INSIDE THIS ISSUE



First Transcatheter Tricuspid Valved Stent Placed – **p. 5**



Taking Ex Vivo Lung Perfusion Beyond the Lab – **p. 9**



3-D Navigation of the Aorta Without Fluoroscopy – **p. 15**



Cardiac Consult

Heart and Vascular News from Cleveland Clinic | Spring 2017

p. 6

Imaging Insights in Valve Disease

Dear Colleagues,

"The finest souls are those that have the most variety and suppleness." The French philosopher Montaigne first used those words to describe individuals, but I'm convinced they apply equally well to institutes and service lines at leading medical centers. In today's shifting healthcare landscape, well-rounded capabilities and flexibility are finer attributes than they've ever been.

That's why, when reviewing this issue of *Cardiac Consult*, I was struck by the sheer variety of activities by my Cleveland Clinic Miller Family Heart & Vascular Institute colleagues reported on in these pages. From novel uses of remote cardiac telemetry monitoring (p. 4) to virtual visits in electrophysiology (p. 8) to the use of virtual reality in surgical training (p. 10) to inventive end-of-life services for heart patients (p. 12), my colleagues are letting a thousand flowers bloom in pursuit of the best outcome and experience for our patients. And that's not even mentioning pioneering clinical feats like the first implantation of a transcatheter tricuspid valved stent (p. 5) or leading-edge applications of ex vivo lung perfusion in lung transplantation (p. 9).

Such variety and dynamism are embedded in Cleveland Clinic's culture, and they're consistently channeled toward our ethic of putting patients first. We welcome the privilege to put them in service of the needs of your most complex patients who may require referral care.

Respectfully,

Lars G. Svensson, MD, PhD CHAIRMAN | Sydell and Arnold Miller Family Heart & Vascular Institute



Cardiac Consult is produced by Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute.

Medical Editor Lars G. Svensson, MD, PhD Institute Chair svenssl@ccf.org

Managing Editor Glenn R. Campbell Art Director Michael Viars

Photography & Illustrations Cleveland Clinic Center for Medical Art & Photography, Russell Lee Photography

Cardiac Consult is written for physicians and should be relied on for medical education purposes only. It does not provide a complete overview of the topics covered and should not replace the independent judgment of a physician about the appropriateness or risks of a procedure for a given patient.

© 2017 The Cleveland Clinic Foundation

About Cleveland Clinic

Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,500 physicians and researchers represent 140 medical specialties and subspecialties. We are a main campus, more than 150 northern Ohio outpatient locations (including 18 full-service family health centers and three health and wellness centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada and Cleveland Clinic Abu Dhabi.

In 2016, Cleveland Clinic was ranked the No. 2 hospital in America in *U.S. News & World Report*'s "Best Hospitals" survey. The survey ranks Cleveland Clinic among the nation's top 10 hospitals in 13 specialty areas, and the top hospital in heart care for the 22nd consecutive year.

RESOURCES FOR PHYSICIANS

Stay Connected with Cleveland Clinic's Heart & Vascular Institute

Consult QD — Heart & Vascular

News, research and perspectives from Cleveland Clinic experts: consultqd.clevelandclinic.org/cardiovascular



facebook.com/CMEClevelandClinic

@CleClinicMD

- in clevelandclinic.org/heartlinkedin
- clevelandclinic.org/cardiacconsult

24/7 Referrals

855.REFER.123 clevelandclinic.org/heartreferrals

Track Your Patients' Care Online

Secure online DrConnect account at clevelandclinic.org/drconnect

"Cleveland Clinic Way" Book Series

Lessons in excellence from one of the world's leading healthcare organizations: clevelandclinic.org/ClevelandClinicWay

Heart & Vascular Vitals: Focus on Vascular Surgery and Medicine

A sampling of Cleveland Clinic Miller Family Heart & Vascular Institute outcomes and volumes. This issue's focus is vascular surgery and vascular medicine. For more outcomes data, visit clevelandclinic.org/outcomes.

> 7,500

Annual vascular surgery case volume for each of the past three years, making Cleveland Clinic the largest vascular surgery program in the U.S.

1950s

Decade when Cleveland Clinic's vascular medicine program was established, making it one of the first in the U.S.

Selected Volumes: Vascular Surgery and Medicine (2016)

50,092

Vascular lab studies

5,681

Wound center visits

855

Peripheral interventions

483

Aortic surgeries

- **90** Endovascular infrarenal stent grafts
- **102** Open abdominal supra- and infrarenal repairs
- 34 Open thoracoabdominal repairs
- 86 Fenestrated stent grafts
- 171 Thoracic stent grafts

92

Lower-extremity bypass procedures

19

EVAR explants

Outcomes & Quality Snapshots: Vascular Surgery

1.7%

In-hospital mortality for vascular surgeries at Cleveland Clinic's main campus in 2016 (N = 1,549)

0%

In-hospital mortality for elective open abdominal aortic aneurysm (AAA) repairs for past three years (2014-2016; N = 216)

100%

Compliance with appropriateness-of-care metrics for carotid disease (N = 289) and AAA disease (N = 116) in 2016 (covering medical therapy, indications, follow-up)

Fast Facts



764

Number of patients with fibromuscular dysplasia (FMD) treated in 2016 (up 40% from 2015), the largest population of FMD patients in the world

247

Number of patients treated for failed endovascular repairs (162 open removal, 85 fenestrated salvage) through 2016, the largest experience in the world



Centralized Cardiac Telemetry Monitoring Slashes Alarm Fatigue, Saves Lives

Fewer than 1 in 4 patients survives an in-hospital cardiac arrest, according to American Heart Association statistics. Thanks to an off-site central monitoring unit (CMU) providing 24/7 cardiac telemetry monitoring for non-critically ill patients, Cleveland Clinic has achieved a striking 93 percent survival rate among patients with in-hospital cardiac arrest when the CMU provided direct notification to on-site emergency response teams.



That accomplishment, reported in a study in *JAMA* (2016;316:519-524) last August, has spurred a wave of inquiries from physicians across the country, according to the study's lead author, Daniel Cantillon, MD, Medical Director of the CMU. "They want to learn more about what we're doing," he says.

Designed as a sort of off-site mission control center, the CMU is staffed by trained technicians who provide urgent notification to bedside nurses or hospital emergency rapid response teams to aid patients in immediate danger of cardiac arrest in multiple hospitals across the Cleveland Clinic health system. The idea is to assign the first line of cardiac telemetry monitoring to these professionals removed from the distractions of normal hospital activities, in order to combat "alarm fatigue," when busy staff become desensitized to the constant noise emanating from monitoring systems.

Creation of the CMU was coordinated with the adoption of standardized criteria — developed by Dr. Cantillon and other Cleveland Clinic cardiologists — for putting patients on telemetry, to avoid unnecessarily monitoring those at low risk. "By eliminating low-risk patients from the monitor, we hoped to better concentrate our efforts on the patients who really require our attention," Dr. Cantillon explains.

The *JAMA* paper reported results from the CMU's first 13 months of operation, which showed the following:

- Telemetry standardization enabled a 15.5 percent monitored census reduction with no rise in cardiopulmonary arrests, compared with the 13 months before CMU launch.
- CMU monitoring detected rate and rhythm changes in 79 percent of patients within one hour of emergency response team activation, and discretionary direct notification was associated with successful resuscitation in 93 percent of patients who coded.
- "We found that there's about a 1 in 4 chance that a patient our technicians call about will have a cardiac arrest," says Dr. Cantillon. "And if a patient arrests, there's a 93 percent chance we'll get them back."

He notes that Cleveland Clinic "has only scratched the surface" of how to advance care in the area of monitoring. He points out that the CMU is now implementing a new telemetry module powered by a dynamic algorithm created by his team to allow monitoring of twice as many patients with the same number of CMU technicians. "That will allow scalability to extend the benefits of this service to the entire Cleveland Clinic health system," he observes.

This distance health approach represents a new paradigm for cardiac telemetry monitoring, Dr. Cantillon says: "By centralizing our system, standardizing our practices and separating monitoring from the distractions of normal hospital activities, we've been able to make important gains."

.....

For more, see **consultqd.clevelandclinic.org/telemetry**.

Contact Dr. Cantillon at cantild@ccf.org.

Transcatheter Tricuspid Valved Stent Implant Marks New Frontier in Percutaneous Valve Care

Transcatheter heart valve replacement has expanded to a new front: In November 2016, a Cleveland Clinic team successfully performed the world's first implantation of a transcatheter tricuspid valved stent.

The procedure was done in a 64-year-old woman with a long history of severe tricuspid regurgitation (TR 4+), which invariably leads to lethal right heart failure. Following stent implantation (see figure), the new tricuspid valve demonstrated excellent valve performance, indicating significant reduction of the patient's severe valve regurgitation. The patient has fared well since the procedure.

A Step Forward in Treating Tricuspid Regurgitation

"This is a step forward in the treatment of tricuspid regurgitation," says Cleveland Clinic cardiothoracic surgeon Jose Navia, MD, who led the team. "The hope is to provide a device that is able to capture the diseased tricuspid valve annulus, which has been enlarged inordinately by the ravages of functional tricuspid regurgitation." Such enlargement causes a reverse flow of venous blood from the right heart that should go to the lungs, Dr. Navia explains.



Figure. Image of the implanted transcatheter tricuspid valved stent.

"This patient's annulus measured 49.7 mm in diameter," notes Samir Kapadia, MD, Section Head of Invasive and Interventional Cardiology. "There are currently no valved stents that can secure such a dimension without extending into any of the chambers and still provide valvular function, yet millions of patients present with this problem worldwide."

That unmet need fueled development of the novel stent used in this first patient — the GATE[™] tricuspid atrioventricular valved stent (AVS) from NaviGate Cardiac Structures Inc. The company licensed the stent technology from Cleveland Clinic, and Drs. Navia and Kapadia serve on NaviGate's scientific advisory board. Dr. Navia is also a company shareholder.

Diffuser Design Enables Easy Vessel Threading

The stent was conceived for placement as a minimally invasive alternative to open valve repair or replacement to treat tricuspid valve regurgitation. Its main point of distinction is its design in the form of a diffuser that enables easy threading through the vasculature to reach atrioventricular valves and avoid protrusion into the adjacent chambers.

Once the device is deployed in the heart, a narrow strap is anchored in the tissue to one side of the loose and leaky tricuspid valve. The strap is pulled taut, bringing the valve leaflets together and restoring normal closure.

Like transcatheter mitral and aortic valve procedures, this first transcatheter tricuspid valve replacement was conducted in a hybrid operating room at Cleveland Clinic.

"Transcatheter tricuspid valve replacement promises to be an alternative treatment for patients in whom open tricuspid valve surgery poses too high a risk," says Dr. Navia. ■

Contact Dr. Navia at naviaj@ccf.org and Dr. Kapadia at kapadis@ccf.org.

Imaging Insights in Valve Disease: High Volumes Translate to Research-Refined Care

For cardiologists specializing in valve disease, practicing at Cleveland Clinic can sometimes feel like being a kid in a candy store.

"We do more heart valve surgeries — and perhaps see more valve patients — than any other center in the world," says Brian Griffin, MD, Section Head of Cardiovascular Imaging. "As a result, we have a huge data set of valve patients we can study to evaluate how they fare over the long term. We've put a lot of effort into trying to understand the factors affecting outcome in patients with relatively common conditions, such as mitral regurgitation, aortic stenosis and aortic regurgitation."

"A lot of effort" may be an understatement, as Dr. Griffin and his Section of Cardiovascular Imaging colleagues published over 100 papers in peer-reviewed journals in 2016 alone. A sizable share of them were large observational studies conducted with Cleveland Clinic cardiac surgeons that focused on using imaging to improve approaches to valve surgery.

Two major themes emerged from these papers:

- In an increasing number of settings, intervening earlier in valve disease appears to be associated with better outcomes.
- Interpretation of strain-based assessment differs greatly depending on the context of the valve lesion being evaluated.

For Valve Interventions, Earlier Increasingly Seems Better

Dr. Griffin says that much of the data guiding valve disease management in recent years is from 20 or more years ago, "when surgical outcomes in valve disease weren't nearly as good as they are now." Moreover, current guidelines on when to intervene in valve disease are founded on studies in relatively small patient samples. "They may be based on studies of 100 or 200 patients, whereas now we have outcomes from thousands of patients," he notes.

He cites the example of mitral regurgitation: "The traditional view is that a pulmonary artery pressure above 50 mm Hg indicates a severe leak and argues for surgical intervention. But last year we published an observational cohort study of 1,318 patients (*J Am Coll Cardiol*. 2016;67:2952-2961) showing that the cut point where you start to see a decline in outcome is a lot lower than 50 mm Hg, and that the risk

effect is continuous across pulmonary vascular pressures. In other words, the higher your pulmonary pressure, the worse you do. So waiting until a patient's pressure rises above 50 may not always be the right thing to do."

Similarly, mounting experience in the use of strain-rate imaging is enabling detection of subtle deterioration in heart function before a patient's ejection fraction starts to change. "We've found in a series of studies of several types of valve lesions that people who have apparently normal ejection fractions but have impaired strain tend to do worse over the long term," says Dr. Griffin. "So the questions we're exploring are whether we should be intervening earlier in valve disease and whether to use newer measures like strain or B-type natriuretic peptide to determine when to intervene.

Other Recent Cleveland Clinic Studies of Imaging-Informed Valve Care

Long-Term Outcomes in Patients with Aortic Regurgitation and Preserved Left Ventricular Ejection Fraction (J Am Coll Cardiol. 2016;68:2144-2153)

More at consultqd.clevelandclinic.org/avsurg

Strain Echocardiography and Functional Capacity in Asymptomatic Primary Mitral Regurgitation with Preserved Ejection Fraction (J Am Coll Cardiol. 2016;68:1974-1986)

More at consultqd.clevelandclinic.org/asymptMR

Characteristics and Long-Term Outcomes of Contemporary Patients with Bicuspid Aortic Valves (J Thorac Cardiovasc Surg. 2016;151:1650-1659.e1)



Multimodal imaging in a patient with severe aortic stenosis. **Top left:** Continuous-wave Doppler across the aortic valve suggesting severe stenosis. **Top right:** Transesophageal echo of the stenotic aortic valve. **Bottom left:** Left ventricular global longitudinal strain analysis. **Bottom right:** Volume-rendered CT of the stenotic trileaflet aortic valve.

"We've applied this pretty broadly," he continues, "from aortic valve disease to mitral valve disease to aortic regurgitation and beyond." In addition to the example studies in the sidebar, Dr. Griffin cites a large cohort analysis in *Circulation* (2016;134:1724-1737) showing that indexing aortic root area to patient height provides independent and improved stratification for mortality risk as compared with aortic diameter alone in patients with a dilated proximal ascending aorta and trileaflet aortic valve. "This has clear implications for timing of surgical intervention in this population."

Strain: One Size Does Not Fit All

Dr. Griffin notes that strain imaging is especially well suited to research at high-volume centers because it can be done post hoc. "You don't have to do the measurements at the time of imaging," he says. "Our images are all digitized, so we can go back and have researchers acquire the strain data after the fact if needed, to answer specific research questions."

But growth in the use of strain imaging has led to some misperceptions among clinicians, cautions one of Dr. Griffin's Section of Cardiovascular Imaging colleagues, Milind Desai, MD, Professor of Medicine, Cleveland Clinic Lerner College of Medicine.

"There's an assumption among some cardiologists that strain-based assessment is a one-size-fits-all approach across various conditions, but we no longer believe that's accurate," says Dr. Desai. "What we're learning from a series of studies is that strain must be understood in the context of the lesion being studied."

He cites the example of mitral regurgitation (MR) versus hypertrophic cardiomyopathy (HCM): "In our data set, 95 percent of patients with MR have a strain better than 18 percent, whereas 95 percent of patients with HCM have a strain worse than negative 18 percent. Yet if you follow these groups over time, mortality is less than 0.5 percent per year in both groups. So strain means very different things in these different settings."

Dr. Desai adds that similar differences in strain are seen between aortic stenosis and HCM, for example, or between aortic stenosis and aortic regurgitation — all with different implications. "And if a patient has mixed valve disease, we

don't yet know which condition is in the driver's seat versus the passenger seat," he notes. "Many factors go into the implications of strain, and plenty of questions remain."

Next Fronts in Valve Imaging Research

Answering those questions is on the priority list of these Cleveland Clinic researchers moving forward, as is fuller evaluation of other emerging biomarkers to help determine optimal timing of valve surgery, such as exercise capacity and blood markers.

Other research priorities include the use of multimodal imaging and 3-D-printed models to devise new ways of placing bioprosthetic valves at the challenging mitral and tricuspid positions.

And continuing advances in transcatheter delivery of aortic valves raise a separate research challenge: how best to individualize the choice between transcatheter and surgical aortic valve replacement at a center like Cleveland Clinic where surgical outcomes are extraordinarily good. "We're lucky to have gifted surgical colleagues and the volumes to make both approaches very low-risk, but that's not the case everywhere," says Dr. Griffin. "Answering nuanced questions like this in a way that's applicable for individual patients is where the valve field is headed."

Contact Dr. Griffin at griffib@ccf.org and Dr. Desai at desaim2@ccf.org.

For Arrhythmia Patients, Virtual Visits Hold Plenty of Virtues

As providers and patients increasingly embrace virtual visits, cardiac rhythm disorders are emerging as a natural starting point for telemedicine-enabled cardiovascular care.

"In electrophysiology, we depend heavily on the patient's history and direct conversation with the patient about his or her symptoms," says Khaldoun Tarakji, MD, MPH, of Cleveland Clinic's Section of Electrophysiology and Pacing. "This lends itself to video chat. When we add in data from the patient's cardiac rhythm monitoring tools, we have most of what we need to care for most arrhythmia issues."

That's the reasoning behind Cleveland Clinic's introduction of the option of telemedicine visits, rather than in-person consultations, with an electrophysiologist for established patients with heart rhythm disorders.

All About Convenience

Distance health makes sense for a tertiary care center like Cleveland Clinic, says Dr.

Tarakji, who leads the health system's virtual electrophysiology effort. That's because it attracts many patients from outside the region for second opinions and procedures — patients who often require periodic or frequent follow-up visits, which can pose hardships and hassles.

This is where the concept of a simple video conversation comes in, as it converts what could be a major travel ordeal and time commitment into a convenient consultation the patient can take part in from home or the workplace.

A Simple Setup

For a virtual electrophysiology consultation, the technology requirements at the provider's end are minimal: two monitors placed side by side, one with a mounted web camera.

To ensure privacy, Cleveland Clinic provides a secure, webbased telecommunications system enterprisewide. The system allows patients to access their physician's "virtual waiting room" using the Cleveland Clinic Express Care[®] Online app on their smartphone or tablet or a webcam on their personal computer.

At the appointed visit time, Dr. Tarakji simply logs on to the website, selects the patient's name in his virtual waiting room



and connects with the patient via real-time video exchange. On the other screen, he calls up the patient's medical record and updates it during their conversation, "just like I would in the exam room," he says.

Patients Are Pleased

Since his first virtual visit in early September 2016, Dr. Tarakji has "seen" a few dozen patients via video chat, and many of his electrophysiology colleagues at Cleveland Clinic have adopted the concept as well.

"Patient feedback has been wonderful," he says. "When patients have worries, keeping the lines of communication open is reassuring."

But he's quick to add that the days of traditional clinic visits are far from over: "Virtual visits don't replace traditional visits in situations when direct contact with the patient is necessary. Plus, there's nothing better than human contact. But virtual visits are a step forward when the alternative is losing the patient to follow-up."

Contact Dr. Tarakji at tarakjk@ccf.org.

Ex Vivo Lung Perfusion: Progress Is at Hand in Closing the Organ Supply Gap in Lung Transplant

Although 1,600 to 1,800 lung transplants are performed every year in the U.S., many patients still die on the waitlist for donor lungs. A leading reason: Up to 80 percent of lungs offered for transplantation cannot be used due to poor function caused by factors including pulmonary edema and atelectasis.

Normothermic ex vivo lung perfusion (EVLP) has been developed as a way to help overcome that challenge. Beyond minimizing ischemia reperfusion injury in donor lungs, EVLP enables repair or reconditioning of marginal lungs that would otherwise be untransplantable. It also extends the time that donor lungs can be preserved prior to transplant compared with traditional cold-storage preservation. This allows better viability testing and the possibility of modifying the lungs pharmacologically or with gene therapy to improve outcomes.

While EVLP has been clinically available in Canada for several years, clinical use in the U.S. is still in its infancy yet holds great promise in those programs with appropriate resources and clinical expertise.

EVLP at Cleveland Clinic

Cleveland Clinic initiated EVLP research activity in 2011 in the lab of Kenneth McCurry, MD. Together with Toshihiro Okamoto, MD, PhD, and other Cleveland Clinic colleagues, Dr. McCurry has used EVLP in more than 50 rejected human lungs and over 30 porcine lungs to investigate important questions surrounding the technology, including the accuracy of evaluating donor lung suitability using EVLP.

Recent work by the McCurry lab yielded two important findings on the assessment of lung function using EVLP:

- The ratio of pressure of arterial oxygen (PAO_2) to fractional inspired oxygen (FIO_2) (i.e., P/F ratio) must be considered in combination with FIO_2 , as the P/F ratio varies at different FIO_2 levels (Okamoto et al., *Transplantation*. 2015;99:2504-2513).
- There is significant correlation between the P/F ratio and other physiologic (airway and vascular) parameters (Okamoto et al., *J Heart Lung Transplant.* 2016;35:1330-1336).

Beyond the Lab

Cleveland Clinic's lung transplant program is currently participating in the multicenter phase 2 trial of the Toronto EVLP System[™] sponsored by United Therapeutics. In this study, donor lungs deemed not transplantable are procured and transported to a perfusion facility near Baltimore. During four to six hours of EVLP, lungs are reconditioned and assessed for transplant suitability. When perfused lungs are judged transplantable, they are transported to Cleveland Clinic, where lung transplantation is performed.

To date, Cleveland Clinic has transplanted two patients with lungs treated in this fashion, and both recipients have done very well.



The ability to use EVLP has brought other benefits. "With EVLP as a backup, we can be more aggressive with lung procurement, which has resulted in some lungs we thought needed EVLP being reassessed as transplantable without using EVLP," explains Dr. McCurry, Surgical Director of Lung Transplantation in the Department of Thoracic and Cardiovascular Surgery. Twelve additional patients received lung transplants under such circumstances in 2016, with 100 percent survival.

Dr. McCurry notes that initiation of the clinical EVLP program has contributed to an increase in Cleveland Clinic's lung transplant volume, with 2016's total of 110 transplants — the second-highest volume in the U.S. for the year — exceeding 2015's volume by 13 percent. ■

For more, see consultqd.clevelandclinic.org/evlp.

Contact Dr. McCurry at mccurrk@ccf.org.

What Heart Programs Can Learn from Fighter Pilots and Other Elite Performers

When you've been No. 1 in your discipline for more than two decades, how do you continue to inspire innovation and drive improvement? Cleveland Clinic's Department of Thoracic and Cardiovascular Surgery is borrowing thoughts from a former Navy SEAL, a former F-18 fighter pilot and the company they formed to foster collaboration among elite performers from diverse disciplines.

Three years ago, Brian Ferguson was a U.S. Navy SEAL looking to develop innovative ways to prepare the special operations community for 21st-century threats and challenges. "At the end of the day, it was about helping a highperformance team in a high-risk environment get better," says Ferguson. "So we started studying other organizations that are elite in their performance."

Aware of Cleveland Clinic's top ranking in heart care, Ferguson contacted Cleveland Clinic cardiac surgeon Douglas Johnston, MD, who invited him to spend a day in the OR. "What intrigued me was that Brian's team of extraordinary performers, already at the top of their game, was asking, 'What are others doing in their industries that could help us get to the next level in ours?"" Dr. Johnston explains.

What Surgeons and Fighter Pilots Have in Common

"Innovation in most organizations is done within the silo of one discipline," says Ferguson. "Physicians talk to other physicians. Special ops talk to other operators. But actually, the best heart surgeons are likely to have more in common with the best fighter pilots, for example, than with other heart surgeons who are less accomplished or driven."

That insight drove Ferguson and former F-18 pilot Ben Kohlmann to found their company, Arena Labs, after their discharge from the Navy. Arena Labs brings together a range of elite performers — not just military and medical, but artists, authors, chefs, finance experts and others. Their vision is to "impact the future of human potential," helping individuals and teams better understand how to use the practices of other disciplines to learn and improve.

"There aren't many professions where you make high-risk, high-cost decisions on a daily basis," says Ferguson. "That's why we wanted to include those who perform high-stakes surgeries. Cleveland Clinic has been the first healthcare organization we've worked with."

Five Principles of Elite Performance

The Arena Labs collaboration has helped Ferguson and Kohlmann uncover five principles of elite performance, applicable in any discipline:

- **Stay humble.** "Guard against the hubris of thinking you're the best," says Ferguson. "No matter how good you are, you can be better."
- Set irrational standards. Set a standard for yourself so high that no one can surpass it.
- **Savor the grind.** Embrace failures and "grinding" (explained below) as learning opportunities for self-actualization.
- **Find balance in fear.** Every job has an aspect of fear. Most people are limited by it. Learn how to manage and balance fear so you can achieve what you want.

Harness the inspired soul. Identify your deeper motivation.

How Surgeons Can Apply Special Ops Training Techniques One of the first ways Cleveland Clinic has applied Arena Labs' elite performance principles is in training residents to "find balance in fear."

"There's no toolset for dealing with anxiety in cardiac surgery, where decisions can mean life or death," says Dr. Johnston. "The ACGME has a sleep curriculum, but nothing on fear."



A cardiac surgery resident takes part in virtual reality training.

"There's no toolset for dealing with anxiety in cardiac surgery, where decisions can mean life or death. The ACGME has a sleep curriculum, but nothing on fear." – Douglas Johnston, MD

Cleveland Clinic has begun to develop a fear curriculum for its cardiac surgery residents, founded in part on military special ops techniques. Based on principles of "stress inoculation" and fear and anxiety management developed by Arena Labs, the curriculum uses virtual reality (VR) to train residents for rare high-stress events in the OR, such as failure of a bypass pump or an anesthesia emergency. Residents wear VR headsets through which they experience re-created scenarios (see photo on facing page) — including the anxiety and adrenaline rush.



"Residents may never encounter situations like these during five or six years in training," explains Dr. Johnston. "We can talk about them, but it's different when residents see, hear and respond firsthand."

VR enables attending physicians to review residents' reactions and thinking processes, and allows residents to safely practice ideal performance under pressure.

See a two-minute video of VR's use in a simulated OR emergency at consultqd.clevelandclinic.org/vr.

The Power of Daily Critique

Another concept Cleveland Clinic has applied stems from Arena Labs' principles of humility and "savoring the grind" — embracing and learning from failures, knowing you can always improve. Surgical teams have begun holding formal debriefs after each procedure.

"We need to foster an open environment where our performance is reviewed daily, not just periodically," says Dr. Johnston. "Our first debrief was after one of our smoothest cases. There were no complications. Yet when our whole team came together to discuss it, we identified six action items for improvement."

For example, nurses noted that valve pieces weren't labeled consistently and were located in three different areas of the OR. "The only reason we learned about and fixed these inefficiencies was because the process of a formal critique among our team led us to look deliberately for things to improve," says Dr. Johnston.

Boundless Opportunities for Healthcare

Individual teams are testing elite performance behaviors (like the stress inoculation training described above) before they are formalized and rolled out department-wide.

"It's still early, but it's been a huge win even in the first few months," says Dr. Johnston. "Qualitatively, results have been outstanding. Enthusiasm is high. Now we need to reinforce it with data tracking." Future metrics may be based on OR errors, adverse event reports and staff turnover.

"We're at the beginning of a collaboration that has major potential for Cleveland Clinic and healthcare in general," says Dr. Johnston. "We have an extraordinary amount of insight coming in from people who are hugely successful in other arenas. If we can assimilate it, the opportunities are boundless." ■

Contact Dr. Johnston at johnstd3@ccf.org.

Palliative and End-of-Life Care in Heart Disease: Excellence Matters Through the Very End

Though it's been a decade since he retired from cardiothoracic surgery, Cleveland Clinic CEO and President Toby Cosgrove, MD, says he's "haunted to this day by some of the deaths on my operating table 20 or 30 years ago." He adds: "For a cardiac surgeon, death is traditionally seen as failure. We view our job as trying to preserve life at all costs."

But in Dr. Cosgrove's case, that view has changed a good bit since he began his prolific surgical practice over four decades ago (see sidebar). Those changes continue, and they helped spur the recent creation of a Center for End of Life Care within Cleveland Clinic's Office of Patient Experience. The center's mission is to standardize the health system's approach to end-of-life care, with the objectives of honoring patients' preferences, improving the experience of their family members and fostering resilience among the healthcare team.

That mission is manifested in two notable initiatives that directly touch patients of Cleveland Clinic's Miller Family Heart & Vascular Institute who have thoroughly exhausted treatment options for their advanced heart disease. These programs both started recently with essential input from heart failure cardiologist Eiran Gorodeski, MD, MPH — are profiled below.

Inpatient Hospice: Comfort Care Where Patients Are

Up to 2014, Cleveland Clinic had offered hospice services in fairly typical settings — at home and in nursing homes — as well as its regional hospitals. In October 2014, growing recognition of the need for more expertly nuanced care at the end of life prompted extension of hospice services to patients throughout Cleveland Clinic's 1,400-bed main campus hospital.

"Because our hospital is large and complex and its patients are very sick, we decided to send our hospice team to the ICUs and floors where patients are actively dying," explains Dr. Gorodeski, who has a specialty interest in end-of-life care.

The resulting inpatient hospice service — one of few in the nation — comes to the patient in the ICU or hospital room, often avoiding the need for transfer to an external location. In 2016, the service was used for 435 patients at Cleveland Clinic, 47 of whom were patients with end-stage cardiovas-cular disease, usually advanced heart failure or complications from a ventricular-assist device.

Most often, an ICU team initiates a hospice consult after discussion with the patient and family. If everyone agrees, the patient is transitioned from acute care to hospice care in place.

Primary goals are controlling symptoms, such as pain and shortness of breath, and making sure the patient doesn't suffer. When necessary, compassionate extubation is performed in a controlled setting. "Our inpatient hospice team delivers care that's complementary to the care from the ICU team, allowing them to focus on their intensivist expertise," Dr. Gorodeski notes.

The team includes a hospice and palliative medicine boardcertified physician, a nurse, a social worker and a chaplain. Key aspects of care include providing guidance about what to expect over the coming days and sometimes recommending "closure activities," or conversations patients may want to have with loved ones before losing the opportunity to do so.

Cleveland Clinic is now assessing the value offered by its inpatient hospice team by interviewing families of cardiovascular disease patients who died on the hospice service and comparing their comments with those from families whose loved ones died on the cardiac service.

Outpatient Palliative Care for Advanced Heart Disease

In August 2015, on the heels of the inpatient hospice service, Cleveland Clinic launched another novel offering: an outpatient palliative care service embedded within its heart failure clinic. The program for patients with advanced heart disease, one of just a handful in the U.S., has been welcomed by cardiologists and patients alike.

"The experience has been an eye-opener," says Dr. Gorodeski. "Our behavior has changed. We've become more attuned to how we talk to patients and what we talk about."

The outpatient program was a natural outgrowth of the inpatient palliative care program initiated when Cleveland Clinic was approved to use LVADs as destination therapy for advanced heart failure.

"As we became more involved with symptom management for inpatients, we needed a way to follow up and ensure ongoing symptom management after they went home," says Krista Dobbie, MD, the board-certified palliative medicine physician who runs the program.

Patients are referred by their cardiologists based on perceived need for palliative services. During its first 12 months, the outpatient palliative service provided care for 71 patients in 160 encounters. Three patients were heart transplant recipients, 20 had LVADs and 48 had symptomatic heart failure without advanced interventions.

Dr. Dobbie complements patients' heart care by managing their pain and other primary complaints, most notably fatigue but also dyspnea, depression, anxiety, drowsiness, nausea and constipation. She also helps patients think through their treatment goals and assists them with complex medical decision-making.

Dr. Gorodeski and his cardiologist colleagues were surprised to learn that many patients are reluctant to tell them when they've had enough intervention. But patients will open up to Dr. Dobbie. "They say, 'I don't want to let down my cardiologist, but I know my body is failing and I don't want to do this anymore,''' she says. At this point, most patients can be smoothly transitioned to hospice without hospitalization, she notes.

"We're proud that Cleveland Clinic is fully there for heart patients at this critical point in their lives, not just when things are going great," Dr. Gorodeski says. ■

Contact Dr. Gorodeski at gorodee@ccf.org and Dr. Dobbie at dobbiek@ccf.org.



Is Death a Failure? Reflections from Dr. Toby Cosgrove

In 2016, Cleveland Clinic CEO and retired cardiac surgeon Toby Cosgrove, MD, was interviewed at length about end-of-life issues he's grappled with over his career and how they've shaped Cleveland Clinic's Center for End of Life Care and the programs profiled on this page spread. An edited transcript of the interview is at **consultqd.clevelandclinic.org/eol**; we share a few excerpts of Dr. Cosgrove's comments here.

- "Death is a natural act, and there are rumors that it's coming to all of us. But we remain uncomfortable with it, societally and professionally. I tend not to remember my successes, but I can remember in vivid detail some of my failures. I still have nightmares about some of them. I would go and replay the event in my mind, everything I did. You question your judgment."
- "We see our job as trying to preserve life at all costs. But sometimes it's at a cost to the patient, not just to society. But it's hard because we now have so many tools and no one wants a patient to die on their watch. That's why you need to set the stage to be able to ultimately go to the family and say, 'It's come to the point where I don't think any more activity is going to benefit your loved one.'"
- "We need to better recognize that death doesn't always have to happen in the ICU, which is where it increasingly seems to happen. It can happen at home, in hospice, in palliative care or on the ward. Part of allowing people to die with dignity lies in not reducing them to feel that they're consuming everybody's emotions and resources."

Research Roundup Quick Takes on Recent Cardiovascular Studies of Note

ABSORB III at Two Years: Jury's Still Out on BVS

The jury's still out on the relative merits of the Absorb[™] everolimus-eluting bioresorbable vascular scaffold (BVS) versus the Xience metal drug-eluting stent (DES). So reported investigators presenting two-year results from the ongoing ABSORB III trial at the American College of Cardiology Scientific Session (ACC.17) in March. Although outcomes were comparable for the BVS and DES between years 1 and 2, patients receiving the BVS had an overall elevated risk of adverse outcomes at year 2 compared with those receiving the DES.

Elevated risk with the BVS appears to have been attributable to placement of the bioresorbable scaffold in vessels that were smaller than currently recommended, notes Cleveland Clinic's Stephen Ellis, MD, the study's lead investigator. "Key takeaways are that this device shouldn't be used in very small vessels and placement must follow rigorous procedural techniques," he says. Definitive word on how the BVS stacks up against a contemporary DES is not expected until results of the ABSORB IV trial emerge in coming years, he adds. More at consultqd.clevelandclinic.org/absorb3.

Registry Study Validates Safety of Valve-in-Valve TAVR

Valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) appears to be at least as safe as — and probably safer than — native valve TAVR, according to the STS/ACC TVT Registry study presented at ACC.17 in March. The analysis assessed outcomes through at least one year of follow-up among 757 ViV TAVR cases and 1,495 matched native valve TAVR cases identified from the registry from November 2011 through September 2015.

ViV TAVR was significantly superior to native valve TAVR in all-cause mortality and stroke, both during hospitalization and at one year. ViV TAVR was also associated with significantly reduced rates of several complications and with higher mean gradients on post-TAVR echocardiography. "This shows that ViV TAVR is very safe for patients with previously placed surgical valves that are dysfunctional and causing problems," says Cleveland Clinic interventional cardiologist E. Murat Tuzcu, MD, who presented the findings. "It should be considered the treatment of choice for inoperable patients and perhaps for patients at high surgical risk." More at consultqd.clevelandclinic.org/vivtavr.

TMAO Proves a Potent Predictor of Events in ACS

For the first time, plasma levels of the gut microbe-dependent metabolite TMAO have been correlated with near-term risk of major adverse cardiovascular events (MACE) and long-term mortality in patients with chest pain and suspected acute coronary syndrome (ACS). So finds a Cleveland Clinic-led clinical study in two independent cohorts — in Cleveland and Sweden — published in the *European Heart Journal* (2017;38:814-824).

The study showed that TMAO predicted near-term MACE even among subjects initially negative for troponin T. "This suggests that TMAO offers prognostic value in ACS beyond what's provided by traditional risk factors and lab tests," says senior author Stanley Hazen, MD, PhD, of Cleveland Clinic. "These findings are important because of the modifiable nature of TMAO — via diet and potential therapies — and because they suggest that a rapid, point-of-care TMAO assay might improve risk stratification of patients presenting with chest pain and suspected ACS." More at consultqd.clevelandclinic.org/tmaoacs.

Sex, CAD Risk and Treadmill Testing

A new sex-specific scoring system to estimate mortality risk among patients undergoing exercise treadmill testing is superior to traditional risk stratification tools, a large cohort study has shown (*JAMA Cardiol.* 2017;2:15-22). The scoring system was developed at Cleveland Clinic to address shortcomings of established instruments like the Duke Treadmill Score and the Lauer nomogram. "We wanted to develop comprehensive sex-specific risk scores to estimate all-cause mortality in a more inclusive and contemporary population," explains lead author and cardiologist Leslie Cho, MD.

She and colleagues retrospectively analyzed 60,000 Cleveland Clinic patients undergoing symptom-limited treadmill testing to derive and validate separate risk scores for men and women. External validation was done in a 49,000-patient cohort from Detroit's Henry Ford Hospital. Validation studies in both cohorts showed the sex-specific scores to offer significantly superior risk stratification compared with the older Duke and Lauer instruments, with particular advantages in identifying patients at highest risk of death. More at consultqd.clevelandclinic.org/cadrisk.

Image of the Issue



3-D NAVIGATION OF THE AORTA WITHOUT FLUOROSCOPY

An innovative endovascular navigation technology developed by Cleveland Clinic researchers has completed a series of four successful preclinical animal studies on its way toward anticipated market approval.

The technology — known as the Intraoperative Positioning System (IOPS) — provides full-color, three-dimensional (3-D) visualization of the aortic anatomy, as in the above images showing cannulation of the right renal artery.

IOPS extracts the centerlines of the aorta and branch vessels from a patient's CT and mathematically constructs a 3-D model of the relevant vasculature to provide GPS-like surgical guidance during minimally invasive endovascular aortic repairs.

The intuitive, customizable interface allows the surgeon to appreciate the true geometry of the vasculature with simultaneous views from multiple angles. Visualization is achieved using a low-level electromagnetic tracking field rather than the ionizing radiation of fluoroscopy. Guide wires and catheters are also rendered in 3-D inside the anatomy, displaying each instrument's position and orientation as well as the shape of its tip.

Preclinical in vivo studies at Cleveland Clinic Lerner Research Institute have demonstrated the system's ability to provide non-radiation-based navigation with superior visualization relative to X-ray fluoroscopy, as reported by lead investigator Matthew Eagleton, MD, at the 2016 VEITH Symposium.

"This technology will limit the need for extensive fluoroscopy units and provide more-detailed anatomy that can be imaged while navigating through it," says Dr. Eagleton, a vascular surgeon at Cleveland Clinic. "It has the potential to revolutionize vascular surgery."

For more, see consultqd.clevelandclinic.org/iops.

Dr. Eagleton (eagletm@ccf.org) has a financial interest in the company developing IOPS, Centerline Biomedical, as chair of its scientific advisory board. Centerline, a Cleveland Clinic spinoff company, plans to submit IOPS for FDA approval.



The Cleveland Clinic Foundation 9500 Euclid Ave./AC311 Cleveland, OH 44195

Cardiac Consult

Save the Dates for Live CME

Intensive Review of Cardiology

Sat.-Wed., Aug. 19-23, 2017 InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration: ccfcme.org/cardioreview

Fundamental to Advanced Echocardiography

Fri.-Sun., Sept. 15-17, 2017 Global Center for Health Innovation | Cleveland, Ohio

Information/registration: ccfcme.org/echocardio

Cleveland Clinic Cardiovascular Update 2017

Thu.-Fri., Oct. 26-27, 2017 Global Center for Health Innovation | Cleveland, Ohio

Information/registration: ccfcme.org/cvupdate17

Treatment of Coronary Artery Disease: Past, Present and Future (Celebrating the 50th Anniversary of CABG)

Fri., Nov. 3, 2017 InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration: ccfcme.org/cabg50years 2nd Annual Advances in Pediatric & Congenital Heart Care Summit: Navigating Shone's Complex

Thu.-Sat., Nov. 9-11, 2017 InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration: ccfcme.org/pediatric-congenital17

Mastering the Mitral Valve

Fri.-Sat., Dec. 1-2, 2017 JW Marriott Essex House New York | New York, New York

Information/registration: ccfcme.org/mitralmasters

These activities have been approved for AMA PRA Category 1 creditTM.

