

CardiacConsult

Heart, Vascular and Thoracic News from Cleveland Clinic | Issue 4 | 2020-2021

> CARDIAC CONSULT FEATURE

Lung Transplant Milestones

- Bilateral transplant for COVID-19-related ARDS
- Passing a volumes landmark

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Dear Colleagues,

This past summer, our lung transplant team performed a successful bilateral lung transplant in a patient with COVID-19-related acute respiratory distress syndrome — one of only about a dozen such transplants reported globally.

As this issue's cover story makes clear, the ability to manage a case of that complexity requires extraordinary clinical resources and experience. So it's little coincidence that just a few weeks before that transplant took place, our lung transplant program completed its 2,000th lung transplant case since its launch in 1990. When that landmark was followed by our 2,000th heart transplant a few weeks later, Cleveland Clinic became the first U.S. institution to surpass both of these milestones in transplant experience.

Coincidentally, this issue includes another story in which the year 1990 looms large. That's when renowned vascular surgeon Juan Parodi, MD, performed the world's first successful endovascular aortic aneurysm repair (EVAR), launching the endovascular revolution. As our story on page 11 notes, Dr. Parodi began his experimental work that led to the first EVAR when he was a trainee at Cleveland Clinic in the 1970s, and our surgeons have been among those who have shaped EVAR's evolution over the ensuing 30 years.

Whether you are looking for unsurpassed experience for referral of an exceedingly complex case or a partner who will always bring to bear a spirit of innovation for the most challenging referrals, Cleveland Clinic welcomes the opportunity to work with you.

Respectfully,

Lars G. Svensson, MD, PhD

CHAIRMAN | Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute



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

Medical Editor

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

Managing Editor

Glenn R. Campbell

Art Director

Michael Viars

Marketing

Jackie Riggle | Colleen Burke | Suzanne Anthony

Photography & Illustrations

Cleveland Clinic Center for Medical Art & Photography
Russell Lee Photography



Cleveland Clinic was named a top U.S. hospital in *U.S. News & World Report's* "Best Hospitals" rankings for 2020-21, as well as the No. 1 hospital in cardiology and heart surgery for the 26th consecutive year.

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Case Study: Bilateral Lung Transplant for COVID-19-Related

ARDS

A 56-year-old physician contracted COVID-19 while caring for patients. He was diagnosed in late March 2020 and treated with a five-day course of hydroxychloroquine and azithromycin. After worsening at home, he was admitted to his local hospital on the East Coast in early April. Despite treatment with steroids, tocilizumab and anakinra, he continued to decline and was transferred six days later to a regional tertiary care center, where he was intubated, placed on a mechanical ventilator and given the experimental treatment of convalescent plasma.

In spite of convalescent plasma, as well as inhaled nitric oxide and proning, his pulmonary status continued to deteriorate and in mid-May (hospital day 45) he was placed on veno-venous extracorporeal life support (VV-ECLS). While on this support, he suffered numerous complications including bacteremia, a bradycardic arrest and a gastrointestinal bleed, but he and his team persevered. His lungs showed no improvement on ECLS and began to manifest signs of irreversible damage, so his medical team reached out to Cleveland Clinic's lung transplant program.

"After assessing his potential suitability for transplantation, and knowing that certain aspects of his clinical status (such as deconditioning) would need to improve prior to transplant, we decided to transfer him to Cleveland Clinic," says Kenneth McCurry, MD, Surgical Director of Lung and Heart-Lung Transplantation at Cleveland Clinic. He explains that in addition to standard criteria to determine candidacy for

lung transplantation, patients with COVID-19-related acute respiratory distress syndrome (ARDS) must also be free of the virus and otherwise have intact organ systems. Exceptions are sometimes made to accept young patients if they have one other failing organ system.

Extensive preparation for transplant

The patient was admitted to Cleveland Clinic in early June (hospital day 66) and kept in COVID-19 precautions while he underwent PCR-based testing of nasopharyngeal swabs and bronchoscopy specimens. When the results came back negative for COVID-19, he was placed in the lung transplantation ICU. Evaluation for bilateral lung transplantation was then completed and rehabilitation started (Figure 1). (Details of the Cleveland Clinic experience with ECLS as a bridge to lung transplantation were recently described in *Annals of Thoracic Surgery* [2018;106:192-198].)

Continued next page >



Figure 1. A chest X-ray taken shortly after transfer to Cleveland Clinic demonstrates the extensive bilateral air space disease typical of COVID-19-related ARDS. The patient's course had also been notable for a right pneumothorax requiring pigtail placement (seen in right chest). The dual-lumen ECLS cannula that was providing access to blood for gas exchange on the ECLS circuit is also visible. This cannula allows single-site upper body access for ECLS, facilitating mobilization.

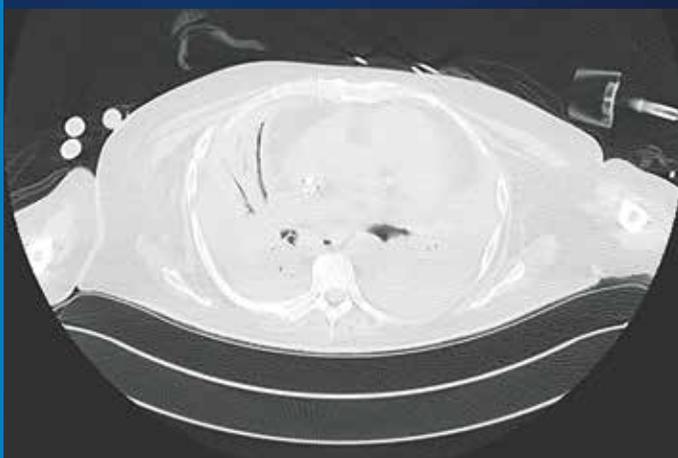


Figure 2. A chest CT taken a few days before transplantation shows densely consolidated lungs with air bronchograms, volume loss in the lungs and bilateral pleural effusions. Also seen is the dual-lumen ECLS cannula that courses through the superior vena cava and right atrium into the inferior vena cava.

“We place a strong emphasis on having our patients who are on ECLS as a bridge to lung transplant awake and ambulating before transplantation,” says Dr. McCurry. “Our protocolized approach has led to very good outcomes.”

At this point, the patient had been in bed for many weeks, often while heavily sedated and under intermittent chemical paralysis. He was flaccid and on many medications. The ICU team began the process of weaning the medications to allow him to be more alert and start physical therapy.

During this time, a few complications developed, including pulmonary hypertension with evidence of right ventricular failure that required conversion to veno-arterio-venous ECLS, a form of ECLS that supports the lungs as well as the right ventricle.

He gradually became alert enough to start to participate in his treatment plan, in collaboration with his wife, the referring medical team (who maintained contact) and the transplant team. During this time, the team discussed the patient's situation with him directly and confirmed his desire to proceed with lung transplantation, if feasible. By mid- to late July, he was able to ambulate and was placed on the transplant list. Due to the severity of his illness and the required mechanical cardiopulmonary support, he had a very high lung allocation score, which is used to determine priority for lungs in the U.S.

Transplantation and recovery

In late July (hospital day 116), bilateral lung transplantation was performed. The patient's lungs were densely consolidated (Figure 2), with a texture and feel that Dr. McCurry describes as more resembling liver rather than lung tissue.

Dr. McCurry emphasizes that considerable effort is taken to protect staff caring for patients with COVID-19, particularly surgical and operating room personnel who work directly with the airway, such as in lung transplantation. “Although we require that patients test negative for the virus before transplantation, we are still concerned that virus might harbor deep in the lungs or that residual viral RNA may pose a risk,” he explains, noting that N95 masks are worn. “There are many unknowns with COVID-19, so continued precautions are warranted.”



After transplantation, the patient was returned to one of the COVID-19-free transplant units established at Cleveland Clinic a few months earlier for all transplant patients. Patients must first be tested for COVID-19, and no visitors are allowed. The rules are the same even for patients with previous COVID-19 infection, as there is no way to know whether they are immune.

The patient's recovery has been slow but unremarkable, with good lung and heart function, Dr. McCurry reports. Not unexpectedly, the patient has had psychological ups and downs. While very motivated at first, he has lapsed into depression at times. His transplant team, along with his wife and referring colleagues, have helped him overcome these periods.

At this writing, six weeks after transplantation, Dr. McCurry is optimistic that the patient will recover, with anticipated discharge in another six weeks if he continues to progress without major setbacks. He is removed intermittently from the ventilator, as part of the weaning process, and while he remains weak, his strength and ambulation are improving.

Between five and six weeks after transplant, he was moved out of the COVID-19-free unit so that his wife could visit and help with rehabilitation. According to Dr. McCurry, risk of catching the virus must be weighed against the many benefits of family support.

Not typical transplant cases

About a dozen cases of bilateral lung transplant for COVID-19-related ARDS have now been reported in the literature worldwide. "These patients are all extremely complex and can be expected to be very sick for a long time," Dr. McCurry notes.

He recommends considering lung transplantation when a patient with COVID-19 is not responding to therapy and is either approaching or at the point of irreversible lung damage and is unlikely to recover. Early consultation with a lung transplant program is advised and can be highly beneficial.

"Extensive resources are required for transplanting and caring for patients with COVID-19-related ARDS, and only transplant programs that are experienced in working with very high-risk patients should be considered for referral," he advises. ■

Contact Dr. McCurry at 216.445.9303.



Another Lung Transplant Milestone: 2,000 Cumulative Cases

The case profiled here wasn't the only lung transplant milestone at Cleveland Clinic in 2020. In July, Cleveland Clinic surgeons completed the institution's 2,000th lung transplant case since its lung transplant program was launched in 1990. This feat, when paired with the institution's 2,000th heart transplant (coincidentally performed in summer 2020 as well), makes Cleveland Clinic the first program in the U.S. to have passed both of these volume milestones.

Cleveland Clinic's lung transplant program has long been one of the largest and busiest in the nation, performing more than 100 transplants nearly every year, with survival outcomes among the best in the U.S. despite a reputation for accepting some of the most challenging cases.

The program is now extending its leadership into the realm of ex vivo lung perfusion (EVLP) to help expand the donor lung supply and offer transplantation to even more patients. As of October 2020, the program had performed EVLP on 103 human donor lungs, with 67 perfused lungs being transplanted. Among recipients of EVLP lungs to date, 30-day survival has been 100% (64/64), and one-year survival has been 93% (38/40).



Four Electrophysiology Clinical Trials to Watch

For clinicians interested in emerging developments in electrophysiology, Cleveland Clinic's Section of Cardiac Electrophysiology is a good place to keep an eye on these days. The section's staff are playing lead roles in at least 10 recent or ongoing major clinical trials in various aspects of the subspecialty. This article profiles the essentials of four of those studies.

STOP AF First

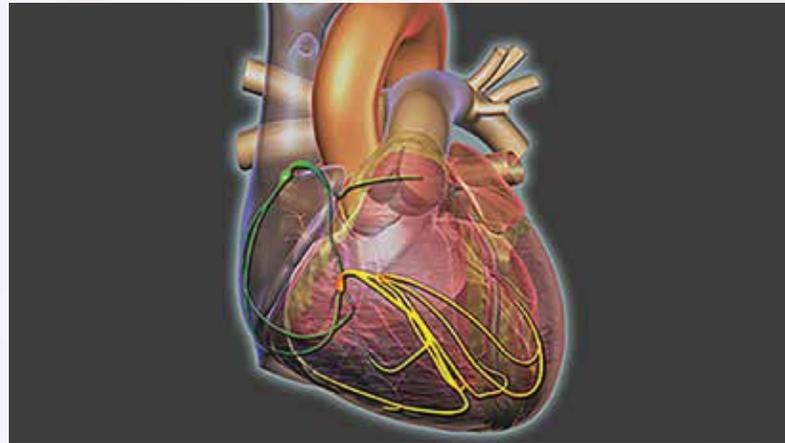
Results of this multicenter randomized trial (NCT03118518) were presented in a late-breaking trials session at the virtual European Society of Cardiology Congress 2020 and published later in the *New England Journal of Medicine*. They showed that initially treating symptomatic paroxysmal atrial fibrillation (AF) with cryoballoon ablation to isolate the pulmonary vein is more effective in maintaining freedom from arrhythmias than anti-arrhythmic drug therapy — and it entails a low risk of complications.

“Improvements in the safety and efficacy of cryoballoon catheter ablation have increased interest in this therapy for AF,” says the study's national principal investigator (PI), Oussama Wazni, MD, Section Head of Cardiac Electrophysiology. “This prospective trial provides good evidence that it's a reasonable first-line option.”

STOP AF First was prompted by the fact that while there is much supportive data for catheter ablation as second-line therapy for AF, few randomized trials have evaluated it — especially cryoballoon catheter ablation — as first-line therapy.

The trial involved 203 patients with symptomatic paroxysmal AF at 24 U.S. sites. Patients were randomized to pulmonary vein isolation with cryoballoon ablation (n = 104) or to anti-arrhythmic drug therapy (n = 99). All underwent ECG monitoring at baseline and at one, three, six and 12 months. The primary efficacy endpoint was freedom from treatment failure at 12 months, defined as any of the following: acute procedural failure; need for subsequent AF surgery or left atrial ablation; documented AF, atrial tachycardia or atrial flutter after 90 days; cardioversion after 90 days; and class I or III anti-arrhythmic drug use after 90 days (ablation arm only).

Freedom from treatment failure at 12 months was achieved by 75% of patients in the cryoballoon ablation group versus 45% of patients in the anti-arrhythmic drug therapy group ($P < 0.0001$ for the difference).



Only two patients in the cryoballoon ablation arm had a serious adverse event (one significant pericardial effusion, one myocardial infarction), representing a 1.9% incidence of serious adverse events — significantly lower than the pre-specified safety performance goal of $< 12%$ ($P < 0.0001$).

“STOP AF First found that this catheter intervention is safe and effective for symptomatic paroxysmal AF without the requirement that patients be drug-refractory,” Dr. Wazni concludes. “If approved for first-line use, it could provide an important therapy option in this setting.”

OPTION

The multicenter OPTION trial (NCT03795298) is investigating whether left atrial appendage (LAA) closure with the Watchman FLX™ device is a reasonable alternative to oral anticoagulation following percutaneous catheter ablation for high-risk patients with nonvalvular AF.

“We know patients may continue to have some atrial fibrillation following an ablation procedure, and no large prospective trials have assessed the safety of discontinuing oral anticoagulation after an apparently successful ablation,” says Walid Saliba, MD, Medical Director of Cleveland Clinic's Atrial Fibrillation Center and Cleveland Clinic's PI for the OPTION trial (Cleveland Clinic's Dr. Wazni serves as overall PI for the



multicenter trial). As a result, guidelines recommend that patients continue oral anticoagulation after catheter ablation based on their stroke risk profile.

To determine whether some patients might be liberated from this requirement, the prospective OPTION trial aims to randomize 1,600 patients from 93 centers in the U.S., Europe and Australia to one of two post-ablation management strategies:

- Watchman FLX implantation with a modified post-implant drug regimen
- Standard oral anticoagulation therapy for the duration of the trial

Efficacy will be assessed as a composite of stroke, all-cause death and systemic embolism over 36 months, with non-procedural bleeding over 36 months serving as the main safety outcome and major bleeding as a secondary outcome. Watchman therapy will be assessed for noninferiority in terms of efficacy and major bleeding and for superiority in terms of nonprocedural bleeding. Study completion is expected by late 2024.

“If the findings are positive,” Dr. Saliba says, “this study will expand the indication for LAA closure with Watchman and give high-risk ablation patients the option to discontinue oral anticoagulation by having the device implanted at the time of AF ablation or shortly after.”

Parallel Mapping for VT

Catheter ablation of scar-mediated ventricular tachycardia (VT) is helpful in reducing the frequency of implantable cardioverter defibrillator (ICD) therapies, including ICD shocks. However, the procedure is associated with an unacceptably high recurrence rate (~30% after 12 months). This is partly due to suboptimal mapping methods for identifying the critical VT sites during sinus rhythm, which often results in insufficient ablation of critical sites and needless ablation of other sites not involved in VT.

The recent international PHYSIO-VT study showed that ventricular mapping during activation from multiple activation directions can enhance the accuracy of mapping and targeting critical VT sites in comparison to standard mapping methods during sinus rhythm. “This method helps reveal additional sites that may be responsible for VT,” says PHYSIO-VT lead author Elad Anter, MD, Associate Section Head of Cardiac Electrophysiology and Director of Cleveland Clinic’s Ventricular Tachycardia Program.

To build on these findings, Cleveland Clinic recently launched a study, Parallel Mapping for Ventricular Tachycardia

(NCT04477499), that uses a new mapping algorithm that may improve the workflow and efficacy of ventricular mapping during activation from multiple directions. The algorithm, developed by Biosense Webster, allows creation of simultaneous maps during activation from different directions. “This study is a natural progression of the PHYSIO-VT,” explains Dr. Anter. “Its goal is to simplify the process of mapping while retaining the highest possible accuracy for identifying critical VT sites that can then be targeted with ablation.”

The prospective single-center study will include 30 patients with scar-mediated VT refractory to drug therapy who are referred for catheter ablation. Ablation in these patients will be guided by findings derived from mapping the ventricle from multiple directions. The primary endpoint is freedom from VT recurrence. Secondary outcomes are freedom from ICD shocks as well as reduction in mapping time and ablation time relative to historical controls. Results are expected at the end of 2022.

SyncAV Post-Market Trial

This large post-marketing study (NCT04100148) is designed to determine whether cardiac resynchronization therapy (CRT) devices programmed with SyncAV software ON have improved long-term CRT response relative to devices programmed with conventional CRT settings (fixed atrioventricular delay).

The prospective multicenter study will enroll 1,400 patients with heart failure who are scheduled to receive a new CRT implant or an upgrade from an existing ICD/pacemaker implant. Two to six weeks after successful implant, patients will be randomized on a 1:1 basis to one of the two programming options above. QRS duration and other rhythm measurements will be collected through 12 months of follow-up.

The primary outcome measure is reduction in left ventricular end systolic volume from baseline to 12 months. Secondary outcomes include the percentage of CRT responders as well as results on the primary and secondary outcomes specifically in female patients. Trial completion is expected in 2023.

The algorithm behind SyncAV was developed at Cleveland Clinic, and Cleveland Clinic electrophysiologist Niraj Varma, MD, PhD, serves as this study’s national PI.

“SyncAV takes the concept of ‘fusion pacing’ to the next level by allowing us to program the patient’s pacemaker for the optimal combination of their heart’s own natural rhythm with customized pacing support to deliver the greatest possible resynchronization therapy,” notes Daniel Cantillon, MD, who serves as the study’s local PI at Cleveland Clinic. ■

Contact Dr. Wazni at 216.444.2131, Dr. Saliba at 216.444.6810, Dr. Anter at 216.444.4293 and Dr. Cantillon at 216.445.9220.



Introducing Robotic Myectomy With Mitral Valve Repair

A minimally invasive, single-incision approach to two coexisting problems

Patients with hypertrophic obstructive cardiomyopathy (HOCM) who require myectomy along with mitral valve (MV) repair are being treated at Cleveland Clinic with a new minimally invasive, robotically assisted procedure performed through a single incision.



“Typical candidates need a septal myectomy but also have a prolonged anterior mitral leaflet and an abnormal, hypermobile papillary muscle in addition to the need for mitral valve repair,” explains Cleveland Clinic cardiothoracic surgeon Per Wierup, MD, PhD, who led efforts to develop the procedure. “If they have this combination of features, and no contraindications for robotic surgery, they are ideal patients for this approach.”

He finds the opportunity to correct two problems through a single incision in a minimally invasive operation highly appealing. “It is a safe alternative to a well-established open heart procedure that allows patients to retain their own valve and leaves them with a septum of normal thickness,” he says. “Because the aortic valve is not touched, the potential complications from a transaortic septal myectomy are avoided.”

Born of experience

Dr. Wierup is one of the Cleveland Clinic cardiothoracic surgeons pushing the boundaries of robotically assisted heart

surgery. To date, they have performed more than 2,000 robotic MV repairs. This unparalleled experience has enabled them to master the procedure. “Patients who come to us needing mitral valve surgery typically receive a robotic repair,” he says.

Cleveland Clinic surgeons also have performed thousands of myectomies, primarily as open heart procedures using a trans-aortic approach. It was this deep experience in both robotic MV repair and trans-aortic myectomy that led Dr. Wierup and colleagues to consider correcting both defects through a single incision in a robotically assisted procedure.

Following the lead of robot-assisted myectomy pioneer Randolph Chitwood, MD, Dr. Wierup performed the first combined myectomy and MV repair with robotic assistance in September 2019. He has since done two additional procedures, all with excellent outcomes.

“The patients spent one day in the ICU and were discharged after three or four days,” Dr. Wierup notes.



Rationale for a new paradigm

Left ventricular outflow tract obstruction (LVOTO) in HOCM can be aggravated by systolic anterior motion of the anterior MV leaflet. “The anterior leaflet is sucked toward the septum, further obstructing outflow,” says Dr. Wierup.

Combining septal myectomy with reorientation of the papillary muscles can decrease LVOTO. However, the surgery typically requires a full sternotomy for the myectomy. The heart must then be opened in a second location to repair the MV.

The new robotically assisted approach was designed to simplify this operation. Dr. Wierup and colleagues detail the surgical approach in a recent article in the *Journal of Cardiac Surgery* (2020;35:3120-3124), which includes the illustrations in the figure at right. “We can see the valve and septum exceedingly well,” he says. “The visualization is fantastic.”

A holistic approach

At Cleveland Clinic, HOCM patients with severe septal hypertrophy continue to undergo septal myectomy performed through a median sternotomy. When the primary problem is MV disease and the patient also has HOCM, they are treated with the minimally invasive robotic approach.

“This gives us two options,” Dr. Wierup says. “Many other institutions that do surgery for HOCM believe only the muscle should be cut out. From this standpoint, we are alone in taking a holistic approach.”

That may change, however, as demand for minimally invasive procedures continues to grow. Yet Dr. Wierup cautions that familiarity with robotic technique is not sufficient for success in robotic myectomy with MV repair; extensive experience in myectomies is also needed.

“These are tricky problems, because fixing one problem can make the other worse,” he explains. “You have to find a good balance, which takes experience-based judgment in addition to the foundational technical ability.”

“This is a much-needed development in the management of hypertrophic obstructive cardiomyopathy, especially since many such patients tend to be younger and would like to return to work sooner and have a less-visible chest scar,” notes Milind Desai, MD, Director of Cleveland Clinic’s Hypertrophic Cardiomyopathy Center. “With the emergence of novel noninvasive therapies, we are entering an exciting phase of management of these patients.” ■

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Contact Dr. Wierup at 216.445.1652 and Dr. Desai at 216.445.5250.

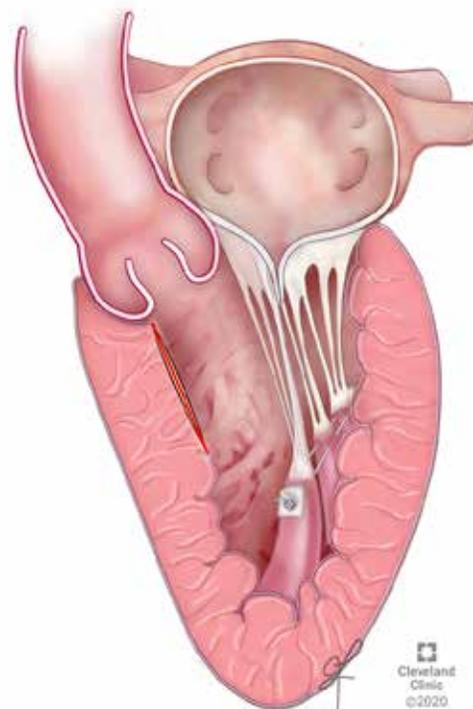
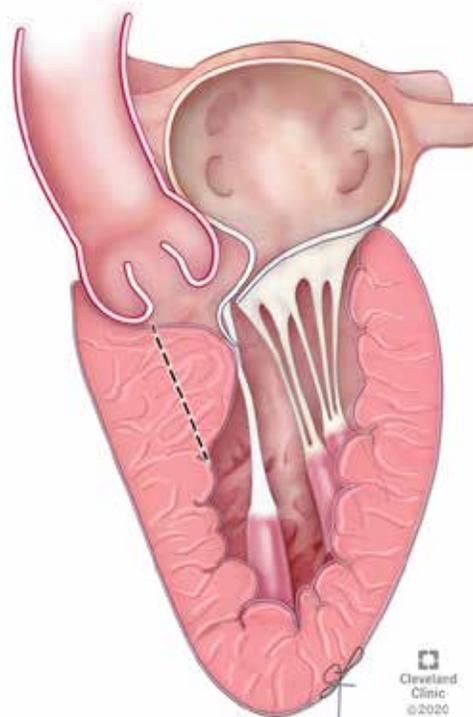


Figure. Illustrations before (top) and after (bottom) robotic myectomy with mitral valve repair. The top panel shows HOCM and systolic anterior motion from anterior papillary muscle, with the dashed line indicating the planned resection line. The bottom panel shows postoperative reorientation of the papillary muscle heads. Reprinted from Kumar et al., *J Cardiac Surg.* (2020;35:3120-3124). © 2020 Cleveland Clinic Foundation.



New Head of Vascular Medicine Looks to Enhance Collaborative Caregiving

Scott Cameron, MD, PhD, has been named to lead Cleveland Clinic's Section of Vascular Medicine, the largest vascular medicine program in the U.S.



"This is an exciting time to head up this program," says Dr. Cameron. "We have a critical mass of experienced veterans and young talent. Our training program is one of the nation's largest, and we hope to make it even larger. Overall, my goal is to make this a hot spot for patients, fellows and referring physicians from around the world."

Path to Cleveland Clinic

Born in Scotland, Dr. Cameron studied pharmacology at the University of Edinburgh and came to the U.S. two decades ago with "two thousand dollars, two suitcases and a one-way ticket."

He earned a doctorate in pharmacology at the University of Rochester and trained as a fellow in clinical chemistry at Johns Hopkins Hospital. He went on to take a medical degree at SUNY Upstate Medical University, did an internal medicine residency at New York Presbyterian Hospital, and completed a five-year clinical and research fellowship in cardiology and vascular medicine at the University of Rochester. His investigative interest in blood vessel disease deepened at every stage of his education and training.

"Most of my research was vascular in nature, so cardiovascular disease was a natural fit," he explains. "I gained subspecialty certification in vascular medicine and vascular ultrasound as well as cardiovascular disease to better align my clinical work and research interests."

Dr. Cameron joined Cleveland Clinic in 2019 and was tapped to lead the Section of Vascular Medicine in mid-2020 upon the retirement of longtime section head John Bartholomew, MD. He is eager to collaborate with colleagues in the institution's

Miller Family Heart, Vascular & Thoracic Institute and beyond. As a cardiologist himself, he believes cardiology and other specialties benefit from greater familiarity with vascular medicine. "About one-third of patients with coronary artery disease also have overt or occult peripheral vascular disease that may be easily overlooked," he notes. "Vascular medicine specialists are trained to recognize subtle manifestations of vascular disease in unusual clinical contexts, including conditions that present as mystery diseases."

"With Dr. Cameron's leadership, our talented and accomplished group of vascular medicine specialists will reach new heights in the clinical and academic arenas," says Samir Kapadia, MD, Chair of Cardiovascular Medicine.

Broad research interests

A prolific researcher, Dr. Cameron has focused his investigations on blood platelets, their changeable phenotypes and their effect on the vascular environment. He and his team found that platelets change their phenotype in diseases such as heart attack and peripheral artery disease. These "reprogrammed" platelets do not respond as predicted to medications, which may account for the heterogeneity of patient response to anticoagulants and anti-thrombotics.

The Cameron team helped establish that platelets are like circulating messengers, carrying information back and forth between blood vessels and organs. "A major goal of my research is to understand the process of platelet reprogramming and identify additional proteins on platelets that could be targets for new medications," he says, adding that the ultimate objective is more-personalized treatment for vascular disease.

Aortic aneurysms are another of his interests. Working with cardiothoracic and vascular surgery colleagues, he has learned that aneurysms and platelets react to one another in a kind of loop that contributes to blood vessel remodeling. They've also identified a platelet receptor that could be a druggable target in patients with aneurysms. "The potential impact of this project is broad and involves classical biochemistry, pharmacology, molecular genetics and physiology, as well as advanced imaging modalities," he concludes. ■

Contact Dr. Cameron at 216.444.1680.



30 Years of EVAR:

Roots of the Pivotal Endovascular Procedure Reach Back to Cleveland Clinic

› EVAR pioneer **Dr. Juan Parodi** surveys the past and future of a revolutionary procedure.



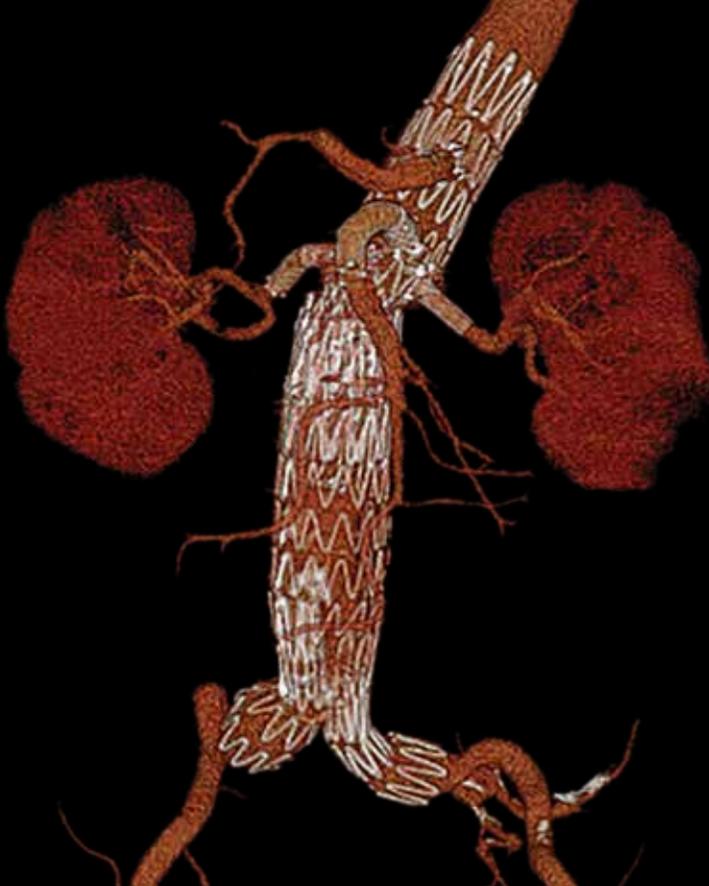
Thirty years ago, vascular surgeon Juan Parodi, MD, set in motion what has since been recognized as an endovascular revolution in the treatment of abdominal aortic aneurysms.

On Sept. 7, 1990, Dr. Parodi teamed with vascular radiologist Julio Palmaz, MD, to perform the world's first successful endovascular aneurysm repair (EVAR). The minimally invasive procedure was done under local anesthesia in a 70-year-old man with severe back pain associated with a 6-cm abdominal aortic aneurysm. It involved placement of a graft designed by Dr. Parodi that consisted of expandable ends, an extra-large Palmaz stent, a Teflon sheath with valve, a wire and a valvuloplasty balloon. The patient fared well, surviving for nine years after the procedure before dying from cancer.

An idea spawned in Cleveland

While this historic first EVAR took place in Dr. Parodi's native Argentina, the procedure's roots can be traced back to Cleveland Clinic, where Dr. Parodi first conceived of the technique during his vascular surgery training at the institution in the mid-1970s.

Following poor outcomes from two abdominal aortic aneurysm open repairs on a single day, the young Dr. Parodi floated an alternate approach with his Cleveland Clinic vascular surgeon mentors, Alfred Humphries, MD, and Edwin Beven, MD. He suggested that it might make sense to try performing the Seldinger technique with a larger catheter and introduce a compressed graft and metal component in lieu of the suture, thereby accomplishing the repair transfemorally.



EVAR in Cleveland Clinic's Department of Vascular Surgery Today

0% Mortality for elective EVAR in 2019 (N = 131)

4.3% Mortality for emergency EVAR in 2019 (N = 23)

“My idea was to exclude the aneurysm from the circulation and prevent rupture,” Dr. Parodi explains. “I thought we could use a fabric graft and metal components to affix and seal the elements in place using an endovascular retrograde access. The goal was an endoluminal technique for a less invasive and morbid procedure that was equally effective as open aneurysm repair.”

He began his early experimental work, including engineering the first prototypes with elastic stainless steel wires, at Cleveland Clinic in 1976, and then continued developing the concept back home in Argentina. He met his collaborator Dr. Palmaz, a fellow Argentinian, in the 1980s and began using a redesigned version of his Palmaz stent in animals, eventually leading to the first human case in September 1990. All his work up to that point was done without external funding support.

Dr. Parodi notes that on the same day as the first EVAR case, his team performed an open aneurysm repair in another patient. When the team checked on the two patients after dinner, the EVAR patient was having dinner while the other patient was still intubated. “That was a strong signal that we were likely on the right track,” Dr. Parodi says.

Refinements and widespread adoption

As Dr. Parodi performed additional EVAR cases in the following months, he began to observe leaks in the distal part of the grafts if the distal aortic neck was too short. His team experimented with graft redesigns and eventually proceeded with an aorto-uni-iliac graft in 1991 that initially occluded the contralateral limb with a detachable balloon and later with a covered stent.

Further refinements followed in response to various challenges that arose, such as creation of a temporary Dacron graft conduit in cases with a narrow external iliac artery or performance of anastomosis between the external iliac artery and the hypogastric artery in the setting of an iliac aneurysm with an endangered internal iliac artery.

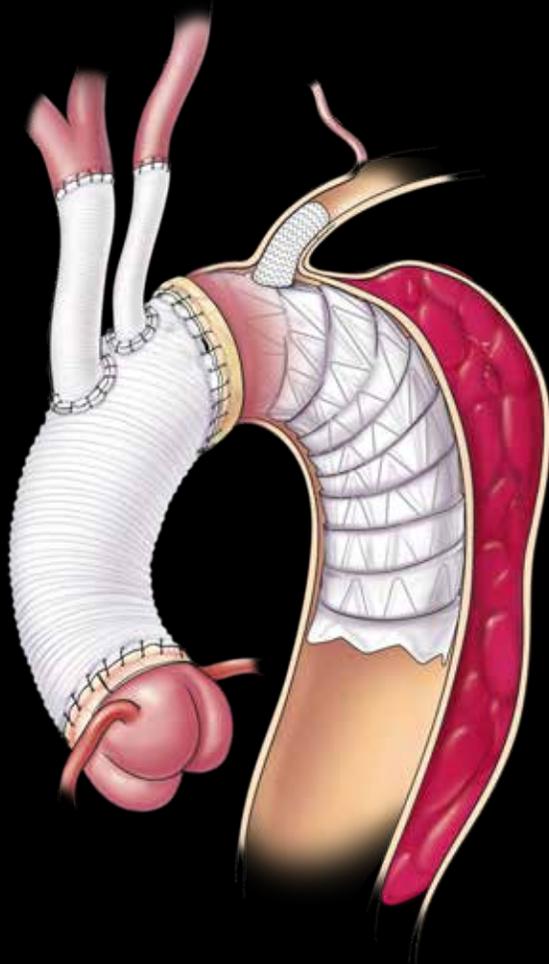
Soon Dr. Parodi began sharing his EVAR technique with colleagues around the world, starting with the landmark publication of his team's first five cases in *Annals of Vascular Surgery* (1991;5:491-499). Notably, the fourth of these initial five cases involved successful treatment of an infrarenal aortic dissection, representing the first of countless aortic dissections subsequently treated with endografts.



In 1992, Dr. Parodi introduced the EVAR technique to vascular surgeons in Europe and the United States. Subsequent uptake of the procedure was swift, with technological advancements in devices for endovascular repair following in short order. As a result, approximately 80% of abdominal aortic aneurysms today are treated with an endovascular approach, and the cumulative worldwide total of EVAR cases surpassed 1 million in 2019.

The evolution of EVAR in the early 2000s was driven at Cleveland Clinic by the late Roy Greenberg, MD, a vascular surgeon who helped develop thoracic, thoracoabdominal and arch branched and fenestrated grafts. Today's stent grafts — fabric tubes supported by a wire scaffold — are guided to the aneurysm site and deployed to seal off the aneurysmal aorta segment, with the graft relining the aorta like an inner tube.

In tandem with this expansion and refinement of EVAR, the annual number of deaths from intact and ruptured aneurysms has steadily decreased in the developed world. Likewise, EVAR helped accelerate the adoption of endovascular strategies by vascular surgeons. This led to the use of endovascular strategies for every area of vascular disease, from the carotid arteries in the neck to the renal and mesenteric arteries in the abdomen and the arteries of the entire lower extremity.



EVAR's evolution continues

"We are excited to continue the legacy of innovation that Dr. Parodi started and our own Dr. Greenberg built upon together with our outstanding aorta team of innovators," says Lars Svensson, MD, PhD, Chair of Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute.

"Our cardiothoracic and vascular teams continue to lead in endovascular trials evaluating new devices for the entire aorta, from the ascending to the aortic arch to the thoracoabdominal segment," adds Sean Lyden, MD, Chair of Vascular Surgery at Cleveland Clinic.

At the same time, Dr. Lyden and his colleagues have also seen how the inappropriate use of these novel devices and techniques can sometimes lead to repair failure. In those cases, cardiac and vascular surgeons work collaboratively across the Heart, Vascular & Thoracic Institute to treat complex failures, often using combined open and endovascular approaches. "Endovascular device failure, whether in the thoracic or the abdominal aorta, often results in a condition requiring advanced endovascular techniques or open aortic replacement," says Cleveland Clinic vascular surgeon Francis Caputo, MD. "This is best handled by a multidisciplinary team of aortic experts working to achieve the best outcomes for patients tailored to their specific condition."

Meanwhile, surgical teams continue to innovate hybrid approaches to achieve durable results. An example pioneered at Cleveland Clinic is the frozen elephant trunk procedure for high-risk patients with extensive aortic disease. "We embraced endovascular technology early in its development, with the perspective that it complements what we do with conventional surgical techniques instead of seeing it as competitive," says Eric Roselli, MD, Chief of Adult Cardiac Surgery at Cleveland Clinic. "Consistent with our patients-first, collaborative approach to care, we have learned how to tailor the various open and endovascular strategies to each patient with a cardio-aortic condition in a hybrid way to provide the best treatment option." ■

Contact Dr. Svensson at 216.444.6962, Dr. Lyden at 216.444.3581, Dr. Caputo at 216.445.9580 and Dr. Roselli at 216.444.0995.



Making the Most of M&M Conferences

How we helped an alliance partner restructure their meetings with a constructive focus on quality

When Deborah Heart and Lung Center in Browns Mills, New Jersey, began its alliance relationship with Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute in August 2019, its aim was to further enhance a well-established tradition of superior caregiving. As a hospital focusing on cardiac, vascular and lung disease, Deborah had a long history of service to its community in the Delaware Valley region of Southern New Jersey. That history was centered on a proud embrace of continuous improvement methods and investigating better ways of providing top-quality patient care and outstanding clinical outcomes.

The center's leadership viewed the alliance relationship with Cleveland Clinic as an opportunity to expand the value of Deborah's services through sharing of clinical best practices to maximize the quality and efficiency of care delivery. "My top priority was to refine quality improvement structures, processes and protocols across all departments of our center," says Kintur Sanghvi, MD, Associate Medical Director of Interventional Cardiology and Endovascular Medicine at Deborah Heart and Lung Center and medical director of its alliance with Cleveland Clinic.

Initial focus on interventional cardiology M&Ms

Not long after the alliance relationship was established, Dr. Sanghvi began working with Cleveland Clinic Heart and Vascular Advisory Services to evaluate the morbidity and mortality (M&M) conferences of Deborah's interventional cardiology team to identify potential opportunities for improvement.

Although the structure and processes of M&M conferences vary among institutions, well-run conferences serve the dual purposes of identifying system or process issues that could compromise optimal care delivery while also providing an educational forum where errors in care delivery can be openly discussed in a nonpunitive fashion, with the purpose of modifying behaviors or processes to prevent repetition of the error.

Insights from the evolution of Cleveland Clinic's M&Ms

Early in his interactions with Cleveland Clinic, Dr. Sanghvi grew interested in what he learned about the evolution in the approach and structure of Cleveland Clinic's interventional cardiology M&M conferences over time. As a result of this evolution, cases at Cleveland Clinic conferences now are presented by physicians in training to an audience of peers that includes physician instructors. After the case presentation, a group discussion is held with questions, peer comments and teaching points derived from a review of current literature. Participants usually include all individuals involved in the patient's care in the catheterization lab as well as some involved prior to and after care in the cath lab, such as emergency

medical services personnel and emergency department, ICU and floor care providers.

The resulting open discussions among this diverse and inclusive group yield several benefits:

- Widespread understanding of both the benefits and the limitations of care provided in a cath lab
- Opportunities for critical appraisal of hospital policy and care paths in the care delivery process as relevant to a particular case
- Opportunities for development of action plans to implement changes to improve care quality and the efficiency of delivery

One-to-one collaboration with physician leaders

As Dr. Sanghvi learned more about this Cleveland Clinic approach, he directly engaged two physician leaders from Cleveland Clinic Heart and Vascular Advisory Services — interventional cardiologist Christopher Bajzer, MD, and cardiac surgeon Edward Soltesz, MD, MPH — to better understand the structure of Cleveland Clinic's M&M conferences and the philosophy behind it. The collaboration included a virtual meeting in May 2020 in which the Cleveland Clinic physicians detailed how their teams approach M&M conference case selection and discussion format. They also shared with Dr. Sanghvi formal morbidity and mortality guidelines for interventional cardiology as well as Cleveland Clinic's specific case review forms and relevant dashboards used for M&M conferences.

These exchanges prompted Dr. Sanghvi to lead an effort to restructure and improve Deborah Heart and Lung Center's M&M conferences, starting with those for interventional cardiology.

Key changes made

Prior to the input from Cleveland Clinic, Deborah's M&M conferences were limited to evaluation of cases with mortality or severe morbidity, and discussions involved cases and images only, without an overview of quality issues or metrics.



In the past few months, Deborah's interventional cardiology section has incorporated in its M&M conferences a number of the quality improvement processes shared by Cleveland Clinic. For conferences from August 2020 onward, these revisions have included the use of adapted versions of Cleveland Clinic's dashboard and case review forms tailored to Deborah's specific needs.

Key process changes to the interventional cardiology M&M conferences include:

- Institution of a consistent and organized structure for all conferences, which has been applied to M&M conferences in all departments across the organization.
- Use of a dashboard and incorporation of National Cardiovascular Data Registry metrics to explicitly promote quality improvement through objective quantification of outcomes and improvements.
- A new standard process whereby the physician involved in a case completes the newly introduced case review form and presents the case, after which a constructive group discussion follows to identify opportunities for improvement and provide general education for the group. Previously, M&M cases had been peer-reviewed, which could sometimes seem punitive and make physicians feel defensive.

Engagement is already up – with goal to improve quality metrics

While the changes are too recent to have yet impacted quality metrics, they have already succeeded in increasing attendance and improving participation in M&M conferences among Deborah physicians.

“The Cleveland Clinic team has been exceptional in their continuous quality improvement processes, and they did not hold anything back,” observes Dr. Sanghvi. “Multiple physician and administrative leaders shared their wealth of knowledge and experience in one-to-one calls that have helped us customize processes to our needs and implement constructive changes with unprecedented speed.”

“This specific collaboration is just one of many benefits arising from our alliance relationship with Deborah Heart and Lung Center,” notes Dr. Bajzer of Cleveland Clinic. “We were able to share some of our structure and process around M&M conferences to improve the value of their team's time spent in terms of continuing education as well as feedback on hospital process and policy and individual practice patterns. We expect these changes to result in even more consistent delivery of high-quality care, which will likely be demonstrated over time in publicly reported quality metrics and benchmarks.”

“One of the big advantages of our alliance with Cleveland Clinic is the ability to collaborate with their staff on opportunities to improve every dimension of care,” adds Joseph Chirichella, President and CEO of Deborah Heart and Lung Center. “In a highly competitive environment, improvements in care, process and cost are compatible with delivering value to patients and payors.” ■

For information on affiliation and alliance opportunities with Cleveland Clinic's Heart, Vascular & Thoracic Institute, email Amanda Lesesky at leseska@ccf.org.

Cleveland Clinic Heart and Vascular Advisory Services at a glance

Collaborative relationships offered

- Advisory services: > 60 assessments completed for health systems, hospitals, physician practices and outpatient offices
- Affiliations and alliances: 14 affiliate or alliance relationships as of autumn 2020

History and scope

- Established 2003
- Provider-based advisory services driven by Cleveland Clinic Heart, Vascular & Thoracic Institute (HVTI) physicians, supported by a team with multidisciplinary expertise
- 20-member core team: HVTI physician leaders + dedicated full-time administrators, clinical consultants, continuous improvement specialists, quality analysts, project managers
- All HVTI physicians and surgeons support the core team

Advisory services offered

Optimizing clinical quality & operational efficiency | Strategy development & enhancement | Resource allocation | Development of existing programs & expansion of services | Advice & education on patient care, strategic planning & clinical innovation

To learn more

Contact Amanda Lesesky, Director, Outreach Programs, leseska@ccf.org



Stroke and Cardiac Procedures:

New Guidance to Avert a Dreaded Surgical Complication, Clearer Answers on Risk in TAVR

How much do patients undergoing cardiac surgery fear stroke? A large survey of coronary artery bypass surgery patients (*Open Heart*. 2018;5:e000911) found that respondents ranked freedom from stroke as their most important disability-related outcome priority, ahead of staying alive for as long as possible and avoiding hospitalization and nursing homes. Patients undergoing transcatheter aortic valve replacement (TAVR) have similar reason to dread stroke, as 30-day mortality among TAVR patients who suffer a stroke is roughly 15%. Survivors of a TAVR-related stroke don't fare well, either: 70% are discharged to a nursing home, and 44% suffer moderate to severe permanent disability.

At the same time, concerns over the risk of perioperative and periprocedural stroke have prompted at least two constructive recent developments. One is the publication of the first comprehensive collection of measures for reducing perioperative stroke risk in cardiothoracic surgery, issued as an American Heart Association (AHA) scientific statement. The other is a growing number of clinical trials evaluating embolic protection during TAVR. Cleveland Clinic clinician-researchers have been involved in both developments, which we profile here.

AHA statement on perioperative stroke risk reduction

The AHA scientific statement on reducing the risk of perioperative stroke was developed by a multidisciplinary panel of experts and published online in *Circulation* (2020;142:e193-e209).

"The main message is that in perioperative care you want to avoid stroke and act on it quickly if it happens," says Cleveland Clinic cardiothoracic surgeon Faisal Bakaeen, MD, who served on the writing group for the statement, which addresses cardiac and proximal thoracic aorta procedures in adults.

The document emphasizes the multiple contributors to stroke risk in this setting and the need for multifaceted strategies to mitigate the risk and consequences of stroke. "The pathogenesis of perioperative stroke is multifactorial," notes Dr. Bakaeen, "but having information on its mechanisms, diagnosis and treatment can minimize the stroke risk for an individual patient and improve the outcome if a stroke should occur."

Scope of the statement

A key focus of the statement is identification of high-risk patients and methods of assessing risk. "The preoperative workup should include assessment of the aorta with CT, taking a history of cerebrovascular disease and doing a physical

exam for possible neurologic symptoms," says Dr. Bakaeen. Discussion is then devoted to considerations in intraoperative management to prevent stroke, including:

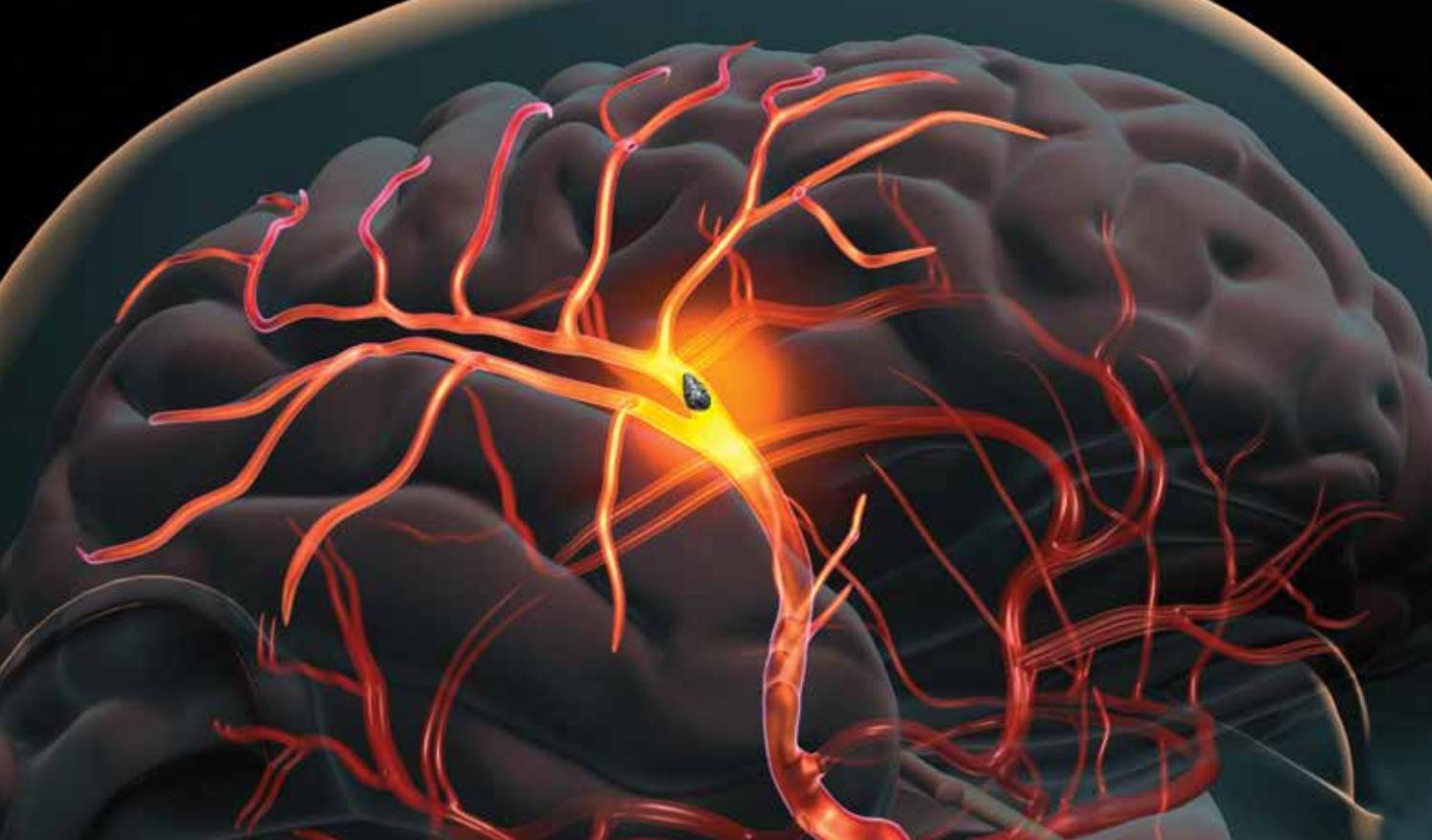
- The value of intraoperative neuromonitoring during aorta surgery
- Assessment of the ascending aorta with epiaortic ultrasound in high-risk cases to optimize cannula and clamp placement
- The no-touch, off-pump technique
- Use of various tools to minimize manipulation of a diseased aorta
- Intraoperative blood pressure management
- Left atrial appendage closure and ablation to reduce atrial fibrillation
- Blood transfusion strategies

A final section addresses diagnosis and treatment of perioperative stroke, including clinical and radiographic evaluation and strategies for medical, endovascular and surgical management.

"With mortality for cardiac and cardio-aortic surgery continuing to improve, it is increasingly important that we expand our focus from not only extending lives but to optimizing patients' quality of life," observes Eric Roselli, MD, Chief of Adult Cardiac Surgery at Cleveland Clinic. "The authors of this statement provide practical recommendations based on literature review to minimize risk and improve rescue from intraoperative and perioperative stroke."

Multidisciplinary expertise is essential

Because intraoperative strokes become apparent when patients awaken from anesthesia, it's critical that a multidisciplinary team be available for immediate action, if required. For this reason, the AHA statement's writing panel comprised representa-



tives of just such a team — neurologists, vascular neurologists, neurosurgeons and specialists in cardiac anesthesiology/critical care medicine — in addition to cardiac surgeons with a specific interest in outcomes, quality and stroke prevention.

“We emphasize collaboration with critical care and anesthesiology to aggressively monitor patients,” says Dr. Bakaeen. “Early extubation for neurological assessment for potential stroke may be required. We also want to detect hypertension or anemia and act quickly to correct it, if any neurological deficit is noted.”

Cleveland Clinic has an emergency response team that’s called to the bedside on suspicion of stroke to order tests and perform any necessary intervention. “If a large vessel is obstructed, mechanical thrombectomy may be undertaken since clot removal can reverse or mitigate the neurological deficit,” Dr. Bakaeen explains. “Systemic thrombolytic therapy is generally contraindicated in postoperative patients, due to increased risk of bleeding.”

The Cleveland Clinic experience

While the methods detailed in the AHA statement are not guidelines since many of the recommendations are based on sparse evidence or expert opinion, Dr. Bakaeen says they are supported by real-world experience. “At Cleveland Clinic we’ve seen a dramatic reduction in stroke incidence after heart

surgery — especially valve and aorta surgery — due to preoperative imaging of the aorta and aggressive patient management in the operating room,” he notes.

“Widespread use of monitoring, corrective intraoperative strategies and selective use of adjuncts such as circulatory arrest, hypothermia and selective brain perfusion have helped us reduce stroke in aorta surgery,” he continues. “We’ve also minimized pump time and ischemia, which has reduced stroke and damage to other organs in all cardiac procedures, including coronary artery bypass and valve operations.”

Optimal care requires a multidisciplinary approach, Dr. Bakaeen adds: “The team strategy starts before surgery, is an active part of surgical planning and execution, and continues postoperatively in the ICU and stepdown unit.”

Dr. Roselli says there’s good reason to expect progress against perioperative stroke to continue apace. “As imaging quality and data analysis improve with advances in computer technology, we’ll progress from making decisions based on average treatment effect toward individualized precision medicine,” he notes. “This will help us understand which techniques are best tailored to each patient around the time of cardiac surgery in support of efforts to prevent strokes from complicating these lifesaving operations.”

Continued next page >



Stroke reduction in TAVR: Clearer answers are coming

Despite advances in device technology and improved operator experience, the rate of stroke following TAVR has remained steady, at just under 2.5%, since 2012 (*JAMA*. 2019;321:2306-2315). “Post-TAVR stroke is not a minor issue,” says Samir Kapadia, MD, Chair of Cardiovascular Medicine at Cleveland Clinic. “We must bring the stroke rate down.”

Cerebral embolic protection devices are the most obvious solution. The Sentinel™ Cerebral Protection System, a downstream filter designed to capture and remove thrombi and debris, is the only such device approved in the U.S. However, the Centers for Medicare & Medicaid Services (CMS) doesn't reimburse for the device, citing insufficient efficacy data. As a result, only 25% of TAVR centers in the U.S. routinely use it.

Cleveland Clinic is one of those centers. Its TAVR team performs some 700 TAVRs a year and attempts to use the Sentinel device in all TAVR patients. “Our post-TAVR stroke rate is 0.2%, compared with about 2.5% nationally,” says Amar Krishnaswamy, MD, Section Head of Invasive and Interventional Cardiology. “We believe the device is tremendously effective.”

Questions about the device's efficacy stem from the lack of a statistically significant reduction in the primary endpoint of the pivotal trial — i.e., brain emboli on MRI. However, there was a 63% risk reduction in clinical stroke among patients receiving the device, which is consistent with the reduction in clinical stroke (60% to 80%) seen in many large, single-center analyses of the device, Dr. Krishnaswamy notes. “That's why a new trial focused on clinical stroke rate, which is most relevant to patients and healthcare providers, is necessary,” he adds.

PROTECTED TAVR aims for definitive data

Cleveland Clinic hopes the multicenter PROTECTED TAVR trial (NCT04149535) will supply the robust data CMS and TAVR operators need to get on board with the device. “With 3,000 patients being randomized to TAVR with or without Sentinel, PROTECTED TAVR is large enough to detect a clinical reduction in stroke at 72 hours,” says Dr. Kapadia, who designed the trial and is serving as national principal investigator. “Since only 25% of patients undergoing TAVR receive an embolic protection device at the time of the procedure, we plan to enroll in sites that do not routinely use the device.”

If PROTECTED TAVR yields results that confirm efficacy for stroke prevention, CMS is expected to reimburse for the device. These two developments would likely boost adoption of the device. The trial is scheduled for completion in mid-2022.

WATCH-TAVR: Stroke reduction for TAVR in AF patients

Cleveland Clinic researchers are at the fore of another multicenter trial evaluating embolic protection during TAVR, this time in the setting of simultaneous placement of the Watchman™ left atrial appendage occlusion device for reduction of stroke risk from atrial fibrillation (AF).

About 30% of patients with aortic stenosis have coexisting AF. However, the combination of TAVR and Watchman implantation in a single procedure has been discouraged by policies that prohibit reimbursement for the Watchman device in this setting. “We'd like to combine the procedures so that these patients aren't subjected to the extra risk, cost and inconvenience of undergoing two separate procedures,” says Dr. Kapadia.

The multicenter WATCH-TAVR trial (NCT03173534), for which Dr. Kapadia is national principal investigator, was designed to show the FDA and CMS that implanting both devices in a single procedure is both safe and financially prudent. The trial is randomizing 312 patients at approximately two dozen U.S. centers to TAVR plus either anticoagulation or Watchman implantation. It's on target for completion in late 2020.

“We expect to see a reduction in bleeding and stroke when patients are off anticoagulants,” says Dr. Krishnaswamy. “We also expect there will be savings by combining the procedures, because the only difference will be the additional cost of the device.”

Additional approaches under study

Two additional neuroprotective devices for use during TAVR have completed clinical trials, but their results had not been published at the time of this writing. One is an embolic deflector, called TriGuard 3™. It deflects emboli from entering the cerebral circulation. The other is a filter that works on the same principle as the Sentinel device.

Other clinical trials are taking a different approach by evaluating whether anticoagulants can prevent formation of small clots on the TAVR valve that tend to break off and cause stroke.

“We're awaiting the data from these trials of new strategies for stroke prevention,” concludes Dr. Kapadia. ■

Contact Dr. Bakaeen at 216.444.0355, Dr. Roselli at 216.444.0995, Dr. Kapadia at 216.444.6735 and Dr. Krishnaswamy at 216.636.2824.

In Case You Missed It

A sampling of recent studies and publications of note from our Heart, Vascular & Thoracic Institute staff*

Klein A, Cremer P, et al. RHAPSODY: riloncept, an IL-1 α and IL-1 β trap, resolves pericarditis episodes and reduces risk of recurrence in a phase 3 trial of patients with recurrent pericarditis. *N Engl J Med*. Epub Nov. 16, 2020.

Bottom line: In this phase 3 trial, riloncept was associated with rapid resolution of recurrent pericarditis episodes and a significantly reduced risk of pericarditis recurrence compared with placebo.

Lincoff AM, Nissen S, et al. Effect of high-dose omega-3 fatty acids vs. corn oil on major adverse cardiovascular events in patients at high cardiovascular risk. The STRENGTH randomized clinical trial. *JAMA*. 2020;324:2268-2280.

Bottom line: Among patients at high cardiovascular risk, there was no significant difference in major adverse cardiovascular events between those receiving daily supplementation with omega-3 fatty acids and those receiving corn oil.

Wazni O, et al, for the STOP AF First investigators. Cryoballoon ablation as initial therapy for atrial fibrillation. *N Engl J Med*. Epub Nov. 16, 2020.

Bottom line: Initially treating symptomatic paroxysmal atrial fibrillation with cryoballoon ablation is more effective in maintaining freedom from arrhythmias than anti-arrhythmic drug therapy and entails a low risk of complications.

Caputo F, Lyden S, et al. Carotid endarterectomy remains safe in high-risk patients. *J Vasc Surg*. Epub Oct. 8, 2020.

Bottom line: In a large retrospective study of patients undergoing carotid endarterectomy at Cleveland Clinic, those with multiple physiologic or anatomic high-risk factors had a rate of stroke, myocardial infarction or 30-day mortality comparable to that of non-high-risk patients.

Cantillon D, Rickard J, Wazni O, et al. Comparative analysis of procedural outcomes and complications between de novo and upgraded cardiac resynchronization therapy. *JACC Clin Electrophysiol*. Epub Oct. 28, 2020.

Bottom line: Rates of procedural success and complications were no different between de novo cardiac resynchronization therapy (CRT) implants and CRT upgrades, according to a large analysis of Cleveland Clinic patients.

Cameron S, Gomes M, Bishop J, et al. Incidence and outcomes of thrombotic events in symptomatic patients with COVID-19. *Arterioscler Thromb Vasc Biol*. Epub Sept. 29, 2020.

Bottom line: Cleveland Clinic's initial experience with thrombotic events in symptomatic COVID-19 patients reveals a markedly lower rate than in prior reports and points away from using D-dimer to exclude thrombus in COVID-19 inpatients.

Jaber W, Rodriguez L, Kapadia S, et al. Structural deterioration of transcatheter versus surgical aortic valve bioprostheses in the PARTNER-2 trial. *J Am Coll Cardiol*. 2020;76:1830-1843.

Bottom line: Compared with surgical aortic valve replacement bioprostheses, the SAPIEN 3 TAVR valve had a similar rate of structural valve deterioration at five years while the SAPIEN XT TAVR valve had a significantly higher rate.

Desai M, Griffin B, et al. Characteristics and outcomes of patients with Takotsubo syndrome: incremental prognostic value of baseline left ventricular systolic function. *J Am Heart Assoc*. 2020;9:e016537.

Bottom line: Markers more sensitive than left ventricular (LV) ejection fraction, such as LV global longitudinal strain, are needed for optimal risk stratification in patients with Takotsubo syndrome, suggests a large observational Cleveland Clinic study.

Nissen SE, et al. How much weight loss is required for cardiovascular benefits? Insights from a metabolic surgery matched-cohort study. *Ann Surg*. 2020;272:639-645.

Bottom line: A large cohort study identified minimum weight loss thresholds for reducing risk of major cardiovascular events and death in patients with obesity and diabetes, suggesting possible benefits of metabolic surgery independent of weight loss.

Jaber W, Harb S, et al. Higher baseline cardiorespiratory fitness is associated with lower arrhythmia recurrence and death after atrial fibrillation ablation. *Heart Rhythm*. 2020;17:1687-1693.

Bottom line: Higher cardiorespiratory fitness is associated with lower rates of arrhythmia recurrence and death in patients undergoing atrial fibrillation ablation.

*Space limitations allow listing of only some principal and/or senior Cleveland Clinic authors here. Follow the reference citation for full authorship of publications listed.

 **2021 CLEVELAND CLINIC
PRIZE ANNOUNCEMENT**

In honor of its centennial anniversary and rich history of innovation and advancements in healthcare delivery, Cleveland Clinic will present the inaugural Cleveland Clinic Prize at the 2021 Medical Innovation Summit. With a significant honorarium, the prize will be awarded to a team, organization or individual who has made a significant contribution to healthcare delivery with a focus on one or more defined areas. Details will be released in early 2021.

For more information, visit
clevelandclinic.org/CCPrize.

Cardiac Consult

20-HV-1973481

> CME PREVIEW

Set Aside Feb. 5 to Get Current on Valve Disease and More

23rd Valve Disease, Structural Interventions and Diastology/Imaging Summit

Livestreamed Fri., Feb. 5 (7 a.m. to 4:30 p.m. ET)

Complimentary registration

Register at ccfme.org/echo

Cleveland Clinic will be offering this long-standing summit again in early 2021, but this installment of the crowd-pleasing CME course will feature a few pandemic-related changes:

- An all-virtual livestream format
- A one-day agenda focused on essentials and high-interest topics
- Complimentary registration for all attendees

“This is the 23rd year for this unique course, and this time it will be offered in a unique format,” says longtime course director Allan Klein, MD. “But its essentials remain the same as always — we’ll have leading experts from Cleveland Clinic and around the world providing commentary and perspective on timely topics in valve disease, structural interventions and diastology/imaging.”

The daylong course will bring together nearly two dozen Cleveland Clinic staff with another dozen experts from top U.S. and international centers. Together this multidisciplinary faculty — featuring cardiac imaging specialists, interventional cardiologists, cardiac surgeons, electrophysiologists and other subspecialists — will review and explore the latest in mitral, aortic and tricuspid valve disease as well as the evaluation and management of diastolic dysfunction and key developments in myocardial and pericardial diseases.

The pace will be brisk, with focused 15-minute presentations by Cleveland Clinic experts supplemented by 25-minute panel discussions featuring faculty from other institutions. Talks will cover topics such as advances in structural interventions, percutaneous mitral valve repair, valve-in-valve procedures and LAA occlusion devices, among others.

Participants will benefit from updates on advanced imaging techniques including 3D echocardiography, strain imaging, interventional echo and cardiac MRI/CT. “The new virtual format will expose attendees to innovations in advanced imaging and allow us to share essential practice pearls,” says course co-director Christine Jellis, MD, PhD.

“This is a high-level course with outstanding faculty and world-class discussion panels,” adds course co-director L. Leonardo Rodriguez, MD. “It’s a one-of-a-kind educational opportunity in cardiovascular medicine.”

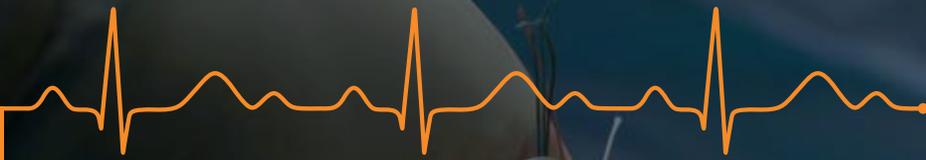
And its virtual format means more clinicians than ever stand to benefit. “We invite all cardiovascular providers who could never get away for past offerings of this summit to join us for this year’s convenient and complimentary virtual course,” says course co-director Samir Kapadia, MD, Chair of Cardiovascular Medicine. ■

This activity has been approved for *AMA PRA Category 1 Credit™*.



HEART, VASCULAR & THORACIC

Vitals



Volumes and outcomes from a sampling of centers in Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute

- › Adult Cardiac Surgery
 - › Ischemic Heart Disease
 - › Vascular Disease
- 

Adult Cardiac Surgery

Cleveland Clinic's Composite Quality Ratings in STS Adult Cardiac Surgery Database

★★★ **3-star** (highest) rating in **all 5 categories** assessed: CABG, AVR, AVR + CABG, MVRR, MVRR + CABG*

*For period 1/1/17-12/31/19 for all categories but CABG, which is for 1/1/19-12/31/19.

Key Data From First Half of 2020

In-Hospital Mortality (1/1/20-6/30/20)		
Procedure/Volume	Cleveland Clinic Observed	STS Expected
Isolated CABG (N = 326)	0.6%	1.3%
Isolated AVR (N = 155)	0.0%	1.4%
AVR + CABG (N = 75)	0.0%	3.1%
Isolated MVR (N = 76)	2.6%	5.0%
MVR + CABG (N = 17)	0.0%	7.5%
Isolated MV repair (N = 253)	0.0%	0.7%
MV repair + CABG (N = 59)	1.7%	3.9%
AVR + MVR (N = 35)	0.0%	—

STS = Society of Thoracic Surgeons; CABG = coronary artery bypass grafting; AVR = aortic valve replacement; MVRR = mitral valve repair/replacement; MVR = mitral valve replacement

Ischemic Heart Disease

SURGICAL TREATMENT

1,732 CABG volume in 2019 > **1,015** isolated CABG | **717** CABG + other > **161 (9.3%)** were reoperations

In-Hospital Mortality, Isolated CABG

Year	Cleveland Clinic Observed	STS Expected
2019 (N = 1,015)	0.5%	1.3%
2018 (N = 852)	0.7%	1.3%

In-Hospital Mortality, CABG + Other

Year	Cleveland Clinic Observed	UHC Expected
2019 (N = 717)	2.2%	7.0%
2018 (N = 624)	3.4%	6.7%

STS = Society of Thoracic Surgeons; UHC = University HealthSystem Consortium

Sources: STS Adult Cardiac Surgery Database and Vizient Clinical Data Base/Resource Manager™. Vizient data used by permission of Vizient. All rights reserved.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

2,014 Coronary interventions performed in 2019

1.08% PCI risk-adjusted in-hospital mortality (all patients),
39% lower than similar hospitals (1.77%)

2.99% PCI risk-adjusted in-hospital mortality for STEMI patients,
47% lower than similar hospitals (5.65%)

(Source: National Cardiovascular Data Registry, CathPCI Registry®, American College of Cardiology Foundation, for rolling four-quarter period through Q1 2020)

55 min Median time to PCI for STEMI patients in 2019
(vs. goal of < 90 min)

98% Proportion of STEMI patients receiving PCI within 90
minutes in 2019

99.6% Proportion of STEMI patients prescribed composite
guideline-directed medical therapy (aspirin, P2Y12 inhibitor, statin)
at discharge in 2019

Vascular Disease

In-Hospital Mortality for Various Vascular Surgery Procedures

Mortality	Procedure	Time Frame/Sample*
0%	Iliac stenting	2019 (N = 214)
0.45%	Lower-extremity percutaneous interventions	2019 (N = 674)
0%	Femoral endarterectomy with stenting	2019 (N = 75)
0%	Lower-extremity bypass	2019 (N = 171)
1.0%	Carotid stenting	2015-2019 (N = 411)**
0.4%	Carotid endarterectomy	2015-2019 (N = 1,509)**

*Volumes include Cleveland Clinic's main campus and Northeast Ohio regional hospitals.

**Includes all Cleveland Clinic services that perform these procedures at main campus and regional hospitals.

Mortality Rates for Abdominal Aortic Aneurysm (AAA) Repair

1.3% Elective open AAA repair, 2019 (N = 76)

16.7% Emergency open AAA repair, 2019 (N = 18)

0% Elective endovascular AAA repair, 2019 (N = 131)

4.3% Emergency endovascular AAA repair, 2019 (N = 23)

Volume Snapshots

7,451 Vascular surgery procedures performed in 2019 in greater Cleveland region

54,250 Noninvasive vascular lab ultrasound studies performed in 2019 in greater Cleveland region

For more data like this, visit clevelandclinic.org/hvtioutcomes and clevelandclinic.org/e15.

