

CARDIAC CONSULT

2023
ISSUE 3

Heart, Vascular and Thoracic News

IS IT TIME TO REDEFINE 'LOW RISK' SAVR? — p. 4

DEAR COLLEAGUES,

This issue of *Cardiac Consult*, like its predecessors, contains no shortage of noteworthy clinical and research developments that we hope will prove edifying and insightful to other cardiovascular and thoracic clinicians. But one particular feature — the case report starting on page 6 — stands out for the attention it draws to an important yet underappreciated aspect of healthcare excellence: continuity of care.



The 36-year-old case patient was admitted to Cleveland Clinic with pulseless electrical activity, fulminant biventricular dysfunction and severe malperfusion to multiple organs. Before he was discharged three months later, he was placed on combined ECMO and Impella support as well as dialysis and was navigated through several serious complications before undergoing successful heart-kidney transplantation. Notably, the same team that initially placed the patient on mechanical support also performed his heart transplant 10 weeks later and was involved with the kidney transplant the following day.

This type of care continuity is a welcome byproduct of Cleveland Clinic's organizational structure and our culture of collaborative, multidisciplinary caregiving. While such continuity of care cannot be guaranteed in all cases, all our patients stand to benefit from the structure and collaborative culture that underlie it. When you have a patient requiring referral for especially complex care needs, we would be honored to bring that structure and culture to bear in their management.

Respectfully,

A handwritten signature in black ink, appearing to read "L. Svensson". The signature is fluid and cursive.

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 for the world's best 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 — Intraoperative photo from a surgical aortic valve replacement (SAVR) operation. A new study concludes that the operative risk of contemporary SAVR is overestimated by current risk models, at least at high-volume centers like Cleveland Clinic. For more, see the article starting on page 4.

RESEARCH ROUNDUP

RECENT STUDIES OF NOTE FROM CLEVELAND CLINIC

CLEAR Outcomes Subanalysis Shows Strong Primary Prevention Effect for Bempedoic Acid

The lipid-lowering drug bempedoic acid (Nexleto[®]) was associated with a significant reduction in major cardiovascular events among patients taking it for primary cardiovascular prevention, according to a prespecified subgroup analysis of the multicenter CLEAR Outcomes trial. The study randomized a mixed population of 13,970 primary and secondary prevention patients with statin intolerance to oral bempedoic acid (180 mg/day) or placebo. Thirty percent of patients (n = 4,206) had no prior cardiovascular events but had clinical features that put them at high risk. Over median follow-up of 39.9 months among these patients, the primary composite endpoint (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke or coronary revascularization) occurred in 5.3% of the bempedoic acid group versus 7.6% of the placebo group — a 30% relative reduction (P = 0.002). “Less than half of U.S. adults who are candidates for lipid-lowering therapy for primary prevention actually receive it,” says first author Steven Nissen, MD, of Cleveland Clinic. “This is a wake-up call to pay more attention to treating these patients.” The study is published in *JAMA* (Epub 24 June 2023).

Study Supports Cardiovascular Safety of Testosterone Therapy When Used as Indicated

Testosterone therapy was not associated with an increase in major adverse cardiovascular events compared with placebo in the TRAVERSE study of middle-aged and older men with documented hypogonadism and preexisting or a high risk of cardiovascular disease (CVD). So reported a Cleveland Clinic-led team of investigators in the *New England Journal of Medicine* (Epub 16 June 2023). The FDA-mandated phase 4 safety study randomized 5,246 men aged 45 to 80 years to daily transdermal 1.62% testosterone gel or placebo gel. All had preexisting CVD or a high risk of CVD, at least one symptom of hypogonadism and two fasting serum testosterone readings below 300 ng/dL. Over mean follow-up of 22 months, there was no significant difference in the composite endpoint of cardiovascular mortality, nonfatal myocardial infarction or nonfatal stroke between the testosterone and placebo groups. “These findings provide reassurance about the cardiovascular safety of testosterone therapy over the typical treatment duration in men in whom it is indicated,” says first author A. Michael Lincoff, MD, of Cleveland Clinic. “They don’t apply to athletes taking super-high doses or people who don’t have low testosterone levels.”

Dual-Chamber Leadless Pacemaker Surpasses Safety and Performance Goals at 90 Days

A first-of-kind dual-chamber leadless pacemaker system showed promising results in the first three months following implantation, according to an ongoing international study with co-leadership from Cleveland Clinic. In the single-arm trial, published in the *New England Journal of Medicine* (2023;388:2360-2370), two miniaturized leadless pacemakers were implanted in the heart’s upper and lower chambers via a catheter through the femoral vein. Implantation was successful in 98.3% of the study’s first 300 enrollees; beat-to-beat wireless bidirectional communication with upper and lower chamber synchrony was achieved in 97.3% of patients; and freedom from complications at 90 days was achieved in 90.3%. Study participants had standard indications for dual-chamber pacing. “These outcomes exceeded the study’s performance goals,” says Cleveland Clinic electrophysiologist Oussama Wazni, MD, MBA. “Until now, leadless pacing has been limited to the heart’s lower chambers. Since dual-chamber pacemakers are the predominant implantable cardiac devices in the U.S., the potential impact of these findings for reducing patient morbidity is significant.”

Donor Smoking or Substance Use Alone Need Not Deter Acceptance of Donor Lungs

Donor lungs that are otherwise appropriate for transplantation should not be rejected solely due to donor smoking or substance use, concludes a retrospective Cleveland Clinic database study published in the *Journal of Thoracic and Cardiovascular Surgery* (Epub 7 Feb 2023). The researchers analyzed 1,366 lung transplants from 1,291 donors performed at Cleveland Clinic from 2007 to 2020. Post-transplant primary graft dysfunction, longitudinal FEV₁ on spirometry and survival among transplant recipients were evaluated according to donor history of tobacco and substance use. No association was found between donor smoking history, pack-years or substance use and primary graft dysfunction at any time point. While donor smoking history was linked to a statistically significant reduction in FEV₁ in double lung transplant recipients at one year, this effect was not clinically significant. Non-risk-adjusted survival at five years was slightly but not significantly lower in recipients with donors who had smoked versus not smoked. “Our study adds to the evidence that lungs from well-selected donors can have comparable allograft function and survival regardless of smoking status,” says Cleveland Clinic cardiothoracic surgeon Kenneth McCurry, MD.

IS IT TIME TO REDEFINE ‘LOW RISK’ SURGICAL AORTIC VALVE REPLACEMENT?

Cleveland Clinic study finds expected STS risk no longer reflects current outcomes

The operative risk of contemporary surgical aortic valve replacement (SAVR) at high-volume centers is overestimated by current Society of Thoracic Surgeons (STS) risk models, conclude Cleveland Clinic researchers based on a retrospective study of a large series of isolated SAVR operations at their institution.

“The outcomes we observed improved over time while the expected risk remained flat,” says the study’s senior author, Lars Svensson, MD, PhD, Chief, Cleveland Clinic Miller Family Heart, Vascular & Thoracic Institute. “These results call for the development of risk models that are more agile and better reflect the variability seen in current practice.”

The study, which was published in the *Journal of Thoracic and Cardiovascular Surgery* (2023;165:591-604), also demonstrated that SAVR provided durable survival benefit in low-risk patients, “supporting early surgery and providing a benchmark for transcatheter AVR,” the investigators write.

Backdrop to the study

Indications for transcatheter AVR (TAVR) now include patients at low operative risk from AVR surgery, and recent randomized trials have demonstrated positive outcomes of TAVR in this population. These developments, together with advancements in TAVR device technology and improvements in echocardiography to guide timing of TAVR in asymptomatic patients, have driven uptake of TAVR for patients at low surgical risk.

Yet over the same time period, the study authors note, SAVR has likewise undergone improvements in technique and safety — but perhaps with less attention. “We suspected that, as a result, STS prediction models might be overestimating the risk of SAVR mortality and morbidity, especially for high-volume centers,” Dr. Svensson says.

“Patients deserve to know not only what a typical outcome is but also what is potentially achievable to minimize their risk.” — LARS SVENSSON, MD, PHD

This prompted him and colleagues to evaluate outcomes after SAVR in patients with STS predicted risk of mortality (PROM) scores of less than 4%. “This mirrors the definition of ‘low risk’ used in the randomized TAVR trials, with key exceptions such as bicuspid aortic valve disease,” Dr. Svensson explains.

They identified all adults with an STS PROM score < 4% who underwent isolated SAVR at Cleveland Clinic’s main campus from January 2005 to January 2017 — 3,474 patients in all. They then compared observed mortality and composite major morbidity or mortality against STS expected outcomes according to the year the operation took place. Time-related mortality was also tracked.

Key results

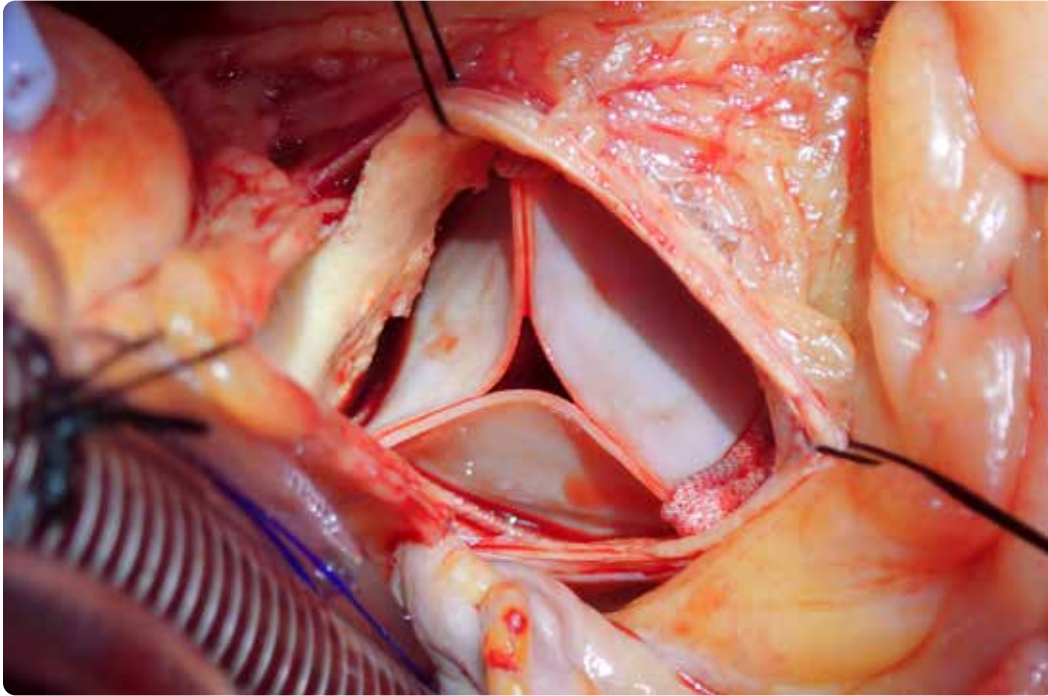
The observed operative death rate across the study period (0.43%) was substantially lower than the STS expected rate (1.6%), yielding an observed-to-expected mortality ratio of 0.27 (95% CI, 0.14-0.42). Observed-to-expected ratios were 0.65 for stroke (95% CI, 0.41-0.89) and 0.50 for reoperation (95% CI, 0.42-0.60).

Lower-than-expected mortality was seen both in the lowest-risk patients (those with PROM scores < 1%) and in patients with PROM scores of 3% to 4%. Overestimation of risk was greatest for patients at the upper end of the PROM range.

Moreover, the probability of major morbidity or mortality declined consistently throughout the study period, from 8.6% in 2006 to 6.7% in 2011 and then to 5.2% in 2016. During this period, the expected risk remained relatively constant, despite increasing use of TAVR at Cleveland Clinic.

Logistic regression analysis showed that several factors were associated with increased risk of major morbidity or mortality: higher mitral valve regurgitation grade; ventricular hypertrophy; pulmonary, renal and hepatic failure; coronary artery disease; and an earlier date of surgery.

Across the cohort, post-SAVR survival was 98% at one year, 91% at five years and 82% at nine years. “These survival rates are superior to those for the general U.S. population when matched for age, race and sex,” Dr. Svensson notes. “They illustrate a durability



AT LEFT — Photo of an implanted bioprosthesis from one of more than 15,000 SAVR procedures performed at Cleveland Clinic in the past 10 years, the highest volume in the U.S. A new study concludes that at high-volume centers like Cleveland Clinic, the operative risk of contemporary SAVR is overestimated by current Society of Thoracic Surgeons risk models.

of benefit that lends support for early intervention and can serve as a valuable comparator as data accumulate on the durability of TAVR in younger patients.”

[A call for refined risk prediction](#)

The researchers conclude that SAVR outcomes in low-risk patients have improved over time and that expected risk no longer reflects contemporary outcomes, at least not at a high-volume center. They note that a similar discrepancy between expected and actual outcomes has been detected in studies of TAVR as well.

“These results for SAVR and TAVR suggest that there is substantial variability in clinical outcomes among institutions and operators,” the study authors write. “It is important to differentiate average outcome probabilities across the nation from those that are achievable in centers of excellence.”

They emphasize that this does not mean volume is the sole contributor to outcomes, noting that Cleveland Clinic adopted a series of process improvements for aortic valve disease care beginning around 2008. These iterative changes included, among others, standardization of preoperative screening and imaging protocols, refinement of intraoperative pump and cardioplegia protocols, adoption of a checklist prior to chest closure to reduce postoperative bleeding and creation of early extubation protocols.

“A distinction should be made between generalizable results — meaning achievable at most institutions performing SAVR — and repeatable results — meaning achievable at institutions willing to

make alterations” in practice patterns and institutional culture, the researchers write. They add that most of the process changes made at Cleveland Clinic can be adopted at other centers, and many have been.

The authors note that their findings support development of a more agile, real-time risk prediction tool. “Optimal counseling on the most appropriate valve therapy for individual patients requires continuously updated risk models that reflect state-of-the-art care,” says Dr. Svensson. “Patients deserve to know not only what a typical outcome is but also what is potentially achievable to minimize their risk.”

These sentiments are echoed by Cleveland Clinic Cardiovascular Medicine Chair Samir Kapadia, MD, who was not among the study authors. “In the current era when many centers are offering aortic valve replacement, including SAVR and TAVR, it is important for patients to have benchmark data like these from high-volume excellent operators, to inform them of their treatment options,” Dr. Kapadia says. “Although randomized trials provide comparative data, there is tremendous variability in outcomes and patient selection among different U.S. centers. It is important for patients to understand these differences before making treatment choices.”

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CASE REPORT: 3-MONTH JOURNEY FROM HEALTH TO MULTIORGAN TRANSPLANT TO DISCHARGE

Young man saved multiple times by rapid collaborative response

A 36-year-old man with no remarkable medical history was transferred from an outside hospital to Cleveland Clinic with pulseless electrical activity, fulminant biventricular dysfunction (Figure) and severe malperfusion to multiple organs. Kidney and liver function was poor. The patient was immediately intubated and placed in the cardiac intensive care unit (ICU).

“This patient was about as sick as possible at presentation,” says Aaron Weiss, MD, PhD, the cardiothoracic surgeon who saw the patient that day and was on his care team throughout his stay. “Fortunately, we have an extremely effective cardiogenic shock team that can be activated at once.”

The Cleveland Clinic shock team consists of a multidisciplinary group of experts who can be assembled rapidly for a conference call to consult on a patient and develop a lifesaving management strategy. Included on the call, often with others, are a heart failure cardiologist, a heart failure cardiac surgeon and an ICU physician. A senior member of the nursing staff is also listening on the line to immediately organize room placement and care preparations as needed.

The shock team can also be accessed from outside the hospital to consult on patients not in the Cleveland Clinic system. This provides expertise to colleagues and facilitates transfer to Cleveland Clinic if appropriate.

ECMO and Impella 5.5 placed for biventricular failure

The shock team determined that the patient needed aggressive acute lifesaving circulatory support to buy time and help salvage his organs. He was immediately placed on the following:

- > Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) to provide full cardiopulmonary support and restore perfusion
- > An Impella 5.5® device via the right axillary artery to unload the left ventricle
- > Dialysis

The patient improved, and he was taken off ECMO after two days and extubated a few days later. Although he made progress and his liver function improved, he remained on dialysis and stayed in the ICU with his heart fully dependent on the Impella 5.5 without evidence of heart recovery.

Major complications develop

Soon after, the patient developed what was suspected to be heparin-induced thrombocytopenia (HIT). Initial testing was positive for HIT, and he was empirically transitioned to bivalirudin therapy. The mechanical support kept the patient stable enough to wait for confirmatory testing, which was negative for HIT.

After a few weeks for further stabilization, the transplant team agreed to list him for heart and kidney transplantation due to end-stage cardiomyopathy with Impella dependence and continued renal failure. He was determined to be status 2 (hospitalized and on mechanical support).

Subsequently, the Impella device — which is not designed for use beyond more than a few weeks — failed, causing a stroke. In an emergency procedure, it was exchanged for a new one via the left axillary artery, and the patient recovered from his stroke within a few days.

Because of this complication, his transplant priority classification was upgraded to status 1 (critically ill and on mechanical support). “If the Impella failed again, it would have been much more difficult to place another device, putting his life in imminent danger without a good solution,” Dr. Weiss explains.



FIGURE — Echocardiograms at patient presentation revealing severe biventricular dysfunction and severe mitral regurgitation.

“The same team that placed this patient on mechanical support also performed his heart transplant and was involved with the kidney transplant. ... That type of continuity can be invaluable in a complex case like this.”

— AARON WEISS, MD, PHD

Heart-kidney transplant

Ten weeks after the patient initially presented, donor organs became available, and he underwent a heart transplant with successful removal of the Impella 5.5. He was returned to the ICU and then underwent a kidney transplant the following day.

“Heart-kidney transplant is an unusual combination, and we typically perform just a handful of them every year at Cleveland Clinic,” says Ventakesh Krishnamurthi, MD, who performed the renal transplant in this case. “While the surgery itself was standard, the behind-the-scenes coordination for such a complex transplantation was anything but.”

The patient had an uneventful recovery and was discharged a few weeks later with excellent function in both transplanted organs. Three months after transplant he was doing well at home, undergoing physical therapy and expected to be able to resume full normal activities.

What saved this patient?

“This young man went from not knowing he was sick to being the sickest patient in the hospital, to walking out the door three months later with a new heart and kidney as well as a new lease on life,” says Dr. Weiss. “This amazing trajectory could only have happened at a large tertiary center like Cleveland Clinic that emphasizes collaborative, multidisciplinary care.”

Care team members identify the following pivotal points in his case:

- › **Activation of the cardiogenic shock team.** “To have the ability to gather a multidisciplinary team of experts in minutes is critical when minutes really count,” says Pavan Bhat, MD, the heart failure cardiologist who participated in the initial cardiogenic shock call and was on the patient’s care team.
- › **Early initiation of full mechanical support.** Immediately using combined ECMO and the Impella 5.5 spared the patient from

developing further organ failure, which would likely have occurred had the team used a less aggressive approach.

- › **Quick, effective management of severe complications.** Suspected development of HIT and the Impella 5.5 malfunction were two major episodes with life-threatening potential. Quick action by the team and determination to continue care for this young patient led to a positive outcome in both situations.
- › **A streamlined transplant process.** Dr. Krishnamurthi emphasizes that because Cleveland Clinic conducts many complex operations, the process of obtaining and maintaining the donor organs and coordinating the surgeries was seamless. “Facilities, physicians and support staff are in the same area, allowing for excellent communication,” he explains. “This fosters the collaborative culture that was essential to saving this patient.”

That collaborative culture also promoted an additional key to success in this case: continuity of care. “The same team that placed this patient on mechanical support also performed his heart transplant and was involved with the kidney transplant by Dr. Krishnamurthi,” says Dr. Weiss. “That type of continuity can be invaluable in a complex case like this.”

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“To have the ability to gather a multidisciplinary team of experts in minutes is critical when minutes really count.” — PAVAN BHAT, MD

WITH BROADER COVERAGE OF CAROTID STENTING LIKELY, TRANSCAROTID ARTERY REVASCLARIZATION IS POISED TO GROW

A look at where TCAR and transfemoral carotid stenting are likely headed

With the Centers for Medicare & Medicaid Services (CMS) expected to update its National Coverage Determination (NCD) on carotid artery stenting (CAS) soon (as of press time), utilization of this less-invasive alternative to carotid endarterectomy (CEA) for atherosclerotic bifurcation carotid disease may be poised to grow substantially.

The current NCD limits CMS payment for carotid stenting procedures to patients deemed to be at high risk from CEA. Many medical and surgical societies contend that since the NCD was last reconsidered in 2009, significant advances in CAS technology and techniques, standards for operators and facilities, and patient selection have brought outcomes with CAS to a level of noninferiority with CEA for appropriate patients. These groups and many clinicians have therefore called on CMS to expand its coverage of CAS to patients with standard surgical risk, to parallel its coverage of CEA.

Such a change would likely fuel greater use of stenting for patients needing intervention for carotid disease, both traditional transfemoral CAS and the direct-access approach of transcrotid artery revascularization (TCAR; Figure 1).

The timing of expanded reimbursement this year could be particularly fortuitous for TCAR. “Studies that have come out in the past year and a half have shown just how safe TCAR is and how effective it can be in treating a broad range of patients,” says Cleveland Clinic vascular surgeon Norman Kumins, MD, who has been performing TCAR since 2015 and participated in the ROADSTER pivotal trials that supported FDA approval of the one TCAR system currently commercially available in the U.S., the ENROUTE® Transcarotid Neuroprotection System.

TCAR essentials

TCAR represents a hybrid approach to CAS that involves a small incision at the base of the neck. A puncture is made in the proximal ipsilateral common carotid artery to enable stent deployment using a specialized arterial sheath to allow blood to flow away from the brain and return via a vein in the groin. This method of stroke protection is known as dynamic flow reversal, in contrast to a traditional embolic filter approach that traps debris distal to the treated lesion. Figure 2 shows debris trapped in a filter using this method.

“TCAR avoids the need to traverse the vasculature all the way from the groin, including avoidance of aortic arch manipulation,” notes Cleveland Clinic vascular surgeon Francis Caputo, MD. “Compared with transfemoral carotid stenting, it’s a simpler procedure that allows direct access to the carotid artery without risk of multiple passes or multiple opportunities to introduce embolic risk. It has shown excellent results so far but has not been compared to traditional CEA in a randomized study. We don’t have long-term data on it yet.”

But the available shorter-term data with TCAR reveal one of its chief advantages, according to Dr. Kumins: low rates of stroke (between 0.8% and 1.4%) in the ROADSTER and ROADSTER-2 clinical trials — rates that compare favorably with stroke risk for both CEA and commercially available transfemoral CAS options.

Another advantage of TCAR is its relative simplicity, which leads to an additional benefit over transfemoral CAS: a short learning curve, with providers typically becoming proficient performing TCAR within five to 10 procedures. “TCAR combines a number of basic surgical maneuvers,” Dr. Kumins says. “Together they allow for relatively rapid adoption of this technology. In contrast, transfemoral CAS is considerably more complicated and has a longer learning curve.”

Choosing among revascularization options

Despite these strengths of TCAR, CEA currently remains the gold standard for patients needing carotid revascularization, and about 90% of patients are eligible for CEA. “That tends to be the first option offered by vascular surgeons unless there’s a compelling reason to do otherwise,” Dr. Kumins notes.

He adds that beyond patients being medically unfit to undergo open surgery, there are several scenarios that argue for a percutaneous strategy, whether TCAR or transfemoral CAS:

- › Location of the carotid lesion high in the neck, in which case surgically accessing the lesion is difficult and risks injury to the cranial nerves

FIGURE 1 — Images of the carotid bifurcation in a typical patient before (left) and after (right) the TCAR procedure.



FIGURE 2 — Photo of a filter from a TCAR procedure that trapped debris (visible at bottom) that could have embolized to the brain.



- › Recurrent stenosis following prior CEA, in which case repeat CEA carries an elevated risk of cranial nerve injury
- › Prior neck surgery, vocal cord injury, neck immobility, prior radiation or other factors leading to hostile neck anatomy

When stenting is the favored approach, several patient characteristics may argue for a transfemoral approach over TCAR, such as prior radiation to the neck, tracheostomy, or limited neck access due to severe obesity, neck immobility or similar issues. On the other hand, a patient with highly tortuous vessels may be better suited to TCAR as opposed to transfemoral stenting with an embolic filter. Beyond these situations, both percutaneous options can be considered, with the choice based on relative risk of stroke and other periprocedural complications.

More technologies are in store

As the field looks toward the prospect of broader coverage of carotid stenting, investigational technologies are proliferating on both the transcarotid and transfemoral fronts.

Cleveland Clinic is participating in ongoing single-arm studies of two such investigational technologies, both involving transfemoral CAS using closed-cell stents. One is assessing the Neuroguard

IEP® System, which consists of a nitinol stent, a prepositioned post-dilation balloon and an integrated microembolic filter delivered on a single catheter to allow for fewer procedural steps. The other is evaluating the CGuard™ Embolic Prevention System, a double-layer stent comprising an inner open-cell nitinol stent and an outer closed-cell mesh layer.

“The new technologies for carotid stenting are going to multiply,” says Dr. Caputo. “Now that both transcarotid and transfemoral approaches are established modalities, a primary issue to consider is when it’s appropriate to use them in asymptomatic patients, particularly with the availability of new medical therapies.”

Answers to that question, he says, are expected from the ongoing multicenter CREST-2 trial (NCT02089217), but results are not anticipated for several years. “One of the most important things we do as vascular surgeons is decide whether or not carotid revascularization is necessary in asymptomatic patients,” Dr. Caputo concludes. “While the proliferation of new approaches and options is very welcome, we need to be judicious in when we apply them.”

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SURGERY FOR INFECTIVE ENDOCARDITIS: WHEN TO REPAIR, WHEN TO REPLACE?

Insights from guidelines and the Cleveland Clinic experience

Options for surgical treatment of infective endocarditis (IE) include valve repair, reconstruction or replacement. Guidelines generally recommend repairing the infected valve whenever possible. However, valve replacement is more commonly performed.

Cleveland Clinic researchers recently analyzed outcomes of 2,760 aortic, mitral and tricuspid valve surgeries for IE performed at their institution from 2002 to 2022. In a presentation at the Society of Thoracic Surgeons 2023 annual meeting, Shinya Unai, MD, Surgical Director of Cleveland Clinic's Endocarditis Center, used the data to illustrate when infected valves should be repaired, how to treat complex repairs and when replacement is the better option.

Aortic valve IE

2016 consensus guidelines from the American Association for Thoracic Surgery (AATS) on the surgical treatment of IE say repair of native aortic valve IE may occasionally be possible when infection is limited to the valve cusps.

Of the 40 native aortic valve surgeries for IE performed at Cleveland Clinic in 2021, 39 were replacements or reconstructions. "There are not many situations where the aortic valve can be repaired — perhaps a single perforation in otherwise healthy-looking cusps," Dr. Unai observes (Figure 1).

When replacement is needed, reconstruction of the valve using the Ozaki procedure is an alternative to replacement with a prosthesis when the infection is limited to the cusps.

In the Ozaki procedure, the diseased valves are excised and replaced with cusps cut to size from autologous pericardium. The technique has multiple advantages, including no need for postoperative anticoagulation and superior hemodynamics.

An allograft may be beneficial when root reconstruction and replacement is needed. "We use allograft for invasive aortic valve endocarditis with annular invasion," Dr. Unai says, "as it is more flexible than a prosthetic valve, which makes it easier to place."

He adds that the Ross procedure is another technique that can be performed to replace the aortic valve and reconstruct the aortic root for invasive disease. In this procedure, the aortic valve is removed and replaced with the patient's pulmonic valve. The pulmonic valve is then replaced with a pulmonary allograft.

"The Ross procedure has long-term durability, making it particularly suitable for younger patients," he explains. "The allograft has the



FIGURE 1 — For IE involving the aortic valve, repair is generally limited to cases such as a single tear in otherwise healthy cusps (left photo), whereas replacement is needed when multiple cusps are infected (right photo).

ability to grow, anticoagulation is not needed and the reinfection risk is the lowest among all strategies."

Be alert for hidden complexities

Valve function is generally visualized with transesophageal echocardiography (TEE), but TEE cannot reveal infection behind calcium deposits. "Aortic valve endocarditis can be complex, even if it doesn't show on TEE or CT," Dr. Unai says. "Surgeons need to be prepared to do a root replacement or place a homograft, if required."

Sixty to 100 root replacements are performed at Cleveland Clinic every year, with a low 30-day mortality rate of 2% to 4%. "It's a technically demanding procedure, but fairly safe," Dr. Unai says.

Mitral valve IE

According to the 2016 AATS guidelines, repair is the preferred option for mitral valve IE.

In a recent study (*J Thorac Cardiovasc Surg.* 2022 Apr 5 Epub), Dr. Unai and colleagues reviewed all isolated mitral valve surgeries at Cleveland Clinic between 2002 and 2020 to identify the factors that influenced outcomes. Of the 326 cases of native mitral valve infection, 120 were repairs and 200 were replacements.

"Patients needing standard repairs, such as for windsock lesions, did well," he notes. "After more complex repairs, defined as lesions larger than 1 cm requiring large patches and NeoChords®, patients

had higher rates of reoperation and mortality. Valve pathology requiring complex repairs is a surrogate of advanced disease, and a complex repair may not necessarily improve long-term outcome. In a sick patient, a replacement with a shorter cardiopulmonary bypass time may have a benefit.”

Extensive bileaflet infection should prompt replacement of the mitral valve, he says.

In the Cleveland Clinic experience, risk-adjusted outcomes of repair and replacement for mitral valve IE, including survival, have been similar in all groups. “The message is simple,” says Dr. Unai. “Repair if it’s straightforward; if not, replace.”

Tricuspid valve IE

The 2016 AATS guidelines recommend that repair of infected tricuspid valves be attempted whenever possible. Cleveland Clinic experience aligns with this recommendation. Of the 23 tricuspid valve IE cases seen in 2021, about 80% were repaired by resecting the infected and damaged tissue, patching the defect with pericardial tissue, and adding NeoChords and an artificial ring.

Replacement is recommended when the entire valve is infected. “We try very hard to repair, but if it doesn’t look like the valve can be repaired with less than moderate tricuspid regurgitation, I would replace it,” Dr. Unai advises.

Two-valve involvement

Due to the proximity of the aortic valve to the mitral and tricuspid valves, IE infection can easily spread from the aortic valve to an adjacent valve. Kissing lesions (Figure 2) — in which floppy vegetations on the aortic valve touch the mitral valve, transferring the infection — are fairly easy to repair, says Dr. Unai.

In complex cases, when roots of both the aortic and mitral valves are infected, the base of the anterior mitral leaflet and aorto-mitral curtain can be reconstructed with an allograft in a “hemi-Commando” procedure, as described by a Cleveland Clinic team (*Eur J Cardiothorac Surg.* 2018;53:1055-1061).

Aortic valve IE extending onto the tricuspid valve is usually repairable with a patch and plication of the septal-anterior commissure, Dr. Unai notes.

Keys to success

It is incumbent upon surgeons who do not treat infected valves on a regular basis to learn these conditions and options. Dr. Unai shares this overarching advice:

- › A good valve repair is better than a valve replacement, which is better than a bad repair.
- › Plan your surgical approach based on imaging, but be prepared to perform a more complex procedure than expected.

- › Radical debridement of the tissue is absolutely essential.
- › Use autologous tissue and avoid foreign material whenever possible.
- › Master alternative options for repair, replacement and reconstruction so that you are prepared to provide the best treatment for every individual.

Moreover, surgical success depends on a solid foundation of comprehensive IE care. “Treating endocarditis effectively is a team sport in which each team member brings expertise to diagnosis

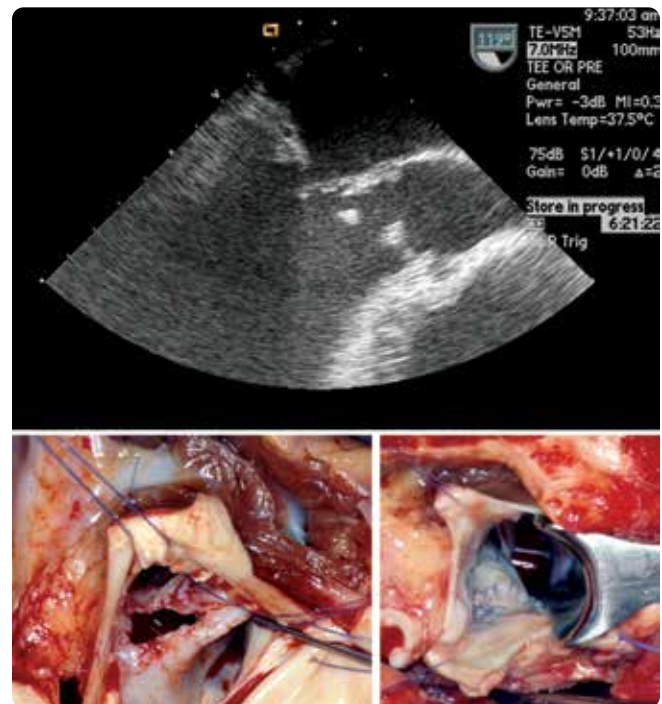


FIGURE 2 — Echocardiogram and operative photos showing a kissing lesion — in which IE vegetations spread from aortic to mitral valve — and its surgical repair.

and management,” says Brian Griffin, MD, Section Head of Cardiovascular Imaging and an IE expert. “We are fortunate at Cleveland Clinic to have an Endocarditis Center with a highly experienced team comprising infectious disease physicians, imaging and valve disease physicians, and superbly experienced surgeons. We often now use multimodality imaging, especially in complex endocarditis. This includes not just TEE but also CT and MRI, and even PET scanning in specific situations. Our ability to recognize complex issues early, and therefore operate earlier than in the past, has led to substantial improvements in outcomes.”

Contact Dr. Unai at 216.445.5902 and Dr. Griffin at 216.444.6812.

STUDY IDENTIFIES GUT MICROBE-DERIVED TMAO AS A NOVEL MEDIATOR OF ABDOMINAL AORTIC ANEURYSM

Findings hold implications for screening and potential nonsurgical therapy

TMAO, a metabolite produced by gut bacteria, has already been linked to myocardial infarction, stroke and other cardiometabolic diseases. Now a new study shows that it also increases risk for abdominal aortic aneurysm (AAA).

The findings, published in *Circulation* (2023;147:1079-1096) by a multicenter team including Cleveland Clinic researchers, are significant for two reasons. First, they suggest that TMAO testing could be used as a screening tool for AAA. Second, they raise the prospect that blocking TMAO could offer a first-ever nonsurgical treatment option for the condition.

“Aortic aneurysm is a horrible silent killer, and we currently have no therapies for it except surgery,” says co-investigator Stanley Hazen, MD, PhD, Chair of the Department of Cardiovascular and Metabolic Sciences in Cleveland Clinic Lerner Research Institute. “Most people don’t present until they have an aortic dissection, at which point a significant number of patients don’t survive. This paper argues that a therapy might be developed to target the gut microbial TMAO pathway and halt the progression of aneurysm growth, so it’s highly exciting for that reason.”

TMAO’s pathologic footprint expands

TMAO (trimethylamine *N*-oxide) is a metabolite that’s produced when gut bacteria digest choline, carnitine and lecithin — nutrients that are most abundant in red meat and other animal products. Multiple studies by Dr. Hazen and colleagues over the past decade have shown direct mechanistic links between high levels of TMAO and cardiometabolic diseases including atherosclerosis, thrombosis and chronic kidney disease.

Study co-investigator Scott Cameron, MD, PhD, says that evaluating

connections between TMAO and AAA just made sense, since atherosclerosis is the leading pathogenic driver of AAA and because TMAO elevation is fairly established in many patients with atherosclerosis. Even so, the connection turned out to be stronger than he expected. “I was quite surprised by how striking the data were,” says Dr. Cameron, Section Head of Vascular Medicine at Cleveland Clinic.

Findings in brief

The research team — led by corresponding author Phillip Owens, PhD, of the University of Cincinnati College of Medicine — first studied plasma samples taken from two independent AAA case-control cohorts numbering more than 2,100 patients. They found that higher levels of TMAO were indeed significantly associated with increased incidence of AAA and with aneurysm growth.

They then conducted animal studies to better understand the connection. First they found that increasing TMAO levels in mouse models of AAA caused the animals’ aneurysms to grow faster. They then gave the mice a drug that blocks TMAO synthesis, fluoromethylcholine, and found that it stopped aneurysm development. Finally, they simultaneously inhibited TMAO synthesis in mice and introduced TMAO directly in drinking water; this caused aneurysms to grow again.

The collective results are compelling, according to Dr. Hazen, who also serves as Co-Section Head of Preventive Cardiology and Rehabilitation at Cleveland Clinic. “There’s ample data arguing that TMAO is contributing to aneurysm development in multiple different animal models, and the human data all support this,” he notes.

An additional mechanistic study showed that a stress sensor protein called PERK (protein kinase R-like endoplasmic reticulum kinase), which is involved in correcting misfolded proteins, plays a key role in the process.

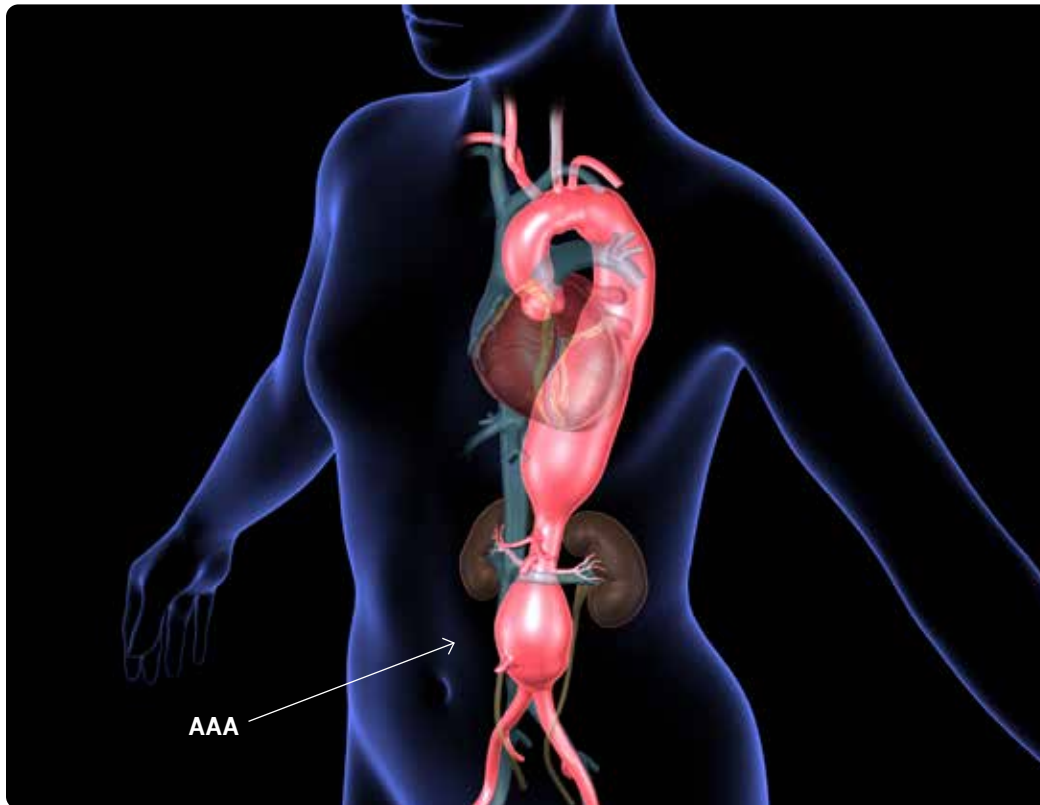
Implications for screening and noninvasive therapy

Drs. Hazen and Cameron stress that their study shows the potential for major new tools in diagnosing and treating AAA.

“We have no medical therapies to treat abdominal aortic aneurysm right now that are particularly effective, and we have no blood tests to predict who is going to have an aneurysm and who will do well.”

— SCOTT CAMERON, MD, PHD

“This adds to the list of conditions that a TMAO-blocking agent could potentially treat, whether it be atherosclerosis, thrombosis, heart failure or chronic kidney disease — and now aneurysm expansion and growth.” — STANLEY HAZEN, MD, PHD



AT LEFT — Abdominal aortic aneurysm (AAA) is estimated to cause 15,000 deaths in the U.S. annually. Currently, the only treatment option is surgical intervention. The current study implicating the gut microbiome and associated metabolites as novel mediators of AAA introduces the prospect of pharmacologic treatment of AAA with targeted nonlethal inhibitors of the gut microbiome.

“We have no medical therapies to treat abdominal aortic aneurysm right now that are particularly effective, and we have no blood tests to predict who is going to have an aneurysm and who will do well,” Dr. Cameron observes.

The study supports the need for more facilities to offer TMAO testing, he adds. For patients who do show elevated levels of TMAO, providers should consider additional imaging to screen for AAA.

The study also suggests a possible new treatment, Dr. Hazen says. His lab developed the tool drug fluoromethylcholine used in the present studies, and his lab has developed additional drugs that are being evaluated to block TMAO formation in humans.

“This adds to the list of conditions that a TMAO-blocking agent could potentially treat,” he says, “whether it be atherosclerosis, thrombosis, heart failure or chronic kidney disease — and now aneurysm expansion and growth.”

He notes that his team will continue to work on follow-up studies.

[Gut-cardiovascular connections mount](#)

Beyond the clinical implications, Dr. Hazen says the study is yet another example of the surprising connections between the gut microbiome and other systems within the body. He adds that it also represents a new frontier in medicine: manipulation of microbes — not by killing them with antibiotics, but by drugging them.

“Gut microbes are linked to our health in so many different ways that we never would have expected,” he concludes. “In this case they are making a metabolite that’s causing aneurysm growth in the host. How cool is that?”

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[Contact Dr. Hazen at 216.444.9426 and Dr. Cameron at 216.444.1680.](#)

INTEGRA-D TRIAL LAUNCH RAISES PROSPECT OF CARDIAC CONTRACTILITY MODULATION AND DEFIBRILLATION IN A SINGLE DEVICE

Clinical testing of the first implantable device combining cardiac contractility modulation with cardioversion/defibrillation is underway following the world's first implantation, which took place at Cleveland Clinic.

The investigational OPTIMIZER® Integra CCM-D System (CCM-D System) merges the Optimizer® Smart System, an FDA-approved cardiac contractility modulation (CCM) device, with a new type of implantable cardioverter-defibrillator (ICD). The result is a single device designed to improve the heart's ability to contract while protecting against sudden cardiac death.

"The device may improve heart failure symptoms while at the same time providing therapy for ventricular tachycardia (VT) and ventricular fibrillation (VF)," says electrophysiologist Niraj Varma, MD, PhD, who performed the first implantation with his Cleveland Clinic colleague Bruce Wilkoff, MD, in May 2023. Dr. Varma serves as U.S. national principal investigator of the INTEGRA-D study, a multicenter trial evaluating the device that was launched with the implantation at Cleveland Clinic.

Although cardiac resynchronization therapy (CRT) provides defibrillation and also treats heart failure with low ejection fraction, it is used only in patients with left bundle branch block, or about 10% to 15% of the heart failure population. The new device potentially applies to another significant portion of heart failure patients.

In contrast to CRT, which reverses ventricular dyssynchrony by pacing the left ventricle, CCM treats the muscle of the failing heart directly by stimulating the ventricular septum for several hours a day. This is nonexcitatory but acts to enhance intracellular calcium release and contractility. Diastolic function also improves. Over time, CCM may reverse the adverse remodeling that occurs during heart failure, thereby strengthening the heart.

Rechargeable battery, fewer procedures and leads

The CCM-D System is similar in size to other ICDs and is the first to be rechargeable. Whereas current defibrillator batteries need replacing every seven to 12 years, the rechargeable defibrillator is expected to last 20 years with only one hour of recharging per week.

The device also requires only two leads. "We previously needed to put in two devices — a CCM device and a defibrillator — to achieve better heart function and prevent sudden death," says Dr. Wilkoff, Director of Cardiac Pacing and Tachyarrhythmia Devices. "Both have leads and need battery changes. This requires multiple procedures that increase the risk of complications, including infection and bleeding. Although antibiotic pouches can reduce

BELOW — Drs. Wilkoff (left) and Varma (right) during the world's first implantation of the investigational CCM-D System.



infection rates, infections are costly, painful and dangerous. Device extraction is expensive and potentially hazardous. Anything we can do to reduce the number of procedures and leads reduces the risk of complications, lowers cost and improves care value."

Study at a glance

INTEGRA-D is a prospective, single-arm trial in which the CCM-D System will be implanted in 300 eligible patients at centers nationwide. The goal is to demonstrate whether the system can safely and effectively convert induced VF and spontaneous VT and/or VF episodes in patients with stage C or D heart failure who remain symptomatic despite guideline-directed medical therapy. Patients must have a left ventricular ejection fraction of 40% or less and cannot be eligible for CRT.

A subset of patients will be induced into VF "on the table" in the procedure room. During follow-up, expected to last at least two years, the inappropriate shock rate and device-related complications will be evaluated.

"If the defibrillator performs according to specifications, it will be approved as a defibrillator," Dr. Varma notes. "It will then be available for established indications for ICD therapies."

Drs. Varma and Wilkoff are paid consultants to Impulse Dynamics, developer of the CCM-D System and sponsor of the trial.

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 Contact Dr. Varma at 216.444.2142 and Dr. Wilkoff at 216.444.4975.

IMAGE OF THE ISSUE

INFRARED FLUORESCENCE IMAGING IN ROBOTIC THORACIC SURGERY

Imaging dye enables vascular assessment to promote procedural precision and safety



ABOVE — Intraoperative image showing use of indocyanine green for vascular assessment of the gastric conduit during robotically assisted esophagectomy.

Cleveland Clinic's thoracic surgery program performs 250 to 300 robotically assisted operations each year, including lobectomies, esophagectomies, operations for benign esophageal disease, and resection of mediastinal tumors.

These high volumes make it easier for the program to adopt new technologies to improve safety and patient outcomes. One example is near-infrared intraoperative fluorescence imaging with the contrast agent indocyanine green (ICG), which Cleveland Clinic surgeons have integrated into a number of robotic thoracic surgery procedures.

The above image illustrates the use of ICG for vascular assessment of the gastric conduit during robotically assisted esophagectomy for esophageal cancer. The presence of ICG (in green) serves to confirm

that vascular perfusion of the conduit is adequate for reconstruction. "This gives us reassurance that we have good blood supply to the very tip of the stomach," says Sudish Murthy, MD, PhD, Section Head of Thoracic Surgery at Cleveland Clinic. "It makes our operations safer for patients."

Another thoracic surgery application of near-infrared intraoperative fluorescence imaging is in lung mapping for robotically assisted pulmonary resection. The contrast agent helps the surgeon identify which part of the lung is not perfused, allowing more precise targeting of the area that has been devascularized for resection.

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[Contact Dr. Murthy at 216.444.5640.](#)

CASE STUDY IN COLLABORATION

IMPROVING OUTPATIENT PROCEDURE EFFICIENCY WITH CONTINUOUS IMPROVEMENT METHODOLOGY

Efficiency is a high priority for healthcare organizations in terms of optimizing resources, standardizing processes, and promoting patient and caregiver experience while also maintaining high-quality and safe patient care.

Analyzing operational data to assess workflow efficiency may uncover process issues. A multidisciplinary team approach to identifying challenges, determining solutions and implementing change, with use of continuous improvement (CI) methodology, aims to achieve successful, sustainable outcomes. This was the result at Deborah Health and Lung Center following a collaborative CI project with Cleveland Clinic's Heart, Vascular & Thoracic Institute (HVTI) Advisory Services team.

Deborah Heart and Lung Center (DHLC) is an 89-bed specialty teaching hospital in Browns Mills, New Jersey, that began an alliance relationship with Cleveland Clinic's HVTI in 2019. Under this relationship, Cleveland Clinic HVTI's Advisory Services team works with DHLC to build upon existing high-quality outcomes, optimize efficient resource allocation, develop and enhance existing programs, and expand services. DHLC leaders and the Advisory Services team recognized an efficiency opportunity for the outpatient procedure unit (OPPU) and embarked on a structured CI project to achieve sustainable results.

Background

The OPPU serves as the entry point for patients coming to the facility for outpatient procedures. Patients who arrive at the OPPU will eventually move to the cardiac catheterization lab, electrophysiology (EP) lab or cardiovascular operating rooms (ORs) for their procedures. Unlike procedures in the cath and EP labs, procedures for vascular surgery cases were identified as not consistently starting on time. The team observed that only 67% of vascular surgery cases started on time for the period of January through July 2022. The DHLC team performed an internal review of reasons for the delays, identifying several possible causes.

DHLC leadership sought to partner with Cleveland Clinic's HVTI Advisory Services team to fully address the issues. As part of an improvement initiative, the team engaged with DHLC's direct clinical caregivers to help them with the CI tools and techniques needed to reach their goals.

CI methodology

HVTI's Advisory Services team began the engagement by working with the DHLC team to thoroughly define the issues and the reason that change was important to service line success. While the impetus for the project was delays in on-time starts for DHLC's vascular ORs, the multidisciplinary team realized that the OPPU provides pre-procedural care for multiple specialties. As a result, improving operational efficiencies for the OPPU required examining multiple factors. Comprehensive data analysis conducted by the Cleveland Clinic team demonstrated key triggers for the delays in patient arrival time to the OR, including processes around obtaining informed consent, patient arrival times, variability in case scheduling and late changes/add-ons, transportation, and patient preparation time. Consequently, the team readjusted its focus to improve efficiencies for the OPPU by standardizing processes that would help not only the vascular ORs but the other procedural areas as well.

The recommended process changes were:

- > A revised informed-consent process (timing, electronic signature, follow-up)
- > Implementation of OR and OPPU huddles
- > Adjustment of patient arrival time
- > Development of standardized workflows for patient preparation in the OPPU
- > Formation of a dedicated patient transport team

The team also conducted initial analysis to define baseline metrics and set targets for future performance in the OPPU. These metrics included:

- > First-case on-time starts
- > Time from when a patient is ready to leave the OPPU to when they actually leave ("OPPU wheels out")
- > Time from patient check-in to OPPU wheels out
- > Time from when patient transport is called to OPPU wheels out

DHLC's OPPU team used a plan-do-check-act (PDCA) approach to enhance communication between the OPPU, procedure areas and

TABLE: Changes in Key Operational Metrics in the OPPU				
Metric	Baseline (Project Start)	Target	Post-Implementation Results	
			60 Days (April 2023)	90 Days (May 2023)
Cardiothoracic OR on-time starts	82%	90%	100% (↑18 percentage points)	94% (↑12 percentage points)
Vascular OR on-time starts	67%	90%	100% (↑33 percentage points)	79% (↑12 percentage points)
Ready time to wheels out	90 min	5 min	20 min (↓70 min)	13 min (↓77 min)
Registration check-in to wheels out	202 min	101 min	95 min (↓107 min)	63 min (↓139 min)
Transport called to wheels out	90 min	5 min	10 min (↓80 min)	3 min (↓87 min)

ORs with use of an electronic patient tracking board. PDCA is an iterative approach to problem solving in which teams develop their initial improvement opportunities, implement plans to address those opportunities, verify the impact of implementation and then act to improve based on what they learned from implementation.

The electronic tracking board is visible to caregivers in the procedural areas. Prior to this initiative, the cath lab, EP lab and OR teams were not aware when a patient’s preparation was complete and the patient was ready for transport from the OPPU to the procedural area. The team recognized an opportunity to improve electronic communication between the OPPU and the procedural areas and enlisted the support of DHLC’s nursing informatics specialist. Nursing informatics helped the OPPU create a “ready” indicator on the patient tracking board to identify when patients were prepared for their procedure. The visible icon notifies the receiving department that the patient is ready for transport. The procedural/OR team then transports the patient from the OPPU to the procedural area if they have completed their patient preparatory work. This follows CI best practices in which work is pulled from one area to another rather than being pushed onto another department. This allowed the procedural/OR teams to transport patients from the OPPU as space in each procedural area became available.

Use of the electronic patient tracking board as a communication mechanism quickly had an impact on the efficiency of patient transport from the OPPU to the procedural areas. “It has made quite a difference in our ability to enhance efficiency in the OPPU and meet our goal for first-case on-time starts,” says Gerilyn Angelo, RN, Director of Medical-Surgical Nursing Services at DHLC.

The HVTI and DHLC teams then collaboratively developed a completion plan to help the OPPU team ensure that its desired performance metrics and targets were maintained. A well-defined completion plan enables achievement of project goals by defining the tasks required for success and identifying specific individuals responsible and accountable for achieving outcomes. The final completion plan is a comprehensive list with established due dates that matches tasks with the accountable individuals.

Sustained improvements

The DHLC team members achieved their target performance metrics within the first 60 days after implementing changes, as shown in the table. After 90 days, the team was still performing above its baseline performance. On-time starts improved improved from 82% to 94% for cardiothoracic ORs and from 67% to 79% for vascular ORs. Other key metrics also demonstrated improvement in team performance.

The DHLC team developed a group text thread with the transport director that allowed communication of the OPPU schedule 24 hours in advance, and the OPPU and procedural teams implemented a small group meeting to plan staffing and resources. These two changes helped drive the improvements noted in the table.

“We solve issues in real time between the OR, OPPU and transport leadership. There is no need for an additional meeting,” observes Ms. Angelo. “It has been a pleasure working with Cleveland Clinic’s Advisory Services team. Timely responses and recommendations for continuous improvements have allowed our OPPU team to achieve our goal for first-case on-time starts.”

Patient-focused impact

“This engagement between DHLC and HVTI’s Advisory Services team demonstrates the effectiveness of Cleveland Clinic’s structured approach to continuous improvement,” says Suma Thomas, MD, MBA, Vice Chair, HVTI Strategic Operations. “This approach enables team members to enhance all aspects of care, including operational efficiencies, patient safety, quality, patient experience and caregiver experience.”

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For information on affiliation or alliance opportunities with Cleveland Clinic’s Heart, Vascular & Thoracic Institute, visit clevelandclinic.org/hvtiadvisoryservices or email [Amanda Leseska at leseska@ccf.org](mailto:Amanda.Leseska@ccf.org).

CME PREVIEW

MASTER AORTIC VALVE DISEASE MANAGEMENT IN MANHATTAN THIS DECEMBER

Popular case-based course takes a multidisciplinary approach to wide range of care issues

A Case-Based Approach to Mastering the Aortic Valve: Imaging, Innovation and Intervention

Fri.-Sat., Dec. 15-16, 2023

InterContinental New York Barclay,
New York City

Information/registration: ccfcme.org/aorticvalve

Cleveland Clinic's crowd-pleasing biennial CME deep dive into aortic valve (AV) disease returns to midtown Manhattan this December with its most ambitious agenda to date.

The course's 16 expert faculty — cardiologists and cardiothoracic surgeons from Cleveland Clinic and three other leading U.S. cardiovascular centers — will touch on a wealth of timely issues in AV disease management across nine topical sessions over a full Friday and a Saturday morning.

Case-based discussion takes center stage, with case presentations figuring into nearly all topical sessions. Two sessions devoted to difficult scenarios in AV disease consist entirely of case studies, with the cases serving as a springboard to explore clinical decision-making. All cases are approached in a multidisciplinary fashion, featuring perspectives from a clinical or imaging cardiologist, an interventional cardiologist and a cardiothoracic surgeon.

Conditions and presentations explored in this comprehensive case-based manner include (among others):

- › Low-flow, low-gradient aortic stenosis
- › AV endocarditis
- › Radiation heart disease with AV involvement
- › Connective tissue disorders

- › AV disease with concomitant left ventricular outflow tract obstruction
- › Heart failure with aortic insufficiency and aortic stenosis

Beyond the case-based explorations, highlights include:

- › A kickoff overview of contemporary developments in AV disease
- › A recap of key papers in AV disease over the past two years
- › A “crystal ball” session profiling likely developments in AV disease in the next few years
- › A “fireside chat” on the past, present and future of transcatheter AV replacement
- › A concluding rapid-fire session on managing post-interventional issues

The program also addresses a number of special issues in AV disease management, such as gender-related differences in aortic stenosis presentation and outcomes as well as management and ethical issues in the care of very elderly patients with AV disease.

“This course will once again provide insights into investigating the patient with aortic valve disease as well as how to achieve excellent outcomes through best practice management and the selection and execution of surgical and interventional treatments,” says course co-director Lars Svensson, MD, PhD, Chief, Cleveland Clinic Heart, Vascular & Thoracic Institute (HVTI). His fellow course co-directors are Milind Desai, MD, MBA, HVTI Vice Chair for Education; Brian Griffin, MD, Section Head of Cardiovascular Imaging; and Samir Kapadia, MD, Chair of the Department of Cardiovascular Medicine.

Adjournment of the course shortly after noon on Saturday allows time for weekend exploration of Manhattan at the height of its holiday decorations.

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



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

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SAVE THE DATES FOR CME

Prevention and Management of Cardiovascular Disease: A Contemporary Update

Thu.-Fri., Oct. 12-13, 2023
Royal Society of Medicine, London, U.K.

Information/registration: rsm.ac/CardiovascularCC

Cardiovascular Update for the Primary Care Provider: Improving Cardiovascular Care Access and Outcomes Across All Communities

Thu.-Fri., Oct. 19-20, 2023
Hilton Cleveland Downtown

Information/registration: ccfcme.org/CVdisparity23

Utilizing Artificial Intelligence in the Prevention and Management of Disease: Applications, Benefits and Current Challenges

Fri.-Sat., Oct. 27-28, 2023
InterContinental Chicago

Information/registration: ccfcme.org/cardiovascularAI23

Advancing Cardiovascular Care: Current and Evolving Management Strategies 2023

Fri., Nov. 3, 2023
Hyatt Regency Columbus, Columbus, Ohio

Information/registration: ccfcme.org/columbusCVcare23

A Case-Based Approach to Managing Aortic Valve Disease: Imaging, Intervention and Innovation

Fri.-Sat., Dec. 15-16, 2023
InterContinental New York Barclay
New York City

Information/registration: ccfcme.org/aorticvalve

8th Annual Advances in Congenital Heart Disease Summit

Thu.-Sat., Feb. 22-24, 2024
Disney's Contemporary Resort
Orlando, Florida

Information/registration: ccfcme.org/congenital

Valve Disease, Structural Interventions and Diastology Summit

Thu.-Sun., March 7-10, 2024
Fontainebleau Miami Beach
Miami Beach, Florida

Information/registration: ccfcme.org/echo

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

TALL ROUNDS®

A unique online continuing education program from Cleveland Clinic's Heart, Vascular & Thoracic Institute. Complimentary CME credit available: clevelandclinic.org/tallrounds