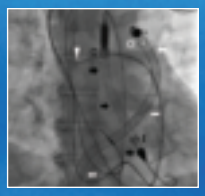
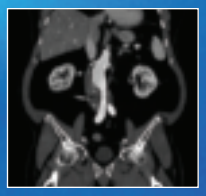
INSIDE THIS ISSUE





Cleveland Clinic

Cardiac Consult

Heart and Vascular News from Cleveland Clinic | 2019 | Issue 3

THEN & NOW

1995-2020: 25 Years of Evolution in Cardiovascular Care **– p. 4**

Dear Colleagues,

Few things endure for a quarter century. That is why my colleagues and I are honored beyond measure for Cleveland Clinic to be named the nation's No. 1 cardiology and heart surgery program by *U.S. News & World Report* for the 25th consecutive year in the publication's latest (2019-20) "Best Hospitals" rankings.

To mark this milestone, we have devoted this issue's cover story to a review of how the cardiovascular specialties have evolved over the past 25 years in a few key therapeutic areas. While this feature notes some Cleveland Clinic contributions to the advances made, it illustrates even more the extent to which all medical progress is a wondrously interconnected global effort, with a team from one center building on an innovation introduced elsewhere and yet another center refining the concept further still. What matters most is never being satisfied until we can offer our patients the best possible outcome and experience.

In Cleveland Clinic's Miller Family Heart & Vascular Institute, we are never satisfied because there is still more that can be done for all of our patients. As we continue that work, we remain grateful to you, our clinical and research partners around the world, for your abiding confidence over the past quarter century. And we look forward to close and fruitful collaboration for many years to come.

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.

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BEST HOSPITALS U.S.News & WORLD REPORT NATIONAL CARDIOLOGY & HEART SURGERY 2019-20

Cleveland Clinic was named a top U.S. hospital in *U.S. News & World Report*'s "Best Hospitals" rankings for 2019-20, as well as the No. 1 hospital in heart care for the 25th consecutive year.

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Samir Kapadia, MD, Named Department Chair of Cardiovascular Medicine

Next step in the career of a versatile interventional cardiologist

Cleveland Clinic's Robert and Suzanne Tomsich Department of Cardiovascular Medicine has a new Chair — **Samir Kapadia, MD**.

Dr. Kapadia succeeds Steven Nissen, MD, who had served as Department Chair since 2006. Dr. Nissen is now directing academic and research activities as Chief Academic Officer in Cleveland Clinic's Miller Family Heart & Vascular Institute.

Trained as an interventional cardiologist, Dr. Kapadia joined Cleveland Clinic in 2003, serving as Director of the Sones Cardiac Catheterization Laboratories since 2009 and as Section Head of Invasive and Interventional Cardiology since 2014. He is also Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University.

He received his medical degree with highest honors from Smt. NHL Municipal Medical College in Gujarat, India, in 1989. In 1993, he completed his internship and residency in internal medicine at Baylor College of Medicine, Houston, where he was named outstanding resident. He completed fellowships in cardiology and interventional cardiology at Cleveland Clinic in 1998 and 2000, respectively, and served as chief interventional fellow. After his training, Dr. Kapadia served from 2000 to 2003 as an interventional cardiologist at the VA Puget Sound Health Care System, Seattle, and held an academic appointment at the University of Washington.

Dr. Kapadia's wide-ranging clinical interests include:

- Percutaneous treatment of valve disease, including transcatheter aortic valve replacement and use of specialized clips for mitral regurgitation
- Complex coronary interventions
- Additional structural heart disease interventions, including atrial septal defect and patent foramen ovale closure and correction of paravalvular leaks

He is a widely published clinical researcher, contributing more than 450 articles and abstracts to the medical literature and playing a leadership role in numerous major cardiovascular trials, including the recent PARTNER 3 and COAPT investigations. He is also an accomplished innovator, with 15 patents to date.

Dr. Kapadia's many editorial appointments include service as chief editor of *Textbook of Interventional Cardiology: A Global Perspective* (2017) and as associate editor of *JACC Cardiovascular Interventions*. He is a member of various professional societies, including the American Heart Association, American College of Cardiology and Society for Vascular Medicine.

"Dr. Kapadia has been a dedicated researcher, educator, innovator and devoted physician to his many patients," says Lars Svensson, MD, PhD, Chair of the Miller Family Heart & Vascular Institute. "We look forward to his energy and enthusiasm taking our cardiology team to the next level of national recognition as new innovations are implemented."

"I am absolutely delighted to have Dr. Kapadia succeed me as Chair of Cardiovascular Medicine," adds Dr. Nissen. "He has the rare combination of exceptional skills in the triad of research, patient care and education. The department will maintain its preeminence in the years ahead under his energetic and innovative leadership."

For his part, Dr. Kapadia says: "I am thrilled and honored to lead our world-renowned team of cardiologists at Cleveland Clinic. I hope to lead by example, fostering innovation, accountability and respect." ■

THEN & NOW

Key Ways Cardiovascular Care Has Evolved Over the Past 25 Years

The 2019-20 "Best Hospitals" rankings from *U.S. News & World Report* mark the 25th straight year that Cleveland Clinic has been recognized as having the nation's No. 1 program in cardiology and heart surgery.

Cardiac Consult celebrates this milestone by looking back at the past quarter century and some of the advances and controversies that have made this a noteworthy period in cardiovascular care.

"The most striking change over the past 25 years has been the broadening of minimally invasive techniques," says Lars Svensson, MD, PhD, Chair of Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute. "These have greatly expanded our ability to care for the frail and elderly, shortened hospital stays and reduced the need for open large-incision surgery for a wide range of conditions. They have also improved patients' satisfaction and ability to return to their previous lifestyle."

Dr. Svensson noted four areas where the counterpoint between open and minimally invasive treatments has been especially dynamic: revascularization for coronary artery disease, aortic valve replacement, repair of aortic aneurysms, and electrophysiology and pacing. We take a look at how these fields have evolved over the past 25 years and where they are likely headed.

CABG and PCI for Coronary Artery Disease

Over the past quarter century, coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) have solidified their status as the twin pillars of coronary care.

Both CABG and PCI have deep roots at Cleveland Clinic, starting with the first use of selective cine-coronary angiography by F. Mason Sones, MD, in 1958. Dr. Sones' work made it possible for René Favaloro, MD, to successfully pioneer coronary artery bypass at Cleveland Clinic in 1967, and that same work led to the development of PCI in Switzerland a decade later.

Continuing CABG refinements. After Dr. Favaloro's pioneering operations, CABG soon became one of the most-performed major surgeries in the world. "Medicare was launched around the same time as CABG," notes Dr. Svensson. "It covered the cost of treatment for older people with coronary artery disease, and this resulted in an explosion of CABG procedures. Cleveland Clinic's heart program was a major beneficiary, as were hospitals nationwide."

CABG was studied and refined at Cleveland Clinic in subsequent years. A team led by Floyd Loop, MD, and Bruce Lytle, MD, established the superiority of the internal thoracic artery (ITA) graft to the saphenous vein graft in the mid-1980s.

"Suturing the left ITA directly to the left anterior descending artery using magnifying loops was popularized and proven beneficial at Cleveland Clinic," says cardiac surgeon Faisal Bakaeen, MD. "This later became the cornerstone of coronary revascularizations."

Over time, it became clear that bilateral arterial grafting was better for most patients, using either a second ITA or a radial artery graft as the second conduit. This became the recommendation of the Society of Thoracic Surgeons (STS) and others.

Dr. Bakaeen is co-author of 2016 STS guidelines that recommend arterial grafting, including bilateral thoracic grafting using a second ITA graft or a radial graft. "You have to tailor the operation to the patient," he explains. "Bilateral ITA grafting may not be possible, or will be less attractive, in complex and high-risk patients or in those undergoing re-operation. But for a typical patient who is young, otherwise healthy and undergoing elective CABG, we believe bilateral ITA grafting is the ideal goal."

Drs. Svensson, Bakaeen and others believe CABG should become a subspecialty of cardiac surgery, allowing more surgeons to acquire the experience and confidence needed to routinely adopt the bilateral ITA and arterial grafting approach.

Pursuing more-perfect PCI. In 1995, the first year it ranked as the nation's No. 1 heart program, Cleveland Clinic performed approximately 2,000 CABG operations. That number dropped progressively thereafter. An important reason was the increasing use of PCI.

Stephen Ellis, MD, who served as Cleveland Clinic's head of interventional cardiology for many years, trained with Andreas Gruentzig, MD, who developed balloon angioplasty in Switzerland in the late 1970s. He has seen the effectiveness of PCI improve over time with the introduction of bare-metal

Continued next page ›

stents in the 1990s and even further in the following decade with the use of drug-eluting stents, which reduced the risk of repeat PCI.

Dr. Ellis led a recent multicenter trial of what promised to be the next major advance in PCI — bioresorbable stents. The short-term results were not favorable for the device being studied due to the risk of thrombosis. Despite the potential for long-term benefits, the device was taken off the market.

Not all the breakthroughs of the past quarter century involved devices and technology. Process improvement initiatives and related efforts focused on enhancing quality in catheterization labs and cardiac operating rooms have resulted in big gains in efficiency and outcomes, even with fewer personnel and lower cost.

For example, Cleveland Clinic's average ECG-to-balloon time for ST elevation myocardial infarction is now well below 60 minutes, far better than the guideline-recommended 90 minutes.

"More and more cardiovascular care will be reimbursed through models like bundled payments that emphasize quality over quantity," says Samir Kapadia, MD, Director of Cleveland Clinic's Sones Cardiac Catheterization Laboratories and Chair of Cardiovascular Medicine. "That makes effective and efficient use of resources a paramount consideration for all institutions, and it's what we've aimed to do with our cath lab process improvements."

CABG vs. PCI. Both CABG and PCI have made big strides in early and late outcomes, but which is better for the patient?

It might be generally said that, in the short term, PCI is less invasive and provides quicker angina relief and faster return to normal activities. In the long term, however, CABG may be better for enduring symptom relief and reduced risk of death or myocardial infarction, especially in patients with complex disease and a high atherosclerotic burden.

While CABG procedures declined to 13% of Cleveland Clinic's overall cardiac surgery volume a few years ago, today the volume has rebounded to 18% as patient selection has improved and it has become clear that diabetic patients fare better with CABG.

"As CABG and PCI continue to evolve, care is becoming more sophisticated, with greater use of arterial conduits, less-invasive techniques, hybrid procedures and new types of stents for PCI," observes Dr. Bakaeen. "But that won't bring an end to the debate over which approach is best. The management of coronary disease is a collaborative heart care team effort that aims to individualize patient recommendations. The important question will always be: Which therapy is best for the individual patient based on disease burden, complexity and comorbid disease?"

SAVR and TAVR

The latest innovations in aortic valve replacement call for precisely that kind of collaborative heart team approach, building on the experience of coronary disease care teams.

Surgical aortic valve replacement (SAVR) was one of the great medical advances of the 20th century, first using simple ball valves in the 1960s and progressing to tilting disc valves in the 1970s and then biological valves in the 1980s.

Transcatheter aortic valve replacement (TAVR) was developed by French interventional cardiologist Alain Cribier in the early 2000s as a minimally invasive alternative for replacement of stenotic aortic valves, based on research by the Danish physician H.R. Andersen.

In 2011, Dr. Svensson — with a team that included Dr. Kapadia and E. Murat Tuzcu, MD, now Chair of Cardiovascular Medicine at Cleveland Clinic Abu Dhabi — performed one of the first FDA-approved TAVR procedures in America, helping set the stage for subsequent broad adoption of the technique. In fact, Cleveland Clinic performed 487 TAVR procedures in 2018, with 0.4% in-hospital mortality.

In 2007, Dr. Svensson and colleagues launched the first of a series of numbered trials called PARTNER that showed a general equivalence in outcomes between SAVR and TAVR and a superiority of TAVR over medical management (with a higher risk of stroke).

PARTNER 3, the most recent trial, concluded that "among patients with severe aortic stenosis who were at low surgical risk, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVR than with surgery."

But Drs. Svensson and Kapadia note that for all its comprehensiveness, PARTNER 3 had many exclusions, as well as subtle differences between its treatment groups, such as a higher rate of concomitant procedures like CABG in the SAVR group (26%) compared with the TAVR group (8%). And the recently released results were only for one year, with follow-up scheduled to continue for 10 years to assess the durability of TAVR devices. "Unless there are extenuating circumstances, like radiation heart disease or dialysis, patients younger than 65 generally should not have TAVR at this point," Dr. Svensson observes.

Open and Endovascular Aneurysm Repair

When Cleveland Clinic was first ranked No. 1 in 1995, open surgery was the gold standard for abdominal and thoracoabdominal aortic aneurysms. Today, Cleveland Clinic has among the nation's most experience and lowest mortality for these often-challenging open procedures. "Our program's vast experience has enabled consistent achievement of less than 1% mortality with open first-time abdominal aortic aneurysm surgery," notes Vascular Surgery Chair Sean Lyden, MD.

But the open thoracoabdominal operation comes with many potential complications, including paraplegia, and requires a long recovery period. The search for a less-invasive alternative to open thoracoabdominal aneurysm repair began with vascular surgeon Juan Parodi, MD, a trainee at Cleveland Clinic in the mid-1970s. In his last year at Cleveland Clinic, Dr. Parodi began contemplating an intravascular approach to aneurysm repair. He worked on the problem after returning to his native Argentina in 1979, and in 1990 he performed the first successful endovascular abdominal aneurysm repair (EVAR) in Buenos Aires.

Continued next page ›

Over the past quarter century, the devices for endovascular repair have grown steadily more sophisticated. Today's stent grafts are fabric tubes supported by a wire scaffold, which are guided to the aneurysm site and deployed in the diseased aorta segment. The stent relines the aorta like a sleeve.

The evolution of EVAR in the early 2000s was promoted at Cleveland Clinic by the late Roy Greenberg, MD, a vascular surgeon who helped develop branched and fenestrated grafts. Cleveland Clinic has led the world in treatment of thoraco-abdominal aneurysms with endovascular devices and has shown the outcomes in high-risk patients to be better than those with open surgery in healthy patients. Cleveland Clinic continues to be involved in clinical trials designed to lead to commercialization of this technology in the U.S.

"Today, about 80% of abdominal aneurysms are treated with stent grafts," notes Heart & Vascular Institute Chair Dr. Svensson. "We hope that in the future we will be able to treat as many thoracoabdominal aneurysms with this minimally invasive approach."

"Expanding indications for endovascular procedures are changing the equation, increasingly giving high-risk patients a chance to receive lifesaving therapy, including in cases of arch aneurysms," says Eric Roselli, MD, Surgical Director of Cleveland Clinic's Aorta Center. He and his colleagues foresee increasing collaboration among cardiac and vascular surgeons on hybrid procedures, where the area near the aortic valve is operated on through an open incision while vessels lower in the body receive endograft repair.

Electrophysiology and Pacing

The treatment of heart rhythm disorders has evolved in several directions since 1958, when Earl Bakken built the first pacemaker at the University of Minnesota.

Today, Cleveland Clinic's Section of Electrophysiology and Pacing, headed by Oussama Wazni, MD, offers a wide variety of highly specialized approaches. These include the newest implantable cardioverter-defibrillators (ICDs), biventricular pacemakers, leadless pacemakers, sophisticated remote monitoring devices, genetic testing, medical management and follow-up, lead extraction, and advanced mapping and ablation therapies.

By the mid-1990s, patients with heart rhythm disorders were able to benefit from almost three decades of innovation — from lithium battery pacemakers to dual-chamber pacemakers to steroid-eluting leads. Microprocessors were making pacemakers reactive to patient activity levels for the first time. All raised pacemaker therapy to new levels of safety and effectiveness.

Around the same time, transcatheter radiofrequency ablation (RFA) was becoming an effective alternative to open heart operations for treating paroxysmal atrial fibrillation — owing much to the improvements in electrophysiological testing and mapping taking place at the time.

Electrophysiologist Bruce Lindsay, MD, who retired from Cleveland Clinic this year, remembers that era well: "The early days of ablation were not easy because we were on the forefront and there was nobody to teach us. We figured it out based on our understanding of physiology."

In fact, "nobody wanted to talk about atrial fibrillation before RFA," Dr. Lindsay says. "There was not much we could do to help patients apart from cut-and-sew so-called maze procedures. Ablation procedures have changed the landscape, and they are now the foremost topic at scientific sessions." Open-chest maze operations are still done in combination with other cardiac surgeries or as a stand-alone operation in selected patients.

Dr. Svensson points out that in the 1980s ablation procedures for ventricular tachycardia or fibrillation were done by excising scar tissue or freezing the scar. "Now this is frequently treated by defibrillation and occasionally by ablation," he says.

Dr. Lindsay was among those who helped demonstrate the feasibility of transvenous cardioversion and defibrillation in the mid-1980s. "Patients used to spend weeks in the hospital and undergo repeated electrophysiology studies to identify drugs that might prevent life-threatening ventricular arrhythmias," he says. "With the advent of ICD therapy, we simply implanted an ICD and sent the patient home within a week."

Lead management, including extraction, is another area where Cleveland Clinic has helped chart new territory since the 1990s. "We help patients plan for lifelong therapy with pacemakers and defibrillators with leads," explains Bruce Wilkoff, MD, Director of Cardiac Pacing and Tachyarrhythmia Devices. "We continue to work on reducing the need for lead extraction while improving the safety of extraction when it's necessary."

"We continue to work on reducing the need for lead extraction while improving the safety of extraction when it's necessary."

– Bruce Wilkoff, MD

While Cleveland Clinic cardiologists have helped direct several recent trials of leadless devices, such devices don't meet the needs of all patients. "Leads are going to be around for a long time to come," Dr. Wilkoff predicts.

Meanwhile, surgical treatment for arrhythmias has been progressing on a parallel track during this period with better lesion sets and ablation methods. Refinements of the maze procedure introduced in 1992 made it a gold standard for treatment of atrial fibrillation.

Cleveland Clinic performed the first operation combining the maze procedure and CABG. A. Marc Gillinov, MD, Chair of Thoracic and Cardiovascular Surgery, says that nearly all patients with preexisting atrial fibrillation who undergo heart surgery should have an ablation or maze done at the same time.

"The addition of an ablation or maze does not increase risk," he says. "The maze works in most people, and it includes excision or exclusion of the left atrial appendage, which is a primary source of stroke and other thromboembolic events."

The Next 25 Years?

The next 25 years will undoubtedly see advances in robotic surgery, off-pump surgery, stents for the treatment of peripheral arterial blockages and continued refinement of therapies for dyslipidemia. Insights emerging from Cleveland Clinic laboratories are pinpointing the roles of the gut microbiome in development of various forms of heart disease. Surgeons and interventional cardiologists will be able to treat patients who are older and sicker than ever before, with technologies enhanced by big data, deep learning and artificial intelligence techniques. Cardiac CT and MRI will combine with virtual reality to create unique 3D imaging environments.

"We are proud to be No. 1," says Dr. Svensson, "but we are never satisfied. Our goal is continual improvement of quality, safety and outcomes. We are grateful for the support of our colleagues worldwide, and are honored to play a role in this great international effort to heal the diseases of the heart and give everyone the best chance at a long, productive, happy and healthy life. Our mantra is to innovate change, improve practice and ensure untouchable high-quality outcomes and value for our patients." ■

First Successful Use of Biventricular Impella Pumps as a Bridge to Heart Transplant

An innovative case leads to general guidelines for when to consider this approach.

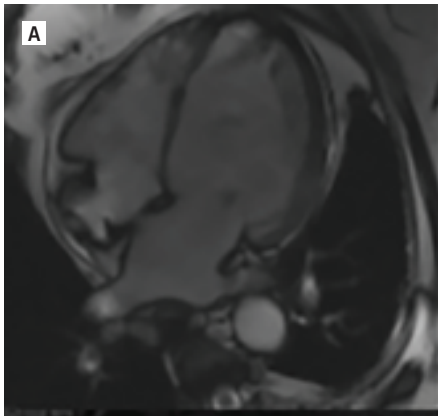
Bridging to heart transplantation with Impella® pumps for both the left and right ventricles in a patient with severe biventricular heart failure is feasible, according to a first-in-world case report from Cleveland Clinic recently published in *ESC Heart Failure* (2019;6:552-554).

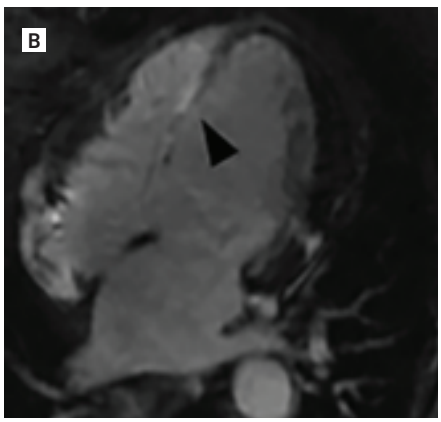
While simultaneous use of right and left ventricular Impella devices in cardiogenic shock as a bridge to recovery or left ventricular assist device (LVAD) has previously been reported, this case marks the first published experience of their use in this fashion as a bridge to heart transplant.

"We have very few options for mechanical bridging to heart transplantation for patients with biventricular heart failure and cardiogenic shock," says the lead cardiologist on the case, Antonio Perez, MD, MBA, Director of Cleveland Clinic's Heart Failure Intensive Care Unit. "Our experience with this patient shows that two Impella devices can successfully be used simultaneously in this setting, providing an important new minimally invasive strategy."

Many patients with cardiogenic shock from biventricular failure that requires acute mechanical circulatory support do not survive the time to transplantation, Dr. Perez explains. Durable VADs implanted into both ventricles have the advantages of high flow, durability and the possibility of patient ambulation, but this strategy requires sternotomy and prolonged intubation and carries risks of bleeding and mediastinal adhesions.

Minimally invasive options — including veno-arterial extracorporeal membrane oxygenation (VA-ECMO) and use of biventricular percutaneous VADs such as the TandemHeart® and Impella devices — involve potentially less periprocedural morbidity and fewer operative risks, but VA-ECMO offers limited durability and





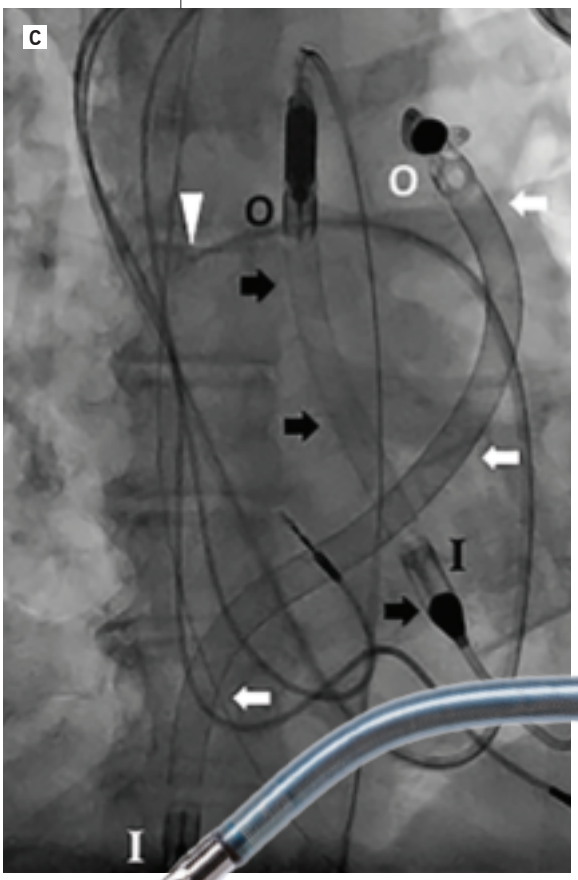


Figure. (A and B) Cardiac MRIs showing thinning of the interventricular septum (A) and fibrosis/scarring of the interventricular septum (B; black arrowhead). (C) Fluoroscopic images showing the pulmonary artery catheter (white arrowhead), the Impella 5.0 (black arrows) and the Impella RP (white arrows). I = inlet and O = outlet for the respective Impella devices. Reprinted from Varian et al., *ESC Heart Failure* (2019;6:552-554), ©2019 The authors.

Impella RP®
Image courtesy of ABIOMED

all of these options preclude ambulation if femoral cannulation is required. The latter is an important limitation if the anticipated wait time to heart transplantation is long.

"For a patient expected to obtain a heart within a short period of time, avoiding the risks of surgical implantation of VADs or an artificial heart has multiple advantages," notes cardiothoracic surgeon Edward Soltesz, MD, MPH, Surgical Director of Cleveland Clinic's Kaufman Center for Heart Failure Treatment and Recovery, who served as surgical lead for this case.

Case details: Developing heart failure

The case patient, a 67-year-old woman presenting with chest discomfort, was diagnosed with complete heart block. Transthoracic echocardiogram (TTE) revealed mildly reduced left ventricular ejection fraction (LVEF) of 45%. No obstructive coronary disease was found by angiogram. She was discharged with a dual-chamber pacemaker.

Three weeks later, she returned with new heart failure symptoms. Now TTE showed LVEF of 15% with multiple segmental wall motion abnormalities. She also developed ventricular tachycardia and was treated with amiodarone and lidocaine infusions.

Cardiac MRI revealed marked thinning of the entire interventricular septum and associated fibrosis and scarring with delayed contrast enhancement (Figure, A and B). Endomyocardial biopsy was deferred because of her clinical instability. She was treated empirically with three days of methylprednisolone.

Dual mechanical support while awaiting transplant

An intra-arterial balloon pump (IABP) was inserted for cardiogenic shock and recurrent ventricular tachycardia. Her cardiac index remained low (1.5 L/min/m^2) despite support.

An Impella 5.0® was placed femorally via surgical cut-down (an initial attempt via axillary approach failed because of small artery size). However, she continued to decompensate, with TTE revealing a newly dilated right ventricle with septal shift to the left.

An Impella RP® was then inserted percutaneously via the right femoral vein. With the Impella 5.0 set to deliver flow of 4.0 to 4.5 L/min, and the Impella RP delivering 4.0 L/min (Figure, C), cardiac index improved to 2.4 L/min/m^2.

The patient developed severe vasoplegia, which was successfully treated with methylene blue. She continued to receive intravenous diuresis and was extubated after five days of biventricular mechanical support. She remained bedbound because of the femoral biventricular Impella cannulation. There were no device complications, and she required no blood transfusions.

Transplant, diagnosis and recovery

On day 20, she underwent heart transplantation with surgical decannulation of the Impella devices. Histology of the heart revealed biventricular cardiac sarcoidosis.

Three weeks after transplantation, she was discharged to inpatient rehabilitation, after which she returned home. One year later, she is thriving and has normal functional capacity.

Learnings from the case

This patient's successful course has led Cleveland Clinic's cardiovascular team to adopt the following approach to mechanical bridging to heart transplant in patients with cardiogenic shock refractory to pharmacotherapy:

- If transplantation can be expected within one week, consider VA-ECMO or biventricular Impella devices.
- For appropriate patients who are likely to wait up to one month, consider biventricular Impella devices.
- In the event of inadequate support or complications from Impella devices (e.g., major bleeding, pump thrombosis, pump failure), be prepared to transition to other forms of biventricular mechanical support on an emergency basis.
- For wait times longer than a month, the primary options are surgical, using biventricular CentriMag™ systems or a Total Artificial Heart®.

"Patient selection is critical to successful bridging to heart transplantation with biventricular mechanical circulatory support," emphasizes Dr. Soltesz.

He explains that the case patient's small body size (surface area 1.9 m^2), common blood type (A) and low panel-reactive antibody score (0%) made her anticipated time to donor heart availability short, which qualified her as a good candidate for this strategy.

"In the right patient, biventricular support with Impella devices minimizes the risk of complications and reduces recovery time," he adds. "These are goals that we are always striving for." ■

Contact Dr. Perez at 216.444.6936 and Dr. Soltesz at 216.444.5680.

Causes of Failed EVAR: A Cautionary Tale in Images

The benefits of endovascular repair of abdominal aortic aneurysm (EVAR) are well established, and Cleveland Clinic is an avid user of EVAR in appropriately selected patients. Yet it remains true that EVAR is not the best choice for all patients and all cases, and EVAR failure is a reality that high-volume vascular surgery programs continue to see.

"Cleveland Clinic has the world's largest experience in treating failed endovascular repairs," says Department of Vascular Surgery Chair Sean Lyden, MD. A review of that experience suggests that most cases of failed EVAR can be attributed to one of a handful of causes. This article illustrates those causes with a collection of images from recent cases encountered among patients presenting to Cleveland Clinic for management of failed EVAR.

1) Poor planning

"In our experience, EVAR failure is most often due to poor planning or simple nonadherence to the instructions for use for the endograft device," says Cleveland Clinic vascular surgeon Francis Caputo, MD.

The CTs in Figure 1 present cases in point. They are from patients with aneurysm necks between 30 and 32 mm, yet these aneurysms were repaired endovascularly with some of the largest devices available, with diameters of 36 mm. Over time, this mismatch resulted in neck dilation, causing aneurysmal degeneration and slippage of the devices.

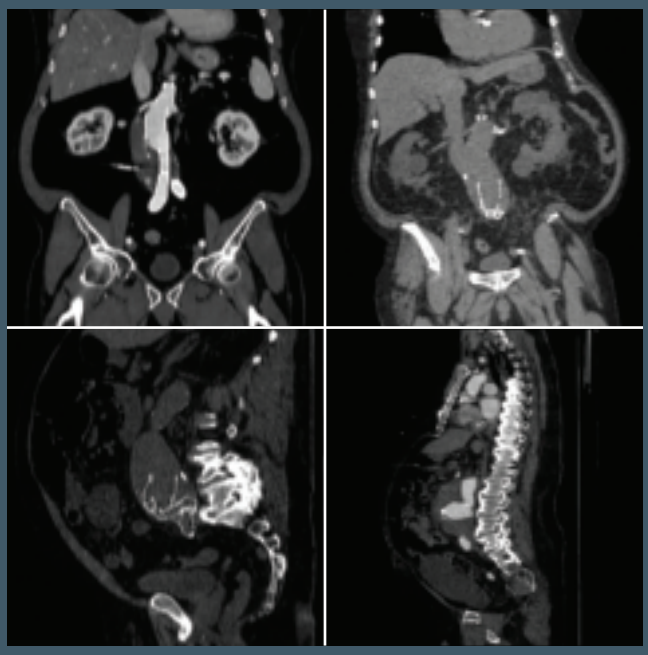


Figure 1

While the effect appears modest in the coronal views in the top row, the sagittal views below show that the grafts have become so crumpled that they are beyond endovascular salvage.

2) Uncertain durability

Durability was a recognized limitation of early endografts, and while next-generation devices have been designed to address durability problems, the success of these efforts is not yet known.

"In our practice, we still encounter degeneration with older endografts, such as fabric tears and fabric absorptions," observes Dr. Caputo, who supplied the photos in Figure 2 as examples. He notes that the photo on the right reveals just how thin device fabric can become.

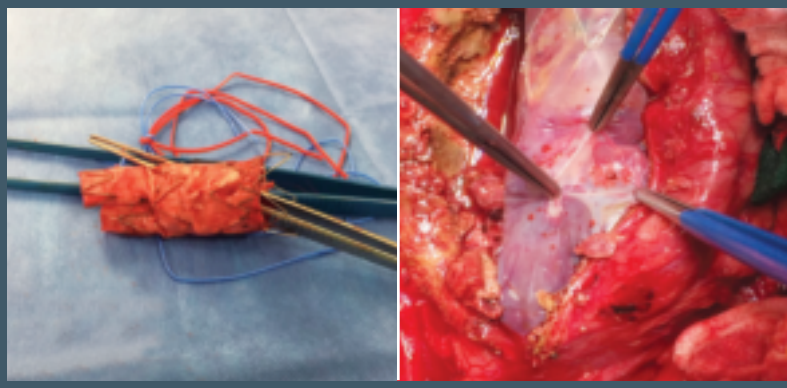


Figure 2

"Durability issues are surfacing even with some newer devices, too, as we have seen in some of the trials of new EVAR devices in which we participate," Dr. Caputo says. An example of a newer device that required removal is shown in Figure 3.

3) Inexperience with open aortic surgery

One side effect of the growth of EVAR is that open aortic surgical repairs are being done less and less often. Yet continuing robust experience is key to superior outcomes. "Cleveland Clinic's vast experience has enabled us to consistently achieve less than 1% mortality with open first-time aortic surgery, which compares favorably with Medicare data suggesting a national rate of 4% to 5%," notes Dr. Lyden.

Figure 3

Diminishing experience with open aortic surgery extends to training programs, Dr. Caputo adds, with today's vascular surgery fellows graduating after having done, on average, only 10 open aneurysm repairs a year. While programs like Cleveland Clinic's are proud to be exceptions to this trend — its fellows graduate with about 80 open aneurysm repairs a year — the broad effect is that experience with open aortic surgery is shrinking.

"We suspect this growing relative inexperience is prompting some surgeons to sometimes undertake complicated endovascular solutions for problems that could be repaired in a much more straightforward manner using open surgery," says Dr. Caputo. He notes that he and his colleagues see evidence of this on a consistent basis.

Consider the CTs in Figure 4 from a 55-year-old man who had undergone an aorto-uni-iliac configuration for EVAR along with a femoral-femoral bypass and three coilings.

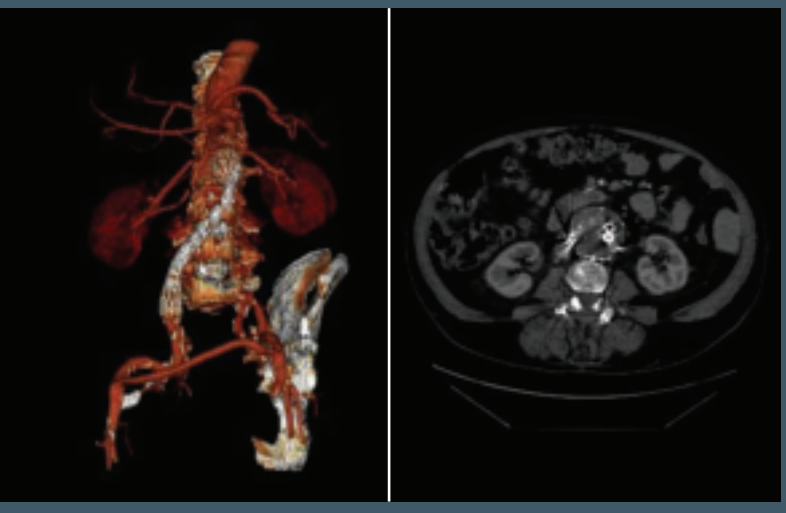


Figure 4

Figure 5

When the patient encountered difficulties and required aortic endograft explant at Cleveland Clinic, the complexity of the material removed was striking, resembling a tackle box, as shown in the top panel of Figure 5. The bottom panel shows the ostia of his right and left renal arteries and of his superior mesenteric artery. "Fortunately, only the intima came out, not the adventitia," Dr. Caputo observes.

Bottom line

In the context of diminishing experience with open aortic surgeries, cases like this remind Drs. Caputo and Lyden of Occam's razor — i.e., that simpler solutions are likely to be better than complex ones. While EVAR remains a valuable minimally invasive option for many patients, they point out, abdominal aortic aneurysms are not suited to one-size-fits-all solutions. "Some patients are still best served by a good old-fashioned open repair," Dr. Caputo concludes. ■

Contact Dr. Lyden at 216.444.3581 and Dr. Caputo at 216.444.4508.

Making Sense of AAOCA: Updates on Studies of an Ill-Defined Congenital Anomaly

It's hard to bring up the congenital anomaly known as anomalous aortic origin of a coronary artery (AAOCA) without stirring up a host of questions: Are all its forms equally dangerous? How do the various anomalies present? What are the long-term outcomes of different surgical repair techniques? Which ones need surgery?

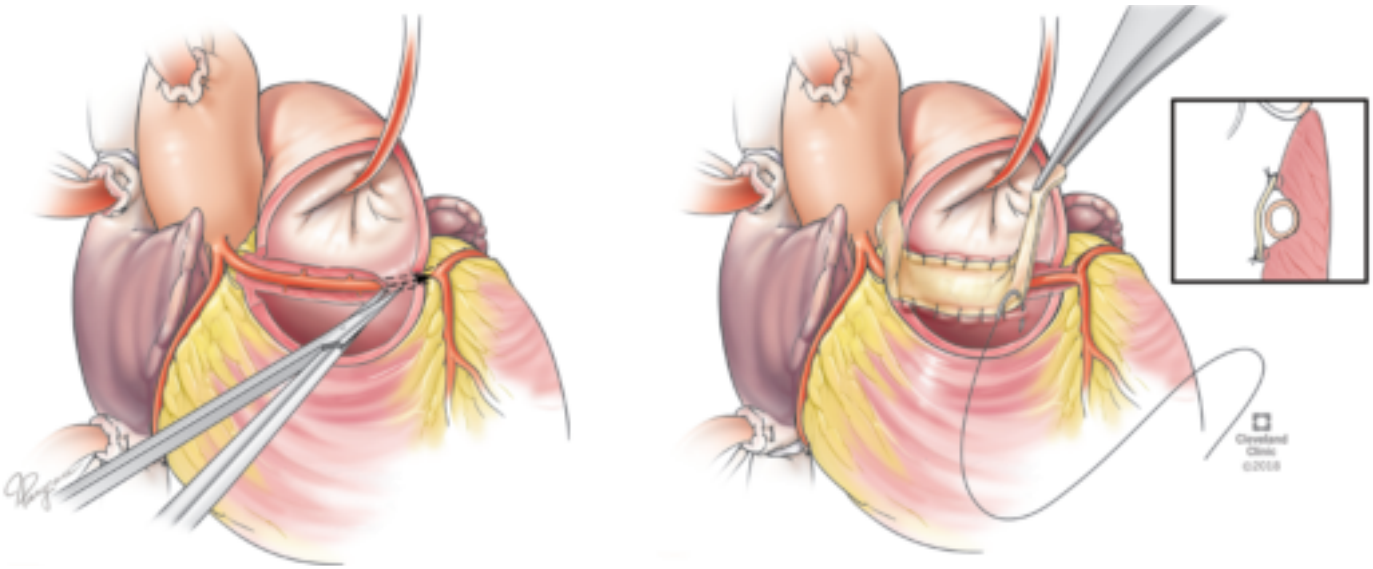


Figure. (Left) Unroofing and skeletonization of AAOLCA (i.e., AAOCA involving the left coronary artery) to coronary bifurcation. (Right) Autologous pericardial patch reconstruction of the right ventricular outflow tract with posterior elongation.

These are some of the key questions expected to be answered with data from a prospective registry of AAOCA patients age 30 and younger established by the Congenital Heart Surgeons' Society (CHSS) and from complementary retrospective and prospective studies of adults with the anomaly seen at Cleveland Clinic.

"Over time, the large body of data we gather will be analyzed to determine associations among clinical events, diagnostic studies and treatment choices," says Tara Karamlou, MD, a Cleveland Clinic cardiothoracic surgeon specializing in congenital heart disease. "These previously unobtainable data will help us develop the predictive models that are so urgently needed."

A little-understood anomaly

AAOCA with interarterial, intramural or intraconal course is a congenital heart anomaly with multiple variants. Its most important manifestation is sudden cardiac death (SCD), which occurs primarily during or just after exercise in otherwise healthy children, adolescents and young adults. Although it's a rare deformity estimated to affect 0.1% to 1.0% of the pediatric and adult population, AAOCA is the second-leading cause of SCD in young athletes in the U.S. In adults over age 30, AAOCA is thought to be a less malignant, often incidental finding, but its prevalence and implications have yet to be determined.

The CHSS registry has been enrolling patients age 30 and younger with AAOCA since 1998. Cleveland Clinic is one of 47 participating institutions. The registry's overarching purpose is to determine the outcome of surgical intervention relative to observation in children and young adults with AAOCA, as well as to describe the natural history of the condition over these patients' lifetimes.

"We don't know the denominator of patients who have this anomaly or its true prevalence," notes Dr. Karamlou. "The information gleaned from this ongoing study will help us characterize the anatomic variations and correlate them with risk of SCD, chest pain and major adverse cardiovascular events."

With nearly 700 patients now enrolled, answers to critical questions are starting to surface. Dr. Karamlou and colleagues have published several papers from this registry cohort. The findings have also been used to shape evidence-based guidelines for AAOCA management (*J Thorac Cardiovasc Surg.* 2017;153:1440-1457) and the management of adults with congenital heart disease (*J Am Coll Cardiol.* 2019;73:1494-1563).

Many unknowns

Five major forms of AAOCA and seven subtypes have been identified. Observational studies suggest the origin and course of AAOCA may impact SCD risk. "Risk may be greater for AAOCA involving the left coronary artery (AAOLCA), but there are reports of SCD associated with AAOCA of the right coronary artery (AAORCA) and single origin of the coronary arteries," says Dr. Karamlou. "Moreover, the fact that AAORCA is more prevalent than AAOLCA may increase the prevalence of SCD in this group."

SCD is hypothesized to occur from transient mismatch of coronary blood flow and myocardial oxygen demand, which results in myocardial ischemia and/or ventricular tachyarrhythmias. Several mechanisms have been proposed to explain the increased risk of ischemia with exercise.

Individual mechanisms may be associated with specific varieties of AAOCA, and any of them may account for the reduction in coronary blood flow leading to SCD. "This hypothesis is consistent with the theory that some AAOCA variants are more 'malignant' than others," says Dr. Karamlou.

There is no typical AAOCA presentation. Although the initial presentation may be SCD, AAOCA is most often an incidental finding on a CT angiogram or echocardiogram taken for another reason or for symptoms related to exertion, such as chest pain. Different institutions use different protocols, and there is no consensus on how AAOCA should be diagnosed or evaluated.

Similarly, treatment of AAOCA is controversial and varies among clinicians. Recommendations include observation alone, exercise restriction, medication, surgical repair or a combination of these. The registry will help establish best practices based on treatment outcomes.

"We believe AAORCA is less dangerous than AAOLCA, but we have no data supporting this or clarifying whether surgery changes the natural history," says Dr. Karamlou. "We believe many patients don't warrant surgery, and we are trying to best identify who they may be. We suspect that unroofing the intramural segment where it makes a hairpin turn (Figure) reduces the risk of SCD, but we're not sure."

AAOCA in adults

"Adults with AAOCA are often inaccurately thought to no longer be at risk for SCD, but this is not based on sufficient data, as there is bias in the evaluation and incidence of autopsy of SCD cases in the adult population," observes Joanna Ghobrial, MD, a cardiologist with Cleveland Clinic's Adult Congenital Heart Disease Center. To fill this void in data for an at-risk population, Cleveland Clinic is conducting complementary prospective and retrospective studies of AAOCA in adults.

The prospective investigation is designed to aid in risk stratification. "This study is prompted by the lack of evidence-based protocols for managing adults with AAOCA, especially since most patients can be asymptomatic up until presenting with SCD and because noninvasive stress tests have not correlated well with future risk of SCD," says Dr. Ghobrial.

The study involves systematic and comprehensive preoperative evaluation with noninvasive and invasive testing to help discern which patients might be at higher risk of SCD. The noninvasive evaluation includes dobutamine PET scans and ECG-gated CT angiography, while invasive testing includes coronary angiography with instantaneous wave-free ratio flow reserve and intracoronary vascular ultrasound at rest and with provocation. "This specifically protocoled evaluation will identify patients with flow compromise in their anomalous coronary artery and aid in future prediction models that identify those patients benefiting most from surgical intervention," Dr. Ghobrial explains.

Meanwhile, the retrospective study is drawing on a database of all Cleveland Clinic patients with the anomaly. An ongoing review of all cardiac catheterizations in Cleveland Clinic's Cardiovascular Disease Registry has turned up at least 4,285 patients to date with incidental or symptom-directed AAOCA.

"The retrospective Cleveland Clinic database doesn't enroll patients who died before reaching adulthood," Dr. Karamlou explains. "This makes it a useful adjunct to the CHSS cohort in that it captures a slightly older population who may have more benign forms of AAOCA, may have concomitant coronary artery disease and may undergo different surgeries. The durability of alternative surgeries needs to be understood."

Going forward

For its part, the CHSS registry will continue enrolling patients indefinitely. "The data we gather will give us the power to address unanswered questions about this rare lesion," says Dr. Karamlou.

As a former John W. Kirklin fellow in the CHSS Data Center, Dr. Karamlou serves on the CHSS Data Center faculty along with Cleveland Clinic's Eugene Blackstone, MD, who established the center with Dr. Kirklin in 1985. As faculty members, they help determine study design, serve as primary investigators, and are involved in reviewing data, analyzing manuscripts and presenting data at national meetings.

"This registry will be the source of critical data for providers," Dr. Karamlou concludes. "There's no better way to understand long-term outcomes and treatment modalities of AAOCA." ■

Contact Dr. Karamlou at 216.442.8278 and Dr. Ghobrial at 216.444.5923.

Data Best Practices Can Pack an Outcomes Punch Even for Lower-Volume Centers

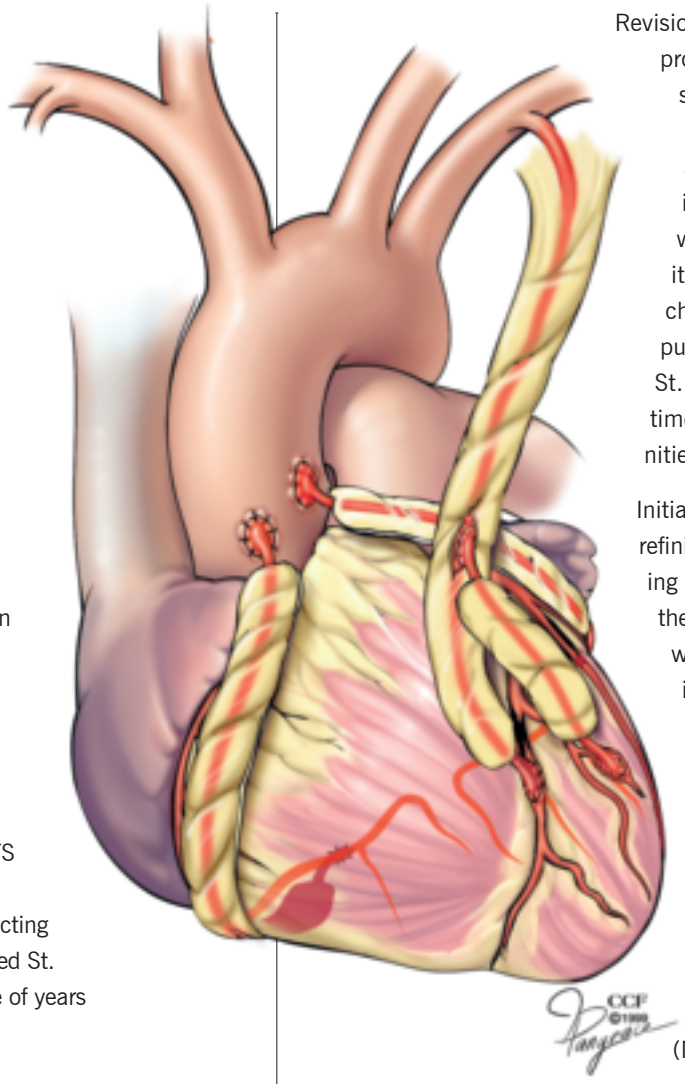
How an allied program achieved a three-star CABG rating with less than 200 cases a year

Superb data-driven quality improvement is not just for large academic medical centers. Just ask St. Luke's Hospital, a nonprofit provider whose primary facility is a 493-bed hospital in suburban St. Louis, Missouri.

St. Luke's — which has been an alliance partner with Cleveland Clinic's Heart & Vascular Institute since 2016 — is proud to have joined the exclusive ranks of hospitals earning a three-star (highest) overall quality rating for coronary artery bypass graft surgery (CABG) in the most recent Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database report. And they did it with an annual CABG volume of less than 200 cases.

"A three-star STS rating is quite an achievement for anyone; for a lower-volume site like St. Luke's, it's phenomenal," says cardiothoracic surgeon Edward Soltesz, MD, MPH, who as Director of Cleveland Clinic's Cardiac Surgery Affiliate Programs oversees quality and process improvement for alliance partners like St. Luke's.

In fact, St. Luke's links its standout STS rating in part to enhancements to its registry-related data review and abstracting process that Cleveland Clinic has helped St. Luke's implement over the past couple of years as part of the alliance relationship.



Providing structure and support

"We had all the pieces we needed for tracking and reporting our outcomes," says Mary Randazzo, BSN, MBA, Cardiovascular Service Line Quality Manager for St. Luke's. "Cleveland Clinic gave us the structure and support needed to develop a reliable, accurate method of reporting and put us on the fast track to actionable, meaningful processes."

Revisions to the data-related processes began with a site visit to St. Luke's nearly two years ago by a Cleveland Clinic quality consultant, who met with the hospital's quality and registry team and chief nursing officer. The purpose was to observe St. Luke's practices at the time and identify opportunities for improvement.

Initial changes involved refining processes for gathering and analyzing data for the national registries to which St. Luke's reports, including the STS Adult Cardiac Surgery Database, the Transcatheter Valve Therapies (TVT) Registry and several registries from the American College of Cardiology's National Cardiovascular Data Registry (NCDR®).

"Cleveland Clinic shared tools and suggested a number of process changes," says Randazzo, who cites a few specific examples:

- The hospital changed which data elements are included and how they are formatted when the registry data team presents metrics to the cardiologists and cardiac surgeons in departmental quality meetings. "Cleveland Clinic led us through an examination of our processes and helped us focus on the

Isolated CABG Procedures at St. Luke's: Risk-Adjusted Metrics*				
	2018 STS mean	2016	2017	2018
Operative mortality (%)	2.3	0.7	1.7	1.2
Reoperation (%)	3.8	2.9	4.5	0
Prolonged ventilation (%)	7.7	5.8	6.8	2.4

*Revisions to St. Luke's data-related processes took place in July 2017.

patient's clinical presentation and methods to capture that more accurately," says Randazzo. "Patient presentation has become an essential part of our discussions." She adds that physicians have since become more engaged with the data: "They are now more aware of their outcomes and how their clinical actions affect the metrics, which fosters greater accountability. Our abstractors have become so well versed in the data that the physicians are eager to rely on them."

- The above approach proved essential for addressing "appropriate use criteria" metrics in the NCDR's CathPCI Registry®. "Cleveland Clinic consultants performed an audit, provided us with resources and helped us implement changes," says Randazzo. "The results were dramatic; we saw measurable, steady improvement."

- Several physician documentation tools have been implemented over time to capture necessary information that was going uncollected. "Cleveland Clinic's insights helped us determine what we needed and how to get it," Randazzo notes.

Size need not be a deterrent

Although the changes were made on a relatively small scale — St. Luke's has three abstractors processing data for three cardiac surgeons and a team of cardiologists — they nevertheless yielded a significant impact, as reflected by the three-star STS rating and improved registry outcomes overall. The table above provides some representative outcomes data.

"St. Luke's has become highly advanced in the way they abstract, review, edit and submit data to the national registries, as well as in how they share metrics with their physicians and leadership," observes Dr. Soltesz. "Their experience shows that no program is too small to benefit from best practices in these areas. The key is to work with us to determine which recommendations work for your site, depending on size and internal resources. Not all recommendations work for all programs."

"When we review programs at potential allied and affiliated hospitals, we do not promise our efforts will increase volumes, but for some 70% of programs they have," adds Cleveland Clinic Heart & Vascular Institute Chair Lars Svensson, MD, PhD. "And for most programs our efforts have been associated with improved STS star ratings."

Continuing communication is central

Stakeholders at St. Luke's note that a key reason for the success of the efforts reported above is the ongoing communication they have with their Cleveland Clinic peers thanks to the alliance partnership. That means Randazzo speaks with her counterpart at Cleveland Clinic at least monthly, and surgeons and cardiologists at St. Luke's are free to call Cleveland Clinic colleagues like Dr. Soltesz when they would like guidance on a challenging case or similar matters.

That ongoing communication includes monthly webinars that Cleveland Clinic's Heart & Vascular Institute offers to all its affiliated and allied providers, focusing on common challenges and solutions, often relating to registry data and analytics. In fact, for one of last year's webinars the St. Luke's quality team was invited to share a checklist for data capture they developed in response to version changes to an NCDR registry. "Most hospitals faced the same challenges we did, so we were able to share a process that worked for us," says Randazzo.

"The St. Luke's team saw an opportunity for improvement, formulated a solution and shared the result," says Dr. Soltesz. "We're gratified by the tremendous progress they've made and how this webinar showed that they've embraced the collaborative ethos at the heart of our affiliate and alliance program." ■

For information on affiliation and alliance opportunities with Cleveland Clinic's Heart & Vascular Institute, visit clevelandclinic.org/heartaffiliates.

› CME PREVIEW

Make Yourself a Master in Aortic Valve Disease Care

Mastering the Management of Aortic Valve Disease: A Case-Based Approach

Fri.-Sat., Dec. 13-14, 2019
JW Marriott Essex House | New York, New York

› **ccfcme.org/aorticmasters**

A day and a half in New York City in December can bring you fully up to speed on all the latest in aortic valve disease management. That's the aim of this Cleveland Clinic-sponsored live CME program.

"For the past two years we've offered a very popular CME event called 'Mastering the Mitral Valve' at this same venue in New York City on a weekend in early December," says course co-director Lars Svensson, MD, PhD, Chair of Cleveland Clinic's Miller Family Heart & Vascular Institute. "This year we decided to mix things up a bit by taking the same approach but applying it to the latest in aortic valve disease care."

The course does so with a dynamic lineup of topics across five broad sessions focusing on the following areas:

- **A Contemporary Framework for Approaching Aortic Valve Disease in 2019.** This session explores subjects ranging from the evolution of the aortic valve center to current guidelines on when and how to intervene to whether there's a role for medical therapy in aortic valve disease.
- **Imaging of the Aortic Valve — From Basic to Advanced Techniques.** A series of six 15-minute case presentations illustrates the role of various imaging modalities in diverse clinical contexts, including several different presentations of aortic stenosis, severe aortic regurgitation, bicuspid aortic valve with aortopathy, and the use of CT and cardiac MRI in workup for transcatheter aortic valve replacement (TAVR).
- **Controversies and Difficult Scenarios in Aortic Valve Disease.** This session fills all of Friday afternoon's agenda with an exploration of 11 clinical challenges such as the choice between valve-in-valve TAVR and redo surgery, surgical aortic valve replacement (SAVR) versus TAVR in the setting of radiation heart disease, and management of acute aortic regurgitation due to aortic dissection.
- **TAVR.** Saturday kicks off with a session of 13 rapid-fire, 10-minute presentations on all the latest issues in TAVR therapy, including various explorations of its use in low-risk patients, cerebral protection, when to perform balloon valvuloplasty, and endocarditis after TAVR.
- **Emerging Technologies.** This concluding session, which is not certified for CME credit, provides updates on a range of new devices for treatment of aortic valve disease — including accessory devices and wearable technology — presented by leading experts in their development and testing.

Sessions are briskly paced with well-focused presentations of 10 to 20 minutes, and all are punctuated with panel discussions and Q&A periods where attendees can interact with the 19 expert faculty from Cleveland Clinic and four other leading U.S. medical centers.

"Like the last offering of our 'Mastering the Mitral Valve' course, this program takes a decidedly case-based approach, with many presenters sharing their insights through practical application in real-world clinical scenarios," notes course co-director Douglas Johnston, MD, a staff cardiothoracic surgeon at Cleveland Clinic.

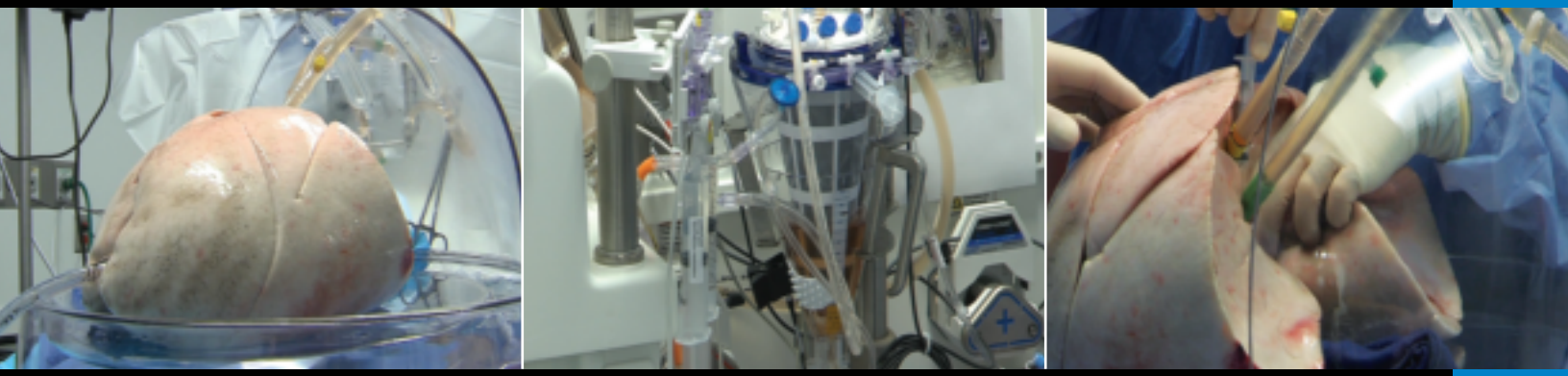
"Cardiologists, interventionalists, cardiac surgeons and others involved in the care of patients with aortic valve disease will leave this course equipped to apply the latest insights from clinical trials and registry studies to their practice, from considerations surrounding TAVR in low-risk patients to best practices in patient assessment," Dr. Johnston adds. ■

Register at ccfcme.org/aorticmasters.
Early-bird pricing ends Oct. 7.

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

For more live cardiovascular CME from Cleveland Clinic, see the back cover of this issue.

Image of the Issue



(Left) Donor lungs are connected to the ex vivo lung perfusion system via a simulated airway connected to a ventilator and cannulas simulating the pulmonary artery and veins. **(Middle)** Perfusate and oxygen are pumped in to achieve normothermia and normal physiologic function for up to four to six hours. **(Right)** Samples of perfusate are taken periodically to gauge oxygenation and other metrics. The team also performs radiography and manual assessment to check for edema and bronchoscopy to check for airway secretions. If functional measures are good over at least three hours, the lungs are used for transplantation.

EX VIVO LUNG PERFUSION IN ACTION AND BY THE NUMBERS

Despite consistently performing one of the highest yearly volumes of lung transplants in the U.S., Cleveland Clinic isn't yet satisfied with the number of patients who can be helped with a lung transplant. That's largely because of missed opportunities represented by the approximately 80% of donor lungs that are deemed marginal and thus declined for transplantation.

To reduce that proportion of declined lungs, Cleveland Clinic obtained and began using the XVIVO Perfusion System (XPS™) for ex vivo lung perfusion (EVLP) in May 2018. Here is a profile of the system's use at Cleveland Clinic in the first 12 months since its introduction:

18 sets of lungs perfused in-house using EVLP

- 15 cases of assessing/reconditioning marginal lungs
- 3 cases performed to overcome logistical challenges to transplant through extended preservation time

10 cases of lung transplant in 11 patients following EVLP
(one EVLP case resulted in two cases of single lung transplant)

- 10 of the 11 transplanted patients have survived

All cases of EVLP are overseen by Toshihiro Okamoto, MD, PhD, Associate Director of the EVLP Program, who leads a team of three physician fellows, a nurse and a perfusionist who work on each EVLP case. Dr. Okamoto and the fellows are on call for all cases, with a dedicated crew of three nurses and six perfusionists trained in EVLP to staff the team whenever needed.

"Our commitment and the manpower we devote to each case set our EVLP program apart," says Kenneth McCurry, MD, Surgical Director of Lung and Heart-Lung Transplantation. "We are developing the deep experience that will guarantee success in EVLP, as you need to do these cases on a frequent basis in the context of a high-volume lung transplant program to develop true expertise."

He adds that a next step for Cleveland Clinic will be the use of EVLP as a platform for delivering therapeutics to further enhance lung function when needed: "We see EVLP as providing opportunity to grow our program and offer transplantation to more patients as well as a chance to deliver a variety of therapeutics to donor lungs to offer patients more than we currently can." ■

Contact Dr. Okamoto at 216.444.7917 and Dr. McCurry at 216.445.9303.

Cleveland Clinic

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Cardiac Consult

Live CME Events from Cleveland Clinic

Contemporary Management of Valvular Disease: Diagnosis, Imaging and Intervention

Fri.-Sat., Sept. 6-7, 2019
InterContinental Boston | Boston

Info/registration: ccfcme.org/bostonvalve2019

CLE: Comprehensive Lifelong Expeditious Care of Aortic Dissection

Thu.-Fri., Sept. 19-20, 2019
InterContinental Hotel & Conference Center | Cleveland

Info/registration: ccfcme.org/aorticdissection19

Global EP Summit 2019

Fri.-Sat., Sept. 27-28, 2019
Hilton Cleveland Downtown | Cleveland

Info/registration: ccfcme.org/globalep19

Old Problems, New Approaches: Innovations in the Management of Congenital Heart Disease

Fri.-Sat., Oct. 4-5, 2019
JW Marriott Essex House | New York City

Info/registration: ccfcme.org/congenitalheart19

Congenitally Corrected Transposition of the Great Arteries: Management and Outcomes from Infancy to Adulthood

Thu.-Sat., Oct. 17-19, 2019
InterContinental Hotel & Conference Center | Cleveland

Info/registration: ccfcme.org/pediatricheart19

Mastering the Management of Aortic Valve Disease: A Case-Based Approach

Fri.-Sat., Dec. 13-14, 2019
JW Marriott Essex House | New York City

Information/registration: ccfcme.org/aorticmasters

(see page 18 for more detail)

These activities have been approved for *AMA PRA Category 1 Credit™*.

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