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PREEMPTIVE ADVANCED MECHANICAL CIRCULATORY SUPPORT IN HIGH-RISK CARDIAC SURGERY — p. 3

DEAR COLLEAGUES,

As this publication went into layout, I was returning from the 2024 annual meeting of the American Association for Thoracic Surgery (AATS). As President of AATS, I was privileged to be involved in content planning for the meeting.

In that capacity, I had a window into some of the knowledge gaps that the AATS aimed to address at the meeting as well as the topics on which AATS members most often focused their abstract submissions. I am pleased to see that two issues that were educational priorities at the AATS meeting — (1) management of complex patients requiring complex operations, and (2) perioperative care — are also major focal points of the cover story for this issue of *Cardiac Consult*.

That article, which begins on the facing page, details how Cleveland Clinic surgeons and cardiologists are pioneering successful management of one of the most complex patient populations encountered today: high-risk cardiogenic shock patients in need of coronary artery bypass grafting, valvular surgery, support devices or heart transplantation. In selected patients, our surgeons are using preemptive advanced mechanical circulatory support with the Impella 5.5 heart pump to reduce the grave risk of postcardiotomy cardiogenic shock and improve patient outcomes. As the article makes clear, success requires exquisite perioperative management in addition to deep surgical expertise and judiciousness.

As this example illustrates, our Heart, Vascular & Thoracic Institute strives to keep pace with the most pressing challenges in our specialties. We welcome opportunities to apply these efforts to best meet the needs of your complex patients who may require referral care.

Respectfully,

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

Cleveland Clinic's Miller Family Heart, Vascular & 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 — Edward Soltesz, MD, MPH (left), and Anthony Zaki, MD, during a recent heart operation. They are among the Cleveland Clinic cardiac surgeons pioneering the preemptive use of advanced mechanical circulatory support to reduce the risk of postcardiotomy cardiogenic shock in high-risk patients who need conventional cardiac operations. For details on the approach, including its evaluation in an ongoing multicenter trial, see the article starting on page 3.

WHAT'S THE ROLE OF PREEMPTIVE ADVANCED MECHANICAL CIRCULATORY SUPPORT IN CARDIAC SURGERY?

Preoperative Impella 5.5 placement can provide a critical safety net for high-risk patients

Often, patients with low ventricular ejection fraction are in need of conventional cardiac surgery but are denied the opportunity. Surgeons may be reluctant to operate because of the risk of postcardiotomy cardiogenic shock, which often requires treatment with high-dose inotropic and vasopressor medications and the use of advanced mechanical support. Despite such measures, cardiogenic shock in this setting is often fatal in the first few postoperative days.

With the goal of expanding treatment options for patients at high risk of cardiogenic shock who are in need of coronary artery bypass grafting (CABG) or valvular surgery, Cleveland Clinic surgeons are *preemptively* employing the Impella 5.5 — a microaxial temporary left ventricular assist device (LVAD) — in selected patients. The device has several advantages over an intra-aortic balloon pump or extracorporeal membrane oxygenation. It can provide full left ventricular support for up to 14 days and allows patients to ambulate and recover while the heart is unloaded and supported. The Impella 5.5 is currently FDA-approved for cardiogenic shock after cardiac surgery or acute myocardial infarction.

"Patients with a low ejection fraction potentially benefit most from CABG or valve repair, so we are trying to make these procedures safer for them," says Edward Soltesz, MD, MPH, Surgical Director of Cleveland Clinic's Kaufman Center for Heart Failure Treatment and Recovery. "In our more than five years of experience employing preemptive Impella support, we have found that it leads to much better outcomes than reactive support."

Determining candidacy: many factors to consider

Use of advanced mechanical circulatory support can be a lifesaving measure, but it also entails risk of serious and even fatal complications, including myocardial puncture, thromboembolism and limb ischemia. Conventional thinking is to not use it for surgical patients until it is needed postoperatively. However, evidence indicates that mechanical support after postcardiotomy cardiogenic shock has developed is associated with high mortality, while preoperative or intraoperative mechanical support offers long-term survival similar to that of patients not requiring it.

Based on their experience, Cleveland Clinic surgeons have published several papers providing guidance on candidacy selection and management strategies for preemptive Impella use: *Innovations.* 2021;16(3):227-230; *Artif Organs.* 2024;48:6-15; and *Ann Thorac Surg.* 2024;117(5):940-941. These articles all stress the importance of thorough coronary target and ischemic territory assessment, as well as myocardial viability and recovery potential.

"For patients with good targets, low scar burden and well-compensated heart failure, preemptive Impella placement is likely unnecessary," says Michael Tong, MD, MBA, Director of Cardiac Transplantation and Mechanical Circulatory Support. "On the other end of the spectrum, very poor targets and extensive scarring are indicators of unlikely success of reparative surgery, and patients should be considered for heart transplantation or placement of a durable LVAD."

"For patients with marginal targets and some increased scar tissue, we can be successful with preemptive mechanical support," adds Faisal Bakaeen, MD, Director of Cleveland Clinic's Coronary Artery Bypass Surgery Center. "Impella support is also an important strategy for patients with kidney or liver dysfunction, to maintain organ perfusion while buying time for the heart to recover."

In a recent study in the *Journal of Thoracic and Cardiovascular Surgery* (*JTCVS*; Epub 2024 Mar 5), Cleveland Clinic surgeons reported on the use of random forest data analysis to assess potential risk factors of postcardiotomy cardiogenic shock. The

"In our more than five years of experience employing preemptive Impella support, we have found that it leads to much better outcomes than reactive support."

— EDWARD SOLTESZ, MD, MPH

"These patients tend to be complex, with a different risk profile than is typically encountered in hospitals with less volume-based experience. Rather than passing over these high-risk patients, we highly recommend referral to a high-volume tertiary center for evaluation and treatment." — FAISAL BAKAEEN, MD

following factors were identified to be highly associated with postcardiotomy cardiogenic shock:

- Pulmonary artery pulsatility index < 3.5 and pulmonary capillary wedge pressure > 19 mm Hg in the setting of ischemic cardiomyopathy
- Cardiac index < 2.2 L/min/m^2 and pulmonary capillary wedge pressure > 21 mm Hg in the setting of nonischemic cardiomyopathy

"Identifying predictors of postcardiotomy cardiogenic shock helps us determine which patients are likely to benefit from preemptive Impella placement," Dr. Soltesz adds. "Ultimately, however, it's a judgment call based on our experience and on consideration of factors such as frailty and length of time the patient has been in intensive care."

"We identified that the biggest predictor of how well a patient will tolerate the open-heart surgery is how well compensated they were going into surgery," notes Dr. Tong.

This is an area where close collaboration with cardiologists, particularly advanced heart failure cardiologists, can be valuable, adds Amanda Vest, MBBS, MPH, Section Head of Heart Failure and Transplantation Cardiology. "Preoperative heart failure optimization can be key to a patient's operative success, often through a combination of diuresis, optimization of medical therapies or, in some cases, the use of temporary mechanical circulatory support to improve a patient's hemodynamics before the surgery," she says.

Perioperative strategies

Cleveland Clinic surgeons emphasize that once the decision is made to pursue a strategy of preemptive Impella use, patients are best managed with thorough preoperative assessment, well-timed intervention and perioperative optimization.

Postoperatively, they aim for early extubation and ambulation. They advise gradual Impella withdrawal by turning down the device by one to two power levels daily, as tolerated. In most cases, the device can be removed four days postoperatively. Weaning and removal should be guided by hemodynamic improvement rather than echocardiographic changes, which manifest more slowly.

The surgeons also emphasize having planned exit strategies if a patient cannot be weaned from the Impella. For particularly high-risk patients, they recommend preoperative evaluation for heart transplantation or durable LVAD placement so that such options can be pursued if needed.

"Our heart failure consultation team routinely meets with patients with low ejection fraction prior to their surgery," Dr. Vest notes, "to determine their wishes and scope to benefit from a transplant or durable LVAD should the postoperative course require these considerations."

The IMPACT trial

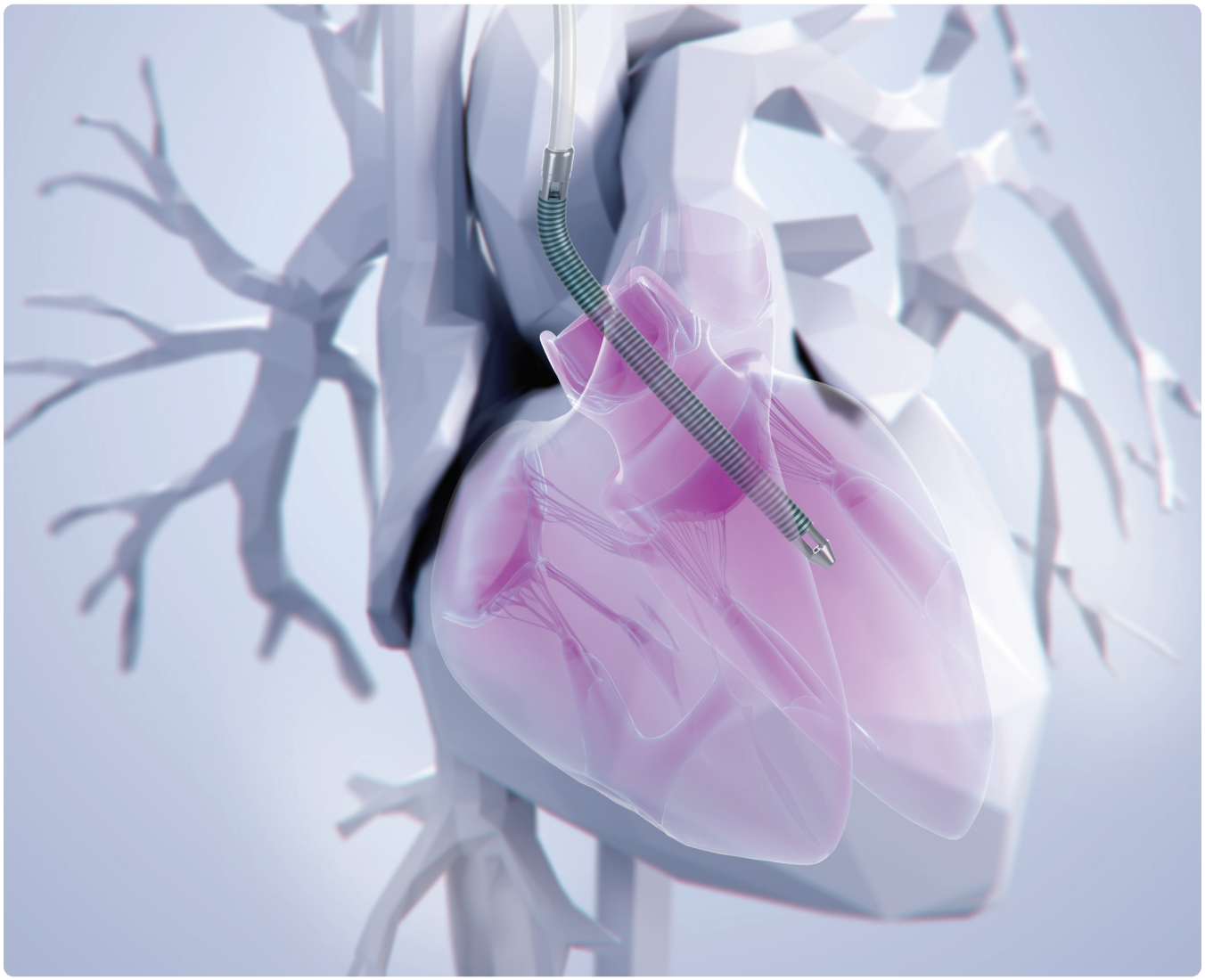
Preemptive use of the Impella 5.5 is currently being investigated in the multicenter, prospective, single-arm Impella-Protected Cardiac Surgery Trial (IMPACT; NCT05529654), which is enrolling 100 patients with low ejection fraction who will undergo CABG and/or valve replacement or repair. Dr. Soltesz is national co-principal investigator of the trial, which is expected to be completed in late 2025.

"We have had excellent outcomes with preemptive Impella placement for selected patients who currently are usually passed over for surgery," Dr. Soltesz notes. "It is our hope that clinical trials will replicate our experience and lead to the addition of more indications for use of this strategy to increase treatment options for patients with heart failure."

Experienced multidisciplinary team critical

Drs. Soltesz, Tong and Bakaeen all underscore the importance of extensive experience in the surgical treatment of patients with poor heart function in order to achieve good outcomes with this strategy. An expert multidisciplinary team is critical, they note, not only for determining a treatment strategy, but also for preoperative assessment and optimization, intraoperative technique and management of recovery.

BELOW — Illustration of an implanted Impella 5.5 device, which Cleveland Clinic surgeons are increasingly using preemptively in selected high-risk cardiac surgery patients to provide left ventricular support and reduce the risk of postcardiotomy cardiogenic shock.



"It is this comprehensive approach to patients with low ejection fraction that has yielded the greatest benefit with minimal risk," Dr. Tong says. "In our recent study in *JTCVS* (Epub 2024 Mar 5), we operated on 238 consecutive patients with an ejection fraction below 30% from 2017 to 2020. The mortality in this group of very sick patients was only 1.7%. Most notably, the mean ejection fraction in this group improved from 25% preoperatively to 39% at 12 months after surgery."

"These patients tend to be complex, with a different risk profile than is typically encountered in hospitals with less volume-based experience," adds Dr. Bakaeen. "Rather than passing over these high-risk patients, we highly recommend referral to a high-volume tertiary center for evaluation and treatment."

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PULSED-FIELD ABLATION: A HIGHLY SELECTIVE CATHETER ABLATION METHOD FOR HEART ARRHYTHMIAS

New nonthermal method promises faster procedure times, less risk to adjacent structures

A new era in catheter ablation therapy for cardiac arrhythmias appears to be underway with the emergence of irreversible electroporation, also known as pulsed-field ablation (PFA).

In December 2023, the FDA approved the first PFA system (PulseSelect, Medtronic) for the treatment of paroxysmal and persistent atrial fibrillation (AF). That same month, Cleveland Clinic enrolled the first patient in the AVANT GUARD randomized trial comparing PFA using the FARAPULSE PFA System (Boston Scientific) with antiarrhythmic drug therapy for first-line treatment of persistent AF — the first randomized controlled study of PFA in this setting.

Evidence indicates that this nonthermal ablation method treats AF with good durability and faster procedure times than conventional ablation techniques — and, most importantly, with low risk to adjacent structures.

Details of the PFA technique, along with an overview of preclinical and clinical trial evidence, were explored in a recent State-of-the-Art Review in *JACC Clinical Electrophysiology* (2023;9[9]:2008-2023) by a Cleveland Clinic team led by Oussama Wazni, MD, MBA, Section Head of Cardiac Electrophysiology and Pacing.

"Pulsed-field ablation is a very promising method of arrhythmia management due to its improved safety compared with thermal ablation," Dr. Wazni says. "We expect there will be widespread adoption of this important new technology now that pulsed-field ablation systems are starting to become commercially available."

"[The AVANT GUARD trial] will determine whether PFA in the setting of persistent AF will reduce recurrence and prevent AF progression as well as heart failure. This study has the potential to be practice-changing."

— OUSSAMA WAZNI, MD, MBA

What is electroporation?

PFA involves electroporation, or the delivery of rapid, high-voltage pulsed electrical fields to tissue, causing cell membranes to become permeable. Depending on the intensity of application, the result can be reversible (a technique used for gene or drug insertion into cells) or irreversible, leading to pores in the membrane and cell death (used for cardiac ablation).

The strength of electrical application can be carefully titrated to destroy only cardiomyocytes and not surrounding tissues, including the esophagus, pulmonary vein and phrenic nerve, which have much higher thresholds for damage from electroporation.

"In contrast to the indiscriminate risk of collateral damage inherent in using thermal energy sources, irreversible electroporation offers the ability to focus ablation on cells implicated in atrial or ventricular arrhythmias," Dr. Wazni explains.

Evidence of safety and efficacy

Multiple preclinical in vitro and in vivo studies have been conducted in the atrium, epicardium and ventricle in swine and canines, setting the stage for clinical trials on patients. Dr. Wazni and Cleveland Clinic colleagues recently reported on the successful use of PFA following prior radiofrequency ablation in swine models, relevant for patients needing redo procedures (*JACC Clin Electrophysiol.* 2024;10[2]:222-234).

At least 10 clinical trials of PFA for paroxysmal or persistent AF have been completed to date, involving more than 1,200 patients and using a variety of devices with catheter designs of different shapes. FDA approval of the PulseSelect system — which has a circular, lasso-type 9-electrode catheter — was based on the single-cohort PULSED AF pivotal study; efficacy was comparable to that of thermal ablation methods among patients with paroxysmal (n = 150) or persistent (n = 150) AF, and PFA entailed a very low incidence of adverse events.

In addition, data on use of the CE-approved FARAPULSE system in a real-world survey of more than 17,000 patients at 106 international centers (MANIFEST-17K) were presented at the 2023

American Heart Association Scientific Sessions. With this system, which employs a pulsed-field pentaspline basket/flower ablation catheter, overall freedom from AF after one year was 73% in paroxysmal and 58% in persistent AF, with a less than 1% rate of major adverse events.

FARAPULSE also recently underwent a randomized clinical trial (ADVENT) involving multiple U.S. centers, with 305 patients assigned to PFA. The system met the standards for noninferiority in safety and efficacy compared with thermal ablation.

Overall, evidence from clinical trials of PFA supports the following:

- Excellent efficacy, with pulmonary vein isolation achieved in almost all patients
- Low rate of major complications, mostly due to pericardial tamponade, stroke or coronary spasm
- Significantly faster procedure time than cryoablation or radiofrequency ablation
- Good overall freedom from AF after one year for paroxysmal and persistent AF, with excellent durability in some cohorts

More trial results emerging

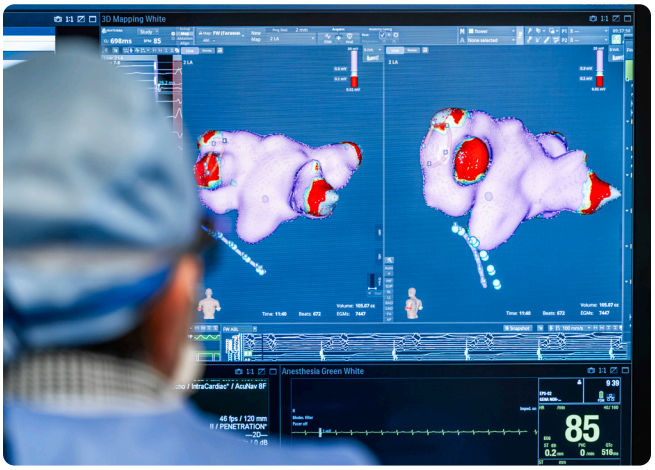
Other major trials of PFA are underway and/or starting to report results. The multicenter, randomized SPHERE Per-AF trial recently showed that a lattice-tip spherical catheter combining pulsed-field and radiofrequency ablation capabilities was noninferior to conventional radiofrequency ablation in both safety and effectiveness among patients with persistent AF (*Nat Med*. Epub 2024 May 17). This investigational device, which received European Union regulatory approval in 2023, was also found superior to the conventional system in measures of procedural efficiency.

Meanwhile, FARAPULSE is being studied for persistent AF in the multicenter, single-arm, open-label ADVANTAGE AF trial (NCT05443594) and the newly launched AVANT GUARD trial (NCT06096337) that started at Cleveland Clinic. The latter study is the first to assess PFA as front-line therapy for persistent AF as well as the first to follow patients using implantable loop recorders.

"We will determine whether PFA in the setting of persistent AF will reduce recurrence and prevent AF progression as well as heart failure," says Dr. Wazni, who serves as lead investigator of AVANT GUARD. "This study has the potential to be practice-changing." Outcomes will be assessed at one and three years using different endpoints.

Unanswered questions

Dr. Wazni notes that several issues related to PFA require further exploration in clinical trials. Optimal "recipes" have yet to be determined for energy intensity (voltage), pulse duration and frequency, biphasic versus monophasic pulse delivery, different electrode configurations, and variations of the diverse device designs and patient characteristics. Investigation of electroporation-induced vasospasm is also needed to develop strategies to prevent this rare but serious complication.



ABOVE — Electroanatomical maps during a recent pulsed-field ablation procedure at Cleveland Clinic.

He adds that comparative costs and benefits of conventional ablation relative to PFA must continually be assessed, as switching to a totally new ablation system will be costly and may not be justified at all centers. In addition to multiple PFA clinical trials, studies of conventional ablation techniques are also ongoing.

"Even with some unanswered questions remaining, pulsed-field ablation holds great promise in making safer ablation available to more patients," Dr. Wazni concludes. "With continually growing operator experience, along with design and application improvements, I expect the advantages of this method will continue to increase."

His colleague Walid Saliba, MD, agrees. "This new method of ablation could potentially revolutionize the treatment of atrial fibrillation," says Dr. Saliba, Medical Director of Cleveland Clinic's Atrial Fibrillation Center. "With the growing evidence favoring early ablation as first-line therapy for many patients with atrial fibrillation, having a procedure like PFA that is faster and safer — and potentially more effective — will be appreciated by patients and physicians alike."

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CAROTID REVASCULARIZATION FOLLOWING THE RECENT CMS COVERAGE DECISION

Insights on how to operationalize policies to prioritize outcomes

When the Centers for Medicare & Medicaid Services (CMS) announced its national coverage determination (NCD) on carotid artery stenting last fall, it brought new options for patients as well as new responsibilities for clinicians and health systems.

"The NCD stated that carotid artery stenting (CAS) — whether transfemoral CAS or transcarotid artery revascularization (TCAR) — would be considered equivalent to carotid endarterectomy (CEA) for Medicare reimbursement purposes," says Sean Lyden, MD, Chair of Vascular Surgery at Cleveland Clinic. "That's liberating because now we don't need to have awkward conversations with patients about what their insurance is before discussing treatment options. But the change stirred up questions about how providers and hospitals should adapt to this new landscape in terms of training and accountability."

Essentials of the NCD

Prior to the 2023 NCD, CMS would reimburse for CAS in a Medicare beneficiary only if the patient was deemed at high surgical risk from CEA and the lesion was symptomatic (causing amaurosis fugax, transient ischemic attack or nondisabling stroke) and greater than 70% stenosed. As a result, only about 5% of patients needing intervention ended up undergoing a CAS procedure.

Under the new NCD, CMS will cover the two stenting procedures — transfemoral CAS and TCAR — under the same conditions that it covers CEA, namely:

- For patients with symptomatic carotid artery stenosis ≥ 50%
- For patients with asymptomatic carotid artery stenosis ≥ 70%

The NCD further specifies that carotid ultrasonography should be the first test to show whether a lesion is present. If revascularization is considered, CT angiography or MR angiography should be performed to confirm the location and extent of stenosis and identify anatomical factors that may determine the best option for a patient. The treatment choice must result from shared decision-making with the patient that includes discussion of risks and benefits of all options, including optimal medical management.

"Some patients are best suited to one of the three options — CEA, TCAR or transfemoral CAS — while others would do fine with any of them," Dr. Lyden says. "You just need to discuss all options and decide with the patient which is best for their individual situation."

"The innovation of a Cleveland Clinic physician, in collaboration with cross-specialty colleagues, pioneered carotid stenting years ago," notes Cleveland Clinic interventional cardiologist Christopher Bajzer, MD. "It's satisfying to see years later that this treatment strategy is recognized by CMS as a valued option for a wider segment of patients with carotid disease. Having this as a treatment option can make all the difference to individual patients."

Getting key players on the same page

The NCD's expansion of the covered patient population means that more carotid stenting procedures will soon be performed than ever before. "Many physicians stopped doing carotid stenting or never got trained in it because there weren't enough cases in the absence of CMS coverage," Dr. Lyden says. "A lot of people need to figure out how to get trained again, and some authoritative group has to come forward with guidance on what adequate training involves and how to ensure good outcomes over time."

The specialties involved — vascular surgery, interventional cardiology, neurosurgery, interventional neurology — have differing guidance documents on these issues, and there is no unified statement from societies in these specialties that hospital medical executive committees can use to guide policy following the NCD.

Helping facilitate such guidance is a key objective of the Multispecialty Carotid Alliance, a national group of physicians of which Dr. Lyden is a leading member. Prior to the NCD, this group developed a white paper detailing data relevant to the status of carotid stenting in the U.S. for consideration by CMS. Now the alliance, which can act more nimbly than most medical or surgical societies, is working with such societies, along with industry, to explore whether consensus guidance can be developed on appropriate requirements for training and outcomes accountability related to carotid stenting.

The alliance also is working to create educational pathways to facilitate training in carotid stenting among interested physicians and trainees in the relevant specialties. Dr. Lyden says that while the alliance may eventually issue guidance on optimal policy for training and outcomes accountability around carotid stenting, for

"You need to get all players together to agree on credentialing requirements for doing these procedures and how to hold physicians accountable for outcomes." — SEAN LYDEN, MD

now they are focused on ensuring high-quality training for interested clinicians. "That's where the demand and need are," he notes.

As alliance members meet with various societies and industry players, they aim to keep the focus on the big picture. "Everyone is wondering how the NCD is going to change the landscape of how patients with carotid disease are treated," Dr. Lyden says. "We're reminding people that it's not about how the relative numbers for each therapy change. It's about whether shared decision-making is happening and whether operators are meeting and maintaining their outcome goals."

The Cleveland Clinic experience

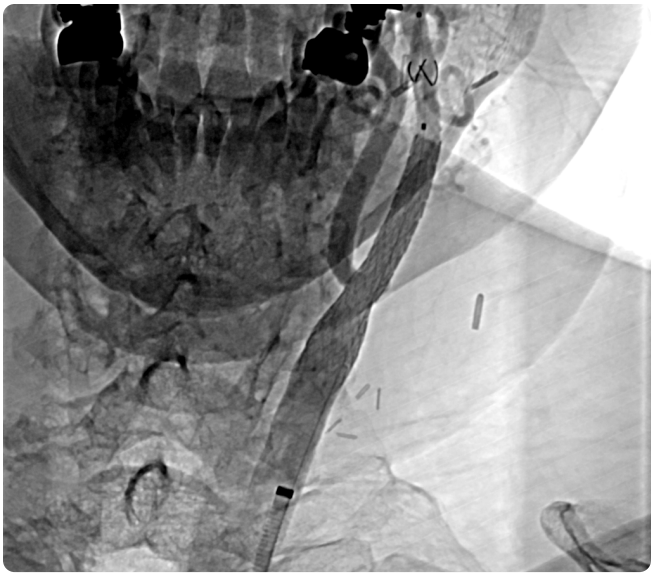
At Cleveland Clinic, soon after the NCD was issued, Dr. Lyden met with his counterparts in the other three service lines that perform carotid procedures (in addition to vascular surgery) — interventional cardiology, neurosurgery and interventional neuroradiology. Leaders of these service lines had been meeting monthly for years to discuss interesting carotid cases and share best practices. They also met quarterly to review outcomes to ensure compliance with targets. "We were already holding all four service lines accountable to the same outcome goals," Dr. Lyden says.

The service line leaders used their post-NCD meeting to promote ongoing consensus and internal collaboration on carotid disease care, and to ensure standardization of care practices in alignment with societal guidelines across Cleveland Clinic.

Most notably, they standardized their training requirements for any provider who wished to offer transfemoral CAS, in anticipation of the increased demand for this stenting procedure. "Previously, we had different requirements for how many carotid stenting cases a physician needed to perform before obtaining privileges to offer transfemoral CAS," Dr. Lyden explains. "After discussion and consulting our individual guidance documents, we agreed to 25 cases as the threshold for privileging across the board."

Advice for others

Dr. Lyden believes this type of consensus and collaboration among relevant service lines is key to offering optimal carotid revascularization services for all hospitals and health systems in the wake of the NCD.



ABOVE — Angiogram showing a carotid artery stent. Carotid artery stenting is now deemed equivalent to carotid endarterectomy for Medicare reimbursement purposes.

"You need to get all players together to agree on credentialing requirements for doing these procedures and how to hold physicians accountable for outcomes," he says. "And best practice is for these players to continue to meet to review outcomes by individual and by specialty to make sure they're in line with goals. This can be done in keeping with a hospital's existing medical executive committee and peer-review processes. If these things are done and patients are experiencing good outcomes and not having strokes, the type of procedure they're getting becomes irrelevant."

Contact Dr. Lyden at 216.444.3581 and Dr. Bajzer at 216.445.3210.

LONG-TERM OUTCOMES OF MITRAL VALVE REPAIR FOR DEGENERATIVE MITRAL REGURGITATION ARE WORSE IN WOMEN THAN MEN

A call for surgical guidelines to adopt sex-specific thresholds of left ventricular size and function

By the time women with degenerative mitral regurgitation (MR) meet recommended thresholds for surgical repair, they are more likely than men to have more frequent and severe symptoms, atrial fibrillation and a higher left ventricular end-systolic diameter indexed to body surface area (LVESDi). Additionally, after surgery, they have worse long-term mortality rates than their male counterparts.

So found a retrospective cohort study of more than 4,500 patients who underwent isolated mitral valve (MV) repair for degenerative MR at Cleveland Clinic, recently published in the *Journal of the American College of Cardiology* (2024;83[2]:303-312). The authors call for consideration of revising surgical guidelines with sex-specific thresholds so that women may be recommended for MV repair surgery earlier.

"Although women and men had similar absolute systolic dimensions at the time of surgery, when indexed to body surface area, women's dimensions were significantly larger," says corresponding author Leslie Cho, MD, Director of Cleveland Clinic's Women's Cardiovascular Center. "It's no surprise that women's outcomes after mitral valve repair are worse than men's since women are being operated on with more advanced disease."

Guidelines make no sex-specific distinctions

Current American College of Cardiology (ACC)/American Heart Association (AHA) and European Society of Cardiology guidelines have uniform thresholds related to cardiac size and function when determining candidacy for MV repair. Moreover, current ACC/AHA Class I recommendations for surgery for severe MR include symptomatic disease, an LVESD of at least 4.0 cm and an LV ejection fraction of less than 60%.

"It's no surprise that women's outcomes after mitral valve repair are worse than men's since women are being operated on with more advanced disease."

— LESLIE CHO, MD

However, notes Dr. Cho, it is well recognized that there are important differences between men and women with severe MR. "At similar levels of clinical severity, women tend to have smaller cardiac dimensions than men, so they tend to be sicker by the time they meet surgical thresholds," she says.

Although MV prolapse is more common in women than men in developed countries, women are often underrepresented in observational studies of MV interventions. The new Cleveland Clinic study was designed to compare long-term all-cause mortality between men and women following MV repair for isolated degenerative MR with respect to baseline measures of LV size and function.

Study cohort and comparisons

All patients underwent isolated MV repair for degenerative MR at Cleveland Clinic between 1994 and 2016. Of 4,589 patients analyzed, 40% (n = 1,825) were women and 60% (n = 2,764) were men. Over median follow-up of 7.2 years, 344 deaths (7.5%) occurred across the cohort.

At baseline, women and men were of similar age, had similar levels of MR and tricuspid regurgitation, had a similar ejection fraction (mean of 59%) and had similar LVESD measures. However, the following key significant differences were found:

- Women more often had comorbidities, including atrial fibrillation (22.9% vs. 18.6%; $P = .001$) and cerebrovascular disease (7.1% vs. 4.8%; $P < .001$).
- Women were likelier to be classified in New York Heart Association class III or IV (37.6% vs. 23.2%; $P < .001$).
- Women had a larger LVESDi (1.9 cm/m^2 vs. 1.7 cm/m^2; $P < .001$).

Important differences in outcomes were also identified:

- All-cause mortality during follow-up trended higher in women (hazard ratio = 1.16; 95% CI, 0.96-1.40).

"The negative consequences of waiting to meet currently recommended thresholds for left ventricular dimensions and function are significantly greater for women than for men." — A. MARC GILLINOV, MD

- Mortality increased for patients below the LVESD surgical threshold of 4.0 cm among women (i.e., at 3.6 cm) but not among men.
- Mortality risk increased at an LVESDi of 1.8 cm/m^2 for women versus 2.1 cm/m^2 for men.
- Mortality increased above baseline at an ejection fraction of 58% in both men and women, but as ejection fraction decreased below that level, mortality increased more sharply in women.

Findings argue for guideline changes

With higher ejection fractions and smaller cardiac sizes than men at similar levels of disease severity, women with MR are less likely to meet thresholds for MV repair under current guidelines.

"Women were found to have higher rates of long-term mortality for the same preoperative ventricular dimensions adjusted to body size as men, and for the same ejection fractions," Dr. Cho observes.

She emphasizes that the study findings are strong, given the large cohort, the long follow-up period and the cohort's uniformity in that all patients underwent isolated MV repair for degenerative MR.

"When a woman (or a man) is found to have severe mitral regurgitation on an echocardiogram, it is time to consult a surgeon," notes study co-author A. Marc Gillinov, MD, Chair of Thoracic and Cardiovascular Surgery. "Waiting to fix the valve is detrimental, particularly for women. With our contemporary mitral valve repair rate of 99.8% and a risk below 0.05%, a simple operation to repair the mitral valve is clearly the patient's best option."

Dr. Gillinov continues: "We hope our study will prompt guideline-setting societies to consider adopting sex-specific ejection fraction and LVESDi thresholds to help determine candidacy for surgical repair to treat mitral regurgitation. The negative consequences of waiting to meet currently recommended thresholds for left ventricular dimensions and function are significantly greater for women than for men."

An additional perspective

"There is increasing evidence that one size does not fit all in optimally timing valve intervention, and that gender and age may modify cardiac remodeling, especially in valve regurgitation," adds Brian Griffin, MD, Section Head of Cardiovascular Imaging, who was not involved in the study. "This paper comes on the heels of prior evidence from our group that women with aortic regurgitation also may benefit from intervention at lower left ventricular size than men. Awareness of these gender differences is important in ensuring the best possible long-term outcomes for patients with these common and very treatable valve lesions."

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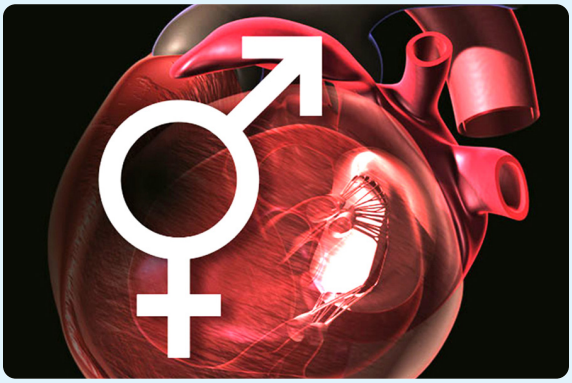
Contact Dr. Cho at 216.445.6320, Dr. Gillinov at 216.445.8841 and Dr. Griffin at 216.444.6812.

KEY FINDINGS



In this study of mitral valve repair, women had:

- **Greater symptom frequency and severity**
- **More comorbidities**
- **Higher LVESDi at surgery**
- **Greater mortality below the LVESD surgical threshold of 4.0 cm**
- **Increased mortality with rising LVESDi**
- **A sharp rise in mortality with declining ejection fraction**

REFER EARLY FOR ENLARGED ROOTS TO AVOID RESIDUAL AR AFTER VALVE-SPARING AORTIC ROOT REPLACEMENT

Residual AR related to severe preoperative AR raises risk of progression and reoperation

Predictors of residual aortic regurgitation (AR) after elective tricuspid aortic valve reimplantation include severe preoperative AR, smaller aortic root graft and concomitant cusp repair. And prevention of residual AR — an uncommon finding immediately following such operations — is important.

Those are two main conclusions of a retrospective analysis of more than 750 patients who underwent aortic valve reimplantation during elective repair of aortic root aneurysms at Cleveland Clinic over an 18-year period. Preoperative characteristics and postoperative outcomes of patients who had residual AR at hospital discharge were compared with those of patients without residual AR. The study was published in the *Journal of Thoracic and Cardiovascular Surgery* (2024;167[1]:101-111.e4).

"We noted that more severe preoperative AR was a predictor of residual AR and the need for leaflet repair," says senior author Lars Svensson, MD, PhD, Chief, Cleveland Clinic Heart, Vascular & Thoracic Institute. "Although long-term survival rates were similar between those who did and did not have residual AR, risk of reoperation was higher if residual AR was present. It's important to more closely follow patients found to have residual AR so that the need for reoperation can be recognized promptly."

Exploring the significance of residual AR after reimplantation

Aortic root replacement with valve-sparing aortic valve reimplantation has excellent outcomes, especially when performed electively in patients with aortic root aneurysm and a tricuspid aortic valve before AR is severe and the leaflets tear from the added stress of a dilated root. The latter scenario makes successful reimplantation more difficult and requires leaflet repairs more often to save the valve. However, residual AR — noted intraoperatively or before hospital discharge — may affect valve durability, and little is known about how it affects outcomes.

This single-center series was designed to characterize patients with residual AR after elective aortic valve reimplantation for aortic root aneurysm and compare baseline characteristics and postoperative and long-term outcomes between patients with and without residual AR.

Study cohort and findings

The study population consisted of 756 patients (mean age, 50 years) who underwent elective tricuspid aortic valve reimplantation for aortic root aneurysm at Cleveland Clinic between 2002 and 2020. All underwent transthoracic echocardiography before hospital discharge. While uncommon, residual postoperative AR occurred in 65 of these patients (8.6%). The residual AR was predominantly classified as mild (n = 58), with rare moderate cases (n = 7). No patients had severe residual AR.

Patients were followed for a median of 3.3 years, with 25% followed for more than 7.5 years and 10% for more than 12 years.

The minority of patients who had residual AR at discharge were more likely to have had severe AR preoperatively compared with those without residual AR at discharge (38% vs. 12%; $P < .0001$). Interestingly, having a connective tissue disorder did not predict residual AR.

Intraoperatively, those with residual AR were significantly more likely to have:

- Thickened cusps (7.7% vs. 2.2%; $P = .008$)
- Concomitant aortic valve repair (38% vs. 23%; $P = .004$)
- Return to cardiopulmonary bypass for additional repair (10.8% vs. 3.3%; $P = .003$)
- Concomitant cusp repair involving more cusp components or a smaller aortic root graft

In-hospital outcomes were similar between the groups with and without residual AR, and no in-hospital deaths occurred. Long-term outcomes, assessed at 10 years, included the following differences in patients with residual AR at discharge relative to those without residual AR at discharge:

- Higher prevalence of either moderate or severe AR (48% vs. 7%; $P < .0001$)
- Lower rate of freedom from reoperation, although still good (89% vs. 98%; $P < .0001$)

Survival rates between the groups were similar at 10 years (97% among those with residual AR vs. 93% among those without; $P = .43$).

"Although residual AR should be avoided if possible, its avoidance should not be the overarching goal when selecting surgical candidates or choosing reimplantation over replacement."

— LARS SVENSSON, MD, PHD

The risk of early reoperation was increased by the presence of residual AR; risk factors for late reoperation included concomitant coronary bypass, lower preoperative body mass index and lower preoperative ejection fraction.

Tips for avoiding residual AR

The rate of residual AR in this Cleveland Clinic series was less than 10%, which is lower than the rate of 25% to 29% reported in another large published series (*J Thorac Cardiovasc Surg.* 2017;153[2]:232-238). Residual AR of greater than mild severity was exceedingly rare, occurring in less than 1% of all patients in the series.

Dr. Svensson notes that a certain measure of expertise is required to repair damaged leaflets in order to preserve a valve with associated tears and severe preoperative AR. "Cleveland Clinic's large surgical volume and extensive experience with concomitant valve repair likely are important reasons for these low rates," he says. "But other factors should also be noted."

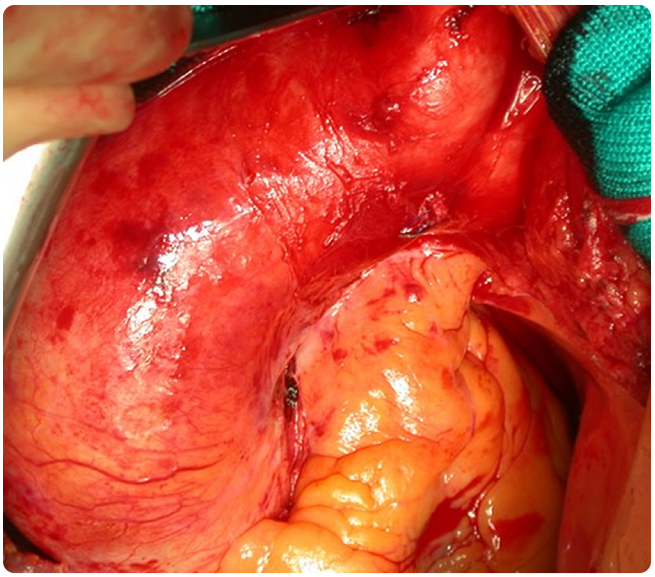
Specifically, he recommends the following:

Refer early for reimplantation. Surgery for enlarged roots should be considered before AR becomes severe, when cusps are more likely to have developed fenestrations, thinning or elongation, making repair more challenging.

Evaluate patient factors carefully. Determining whether reimplantation or replacement is the best strategy is critical. Not only are a patient's age, functional status, aneurysm size and severity of regurgitation important to consider, but a systematic assessment of commissures, leaflets, annulus, sinuses of Valsalva and sinotubular junction (the CLASS schema) should be done.

Pay close attention to cusps. Cleveland Clinic surgeons avoid reimplantation if a patient has extensive cusp damage, especially involving two or more prolapsing cusps, and they do not reimplant calcified cusps or attempt decalcification.

"Although residual AR should be avoided if possible, its avoidance should not be the overarching goal when selecting surgical candidates or choosing reimplantation over replacement," notes Dr. Svensson. "Enabling a patient to improve from severe to mild regurgitation should also be considered a successful outcome."



ABOVE — Operative photo of an aortic root aneurysm. The Cleveland Clinic study shows that valve-sparing aortic root replacement to repair such aneurysms can demonstrate excellent durability, but residual aortic regurgitation following reimplantation raises the long-term risk for aortic valve reoperation, requiring close postoperative monitoring.

"This is an important study that highlights the value of early and detailed evaluation of significant AR in the setting of a dilated aortic root," adds cardiologist Milind Desai, MD, MBA, Medical Director of Cleveland Clinic's Aorta Center. "Such an evaluation can enable early referral to an experienced center for a valve-sparing root replacement, giving the patient the best chance of AR-free survival in the future."

Contact Dr. Svensson at 216.445.4813 and Dr. Desai at 216.445.5250.

LUNG CANCER STUDY LINKS PREOPERATIVE FACTORS WITH SPREAD THROUGH AIR SPACES

Risk of lung cancer spread through air spaces (STAS) is increased in younger patients with clinical T1-3N0 M0 disease, solid tumors ≥ 2 cm, *KRAS* mutations and high uptake on PET scans.

So reveals a retrospective Cleveland Clinic study of preoperative predictors of STAS in non-small cell lung cancer (NSCLC). The findings were published in the *Journal of Thoracic and Cardiovascular Surgery* (Epub 2023 Nov 23).

"Our study identifies preoperative characteristics that are predictive of STAS," says thoracic surgeon Monisha Sudarshan, MD, MPH, the study's principal investigator. "The results can be used to guide decisions about whether to perform sublobar resections or more extensive surgery."

STAS (see Figure) is associated with higher rates of NSCLC recurrence and lower rates of survival, particularly in patients who undergo limited resection, but it can't be used intraoperatively because of low sensitivity and specificity on frozen sections. As a result, final pathology from supposed "definitive" segmentectomies or wedges sometimes indicates STAS, creating a treatment conundrum for surgeons.

To address that situation, the researchers analyzed data from 439 patients with clinical T1-3N0 M0 NSCLC who underwent primary surgery at Cleveland Clinic from 2018 through 2021.

Preoperative markers evaluated were age, sex, smoking status, tumor size, ground-glass opacities, maximum standardized uptake value (max SUV) on PET, and molecular markers on biopsy.

"We used nonlinear, nonparametric machine learning to analyze preoperative predictors of STAS, which is not common in the literature," notes first author Sadia Tasnim, MD, a Cleveland Clinic thoracic surgery fellow. "This approach facilitated straightforward interpretation of confounders and is superior to multivariable logistic regression for predicting events."

At least one STAS-positive tumor was found in 177 of the patients; the remaining 262 patients had no STAS-positive tumors. Overall, 179 STAS-positive tumors and 293 non-STAS-positive tumors were evaluated.

Age ≤ 50 years, solid tumor, size ≥ 2 cm and max SUV ≥ 2.5 all were independently predictive of STAS, with probabilities of 50%, 40%, 38% and 40%, respectively. STAS tumors also were more likely to harbor *KRAS* mutations and to be *PD-L1* negative.

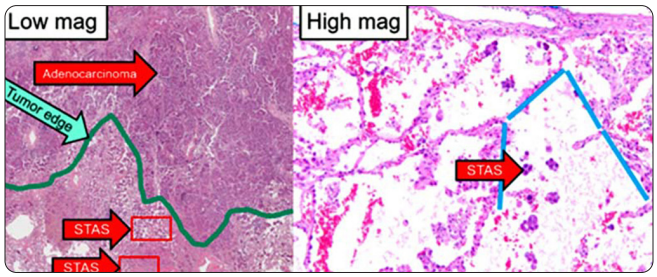


FIGURE — Pathological findings of spread through air spaces (STAS). Images courtesy of Sanjay Mukhopadhyay, MD, Cleveland Clinic.

Non-STAS tumors, in contrast, were more likely to express *PD-L1*. Gender, body mass index, race and smoking status were not linked with predisposition to STAS.

"We hypothesized that STAS would be more likely in older patients, based on previous literature reports, but our study showed the opposite," Dr. Sudarshan notes. "We hope to do a study of STAS in younger patients to better understand why this was so."

Of the 42 patients who had a recurrence of cancer, 19 were in the STAS group and 23 in the non-STAS group. However, no difference in freedom from recurrence was seen between the groups.

The authors note that while the factors identified are individually predictive of STAS, taken together they may have an even more powerful effect on treatment. For now, they hope their data will lead to "lightbulb" moments for thoracic surgeons treating patients with features predictive of STAS and will prompt consideration of a procedure other than sublobar resection in these cases.

"Future studies are needed to determine the role of completion lobectomy versus observation or segmentectomy versus lobectomy for patients with STAS," Dr. Sudarshan concludes. "The role of driver mutations in predicting STAS and their pathophysiology also should be explored to elucidate the natural history and guide targeted therapy for STAS."

Contact Dr. Sudarshan at 216.445.9579.

EXCELLENT OUTCOMES ACHIEVABLE WITH SURGICAL RESECTION OF BENIGN CARDIAC TUMORS

Most patients who undergo resection of benign primary cardiac tumors can be considered cured, concludes a large database study presented by Cleveland Clinic researchers at the 2024 annual meeting of the Society of Thoracic Surgeons.

"We found that surgical resection of these tumors yields excellent outcomes," says senior investigator and cardiothoracic surgeon Eric Roselli, MD. "In patients with myxomas, resection restores survival to a level observed in a matched general U.S. population."

With a prevalence of no more than 0.3% in autopsy series, primary cardiac tumors are rare. Most are benign and carry a good prognosis, but they can have hemodynamic and arrhythmic implications for patients. Surgical resection remains the preferred treatment, but few studies have been done in patients undergoing resection. "This may be the largest reported experience with surgical resection for benign cardiac tumors at a single institution," Dr. Roselli notes.

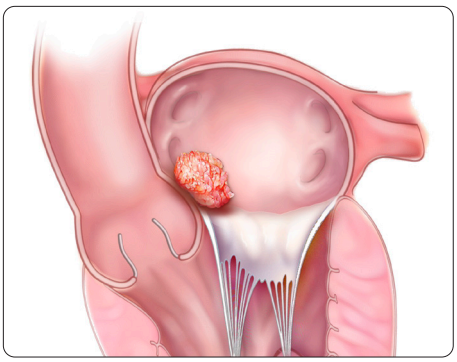
The researchers analyzed surgical resections of benign primary cardiac tumors in 563 patients at Cleveland Clinic from 1965 through 2022. Most tumors were myxomas (62%) or papillary fibroelastomas (30%), with the remainder consisting of rare tumor types including lipomas (2.8%), paragangliomas (1.8%), fibromas (0.9%) and hemangiomas (0.9%).

Mean age at resection was 59.2 years in the myxoma group, 64.9 years in the papillary fibroelastoma group and 54.4 years in patients with other tumors. Concomitant surgical procedures, most commonly valve procedures, were done in 36% of the myxoma group, 73% of the fibroelastoma group and 56% of patients with other tumors.

Intracardiac tumors were left-sided in 92% of myxomas, 81% of papillary fibroelastomas and 56% of other rare tumors. The left atrium was the site of most myxomas (89%), whereas fibroelastomas occurred at various sites, including the aortic valve (38%), left atrium (20%) and left ventricle (19%). The rare tumors were found in the right atrium (29%), left atrium (24%), left ventricle (24%) and right ventricle (18%).

A generally steady increase in the prevalence of benign cardiac tumors was observed over the study period, likely due to improvements in noninvasive diagnostic tools, with the largest increases seen after the year 2000.

There were 10 operative deaths (1.8%), six following major concomitant procedures and two in cases involving extensive tumors early in the study period.



AT LEFT — Illustration of an atrial myxoma, one of the most common tumor types in the study.

Median duration of follow-up was 4.5 years, with 25% of patients followed for more than 12 years and 10% for more than 20 years. Survival rates were 97% at six months, 96% at one year, 88% at five years, 73% at 10 years, 59% at 15 years, 46% at 20 years and 36% at 25 years.

Survival in patients with cardiac myxomas was significantly higher than in patients with the other tumor types ($P < .001$) and was comparable to that of the general U.S. population. Two tumors — both left atrial myxomas — recurred during follow-up.

"Over nearly six decades, we observed only two tumor recurrences among more than 550 patients," Dr Roselli says. "This confirms that good long-term results are achievable for almost all patients, although careful and complete surgical excision is likely crucial."

"Despite the relative rarity of benign cardiac tumors, Cleveland Clinic now performs 40 to 50 of these surgeries per year," notes co-investigator A. Marc Gillinov, MD, Chair of Thoracic and Cardiovascular Surgery. "When these surgeries are performed at a high-volume center, the outcomes can be excellent in the short and long term. In addition, isolated myxomas and fibroelastomas can often be removed using robotic technology, which enables very small incisions."

Contact Dr. Roselli at 216.444.0995 and Dr. Gillinov at 216.445.8841.

CASE STUDY IN COLLABORATION

USING RAPID IMPROVEMENT METHODOLOGY TO REDESIGN TAVR RECOVERY AND DISCHARGE PROCESSES

How our HVTI Advisory Services team facilitated swift improvements for an allied health organization

Consistent analysis of clinical operations and an ability to adapt plans of care to meet the needs of patients are critical to growth, efficiency improvement, wise resource allocation, cost containment and provision of safe and high-quality care. Healthcare organizations develop strategies and implement enhanced workflows to increase access to services, improve efficiencies and enhance patient experience.

Transcatheter aortic valve replacement (TAVR) and other percutaneous valve procedures are increasing in prevalence, so optimizing workflows is important to cardiovascular service line success. Transitioning patients determined to be low risk for TAVR procedures to same-day discharge, rather than admission to an intensive care unit, is one strategy that offers several benefits for patients and organizations.

That is the experience of The Valley Hospital, which recently collaborated with the Advisory Services team of Cleveland Clinic's Heart, Vascular & Thoracic Institute (HVTI) to drive improvements in the recovery and discharge of its patients undergoing TAVR. The Valley Hospital, part of Valley Health System serving northern New Jersey and southern New York, is a fully accredited, acute care, not-for-profit hospital that has had an alliance relationship with Cleveland Clinic's HVTI since 2015.

Identifying the need

Postprocedural care for TAVR patients can range from critical care admission to same-day discharge. The Valley Hospital recently assessed its processes for TAVR patient management and discharge and identified an opportunity for enhancement. Valley noted that 100% of TAVR patients were transferred to the cardiac surgery intensive care unit (CSICU) for recovery. This suggested there was an opportunity to develop a streamlined process to identify low-risk patients who would benefit from a fast-track recovery strategy. This change in patient throughput would also open bed capacity in the CSICU that could be used for acute patients requiring that level of care.

Valley sought to establish better-defined TAVR admission and discharge criteria, recognizing that appropriate, tailored postprocedural care provides an optimal patient experience without compromising patient outcomes or safety. The objectives were to align with industry best practice for TAVR recovery, increase the availability of the hospital's critical care resources for the most acute care needs, enhance patient experience and reduce the economic burden of TAVR care.

Rapid improvement methodology to the rescue

To achieve its objective, Valley enlisted the assistance of Cleveland Clinic's HVTI Advisory Services team. The team conducted a rapid improvement event (RIE), also known as a Kaizen event, with members of Valley's cath lab, same-day medicine and step-down unit teams, all of which are central to TAVR care and recovery.

Successful RIEs are driven by cross-functional teams to ensure buy-in. They are designed to rapidly yield measurable results by analyzing and improving a narrowly defined process.

The RIE is part of the Lean Six Sigma process improvement approach, which achieves the greatest success when used by individuals with expertise in utilizing Lean Six Sigma tools. The HVTI Advisory Services continuous improvement team brought such expertise to bear by helping the Valley team assess TAVR processes and analyze recovery and discharge data. The teams could then determine the root cause of the issue, design experimental solutions, implement systems-based thinking, develop process efficiencies and outline standardized workflows.

Translating the methodology to action

Since the data showed 100% of TAVR patients were admitted to and recovered in the CSICU, and the team's RIE process identified a need for new standardized workflows, criteria for patient transfer between units and indications for admission to a step-down unit needed to be developed. The group recognized it was imperative that these new workflows be effective in improving patient flow and optimizing care delivery.

TABLE. PROGRESS TO DATE ON KEY METRICS AND TARGETS IDENTIFIED IN THE RAPID IMPROVEMENT EVENT (RIE)

Metric	Post-RIE Target	Actual Results		
		Days 1-30	Days 31-60	Days 61-90
Written criteria defining TAVR patient risk (low/moderate/high)	Criteria written and adhered to 100%	100%	100%	100%
Written standard workflow for handoff from procedural area to same-day medicine	Handoff documented and adhered to 100%	100%	100%	100%
Written standard workflow for handoff from same-day medicine to step-down unit	Handoff documented and adhered to 100%	100%	100%	100%
Written standard workflow for TAVR patient recovery in same-day medicine unit	Documented and adhered to 100%	100%	100%	100%
Written standard workflow for TAVR patient admission to step-down unit	Documented and adhered to 100%	100%	100%	100%
Low-risk TAVR patients' admission rate to step-down unit	100%	50%	50%	70%
Completion plan achieved within 3 months	100%	74%	89%	93%
Total direct cost of care for TAVR cases	Recognize savings in direct cost per case	$1,677 in savings (1 case)	$3,354 in savings (2 cases)	$11,739 in savings (7 cases)

The process led to defining a target state (Table), which was set in collaboration with Valley's leadership and finance teams and guided by best practices for cath lab services and continuous improvement from Cleveland Clinic's HVTI.

The Valley team and leaders, together with HVTI Advisory Services continuous improvement personnel, implemented the RIE methodology and visualized their processes for TAVR care. The multidisciplinary team identified 84 improvement opportunities in the recovery, admission and discharge processes. They were broadly categorized as follows: standard work, systems thinking, siloed teams, education and training, visual management, and patient flow. The team then proposed solutions and designed rapid experiments to meet their vision using Cleveland Clinic best practices and structured facilitation.

After developing written criteria and standardized workflows and applying the rapid experiments they had designed, the Valley team met most of their targets within 30 days of the RIE, and they realized a savings of $1,677 per TAVR patient and cumulative savings of $16,770 within 90 days (Table).

Engagement drives success

"Keys to success were the collaboration between the Cleveland Clinic and Valley teams and the engagement and backing of Valley executive leadership, which supported the RIE and committed the necessary time for the team to participate," says Suma Thomas, MD, MBA, Vice Chair of HVTI Strategic Operations. She notes that this enabled a multidisciplinary team — which faced numerous deadlines and staffing challenges — to pause its day-to-day work to complete the RIE with 4.5-day attendance and full commitment.

Executive leaders trusted the process, nurtured a team spirit and instilled confidence in the team members. Their support enabled team members to take ownership of the initiative by designing their own solutions, which enhanced the team's commitment to sustaining and achieving the RIE's outcomes.

"The partnership and expertise of Cleveland Clinic's continuous improvement team facilitated our advancement in the care of our TAVR patients while engaging our clinical and administrative teams," says Derrick Lieb, DNP, MS-HCM, RN, NEA-BC, Assistant Vice President of The Valley Heart and Vascular Institute.

"Including front-line staff in design and decision-making is key to sustaining changes," adds Josh Gregoire, MS, MPH, RN, NEA-BC, Assistant Vice President of Quality/Performance Improvement and Clinical Operations, Valley Health System. "It's exciting to observe staff as they realize the important role they play in questioning and reinforcing processes."

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

CME PREVIEW

GLOBAL EP SUMMIT 2024 WILL KEEP YOU CURRENT IN A FAST-CHANGING DISCIPLINE

Sixth annual CME course takes place in Cleveland Sept. 20-21

Global EP Summit 2024

Fri.-Sat., Sept. 20-21, 2024
Hilton Cleveland Downtown, Cleveland, Ohio
Information/registration: ccfcme.org/globalep24

Rapid changes in electrophysiology (EP) prompted Cleveland Clinic to offer its inaugural Global EP Summit in 2019. Since then, the changes have only accelerated, but the summit's objectives remain the same for its sixth annual offering this September.

"The Global EP Summit brings together leaders from EP groups all over the world to exchange ideas in a way that's accessible to all attendees," says course co-director Tyler Taigen, MD. "Our goal is to create a forum to discuss and even debate top clinical questions and challenges and then follow that with a firsthand look at new and future approaches from leading innovators in the world."

The two-day CME course features a powerhouse faculty of more than 40 Cleveland Clinic experts plus 16 guest faculty from across the U.S. as well as Canada and Europe. Scores of experts in EP are joined by leading authorities in other cardiac subspecialties, cardiac surgery, vascular neurology and beyond to keep participants up to speed across the spectrum of EP practice and research.

"This year's summit will highlight the latest advances in pulsed-field ablation for atrial fibrillation (AF), management of ventricular tachycardia (VT), left atrial appendage (LAA) closure, lead management and device therapy," notes course director Oussama Wazni, MD, MBA. "There will also be expert discussion on the latest in syncope management and case-based discussions covering many aspects of clinical EP."

The summit's 11 sessions will cover a broad scope of content at a brisk pace. Presentations are well focused, at 10 minutes each, but collectively address the essentials in all key areas of EP practice. A few examples:

- The kickoff session, on hot topics in AF ablation, features 10 timely topics with a particular concentration on leading issues in pulsed-field ablation.
- A session on clinical management of AF tackles eight distinct aspects of care, covering topics from the benefits of early rhythm control to the prospects for predicting and preventing AF.
- A session on LAA closure explores issues and strategies across 10 presentations ranging from takeaways from the Cleveland Clinic-led WATCH-TAVR trial to new devices to use of the hybrid convergent procedure.
- A session on ventricular arrhythmia management addresses key issues and questions in VT care across seven presentations that culminate in a 20-minute roundtable discussion on multidisciplinary approaches.

Additional sessions address other fundamental EP areas, including stroke prevention in AF, pacing and lead management, and sudden cardiac death.

Following coverage of these core topics during the full day on Friday and the first half of Saturday morning, the remainder of the summit features a number of more eclectic sessions:

- An "Innovations in EP" session shares updates from Cleveland Clinic's VT and AF registries as well as a discussion of AF and the gut microbiome, updates on artificial intelligence in EP, and more.
- A special debate features pro and con arguments on the role of cardioneuroablation in vasovagal syncope.
- A "Cleveland Clinic EP in Action" session shares insights from EP quality improvement initiatives and complex case scenarios.
- A concluding open forum session features case-based discussions of key issues in EP practice from preceding portions of the summit.

Midafternoon adjournment on Saturday allows attendees to enjoy the rest of the weekend during one of the most lovely times of the year in Northeast Ohio.

"We urge electrophysiologists and other cardiovascular clinicians to join us at this gathering of global experts for updates in all aspects of clinical EP as well as the latest science and innovation," says course co-director Pasquale Santangeli, MD, PhD. In addition to Drs. Santangeli, Wazni and Taigen, the summit is co-directed by Ayman Hussein, MD, and Walid Saliba, MD.

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Further information, including registration, is at ccfcme.org/globalep24. Early-bird pricing ends Aug. 20.

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

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SAVE THE DATES FOR CME

State-of-the-Art Topics in the Prevention and Management of Cardiovascular Disease
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InterContinental Cleveland | Cleveland, Ohio
Information/registration: ccfcme.org/cvd2024

Global EP Summit 2024
Fri.-Sat., Sept. 20-21, 2024
Hilton Cleveland Downtown | Cleveland, Ohio
Information/registration: ccfcme.org/globalep24

Cardiovascular Update 2024
Thu.-Fri., Oct. 31-Nov. 1, 2024
Hilton Cleveland Downtown | Cleveland, Ohio
Information/registration: ccfcme.org/cvupdate24

Advancing Cardiovascular Care 2024
Fri., Nov. 8, 2024
Hyatt Regency Columbus | Columbus, Ohio
Information/registration: ccfcme.org/columbuscvcare24

Dimensions in Cardiac Care 2024
Sun.-Tue., Nov. 10-12, 2024
InterContinental Cleveland | Cleveland, Ohio
Information/registration: ccfcme.org/cardiaccare24

Case-Based Management of Tricuspid and Mitral Valve Disease 2024
Fri.-Sat., Dec. 6-7, 2024
JW Marriott Essex House | New York, New York
Information/registration: ccfcme.org/mitralvalve

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