’s CoreValve® U.S. Pivotal Trial at UH Case Medical Center in October 2011. To temporarily improve function until the large valve was approved for testing, Drs. Costa and Markowitz performed a successful balloon aortic valvuloplasty. By that December, Medtronic won investigational approval, and the patient became one of the first in the U.S. to receive the 31 mm CoreValve implantation. The patient had a successful procedure and was discharged from the hospital eight days later.

Looking to the Future

UH Case Medical Center is one of a highly select group of U.S. sites participating in Medtronic’s CoreValve U.S. Pivotal Trial. Patients who are high risk for aortic valve replacement are randomized to receive conventional surgery versus TAVR, while the extreme high-risk group will receive TAVR only, providing a true comparison of outcomes between the two approaches. To receive more information on our program, email us at HVInnovations@UHhospitals.org.
Save the Date

Continuing Education Events

Care for the Dialysis Patient
**When:** Tuesday, March 5, 2013, 6 p.m. to 8 p.m.
**Where:** Cleveland Racquet Club (Shaker Heights, Ohio)

4th Annual Update on Vascular Disease: Dilemmas and Trends in Vascular Disease
**When:** Saturday, April 6, 2013, 7:30 a.m. to 2:30 p.m.
**Where:** Corporate College East (Warrensville Heights, Ohio)

Cardiovascular Symposium
**When:** Thursday, March 14, 2013, 7:30 a.m. to 4:30 p.m.
**Where:** Corporate College East (Warrensville Heights, Ohio)

For more information, including program agenda and how to register, contact us at HVInnovations@UHhospitals.org.

Recent Grants

With funding from the National Institutes of Health through Case Western Reserve University School of Medicine, two new studies conducted at UH Case Medical Center will help continue leading-edge research that brings high-quality care to patients.

Reena Mehra, MD, MS, Director, Sleep and Cardiovascular Research, Division of Pulmonary, Critical Care and Sleep Medicine, UH Case Medical Center; and Associate Professor of Medicine at Case Western Reserve University School of Medicine, is leading the investigation of a study examining sleep apnea as a possible contributor to paroxysmal atrial fibrillation (AF). Despite AF’s high prevalence, exact causes of AF are still unclear. This study, funded by a $3.8 million grant from the National Heart, Lung, and Blood Institute (NHLBI), may clarify whether the bouts of intermittent hypoxia that characterize sleep apnea contribute to heart changes that lead to arrhythmias and reduced blood oxygen levels. Dr. Mehra and her colleagues also will consider the role of inflammatory and stress responses as potential mediators between sleep apnea and AF. Findings are expected to lead to better AF prevention and treatment approaches.

Dr. Mehra is also leading another NHLBI-funded study to assess the relationship of baseline sleep disordered breathing and electrophysiological indices as predictors of newly diagnosed incident atrial fibrillation in an observational cohort of 3,000 older male participants. Additionally, the NHLBI-funded Heart Failure Disease Management in Skilled Nursing Facilities trial will soon begin enrollment, led by Rebecca Boxer, MD, MS, Assistant Professor of Medicine at Case Western Reserve University School of Medicine. The randomized controlled trial will attempt to improve recent disturbing outcomes of older, medically frail heart failure (HF) patients who are discharged to rehabilitation facilities.

Physician Accolades

September 2012: Albert L. Waldo, MD, FACC, FAHA, FHRS, was honored with the Distinguished Physician Award, the highest honor University Hospitals bestows on its physicians. Dr. Waldo, Associate Chief of Cardiovascular Medicine for Academic Affairs, UH Case Medical Center, is an international authority on atrial fibrillation. He was among the first to map the electrical activation of the human heart and described entrainment of cardiac arrhythmias. Dr. Waldo’s scientific articles have appeared in more than 400 publications, and he has received numerous accolades, including Distinguished Scientist Awards from the Heart Rhythm Society (1997) and American College of Cardiology (2009). He is The Walter H. Pritchard Professor of Cardiology, Professor of Medicine and Biomedical Engineering at Case Western Reserve University School of Medicine and Case School of Engineering.

November 2012: Mukesh K. Jain, MD was awarded the 2012 Russell Ross Memorial Lecturer in Vascular Biology by the Council on Arteriosclerosis, Thrombosis, Vascular Biology (ATVB) and the American Heart Association. Dr. Jain is internationally recognized for studies, funded in part by the National Institutes of Health through Case Western Reserve University School of Medicine, that have established a central role for a family of genetic factors, called Kruppel-like factors, that regulate cardiovascular biology in health and disease. Dr. Jain is currently Vice President for the American Society for Clinical Investigation and will serve as President-elect and then President in successive years. He is the Chief Research Officer, UH Harrington Heart & Vascular Institute at UH Case Medical Center; Ellery Sedgwick Jr. Chair and Distinguished Scientist; Director, Case Cardiovascular Research Institute; and Professor at Case Western Reserve University School of Medicine.

Win an Apple iPad 2!

Your feedback is important to us. As a medical professional, your input is invaluable in helping us shape future issues of Heart & Vascular Innovations. We want to know what’s important to you. Do you want to read about leading-edge research, learn about the latest technology, or hear firsthand case studies of how others in your specialty are improving and saving lives? Tell us what you want to read about and your name will be entered to win one of two Apple iPad 2s! Simply visit UHhospitals.org/innovations.