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Heart, Vascular and Thoracic News

ROBOTICALLY ASSISTED CABG: A TECHNOLOGY WHOSE TIME HAS COME — p. 4

DEAR COLLEAGUES,

Ever since Cleveland Clinic completed the world's first successful series of coronary vein graft surgeries in 1967, our surgical teams have never stopped refining coronary artery bypass graft surgery (CABG).

In 1968, the year after their breakthrough, bypass procedures were successfully combined with left ventricle reconstruction and valve replacement. In 1970, our surgeons began using internal thoracic artery (ITA) coronary anastomoses. They soon standardized this method and documented its superb long-term outcomes in a landmark 1986 study that established ITA-to-LAD (left anterior descending artery) grafting as the standard of care. And in recent years, our surgeons have been leading proponents of the merits of multiarterial grafting.

Now, as reported in this issue's cover story on page 4, we have relaunched our robotically assisted CABG program to offer a growing number of qualifying patients a minimally invasive option for their CABG procedure. Although Cleveland Clinic first performed robotically assisted CABG more than a decade ago, we held off on widespread offering of the option until we felt the technology and patient selection criteria had sufficiently matured, as safety and great outcomes are always top priority. That time of maturation has now come, and we are happy to consult with appropriate patients on whether they may be good candidates.

When you consider Cleveland Clinic as a referral destination for your patients, please know that we will approach their treatment with this same dedication to continually refining care standards to optimize patient outcomes and experience.

Respectfully,

Lars G. Svensson, MD, PhD
Chief, Heart, Vascular and Thoracic Institute

Cleveland Clinic's Heart, Vascular and Thoracic Institute is nationally and internationally renowned as a leader in cardiovascular care. Its teams are dedicated to continuously improving upon their standard-setting clinical outcomes, unsurpassed volumes and experience, and rich legacy of innovation and research leadership.

ON THE COVER — Cardiothoracic surgeon Donna Kimmaliardjuk, MD, stands behind the robot arms during a recent robotically assisted coronary artery bypass graft surgery (CABG). The feature starting on page 4 details why and how Cleveland Clinic recently relaunched its robotically assisted CABG program and which patients are optimal candidates for a robotically assisted procedure.

[RESEARCH ROUNDUP]

RECENT STUDIES OF NOTE FROM CLEVELAND CLINIC

LAA Occlusion Versus Oral Anticoagulation After AF Ablation

In patients at moderate to high risk of stroke who undergo catheter ablation for atrial fibrillation (AF), left atrial appendage occlusion (LAAO) significantly lowers the risk of nonprocedural major or clinically relevant bleeding compared with oral anticoagulation (OAC; 95% nonwarfarin) while maintaining similarly low rates of stroke, death or systemic embolism. So finds the multicenter randomized OPTION trial comparing the two postablation strategies among 1,600 patients. At 36 months, nonprocedural major or clinically relevant bleeding occurred in 8.5% of the LAAO group versus 18.1% of the OAC group ($P < .0001$ for superiority). The composite of stroke, death or systemic embolism occurred at similar rates in the two groups, as did major bleeding alone, including procedural bleeding. "This shows that LAAO can be performed safely and effectively in AF ablation patients, positioning it as an appealing alternative to chronic nonwarfarin oral anticoagulation," says lead investigator Oussama Wazni, MD, MBA. The findings were published in the *New England Journal of Medicine* (Epub 2024 Nov 16).

Risk Model Predicts Outcomes in Recurrent Pericarditis

A Cleveland Clinic team has developed the first risk-stratification model for predicting long-term outcomes in patients with recurrent pericarditis. Developed from a retrospective study of 365 patients using traditional and machine learning methods, the model showed high discriminative ability in an internal validation study (*J Am Coll Cardiol.* 2024;84[13]:1193-1204). It relies on 10 variables found to be most prognostically predictive in recurrent pericarditis: age, sex, number of prior recurrences, etiology, heart rate, severity of late gadolinium enhancement on cardiac MRI, left ventricular ejection fraction, steroid dependency, colchicine use and use of a disease-modifying antirheumatic drug. "We are hopeful this novel machine learning model will improve identification of patients at elevated risk for recurrent pericarditis and enable earlier anti-inflammatory therapy initiation," says senior author Allan Klein, MD.

Modified Aortic Reimplantation Yields Excellent Long-Term Outcomes

For patients with a proximal aortic aneurysm or dilation, a modified aortic reimplantation technique — i.e., reducing the anulus size to match patient characteristics and creating neosinuses — results in excellent long-term survival and freedom from reintervention. So concludes a long-term analysis of 491 patients who underwent the operation at Cleveland Clinic over a 20-year period (*J Thorac Cardiovasc Surg.* Epub 2024 Aug 22). At 15 years after the operation, survival was 87% and freedom from reintervention on the aortic valve was 95%. "This shows the modified aortic reimplantation technique is reliable and reproducible," says senior author Lars Svensson, MD, PhD, who performed the operations in this series. "Because of the excellent long-term outcomes, we especially recommend this procedure for younger patients, who often have a connective tissue disorder."

History of COVID-19 Infection Doubles MACE Risk

A history of COVID-19 appears to double the risk of major adverse cardiac events (MACE), finds an analysis of U.K. Biobank data co-led by Cleveland Clinic researchers (*Arterioscler Thromb Vasc Biol.* Epub 2024 Oct 9). The study compared 10,000 patients who tested positive or were hospitalized for COVID-19 in 2020 with over 217,000 population controls and nearly 39,000 propensity score-matched controls from the same period. The risk of MACE during follow-up (up to 1,000 days) was elevated among people with COVID-19 at any level of severity (hazard ratio [HR] = 2.09 [95% CI, 1.94-2.25]) and especially among those hospitalized for COVID-19 (HR = 3.85 [95% CI, 3.51-4.24]). A genetic interaction was also seen, with risk increased in subjects with non-O blood types relative to those with blood type O. "These findings suggest that severe COVID-19 infection is a coronary artery disease risk equivalent and that we should consider factoring such a history into cardiovascular disease prevention plans," says co-senior author Stanley Hazen, MD, PhD.

SURPASS Reassures on Real-World Use of LAAO Device

Routine clinical use of the WATCHMAN FLX™ left atrial appendage occlusion (LAAO) device achieves similar safety and efficacy outcomes through one year as those in the PINNACLE FLX clinical trial, which led to the device's FDA approval for stroke prevention in patients with nonvalvular atrial fibrillation. So found the real-world SURPASS study involving more than 95,000 patients from the American College of Cardiology's NCDR LAAO Registry™. The study (*Circ Cardiovasc Intervent.* Epub 2024 Jul 26) found comparable rates of death, ischemic stroke and major bleeding through one year between SURPASS and the PINNACLE FLX trial. "The WATCHMAN FLX is now widely implanted by thousands of operators, and this large national dataset confirms that its favorable clinical trial outcomes are being replicated in the community," says lead investigator Samir Kapadia, MD.

[COVER STORY]

ROBOTICALLY ASSISTED CABG: A TECHNOLOGY WHOSE TIME HAS COME

Why and how we're using robotic assistance for qualifying CABG candidates

The LIMA-LAD (left internal mammary artery to left anterior descending artery) graft is considered the holy grail of coronary artery bypass graft surgery (CABG) due to its durability and proven ability to improve survival. Cleveland Clinic cardiac surgeons now offer minimally invasive, robotically assisted LIMA-LAD grafting to patients who qualify.

"Avoidance of sternotomy is the major difference between robotically assisted CABG and standard CABG," says Donna Kimmaliardjuk, MD, who co-directs Cleveland Clinic's robotic CABG program with colleague Faisal Bakaeen, MD. "This is a far less invasive procedure, with just a small incision made between the ribs.

"In terms of outcomes," she continues, "robotically assisted CABG is very safe, and patients get a great bypass. The advantage is in its faster recovery time. It's far easier to recover from a 2- to 3-inch thoracotomy than from a sternotomy. Patients can return to their usual activities, including work and sports, much faster."

A continually maturing technology

Cleveland Clinic surgeons started doing robotically assisted coronary artery bypass more than a decade ago, but they found the approach and technology were not sufficiently advanced to make the procedure as safe and effective as conventional CABG. Both the technology and patient selection criteria have since improved within the framework of a rigorous process and a dedicated team approach, so Cleveland Clinic relaunched its robotically assisted CABG offerings in early 2024.

Currently, only single-vessel bypasses are performed with robotic assistance. Dr. Kimmaliardjuk expects that will change. "Our goal is to develop the ability to do double- or triple-vessel bypasses through a small incision," she says.

Who qualifies?

The ideal candidates for robotic CABG are those needing only a single LIMA-LAD bypass. For those with blockages in other arteries that are amenable to stenting, the option of a hybrid procedure is available. The hybrid procedure is done in conjunction with interventional cardiologists.

"We have shown that using arteries to bypass all important target vessels improves survival," says Dr. Bakaeen, Director of Cleveland Clinic's Coronary Artery Bypass Surgery Center. "However, using arteries to bypass less-important vessels will not necessarily increase survival. These vessels can be stented."

"The ability to offer patients the holy grail of a LIMA-LAD bypass without a traditional full sternotomy has significant implications for the future of coronary revascularization," adds interventional cardiologist Khaled Ziada, MD. "Interventional cardiologists and cardiac surgeons can map out a plan to give patients the best of both worlds: second- and third-generation stents for non-LAD lesions, which compare favorably with vein grafts, and a mammary bypass for the LAD, which has traditionally been superior to stenting in this territory. Clinical trials will need to establish the potential advantages of this approach in the near future."

Robotic technology has increased the pool of candidates who receive a LIMA-LAD graft to include certain populations who are regularly excluded due to technical challenges. These include patients with obesity.

"The beauty of robotic surgery is that it allows us to harvest a mammary artery of sufficient length to reach the target and even bypass more distal disease," Dr. Bakaeen notes. "Additionally, better visualization makes harvesting the artery less traumatic."

Interventional cardiologists generally serve as gatekeepers to robotic CABG, identifying potential candidates based on angiography. The surgeons review the pros and cons of conventional versus robotic approaches with the candidates and cardiologists.

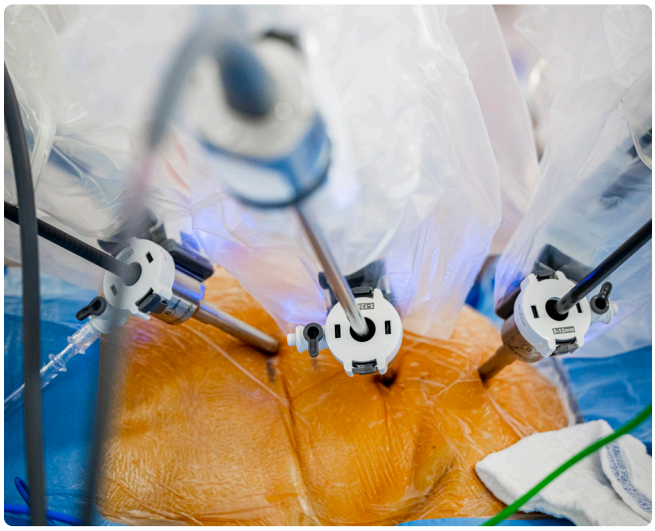
"We arrive at what we feel is the best option for a given patient," Dr. Kimmaliardjuk explains, "taking into account how many vessels need to be bypassed, the patient's overall health, the presence of comorbidities, and the patient's ultimate goals and expectations for quality of life and longevity."

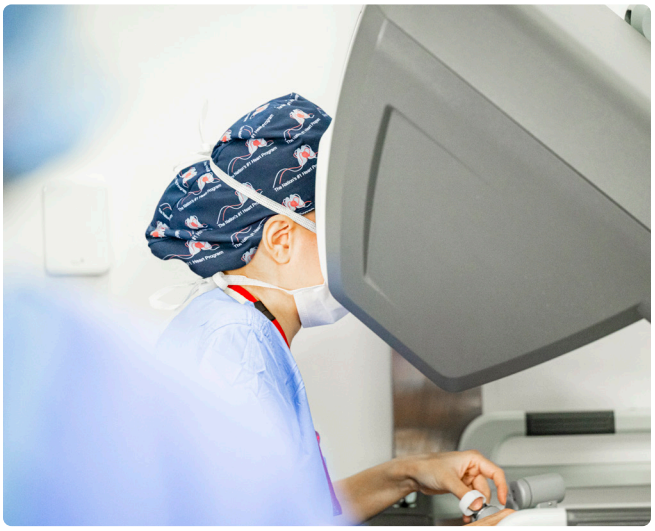
Technical criteria

Technical criteria for robotic CABG include:

- Limited, focal atherosclerotic disease in the LAD
- Location of the LAD on the surface of the heart muscle
- No subclavian artery stenosis that could impact blood flow through the LIMA
- Ability to tolerate single-lung ventilation, because the left lung is deflated to allow visualization of the mammary artery

BELOW — Images from a recent robotically assisted CABG operation at Cleveland Clinic. (Left) Robotic ports placed via small incisions between the ribs. (Right) Dr. Kimmaliardjuk controlling the robot arms from the robot console.





› Absence of scar tissue on the left side of the chest, as it could prevent safe access to the LIMA or heart

It is not necessary for patients to have a usable conduit other than an IMA, since bilateral IMA grafting is not performed and radial arteries are not used.

Quality control

The goal of robotic CABG is to provide a LIMA-LAD graft equal in quality and durability to that achieved with a sternotomy.

"The LIMA-LAD graft is the most important thing we can do for a patient with coronary artery disease," Dr. Bakaeen observes. "In younger patients with LAD disease, robotically assisted MIDCAB [minimally invasive direct coronary artery bypass] can provide a lifetime solution."

"We never want to compromise quality or safety for the sake of cosmesis," Dr. Kimmaliardjuk notes. "If we have any concern for the patient's safety or the quality of the bypass during the surgery, we can convert to sternotomy."

Quality is enhanced by careful patient selection and perfect execution. "We assess graft flow in the operating room as a form of quality control, and we verify graft patency before closing," Dr. Bakaeen says. "We do not accept results that are less than perfect."

Safety is secured by the high level of expertise across the multidisciplinary team involved in the care of these patients, including cardiologists, cardiac anesthesiologists and intensivists.

"As surgeons, we play an important, but only partial, role in the total experience," Dr. Kimmaliardjuk says.

"As interventional cardiologists, we work very closely with our surgical colleagues to provide each patient with an individualized heart team approach," adds Laura Young, MD, of the Section of Interventional Cardiology. "With the recent advancements in robotic CABG, we can offer more patients a hybrid approach of stenting and bypass surgery to provide the most optimal, durable results with the least invasiveness."

"We're excited about this program," Dr. Kimmaliardjuk says. "It is young, but we have achieved excellent results. To date, all LIMA-LAD grafts remain open, and there have been no conversions to sternotomy."

"Cleveland Clinic has consistently received a three-star (highest) rating for CABG from the Society of Thoracic Surgeons (STS), and our operative mortality rate for isolated CABG has been less than half the rate predicted by the STS risk model for many consecutive years," notes Dr. Bakaeen. "It is with this emphasis on quality and excellence that we have relaunched the robotic CABG program for the benefit of patients."

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Contact Dr. Kimmaliardjuk at 216.445.7208, Dr. Bakaeen at 216.444.0355, Dr. Ziada at 216.444.0926 and Dr. Young at 216.444.0424.

AORTIC VALVE REPLACEMENT FOR MODERATE AORTIC STENOSIS SAVES LIVES IN COHORT STUDY

Large longitudinal investigation supports earlier intervention over clinical surveillance

Patients who undergo aortic valve replacement (AVR) for moderate aortic stenosis (AS) fare better, on average, than comparable patients managed with clinical surveillance, with significant improvements seen in survival and left ventricular remodeling over multiyear follow-up.

So finds a retrospective analysis of more than 1,400 patients with moderate AS who were treated at Cleveland Clinic with AVR (either surgical [SAVR] or transcatheter [TAVR]) or managed with clinical surveillance. The study was published online in *Open Heart* (2024;11[1]:e002616).

"We found a significant advantage to replacing the aortic valve in patients with moderate AS rather than waiting until symptoms became severe," says senior and corresponding study author Samir Kapadia, MD, Chair of Cardiovascular Medicine at Cleveland Clinic. "Increasing evidence indicates that intervention is a promising alternative to conservative management in the setting of moderate AS."

Moderate AS – more worrisome than traditionally believed

AS, increasingly seen in an aging population, is not treated with AVR per current guidelines except in patients with severe symptomatic disease or evidence of left ventricular systolic dysfunction, or in those with moderate AS who are undergoing open-heart surgery for another indication. Otherwise, surveillance is recommended every year or two for moderate AS until patients meet the criteria for intervention.

However, over the past several years, multiple studies have shown that moderate AS has a poorer prognosis than previously thought, with a clear increased risk of heart failure, cardiovascular mortality and all-cause mortality.

"Our study findings make us more inclined to offer intervention to our AS patients earlier in the disease process, especially in light of treatment advances and increased understanding of the poor prognosis associated with moderate AS."

— SAMIR KAPADIA, MD

Little has been published on intervention for moderate AS, mostly studies with small sample sizes and short follow-up times. The current study was designed to compare long-term clinical outcomes and echocardiographic changes in such patients managed with either AVR or clinical surveillance, using real-world data from a large health system.

Study population

The analysis included 1,421 patients (mean age, 75.3 ± 5.4 years; 60% men) with moderate AS of the native valve (defined as an aortic valve area of 1.0-1.5 cm^2 at index echocardiogram). Patients were selected from the Cleveland Clinic echocardiography database between 2008 to 2016 and followed until 2018 (median follow-up, 6 years).

Cohorts were categorized by the following management strategies:

- Clinical surveillance (n = 1,122)
- SAVR (n = 220; 73.6% of AVR group)
- TAVR (n = 79; 26.4% of AVR group)

AVR associated with improved survival

Overall, 363 patients (25.5%) died during follow-up. Among these deaths, 266 (18.7% of the overall cohort) were classified as cardiovascular deaths.

Comparisons between the AVR and clinical surveillance groups revealed that intervention was associated with lower risks of all-cause death (adjusted hazard ratio [HR] = 0.51; 95% CI, 0.34-0.77; P = .001) and cardiovascular death (adjusted HR = 0.50; 95% CI, 0.31-0.80; P = .004).

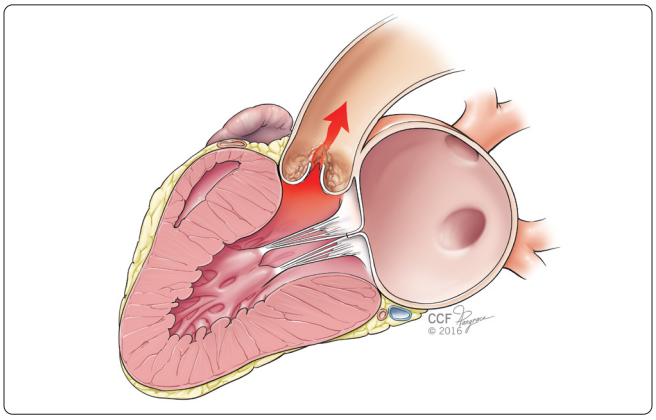
These outcomes were evident regardless of sex, receipt of other open-heart surgeries or underlying malignancy.

Significance of baseline LVEF

Survival benefits associated with AVR were significant only among patients with preserved (≥ 50%) left ventricular ejection fraction

"This study is a significant step in unraveling the moderate stenosis enigma, but further studies and trials are necessary to continue demystifying moderate stenosis." — MARIJAN KOPRIVANAC, MD, MS

BELOW — Illustration of a stenotic aortic valve. A new Cleveland Clinic study shows aortic valve replacement confers favorable clinical outcomes and left ventricular remodeling even in moderate cases of aortic stenosis, before symptoms become severe.



(LVEF), although there was a trend toward greater survival with AVR among patients with low LVEF.

Dr. Kapadia notes that the small number of patients with reduced LVEF in the AVR cohort may have limited the findings. It is also possible, he adds, that patients with low LVEF already have cardiac damage that cannot be significantly remedied with AVR. "More study is needed of this important question," he says.

Improved heart remodeling

Improved echocardiographic findings were also evident in patients who underwent AVR. In multivariable-adjusted analysis, these patients had significantly higher LVEF and lower right ventricular systolic pressure over time than patients managed with clinical surveillance, who worsened in both of those parameters over the study period.

Studying TAVR independently

Both TAVR and SAVR groups demonstrated significant benefit over clinical surveillance. Most AVR patients in the study had a surgical rather than transcatheter approach, reflecting the time period analyzed (2008-2016). Despite the small TAVR cohort size, a lower incidence of all-cause mortality was still evident in that group compared with clinical surveillance (adjusted HR = 0.45; 95% CI, 0.22-0.91; P = .026).

Several multicenter randomized controlled trials are underway to compare various TAVR devices against medical management for moderate AS: TAVR UNLOAD (NCT02661451), Evolut EXPAND TAVR II (NCT05149755) and PROGRESS (NCT04889872), with Cleveland Clinic participating in the first two trials.

"Our study findings make us more inclined to offer intervention to our AS patients earlier in the disease process, especially in light of treatment advances and increased understanding of the poor prognosis associated with moderate AS," Dr. Kapadia concludes. "I look forward to gaining more clarity from randomized controlled trials about identifying candidates and optimum timing for intervention."

Additional perspectives

"Now that procedural mortality is low for both TAVR and SAVR in expert centers, the next frontier in research in aortic valve disease is determining the optimal time to replace the valve," adds Brian Griffin, MD, Medical Director of Cleveland Clinic's Valve Center, who was not involved in the study.

"It has become clear in a number of studies," he continues, "that patients undergoing AVR do not always enjoy the survival benefit expected. This paper provides further insights into this phenomenon and raises the question of whether AVR should be performed at an earlier stage, at least at centers with outstanding procedural outcomes for SAVR and TAVR. Further studies are underway to try to address this important question."

"With the development of minimally invasive techniques for SAVR, such as mini-thoracotomy and partial sternotomy, patients experience less pain, faster recovery, earlier discharge (as soon as three days) and smaller scars compared with traditional complete sternotomy," adds cardiac surgeon Marijan Koprivanac, MD, MS, who was not involved in the study. "Considering this, along with the proven durability of SAVR and less than 1% mortality at some centers of excellence, the discussion about intervening in moderate AS becomes much easier. Given these important findings, intervening in moderate AS seems justified, and using safe, minimally invasive techniques to improve patient experience and outcomes may help avoid progression of heart failure due to AS. This study is a significant step in unraveling the moderate stenosis enigma, but further studies and trials are necessary to continue demystifying moderate stenosis."

Contact Dr. Kapadia at 216.444.6735, Dr. Griffin at 216.444.6812 and Dr. Koprivanac at 216.444.2035.

ARISE II UNDERWAY TO EVALUATE ASCENDING AORTA STENT GRAFT FOR ENDOVASCULAR REPAIR

Multicenter pivotal study is one outgrowth of the Cleveland Clinic-led MATADORS research collaboration

A first-of-its-kind ascending aorta stent graft (ASG) is being evaluated in the pivotal ARISE II trial. The investigation comes on the heels of the completed early feasibility ARISE I study, in which the novel endovascular device was implanted in 19 patients with Stanford type A aortic dissection at nine U.S. sites.

Updates on the ARISE trials were presented by Cleveland Clinic staff at the 104th annual meeting of the American Association for Thoracic Surgery (AATS) earlier this year. "We're in an exciting period of aortic management, with significant advances in monitoring and treatment on the horizon," says cardiothoracic surgeon Patrick Vargo, MD, Cleveland Clinic's site principal investigator in the ARISE trials.

TEVAR for the ascending aorta: An unmet need

The ascending aorta can be viewed as the final frontier of thoracic endovascular aortic repair (TEVAR), according to Eric Roselli, MD, national principal investigator of ARISE I and II and Chief of Adult Cardiac Surgery at Cleveland Clinic. Until recently, all endovascular stents for the aorta were designed for the descending or abdominal portions, which are straighter than the ascending aorta and have less dynamic pulsatility because of their greater distance from the heart.

"The ascending aorta has always posed special challenges to endovascular intervention," says Dr. Roselli, who also serves as Cardiac Surgery Director of Cleveland Clinic's Aorta Center. "We're now making progress in minimally invasive alternatives to open surgery for our high-risk patients."

The device studied in both ARISE trials is the GORE® ASG (Ascending Stent Graft). This investigational device is shorter than stents used in other parts of the aorta and is designed to articulate so it can foreshorten along the inner curve as it is deployed, allowing conformance to the shape of the vessel. "This purpose-driven design allows for incredibly precise deployment to avoid coronary obstruction and valve impingement, problems that plague other endovascular stents deployed off-label in the ascending aorta," Dr. Roselli says.

> "The ascending aorta has always posed special challenges to endovascular intervention. We're now making progress in minimally invasive alternatives to open surgery for our high-risk patients." — ERIC ROSELLI, MD

ARISE I demonstrates feasibility

The ARISE I single-arm study (*J Endovasc Ther.* 2023;30[4]:550-560) implanted the ASG in 10 patients with DeBakey type I disease (ascending aorta and aortic arch) and nine with type II disease (ascending aorta only). Patients were 58% female and had a mean age of 76 (range, 47-91). All were at high surgical risk, with 84% having acute dissection. Patients with severe aortic insufficiency or previous thoracic aortic surgery were excluded, as were those whose entry tear was less than 2 cm above the coronary ostia.

Thirty-day major adverse cardiovascular and cerebrovascular events occurred in five patients (26%), consisting of three deaths (16%), one disabling stroke (5%) and one myocardial infarction (5%).

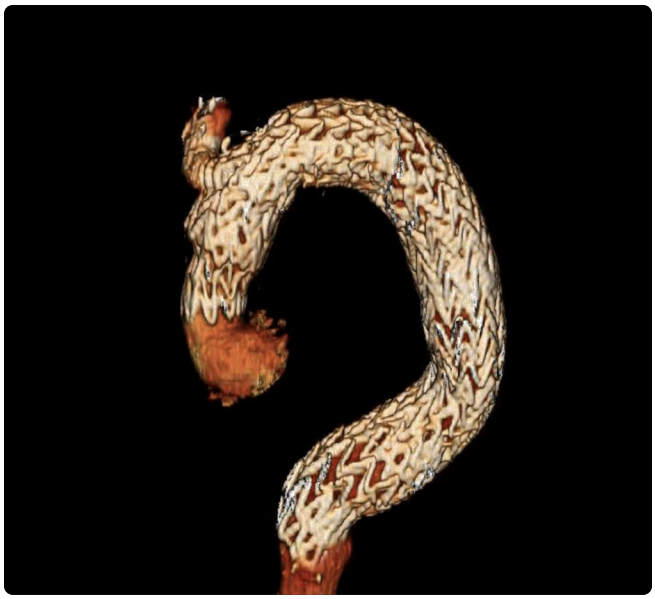
Dr. Vargo notes that acute ascending aortic dissection is associated with a reported 58% in-hospital mortality rate if repair is not performed. "The takeaway from ARISE I is that ascending aortic dissection can be treated with endovascular stent placement with high technical success and acceptable safety in high-risk patients who are not surgical candidates," he says.

ARISE II – current pivotal study

ARISE II (NCT05800743) is recruiting 370 high-risk patients at 27 sites in the U.S. who have nonacute type A pathologies of the ascending aorta and arch (e.g., fusiform and saccular aneurysms, pseudoaneurysms, chronic type A dissections and other isolated lesions). Patients are undergoing TEVAR with ASG alone or ASG plus a thoracic branch endoprosthesis and will be compared with similar patients from a high-risk open surgical registry.

Primary outcome measures (successful implantation, graft patency, absence of reintervention, and absence of major adverse cardiovascular and cerebrovascular events) are being assessed at

BELOW — Example of a device configuration from the ARISE II trial of the investigational ascending aorta stent graft.



BELOW — Dr. Roselli (center) during an aorta surgery. He is national principal investigator of the ARISE I and II trials.

30 days. Patients will be followed periodically through 60 months. The primary completion date is expected to be late 2029.

"Ascending stent grafting is an exciting development for the treatment of patients with type A aortic dissection and other ascending aortic pathologies who are at high surgical risk," notes Vidyasagar Kalahasti, MD, a staff cardiologist in Cleveland Clinic's Aorta Center. "ARISE II is a very important and pivotal study to potentially expand its use in other ascending aortic pathologies after demonstration of technical feasibility in the ARISE I trial."

Outgrowth of an interdisciplinary research project

Drs. Roselli and Vargo note that development of the ASG was aided by a collaborative research project that Dr. Roselli helped launch in 2016 known as MATADORS (Multidisciplinary Study of Ascending Tissue Characteristics and Hemodynamics for the Development of Novel Aortic Stentgrafts).

"MATADORS began in part to better understand the biomechanics and boundary conditions of the ascending aorta for devices like the one being used in the ARISE trials," Dr. Roselli explains. "It also has led to important discoveries in the realm of basic and translational research around the mechanisms of disease involving the thoracic aorta."

Aggrecan, a novel biomarker of aortopathy

One such discovery was the focus of a presentation at the AATS meeting by Cleveland Clinic cardiac surgery research fellow Benjamin Kramer, DO, PhD, that won the 2024 AATS Nicholas T. Kouchoukos Award for Outstanding Aortic Symposium Manuscript. This prospective research led to the identification of aggrecan, a large proteoglycan, as a blood biomarker of diseased aortas.

In a healthy aortic wall, aggrecan is deposited along with collagen fibers and smooth muscle cells in an orderly array that contributes to the vessel's integrity and elasticity. In prior studies, Cleveland Clinic investigators compared healthy and diseased ascending aorta samples and found that the latter had dramatically increased amounts of aggrecan and that the orderly structure was disrupted, likely contributing to the aortas' predisposition to type A dissections.

The new research discovered that aggrecan can be detected in the blood, with patients about to undergo surgery for ascending aortic aneurysm or dissection having significantly higher levels than those undergoing coronary artery bypass grafting or healthy controls.

"The identification of this blood biomarker associated with aortic wall fragility has the potential to lead to better surveillance of patients with aortic aneurysm," Dr. Vargo notes. "This could give us another means beyond aneurysm size for determining the appropriate time to intervene."

Contact Dr. Vargo at 216.444.2288, Dr. Roselli at 216.444.0995 and Dr. Kalahasti at 216.445.7259.

PERCUTANEOUS ARTERIAL BYPASS FOR LONG FEM-POP LESIONS: USES EXPAND AS EXPERIENCE MOUNTS

Early learnings on use of the minimally invasive alternative to surgical bypass

Soon after the first percutaneous transmural arterial bypass (PTAB) system received FDA approval in June 2023 to treat long-segment, complex femoropopliteal disease, Cleveland Clinic vascular surgeons performed the first commercial implantation of the system in the U.S.

Since then, PTAB has begun to leave its mark on the treatment landscape, offering a minimally invasive alternative to open surgical bypass for appropriate patients and showing promise in clinical scenarios extending beyond its initial instructions for use (IFU).

Cardiac Consult caught up with some Cleveland Clinic staff about their experience so far with PTAB technology and how its use may evolve.

PTAB at a glance

The PTAB system (DETOUR™ System) enables creation of a percutaneous femoropopliteal bypass using standard endovascular techniques, a crossing device and a stent graft. The system's IFU call for a proceduralist to enter the superficial femoral artery (SFA) origin and use the crossing device to cross into the femoral vein at least 3 cm distal to the origin of the vessel. The device is fed down the femoral vein and reenters the popliteal artery, landing above the tibial plateau in a nondiseased portion of the popliteal artery. Stent grafts are then lined from the distal end to the SFA origin.

"The system allows us to access an area of the popliteal artery behind the knee," says vascular surgeon J. Eduardo Corso, MD. "We normally don't perform open bypasses there because the patient would need to be flipped over to gain access. While we usually go either above the knee or below the knee with a prosthetic or vein bypass, with PTAB we can access the popliteal artery further down than the above-knee target and stent all the way down to the knee. The stents perform well in that area, a spot where many stents traditionally do not."

He notes that results in his PTAB cases to date compare favorably with those for prosthetic bypasses, particularly relative to bypasses below the knee, where outcomes beyond a year or two can be poor. "Also, PTAB does not compromise a potential future bypass to a location below the knee," Dr. Corso says.

Moreover, patients welcome PTAB's fully percutaneous approach. "Instead of a three- or four-day hospital stay and a 3% to 4% risk of major infection with bypass surgery, patients get an overnight stay or outpatient procedure with PTAB and almost no infection risk," notes Sean Lyden, MD, Chair of Vascular Surgery at Cleveland Clinic. "When patients learn about PTAB, they're eager to consider it."

Who's a candidate?

Only a relatively small minority of patients with peripheral artery disease (PAD) qualify for PTAB based on their disease anatomy. The PTAB system is officially indicated only for patients with long lesions (20-46 cm in length). "That represents only about 10% of the PAD patients we see," Dr. Lyden says. "The other 90% either have lesions that are too short or disease that is too extensive for this treatment."

Additionally, Drs. Lyden and Corso note, PTAB is not appropriate for patients whose popliteal artery is diseased or occluded and for those who have a compromised venous system with small veins.

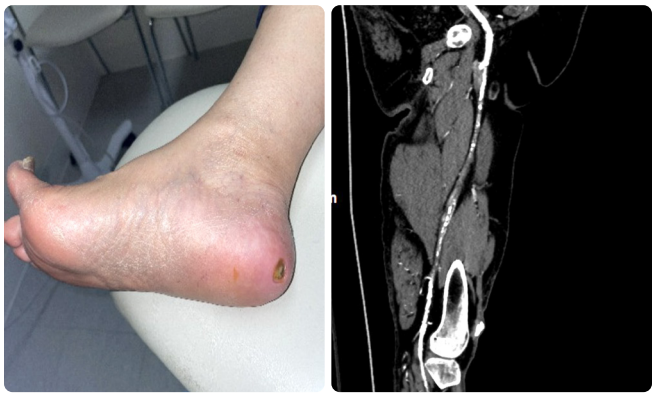
Dr. Corso says he has successfully performed PTAB in patients who had previous stenting procedures that failed and in patients in whom a prior femoral endarterectomy and profundoplasty was insufficient to address their moderate to severe PAD symptoms. "PTAB is a good option for patients with lesions that aren't easy to treat with a balloon or a stent and for whom open surgical bypass is difficult or too risky, perhaps because of likely poor wound healing," he says.

Measured assessment of expanded applications

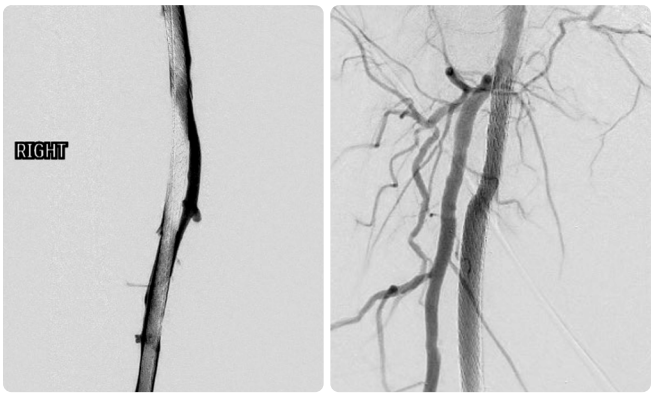
The formal indication for PTAB — symptomatic femoropopliteal lesions 20 to 46 cm in length with chronic total occlusion or diffuse stenosis of more than 70% — is based on the patient populations of the DETOUR 1 and 2 clinical trials that supported FDA approval. Pooled two-year data from these trials in 273 patients showed a clinical success rate of 95.3%, primary patency of 69.2%, freedom from target vessel revascularization of 68.1% and freedom from symptomatic deep vein thrombosis of 96.7%.

At the Vascular InterVentional Advances (VIVA) 2024 conference in November, Dr. Lyden reported final three-year results from the DETOUR 2 trial that are consistent with the above findings.

BELOW — Photo of a foot wound and CT of the diseased vessel segment in a patient prior to treatment with PTAB.



BELOW — Venograms from PTAB procedures. (Left) Image showing how the vein shares space with the stent graft following deployment. (Right) A representative PTAB completion image.



Meanwhile, in the nearly year and a half since the PTAB system won U.S. regulatory approval, its use in clinical practice has begun to expand a bit beyond its initial trial-based indication.

"The DETOUR trials were very specific about how large the artery had to be where you started the procedure and where you could finish it," Dr. Lyden says. "But just as for previous treatments in other realms of vascular surgery, operators in the real world look for ways to replicate the anatomic situation from the IFU so they can safely extend the treatment to a broader population."

Drs. Lyden and Corso have been privy to such extensions of the PTAB procedure via a series of advanced-user forums convened by the PTAB system's manufacturer. The aim is to exchange operators' experience with PTAB and lessons from new ways in which some operators are using the procedure. "The forums help maximize learning about the new technology and ensure that no one is working in isolation in these early days," Dr. Lyden says.

During the forums, Cleveland Clinic advocates for a measured, iterative approach to expanding how PTAB is used. "We feel the best way to do this is to take small steps outside the boundary conditions and to ensure reproducibility of results before proceeding further," Dr. Lyden says, citing three examples undertaken by Cleveland Clinic to date:

- Considering use in patients with a slightly smaller vessel diameter than the 5.5 mm recommended in labeling, to allow for the dilation that occurs once blood flow is restored
- Increasing the puncture distance beyond the tibial plateau from the recommended 10 cm so long as the landing zone is still in healthy vessel
- Considering use in the setting of a nonpatent proximal SFA if the SFA can be recanalized and allow passage of the crossing device

These extensions of the IFU have yielded outcomes consistent with those in the pivotal DETOUR trials both at Cleveland Clinic and elsewhere, Dr. Lyden reports.

He says the advanced-user forums allow early adopters of PTAB to pool their experience with small innovations they have each tried on their own; participants plan to start collecting data and potentially publish their collective experience.

Meanwhile, the manufacturer of the PTAB system has started a postmarket registry to capture outcomes of all uses of the system in clinical practice. Cleveland Clinic is participating in the registry, which is part of the Society for Vascular Surgery's Vascular Quality Initiative.

"We are very supportive of this registry as an effort to accurately understand real-world use of PTAB," Dr. Lyden says. "It's an ideal way to ensure safety and efficacy for the system's established indications and to guide and refine potential innovations in its use."

An additional perspective

"PTAB offers reduced hospital stays and reduced infection risk for patients with complex PAD," adds Aravinda Nanjundappa, MBBS, MD, a Cleveland Clinic interventional cardiologist and vascular medicine specialist. "While PTAB is currently indicated for lesion lengths of 20 to 46 cm, it has shown promise in treating failed prior interventions and patients unsuitable for traditional bypass, and this ongoing data collection is likely to gradually expand its application to more patients."

Contact Dr. Corso at 440.333.8600, Dr. Lyden at 216.444.3581 and Dr. Nanjundappa at 216.445.5846.

REGISTRY STUDY IDENTIFIES HALLMARKS OF APICAL HYPERTROPHIC CARDIOMYOPATHY

New risk score pools factors that may predict adverse outcomes in this uncommon phenotype

Cleveland Clinic researchers have identified five specific characteristics that distinguish patients with apical hypertrophic cardiomyopathy (aHCM), a distinct but little-known variant of HCM. The results — from a registry study of one of the largest reported cohorts with aHCM in a non-Asian population — were published in *JACC: Advances* (2024 Epub 1 Sep).

"We felt it was important to identify specific characteristics in patients with apical HCM that impact their future outcome, given the known phenotypic differences between apical and obstructive HCM," says senior and corresponding author Milind Desai, MD, MBA, Director of the Hypertrophic Cardiomyopathy Center at Cleveland Clinic. "We also created an apical HCM risk score, which uses age, apical aneurysm, left atrial volume index, serum creatinine and right ventricular systolic pressure to help predict the likelihood of adverse events in this population."

Understanding apical HCM

Apical HCM, which involves hypertrophy confined primarily to the left ventricular apex, is a relatively uncommon phenotype, reported in approximately 1 in 4 Asian patients with HCM and 10% or fewer non-Asian patients. Management can be challenging because the phenotype is not adequately addressed in major HCM guidelines and differs from that of the approximately 70% of HCM cases that involve dynamic left ventricular outflow tract obstruction.

Symptoms associated with aHCM are caused by diastolic dysfunction, abnormal lusitropy, microvascular angina and low stroke volume resulting from a small ventricular cavity. Recent reports have called into question long-held assumptions that aHCM is a more benign variant of HCM and that prevalence is low in non-Asian populations.

Mining data for aHCM insights

Data for the new research were from 462 patients diagnosed with aHCM at Cleveland Clinic between January 2001 and February 2021. Diagnosis was based on typical features, including apical wall thickness ≥ 15 mm and a ratio of maximal apical to posterior wall thickness ≥ 1.5, as assessed by experienced cardiologists using 2D transthoracic echocardiography and, in 53% of patients, cardiac magnetic resonance imaging.

The cohort comprised 6.8% of the 6,785 patients in the institution's HCM registry during the study period. The aHCM cohort had a mean age at diagnosis of 58 years and was 68% male and 70% white.

Goals of the analysis were to describe characteristics that distinguish aHCM and then use those factors to develop a risk score for patients with the condition. The primary endpoint was a composite of death, appropriate defibrillator discharge or need for cardiac transplantation over the duration of follow-up in the registry.

To identify variables potentially linked to the primary endpoint, the authors conducted univariable survival analysis, after which variables were assessed in a multivariable Cox regression model to determine which were predictive of survival.

At baseline, 67% of patients were asymptomatic and 69% had no risk factors for sudden death. Baseline imaging revealed the following cohort characteristics:

- Mean left ventricular ejection fraction of 64% ± 8%
- Mean left atrial volume index of 36 ± 15 mL/m^2
- Mean right ventricular systolic pressure of 32 ± 10 mm Hg
- 11% prevalence of apical aneurysm

Over mean follow-up of 6.3 years, the primary composite endpoint occurred in 80 patients (17%), including death in 62 (13%). This translated to a composite event rate of 2.8% per year and a death rate of 2.1% per year. The authors note that these are higher than the rates of 1.3% and 1.1% per year, respectively, in an earlier report of Cleveland Clinic experience in patients with obstructive HCM (*J Thorac Cardiovasc Surg.* 2018;156[2]:750-759).

"The difference likely reflects a lack of proven treatments for apical HCM, whereas septal reduction therapies have been shown to provide excellent symptom relief and longer-term survival for obstructive HCM," Dr. Desai notes. "It also suggests that apical HCM is not as benign as initially believed."

Risk score components

In the multivariable model, five variables were found to be statistically significantly predictive of the primary endpoint:

- Age ≥ 65 years at diagnosis (particularly > 80 years)
- Presence of apical aneurysm at baseline

- Serum creatinine > 1.4 mg/dL
- Left atrial volume index ≥ 48 mL/m^2
- Right ventricular systolic pressure > 50 mm Hg

Using the five variables above, the authors developed an aHCM-specific risk prediction score with a range of 0 to 8 points. Factors with the highest individual scores were age > 80 (3 points) and left atrial volume index ≥ 48 mL/m^2 (2 points).

Applying the aHCM risk score to the study participants, the authors observed a graded increase in the rate of the composite primary endpoint that corresponded with increasing risk scores, as follows:

- 1.3% per year with a score of 0
- 2.4% per year with a score of 1
- 6% per year with a score of 2
- 7% per year with a score ≥ 3

The aHCM-specific risk score showed good discrimination, with a C statistic of 0.75, and good calibration, with an expected-to-observed ratio of 1.02 and a calibration slope of 0.91. These associations were stronger than those of American College of Cardiology/American Heart Association risk factors, and there was no association between the European Society of Cardiology risk score and this study's primary endpoint on univariable analysis.

Clinical perspectives

The authors believe the risk score holds promise for improving prognostication for longer-term composite events in aHCM patients with no need for cumbersome computation, but they caution that their results require external validation.

"In the meantime," Dr. Desai recommends, "clinicians should recognize that patients with apical HCM do not have a benign prognosis and should undergo diligent phenotypic characterization and risk stratification that goes beyond standard guideline-recommended stratification tools."

"Once apical HCM is suspected," adds co-investigator Nicholas Smedira, MD, MBA, Surgical Director of the Hypertrophic Cardiomyopathy Center, "every effort should be made to identify the area with maximal wall thickness and apical aneurysm formation using multimodality imaging. Mounting evidence suggests that debulking apical myectomy may be of benefit as an alternative to heart transplant in severely symptomatic apical HCM."

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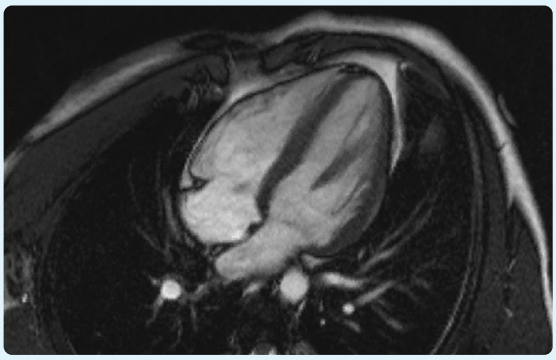
Contact Dr. Desai at 216.445.5250 and Dr. Smedira at 216.445.7052.



More HCM Research

Researchers with Cleveland Clinic's Hypertrophic Cardiomyopathy Center published several other notable clinical investigations in recent months.

In a study published in the *American Journal of Cardiology* (2024;227:48-56), they prospectively assessed imaging modalities for key measurements that guide surgical myectomy. The study concluded that for measuring septal wall thickness, preprocedural cardiac magnetic resonance imaging should remain the mainstay, as intraoperative 3D transesophageal echocardiography (TEE) with multiplanar reconstruction overestimates septal thickness, especially in milder hypertrophy. In contrast, 3D TEE multiplanar reconstruction remains the mainstay for measuring mitral leaflets, and such measurements vary enough among modalities and techniques that extrapolation should be avoided.

Additionally, Cleveland Clinic-led researchers with the pivotal VALOR-HCM study of mavacamten published subanalyses of the trial focused on findings from ventricular strain imaging (*Circ Cardiovasc Imaging*. 2024;17[9]:e017185) and left atrial strain imaging (*JACC Cardiovasc Imaging*. 2024 Epub 2 Sep) at 56 weeks of follow-up. Among the study's population of patients with severe symptomatic obstructive HCM, treatment with mavacamten provided sustained improvement in left ventricular global longitudinal strain with no detrimental effect on right ventricular systolic function, as well as sustained improvement in left atrial volume index and left atrial strain. These findings are in addition to the drug's significant effect in reducing the need for septal reduction therapy, the study's primary endpoint.

HELLER MYOTOMY FOR ESOPHAGEAL ACHALASIA: 15-YEAR FREEDOM FROM REINTERVENTION IS > 80%

25-year series of over 1,000 patients reveals good long-term palliation, esophageal preservation

Fifteen years following Heller myotomy for esophageal achalasia, over 80% of patients are free from reintervention, and the vast majority of patients who need a reintervention can be taken care of with endoscopic procedures such as pneumatic dilation or peroral endoscopic myotomy (POEM).

So found a retrospective study of 1,010 patients treated with Heller myotomy for esophageal achalasia at Cleveland Clinic from 1995 to 2020, during which fewer than 2% required esophagectomy. The results were presented earlier this year at the 104th annual meeting of the American Association for Thoracic Surgery.

"Scarce long-term outcomes data have been published for this relatively rare surgery," says senior investigator Siva Raja, MD, PhD, Surgical Director of the Center for Esophageal Diseases at Cleveland Clinic. "As a result, there is no consensus on optimal follow-up, and clinicians have struggled to advise patients about their prospects beyond the first few postoperative years."

Heller myotomy, the longtime standard

Achalasia is a rare esophageal motility disorder involving the absence of esophageal peristalsis and a nonrelaxing lower esophageal sphincter. Patients may have significant swallowing problems, regurgitation, chest pain and weight loss. "Although achalasia is not a malignant disease, the quality-of-life effects can be quite significant," Dr. Raja notes.

For over a century, the classic treatment has been Heller myotomy to create a surgical division of the lower esophageal sphincter, facilitating passage of food out of the esophagus.

The methods have evolved over the years: Originally performed with a thoracotomy, it is now often accomplished laparoscopically or robotically — and, more recently, endoscopically. Heller myotomy is usually accompanied by a Dor fundoplication, involving partial wrapping of the stomach around the esophagus to create a low-pressure valve to reduce reflux.

Despite the considerable experience surgeons have had with Heller myotomy, how the procedure relieves symptoms of achalasia is not completely understood. This study was designed not only to assess long-term symptom palliation and need for reintervention after the procedure, but also to analyze effects on esophageal emptying over time.

Study design and reintervention rates

Across the cohort of 1,010 patients from 1995 to 2020, 74% of myotomies were performed laparoscopically and 19% with robotic assistance. "Robotic myotomy was used almost exclusively in the last five to six years of the study period," Dr. Raja notes. Nearly all patients also underwent Dor fundoplication.

Patients were assessed annually for at least the first three years after myotomy, and every two to three years thereafter.

Over the course of the study, 187 reinterventions were performed in 134 patients, as follows:

- Pneumatic dilation (n = 122)
- POEM (n = 39)
- Repeat Heller myotomy (n = 10)
- Esophagectomy (n = 16)

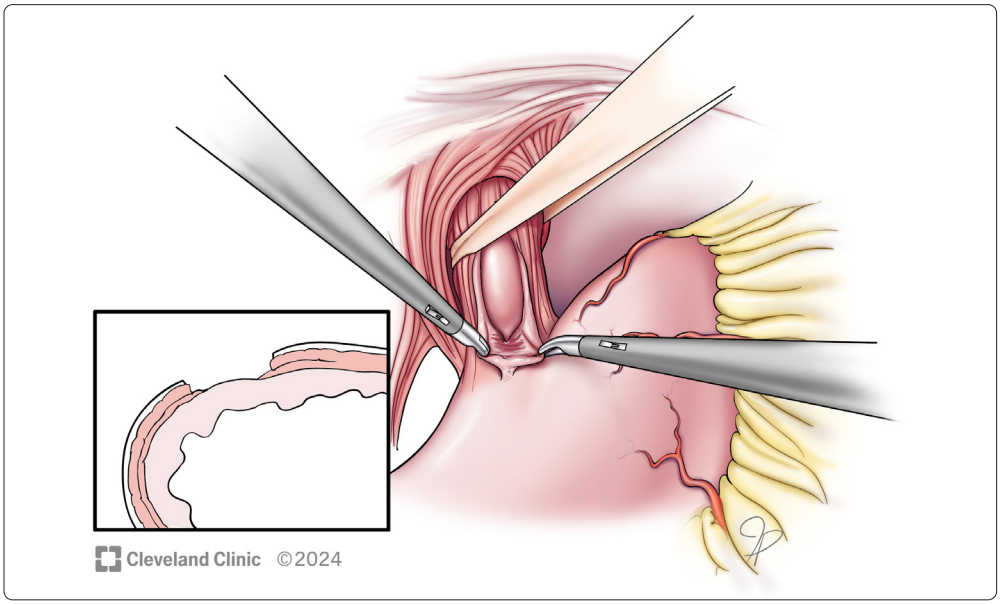
Patients who underwent reintervention were at increased risk for a subsequent one: While 81% of the entire cohort was free from reintervention after 15 years, only 64% of those patients who underwent reintervention were free from a second reintervention 12 years after the first.

Symptom palliation

Follow-up monitoring included Eckardt scoring, which assigns a point value from 0 (never) to 3 (with each meal) for each of three symptom categories — dysphagia, chest pain and regurgitation — as well as for weight loss, where 0 denotes no weight loss and 3 indicates loss of more than 10 kg.

Conventionally, an Eckardt score ≤ 3 is considered successful. In this cohort, a score ≤ 3 was achieved in 93% of patients at one year and 73% at 10 years. Patients who eventually needed a reintervention had higher scores early on.

"We could predict patients who required a reintervention based on early appearance of symptoms," Dr. Raja says. "The good news is that after we reintervened, these patients achieved Eckardt scores close to those of the overall group."



LEFT — Illustration of a key step in the Heller myotomy procedure, which involves surgical division of the lower esophageal sphincter to facilitate passage of food. Here a bougie is passed to assist myotomy.

He adds that while the presence of symptoms at the first preoperative visit does not provide good prognostic information, patients with persistent symptoms within the first two years need to be followed closely and considered for reintervention. Most reinterventions were needed in the first few years after myotomy.

Esophageal emptying doesn't correlate with symptom relief

Follow-up monitoring also included timed barium esophagogram (TBE), which involves measuring the height and width of the esophageal column with an X-ray at one and five minutes. The TBE was devised at Cleveland Clinic about 30 years ago specifically for patients with achalasia to indicate how quickly the esophagus empties.

"A normal esophagus empties in about 30 seconds," Dr. Raja notes, "whereas a patient with achalasia may feel great even if it takes five minutes to completely empty, as it could have taken hours to days to empty prior to surgery." Using five minutes as the standard, 56% of patients in the cohort achieved complete emptying immediately after myotomy, which gradually decreased to 24% at 10 years.

Interestingly, he adds, it was not necessary to have complete emptying to achieve excellent symptom relief. Few patients who required a reintervention ever achieved complete emptying at five minutes. After reintervention, TBE improved only modestly, yet patients achieved good Eckardt scores.

"There is a discordance between how patients feel and how their esophagus behaves," Dr. Raja says. "We still do not understand this adequately."

Implications for practice

In view of these findings, Dr. Raja recommends that patients have annual follow-up with Eckardt score assessment and TBE for the first three years after myotomy, after which the follow-up interval can be lengthened to every two to three years. "The risk of symptom recurrence and need for reintervention are greatest early on after myotomy," he explains. He recommends endoscopic surveillance every five years in all patients on a lifelong basis, as well as in the wake of worsening symptoms or emptying.

Dr. Raja emphasizes that this large series demonstrates that Heller myotomy provides durable long-term palliation for esophageal achalasia, with the esophagus preserved in more than 98% of cases. "Regarding the role of newer endoscopic interventions for this indication, this is the bar that must be met," he concludes.

"Not only does this study demonstrate the long-term success in palliation with Heller myotomy, it also guides our surveillance for these patients after their surgery and our strategies for reintervention in case they need it," adds Cleveland Clinic thoracic surgeon Monisha Sudarshan, MD. "For such a rare disease and infrequent surgery, these results will be vital in shaping our practice for patients with achalasia."

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Contact Dr. Raja at 216.444.4063 and Dr. Sudarshan at 216.445.9579.

[CASE STUDY IN COLLABORATION]

CLINICAL ASSESSMENT AND COLLABORATION DRIVE SUSTAINED IMPROVEMENT IN POST-CABG PROLONGED VENTILATION RATES

How Cleveland Clinic supported an alliance hospital to improve early extubation practices

Prolonged ventilation has been identified by the Society of Thoracic Surgeons (STS) as a key quality measure following cardiac surgery due to its incidence, as it affects up to 22.7% of patients,[1] and its impact on postsurgical recovery and quality metrics. Furthermore, prolonged ventilation beyond three days has reportedly been associated with in-hospital mortality rates as high as 25% to 50%.[1]

Weaning from mechanical ventilation following cardiac surgery may be challenging for some patients due to several factors, such as preexisting lung disease, heart failure, severe obesity and advanced age. However, the timing of extubation plays a critical role in determining surgical outcomes. During the immediate postoperative period, the return of spontaneous breathing and timely extubation are priority clinical milestones that should occur within 24 hours of surgery. Prolonged ventilation (intubation) is defined by the STS as total intubation time of more than 24 hours following isolated coronary artery bypass graft surgery (CABG), measured from the time of exiting the operating room to extubation.

Early extubation is a priority since it reduces length of stay in the cardiovascular intensive care unit and the hospital and also lowers patients' risk of developing pneumonia and other infectious complications, as well as reducing the cost of care.

Prolonged ventilation is one of many metrics for which Cleveland Clinic's Heart, Vascular and Thoracic Institute Advisory Services and Affiliate Program (ASAP) offers assessment and proactive solutions to hospitals domestically and internationally.

"Early extubation following heart surgery … takes perioperative planning, standardization of care protocols and real-time intervention from bedside caregivers …. We congratulate the St. Luke's cardiac surgery team on the sustained high-level performance of their program."

— EDWARD SOLTESZ, MD, MPH

Value of Cleveland Clinic's Advisory Services and Affiliate Program

St. Luke's Hospital, a 493-bed hospital located west of St. Louis in Chesterfield, Missouri, entered an alliance relationship with Cleveland Clinic's Heart, Vascular and Thoracic Institute in 2016. During Cleveland Clinic's initial comprehensive service line assessment, which included postoperative critical care management, it was apparent that St. Luke's cardiovascular service line prioritizes patient safety and is dedicated to achieving quality outcomes. Participation in the STS Adult Cardiac Surgery Database has helped prioritize the hospital's quality improvement efforts.

One year following affiliation, the St. Luke's cardiac surgery team had achieved a post-CABG prolonged ventilation rate that was better than the STS national average (5.5% vs. 5.73%). However, the clinical providers and administrators were confident they could improve their performance on this metric, and they invited input from Cleveland Clinic to assist.

Actions taken

Cleveland Clinic's ASAP team conducted an in-depth evaluation of St. Luke's outcomes, a thorough review of individual cases, and a comprehensive review of clinical practices, policies and protocols as well as staffing and workflows. Following the assessment, a detailed report of findings and recommendations was provided to St. Luke's. The ASAP team then worked closely in collaboration with the St. Luke's team to implement recommended changes and track and trend outcomes.

Several clinical practice changes were recommended and implemented, including:

- Protocol and workflow enhancement
- Staffing modifications
- Communication improvement

BELOW — Percentage of St. Luke's Hospital patients undergoing isolated CABG who had prolonged ventilation time since the improvement initiative began.

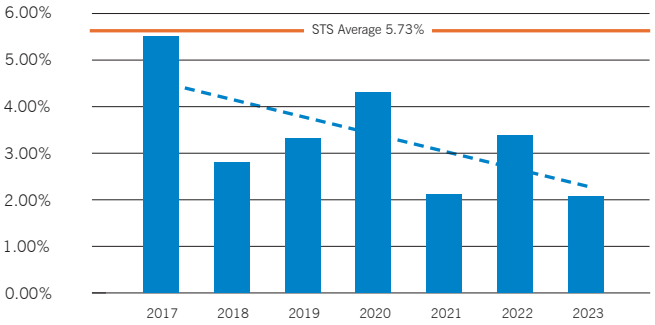

TABLE. St. Luke's Hospital's Ratings on CABG Quality Metrics From the Society of Thoracic Surgeons (STS)

STS CABG Domain	Jan. 2019 to Dec. 2021	Jan. 2020 to Dec. 2022	Jan. 2021 to Dec. 2023
Overall	★★★	★★★	★★★
Absence of mortality	★★★	★★★	★★★
Absence of morbidity	★★★	★★★	★★★
Use of internal mammary artery	★★★	★★★	★★★
Medications	★★★	★★★	★★★

Swift and sustained improvements

The changes were associated with swift improvement in St. Luke's rate of prolonged ventilation in post-CABG patients, which declined from 5.5% in 2017 to less than 3% in 2018.

Over the course of St. Luke's alliance with Cleveland Clinic, additional clinical and program changes were implemented to optimize and sustain postoperative critical care practices. These included changes in:

- The postoperative care model
- Staff education
- Data transparency
- Metric tracking

Together with Cleveland Clinic's recommendations, the commitment of St. Luke's Hospital to implementing best practice strategies to improve prolonged ventilation metrics has yielded sustained improvement, as shown in the figure above.

Broader quality-ratings success

St. Luke's was able to leverage improvement in preventing prolonged ventilation — along with optimization of other clinical processes — to achieve a three-star CABG composite quality score rating from STS in 2018, and it has sustained this top rating (see table above). These improvements cemented the hospital's status as one of the nation's top-performing cardiac surgery programs for CABG, since only 20% of STS registry participants receive a three-star rating for isolated CABG.

To support this sustained success, Cleveland Clinic and St. Luke's continue their collaboration on quality, data registries and clinical best practices through routine meetings involving physicians, nursing leaders and quality improvement team members from both organizations. Further value is provided through annual site visits for clinical observation, evaluation of real-time care processes, and sharing of care protocols and staff education resources.

"Since our collaboration with Cleveland Clinic began in January 2016, we have seen additional improvements in quality and have sustained great process changes with their support," says Sue Scego, RN, BSN, MHA, Executive Director of St. Luke's Heart & Vascular Institute. "An example is our continued three-star STS rating in CABG, the highest possible rating for surgical excellence and patient outcomes. We were able to implement additional evidence-based process changes on a large scale to make meaningful progress in prolonged ventilation, which has enabled us to outperform other programs in this category."

"Early extubation following heart surgery is an important but difficult metric to address," notes Edward Soltesz, MD, MPH, Director of Cardiac Surgery Affiliate Programs at Cleveland Clinic. "It takes perioperative planning, standardization of care protocols and real-time intervention from bedside caregivers. Furthermore, sustaining a three-star STS rating year over year requires tremendous commitment, multidisciplinary decision-making and dedication to quality. We congratulate the St. Luke's cardiac surgery team on the sustained high-level performance of their program."

REFERENCE

1. Nicolotti D, Grossi S, Nicolini F, et al. Difficult respiratory weaning after cardiac surgery: a narrative review. *J Clin Med.* 2023;12[2]:497.

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

[CME PREVIEW]

STRUCTURAL VALVE IMAGING SUMMIT RETURNS WITH STATE-OF-THE-ART PROGRAM, ABUNDANT EXPERT INTERACTION

27th offering of this CME favorite to be held March 6-9 in Hollywood, Florida

27th Structural Valve Imaging Summit

Thu.-Sun., March 6-9, 2025
The Diplomat Beach Resort
Hollywood, Florida
Information/registration: ccfcme.org/echo

Over a long weekend in early March, Cleveland Clinic will be convening more than two dozen experts in structural heart disease and imaging in Southeast Florida for this premier CME course.

"Now in its 27th year, our state-of-the-art program spans all aspects of valve disease, structural interventions, myopericardial diseases and more," says summit co-director Christine Jellis, MD, PhD, MBA, of Cleveland Clinic's Section of Cardiovascular Imaging. "With a focus on innovation and by leveraging the considerable experience of Cleveland Clinic, we showcase new technologies, provide practical clinical pearls and offer hands-on technical experience through interactive workshops."

"The course uses a mix of formats, including many case-based discussions, to focus on the latest advances in structural and valve disease and the imaging that guides procedural treatments," adds summit director Allan Klein, MD, who leads Cleveland Clinic's Pericardial Diseases Center. "New this year will be a debate on artificial intelligence and a fun *Jeopardy*-style session on echocardiography and other imaging modalities. There will also be a hands-on learning lab with structural interventions and imaging demonstrated by leading experts using the latest devices and imaging equipment."

The faculty — drawn from Cleveland Clinic sites in Ohio and Florida as well as several other top U.S. institutions — includes leaders in cardiovascular imaging, interventional cardiology, electrophysiology, heart failure and congenital heart disease, as well as cardiac surgeons, sonographers and other expert clinicians.

All the latest in structural disease and imaging

The first four of the summit's seven main sessions are devoted to the latest developments in each of the major areas of valve disease — mitral, aortic and tricuspid — and in structural interventions for atrial fibrillation and left atrial appendage closure. These sessions all feature discussions specific to imaging strategies and surgical and interventional approaches, along with other timely topics of interest and illustrative case presentations. "We will spotlight the latest advances, with a focus on surgical as well as structural interventional management and the underlying imaging that informs decision-making," says summit co-director Samir Kapadia, MD, Chair of Cardiovascular Medicine.

Additional sessions are dedicated to diastology and to myocardial and pericardial diseases. Highlights of these include a preview of forthcoming diastology guidelines; insights on the latest in diagnosis and management of recurrent pericarditis, hypertrophic cardiomyopathy and cardiac amyloidosis; and exploration of the role of pulsed-field ablation for atrial fibrillation in patients with structural heart disease.

Further highlights include a collection of lively debates — on transcatheter versus surgical aortic valve replacement in a 65-year-old, on medical management versus early structural intervention for severe tricuspid regurgitation with minimal symptoms, and on whether echocardiograms of the future will be read by artificial intelligence or clinicians.

The agenda also includes two simultaneous sessions where attendees can choose between how-to sessions — one on 3D image reconstruction and cropping in valve disease, and one on strain and diastology implementation/interpretation — and in-depth expert discussions on complex case presentations.

Abundant interaction — and afternoons free

In these simultaneous sessions and in Q&A segments that conclude all the main sessions, attendees can directly discuss questions and cases with faculty. "A fundamental aspect of our course is the abundant opportunity for interaction with experts in diagnosis and management of complex cases of structural heart disease," says summit co-director Leonardo Rodriguez, MD, Program Director of Cleveland Clinic's Advanced Imaging Fellowship.

The summit's core agenda runs from Friday through Sunday, with early starts each morning and adjournment by lunchtime so attendees can enjoy Florida's March climate all afternoon. The summit kicks off with an optional learning lab on interventional echocardiography on Thursday evening, March 6, featuring hands-on instruction from a multidisciplinary slate of instructors.

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

CARDIAC CONSULT STAFF

Cardiac Consult is produced by Cleveland Clinic's Heart, Vascular and Thoracic Institute.

Medical Editors

Lars G. Svensson, MD, PhD | svenssl@ccf.org

Brian Griffin, MD | griffib@ccf.org

Oussama Wazni, MD, MBA | waznio@ccf.org

Managing Editor

Glenn R. Campbell

Art Director

Chip Valleriano

Marketing

Colleen Burke, **Jackie Riggle**, **Suzanne Anthony**, **Morgan Bischof**

Photography

Shawn Green, Brian Kohlbacher, Russell Lee

Illustration

Joseph Pangrace

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