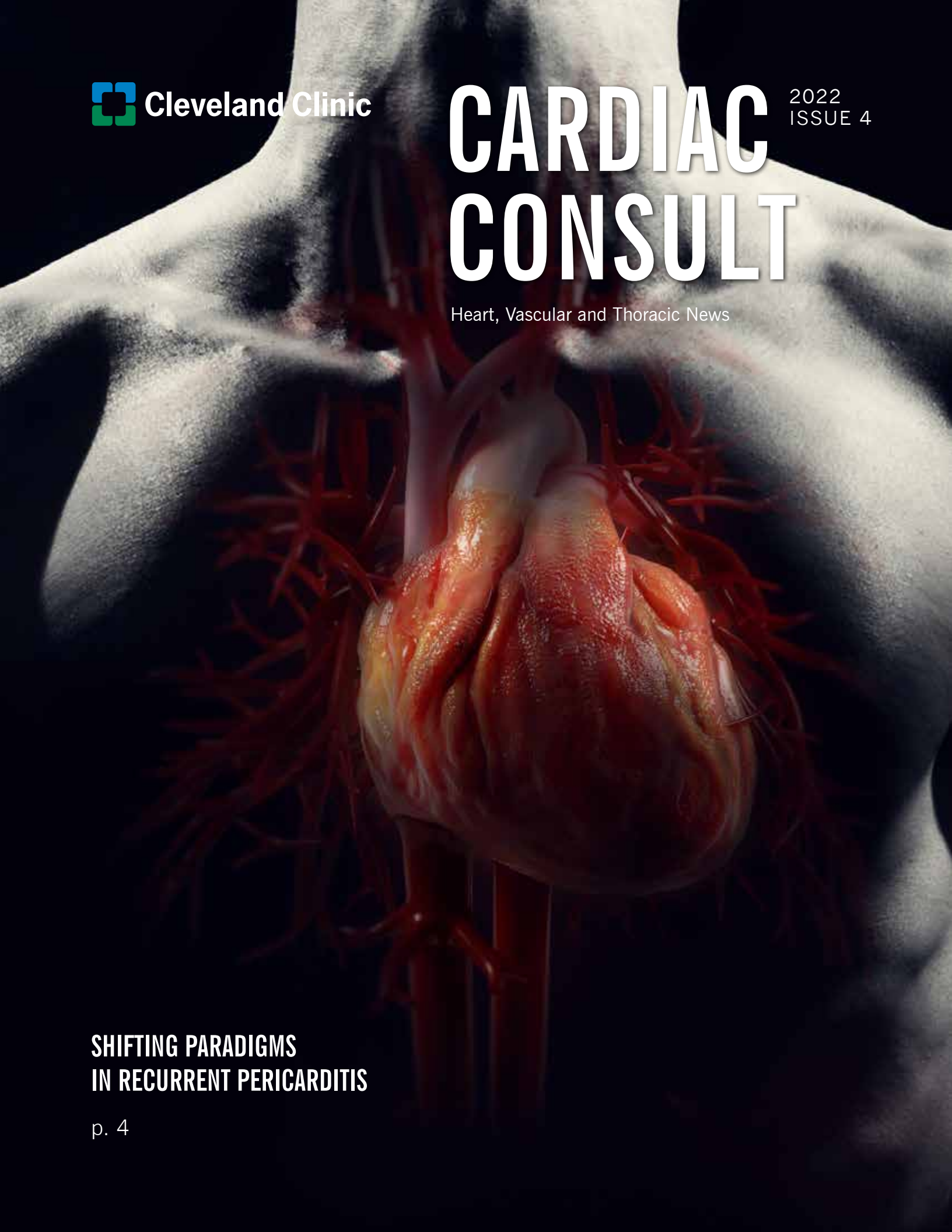

Cleveland Clinic

CARDIAC CONSULT

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Heart, Vascular and Thoracic News

SHIFTING PARADIGMS IN RECURRENT PERICARDITIS

p. 4

FROM THE CHAIR

"If you can look into the seeds of time, and say which grain will grow and which will not, speak then to me." — SHAKESPEARE

In today's era of rapid change and advances, we do not know what will succeed and what will not, but we can still strive to shape the future. In fact, shaping the future is an essential responsibility of healthcare leaders.

As a recognized leader in cardiovascular and thoracic care, Cleveland Clinic's Heart, Vascular & Thoracic Institute embraces this responsibility in a diversity of ways. This issue of *Cardiac Consult* provides a sampling:

- The cover story on recurrent pericarditis (page 4) profiles a major review article in which our pericarditis experts call for an update to management guidelines to reflect important advances in imaging and drug therapy, including some based on a Cleveland Clinic-led multicenter trial.
- The story on page 8 reports on the latest study in a decade-long string of research led by our Stanley Hazen, MD, PhD, that is methodically elucidating the substantial role of the gut microbiome in a spectrum of cardiometabolic diseases — and identifying promising targets for intervention.
- The article on page 10 shares how our staff are joining others to call on the Centers for Medicare & Medicaid Services to bring reimbursement policy for carotid artery stenting in line with well-established clinical trial evidence.
- The report on our growing experience with post-TAVR cardiac surgery on page 14 provides useful guidance on how best to manage a highly challenging patient presentation that is on course to grow ever more frequent in the years ahead.

The future remains unknowable, but we will continue to work with colleagues around the nation and the world to bend it toward better care and outcomes for all patients through research, education and patient advocacy.

Respectfully,

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

Cleveland Clinic was named a top U.S. hospital in *U.S. News & World Report*'s "Best Hospitals" rankings for 2022-23, as well as the No. 1 hospital in cardiology and heart surgery for the 28th consecutive year.

ON THE COVER — Pericarditis, the most common form of pericardial disease, recurs in 15% to 30% of patients who experience an initial episode. A new review by Cleveland Clinic experts makes the case for updating management guidelines for recurrent pericarditis to reflect recent advancements that help considerably curb symptoms and shorten treatment duration. See page 4 for more.

RESEARCH ROUNDUP

RECENT STUDIES OF NOTE FROM CLEVELAND CLINIC

Dietary Supplements Don't Stack Up to Low-Dose Statin for LDL-C Lowering

Despite marketing claims, none of six dietary supplements commonly used for lipid lowering significantly reduced LDL cholesterol (LDL-C) versus placebo in adults with elevated atherosclerotic risk, finds the prospective Supplements, Placebo or Rosuvastatin Study (SPORT). The Cleveland Clinic trial randomized 190 adults with increased 10-year risk for atherosclerotic cardiovascular disease to 28 days of treatment with fish oil, cinnamon, garlic, turmeric, plant sterols, red yeast rice, placebo or low-dose statin therapy (rosuvastatin 5 mg/day). While rosuvastatin significantly lowered LDL-C compared with placebo (35.2% relative reduction; $P < 0.001$), none of the supplements did, and the garlic supplement was associated with a significant LDL-C *increase* versus placebo. "Despite a lack of evidence, use of dietary supplements has risen exponentially in the past three decades, including for dyslipidemia," says cardiologist Luke Laffin, MD, who presented the study at the American Heart Association meeting in November. "Our findings run counter to the 'cholesterol health' claims made by supplement manufacturers. More patient education is needed on these supplements' lack of benefit for reducing key cardiovascular risks."

Reimplantation vs. Bentall Root Procedure for Aortic Root Aneurysm: Which to Choose?

For patients with aortic root aneurysm with or without aortic regurgitation, both valve-sparing reimplantation and root replacement with a Bentall-type procedure are associated with excellent early and long-term outcomes. So finds a retrospective analysis from Cleveland Clinic (*Aorta.* 2022;10:57-68), prompting its authors to recommend reimplantation for most patients in this setting. Of 643 adults with tricuspid aortic valves who underwent elective aortic root replacement at Cleveland Clinic over a 17-year period, 448 underwent aortic valve reimplantation and 195 underwent a Bentall operation with a mechanical or tissue prosthesis. Operative mortality and in-hospital adverse events were comparable between the two groups. At 10 years, the reimplantation group had 95% survival and 98% freedom from aortic valve reintervention. "Given the need for lifelong anticoagulation with mechanical valves and the risk of deterioration with bioprosthetic valves, these long-term results make reimplantation the better choice for most patients," says lead author and cardiothoracic surgeon Lars Svensson, MD, PhD.

Patient Selection Algorithm Optimizes Outcomes of Robotic Mitral Valve Surgery

An algorithm for selecting patients with degenerative mitral valve disease for robotically assisted surgery leads to outcomes at least as good as those for patients undergoing sternotomy. So finds a nonrandomized study of the Cleveland Clinic-developed algorithm, which bases patient selection on features of preoperative transthoracic echocardiography and CT. The algorithm was applied to 1,000 consecutive patients undergoing surgery for isolated degenerative mitral regurgitation at Cleveland Clinic. Under the algorithm, 605 patients were selected for robotic surgery and 395 for sternotomy. No hospital deaths occurred across the cohort, and valve repair led to no or mild mitral regurgitation in 99.7% of patients at discharge. Compared with sternotomy, robotic surgery was associated with a lower rate of postoperative stroke (0.5% vs. 1.0%), significantly lower rates of new-onset atrial fibrillation and blood transfusion, and shorter hospital stays. "Postoperative outcomes were comparably excellent between groups, validating this screening approach," says Marc Gillinov, MD, Chair of Thoracic and Cardiovascular Surgery. The study and algorithm were published in the *Journal of Thoracic and Cardiovascular Surgery* (2022;164:1080-1087).

Preexisting Atrial Fibrillation Predicts Worse Cardiac Outcomes After Noncardiac Surgery

Patients with preexisting atrial fibrillation (AF) have a 31% increased risk of death within 30 days after noncardiac surgery relative to matched patients without AF, according to a nationwide cohort study led by Cleveland Clinic researchers. The study also showed similarly elevated risks of stroke and heart failure hospitalization with preoperative AF. The findings are from a propensity analysis of over 3 million Medicare beneficiaries undergoing a variety of noncardiac operations. The investigation, the largest to date examining preoperative AF in noncardiac surgery, was published in the *Journal of the American College of Cardiology* (2022;79:2471-2485). "This real-world study provides strong evidence that preexisting atrial fibrillation puts patients at increased risk after noncardiac surgery beyond what's predicted with traditional risk assessment," says cardiologist and co-author Amgad Mentias, MD. The authors call for AF to be added as a variable in perioperative risk scores for predicting cardiovascular morbidity and mortality.

RECURRENT PERICARDITIS: IT'S TIME TO RECOGNIZE THE PARADIGM SHIFT IN IMAGING AND THERAPEUTICS

Targeted IL-1 blockers and CMR techniques allow more-tailored treatment strategies

The diagnosis and management of recurrent pericarditis have advanced dramatically since European guidelines were last published more than seven years ago. Important new evidence has emerged supporting earlier treatment with interleukin-1 (IL-1) blockers and the use of cardiac magnetic resonance imaging (CMR) for diagnosis, risk stratification and treatment decisions.

These developments have produced a paradigm shift in management of recurrent pericarditis while also opening exciting new avenues of research. So concludes a team of Cleveland Clinic clinician researchers in a recent narrative review of the condition published in *JAMA Cardiology* (2022;7:975-985).

"The emergence of advanced imaging — including echo as well as CMR — as a comprehensive diagnostic and monitoring tool and the addition of IL-1 blockers to the treatment armamentarium have significantly changed our ability to manage this very difficult condition," says the review's corresponding author, Allan Klein, MD, Director of the Center for the Diagnosis and Treatment of Pericardial Diseases at Cleveland Clinic and a past president of the American Society of Echocardiography. "Our review provides a state-of-the-art algorithm for pericarditis management and urges professional societies to upgrade their guidelines on diagnosis and treatment."

"The emergence of advanced imaging — including echo as well as CMR — as a comprehensive diagnostic and monitoring tool and the addition of IL-1 blockers to the treatment armamentarium have significantly changed our ability to manage this very difficult condition. Our review … urges professional societies to upgrade their guidelines on diagnosis and treatment." — ALLAN KLEIN, MD

Updated guidance needed

While echocardiography is recommended as the first imaging test for evaluating pericardial disease, guidelines typically reserve more-advanced imaging methods, such as CMR and CT, for cases in which the diagnosis is unclear. But CMR has evolved in recent years, with potential benefits for using it much earlier in the process for patients with complicated pericarditis.

Similarly, traditional treatment of recurrent pericarditis — a combination of anti-inflammatory drugs including NSAIDs, colchicine and prednisone — often leads to steroid dependence, with many patients needing years of therapy, and accompanying side effects. The advent of new effective and targeted therapies, such as IL-1 blockers, is changing best treatment strategies.

To update physicians on current diagnostic and therapeutic approaches to recurrent pericarditis, the review's authors emphasized developments since publication of the 2015 European Society of Cardiology (ESC) guidelines on pericardial disease (*Eur Heart J.* 2015;36:2921-2964). They searched PubMed and Cochrane databases for relevant publications up to April 2022. Major highlights of the review are briefly summarized below.

Pericardial characterization with CMR

Information gleaned from CMR can help with diagnosis, monitoring and management of pericardial disease. CMR allows for assessment of pericardial anatomy and cardiac hemodynamics, characterization and quantification of pericardial effusion, and disease staging.

Pericardial tissue characterization — i.e., detailing anatomy and histopathology to identify the presence and stage of pericardial inflammation — forms the basis for personalized therapy. It is assessed mainly using late gadolinium enhancement (LGE) and edema-weighted T2 STIR sequences (Figure 1).

The presence of both LGE and pericardial edema on T2 STIR imaging has a sensitivity of 73% and a specificity of 99% for

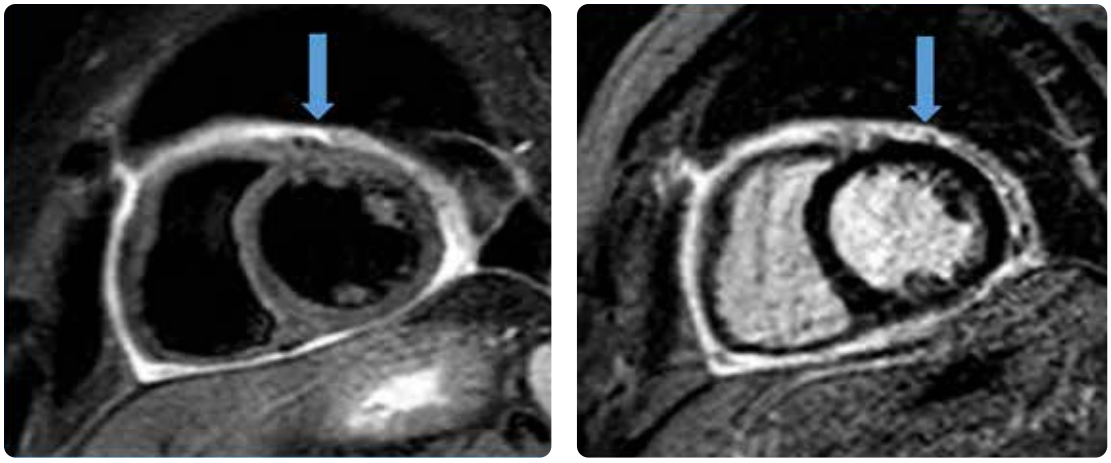

FIGURE 1 — CMR images providing tissue characterization of a patient with active recurrent pericarditis. On the left is a T2W STIR image; on the right is an LGE image.

recurrent pericarditis, which is superior to the diagnostic yield of clinical criteria alone. "These CMR features can better establish the diagnosis of recurrence compared with conventional clinical criteria, suggesting that they should be added to diagnostic scores," Dr. Klein urges.

Moreover, CMR can also help determine prognosis and steer therapy. Decisions for starting, escalating, tapering and stopping anti-inflammatory treatment depend on the extent of inflammation. "The magnitude of pericardial delayed hyperenhancement informs the expected clinical course and provides insights into the appropriate duration of treatment," notes review co-author Paul Cremer, MD, staff cardiologist in Cleveland Clinic's Section of Cardiovascular Imaging.

Earlier use of IL-1 blockers

Anti-inflammatory medications currently form the backbone of recurrent pericarditis treatment. "We see patients who receive these medications for three to four years, eventually becoming dependent on corticosteroids and colchicine for relief of their chest pain," says review co-author Sachin Kumar, MD, senior resident at Cleveland Clinic.

The most recent options — IL-1 blockers — have demonstrated marked efficacy and are currently recommended for infection-negative, corticosteroid-dependent disease that is not responsive to colchicine. The first IL-1 blocker to gain FDA approval for recurrent pericarditis was rilonacept in 2021, following the pivotal RHAPSODY trial (*N Engl J Med.* 2021;384:31-41) led by Dr. Klein.

Anakinra has since become an additional option, although its use for recurrent pericarditis is off-label. Use of anakinra in this setting has been supported by the AIRTRIP randomized trial in Europe (*JAMA.* 2016;316:1906-1912).

Although all the IL-1 blockers are costly, the review authors identify a clear role for these agents in the management of patients with multiple recurrences. In a treatment algorithm provided in the review, they recommend IL-1 inhibitor therapy *instead of corticosteroids* in patients with recurrent pericarditis who have a high C-reactive protein level and are positive for LGE despite NSAIDs and colchicine treatment.

They also urge further research to better define the use of IL-1 blocker therapy.

Pericardiectomy for refractory or constrictive disease

Complete radical pericardiectomy is reserved for patients with recurrent pericarditis with debilitating symptoms despite medical therapy. For patients with constrictive disease without signs of inflammation on CMR or who have pericardial calcification on cardiac CT, the condition is likely irreversible, indicating the need for radical pericardiectomy. In the past, pericardiectomy was thought to have a high operative mortality risk of 6% to 18%, but recent reports from specialized centers suggest the risk is dependent on the causes and comorbidities, with operative mortality less than 1.5%.

"We have found that the timing of surgery, preferably when the inflammatory markers are normal, makes the operative approach somewhat technically easier, while the etiology of pericarditis is one of the most important factors influencing outcomes," observes Cleveland Clinic cardiothoracic surgeon Marijan Koprivanac, MD. "As diagnostic tools and medical management have evolved, so has the surgical approach, with complete radical pericardiectomy replacing partial pericardiectomy as the treatment of choice for patients with pericarditis refractory to medical management" (see sidebar on next page).

Making the case for change

In addition to proposing a new integrated approach to pericarditis using advanced cardiac imaging and IL-1 inhibitors, the review provides extensive tables comparing various imaging methods for use in pericarditis, describing the spectrum of pericarditis with regard to imaging features and treatment practices, and summarizing key clinical trials of therapies.

"Recent advances have real-world clinical implications and should now be incorporated into practice guidelines," concludes Dr. Klein. "Better standards are critical to providing accurate diagnosis of patients with recurrent pericarditis and helping them avoid long-term complications of steroids with the new targeted therapies."

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FIGURE 2 — Among patients with an initial episode of pericarditis, 15% to 30% experience recurrence. The new review article from Cleveland Clinic experts calls for updates to practice guidelines to reflect advances in imaging and treatment of recurrent pericarditis.

PERICARDIECTOMY IN PERSPECTIVE

A Shift in Surgical Care as Well

Cleveland Clinic performed 688 pericardiectomies from 2000 through mid-2022, averaging around 40 per year in recent years, as follows:

- 43 in 2021
- 36 in 2020
- 39 in 2019
- 31 in 2018
- 48 in 2017
- 37 in 2016

Those volumes — among the highest in the nation — have given rise to a number of insights about the operation. Most notable is the preferability of complete radical pericardiectomy over the limited anterior "phrenic to phrenic" off-pump approach (partial pericardiectomy) that dominated practice for decades.

"Historically, we and others believed that partial pericardiectomy was sufficient to relieve constriction and patients' symptoms, but over time we learned that many patients returned for re-excision of remaining pericardium," explains cardiothoracic surgeon Marijan Koprivanac, MD.

As a result, for the past 15 years Cleveland Clinic surgeons have performed pericardiectomy via median sternotomy with routine use of cardiopulmonary bypass to achieve radical resection of the pericardium, including complete removal from the phrenic nerve, leaving behind a small amount of fat. "Historically there was fear of injuring the phrenic nerve, which could cause serious breathing problems, but we and others have found that experienced operators can safely strip pericardium from the phrenic nerve," Dr. Koprivanac says. "Why leave any pericardium when there is a risk that it could cause further constriction and symptoms?"

Evidence to date suggests that radical pericardiectomy yields superior survival and functional outcomes, which Dr. Koprivanac says he and his colleagues expect to confirm in a forthcoming study of long-term outcomes from Cleveland Clinic's pericardiectomy experience to date. He hopes such data will help shift more surgeons and centers to abandon partial pericardiectomy. "We continue to need to perform redo pericardiectomies on patients who have symptom recurrence after partial pericardiectomy," he notes.

The forthcoming analysis of Cleveland Clinic experience should also help inform practice based on pericarditis etiology. "Both survival and symptomatic outcomes appear to be better when pericardiectomy is performed to address idiopathic pericarditis as opposed to pericarditis related to radiation heart disease or reoperation," Dr. Koprivanac says. "We believe this is because the latter situations involve pathology beyond just the pericarditis itself. Our data should help illuminate the influence of etiology on pericardiectomy outcomes and help us continue to improve the safety and outcomes of this procedure."

PRIMARY TRIAL AIMS TO GUIDE CHOICE OF PERCUTANEOUS VS. SURGICAL REPAIR OF DEGENERATIVE MITRAL REGURGITATION

As use of the MitraClip™ device for transcatheter edge-to-edge repair (TEER) of the mitral valve expands, demand is growing for data comparing this percutaneous procedure to surgical mitral valve repair. In response, the National Institutes of Health (NIH) is funding the multicenter PRIMARY trial to generate such data and improve guidance for patients.

The open-label, randomized study is comparing TEER with surgical repair in 450 patients aged 65 or older with primary degenerative mitral regurgitation (MR) and no other requirements for cardiac surgery. It launched in early 2022 and is enrolling patients at 20+ North American and European centers, including Cleveland Clinic.

"There is growing interest in the use of MitraClip in patients with degenerative MR (MR caused by prolapse), but we don't have an evidence base to tell us in which patients it's a good option," says cardiothoracic surgeon Marc Gillinov, MD, who chairs the NIH-funded Cardiothoracic Surgical Trials Network, which runs the trial. The issue is especially pressing in some European countries where MitraClip is now being used more often than surgery for mitral valve repair.

"We hypothesize that surgery — even robotically assisted surgery — will create a more complete repair, but it's also more invasive," says Dr. Gillinov, Chair of Thoracic and Cardiovascular Surgery at Cleveland Clinic. "The PRIMARY trial should help indicate which therapy is better in which patients. As a government-funded study, it's designed to answer that patient-centered clinical question."

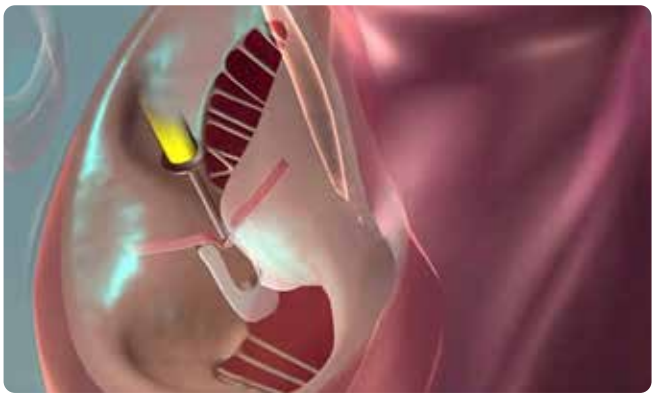
Study essentials

Enrollees must have severe primary degenerative MR and be appropriate candidates for surgical or percutaneous mitral valve repair. Because enrollees may be at any level of surgical risk (low, intermediate or high) and MitraClip is authorized for U.S. commercial use only in patients at prohibitive surgical risk, the trial is being conducted under an investigational device exemption (IDE). MitraClip is the only TEER device approved in the U.S.

The primary endpoint is a composite of all-cause mortality, valve reintervention, hospitalization for heart failure or onset of ≥ 3+ MR by transthoracic echo at three years. Secondary outcomes include quality-of-life measures and adequacy of MR correction, defined as < 2+ MR, at one year. Outcomes will be measured over five years.

The PRIMARY trial is notable for using the adequacy of MR correction as a secondary endpoint, which is novel for a large trial of this type. So says Cardiovascular Medicine Chair Samir Kapadia, MD, who co-leads the study at Cleveland Clinic with Dr. Gillinov.

FIGURE — The PRIMARY trial is comparing percutaneous MitraClip therapy (shown below) with surgical repair of primary degenerative MR.



Also notable, he says, are the study's inclusion of patients at all surgical risk levels, which could support broader applicability of MitraClip, and its use of a superiority design to detect a difference between treatments rather than to establish noninferiority.

"Most trials comparing surgery with minimally invasive therapies have used a noninferiority design," Dr. Kapadia explains. "To show that patients should undergo surgery rather than a percutaneous procedure, you have to design a study to show that surgery is actually superior. This aspect of PRIMARY's design is notable."

One of two complementary trials

The superiority design is a key distinction between PRIMARY and another ongoing randomized trial comparing MitraClip with surgical mitral valve repair — the MitraClip REPAIR MR Study sponsored by Abbott Medical Devices, which is using a noninferiority design. REPAIR MR also is limited to patients at intermediate surgical risk, whereas PRIMARY includes patients at all risk levels.

"It's always best to have more than one trial and more than one set of investigators," says Dr. Gillinov. "If two trials confirm one another, there's more confidence their results weren't due to chance."

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STUDY SHEDS LIGHT ON RED MEAT'S CONTRIBUTION TO ATHEROSCLEROSIS RISK IN OLDER ADULTS

Increased risk is partly mediated by microbiota-derived metabolites of L-carnitine, choline

The increased risk of incident atherosclerotic cardiovascular disease (ASCVD) associated with red meat consumption is mediated in part by microbiota-generated metabolites of L-carnitine and choline that are abundant in red meat. So concludes a large observational study of healthy subjects aged 65 or older from a research team led by investigators at Tufts University and Cleveland Clinic.

Findings over 12.5 years of follow-up revealed a significant association between ASCVD and metabolites in the gut microbiome following consumption of red meat but not of poultry, fish or eggs. The findings also showed that elevated risk due to red meat consumption is mediated in part by blood glucose, insulin and C-reactive protein levels — but not by blood pressure or cholesterol levels.

"For years clinicians have been advising patients about the cardiovascular risks of unprocessed red meat and other animal-source foods, but this has largely been based on associative data without a mechanistic explanation," says Cleveland Clinic cardiologist and study co-author W.H. Wilson Tang, MD. "By incorporating mediation analysis with gut microbial metabolites in a well-defined cohort, we've demonstrated a clear mechanistic link by which such dietary compounds can promote atherosclerotic cardiovascular diseases."

These insights may help support development of new interventions targeting links between diet and gut microbes to curb cardiovascular risk. The study also sheds light on potential prevention strategies for people over 65, a population in which research on the gut microbiome's impact on heart health has been scarce.

Diet-related metabolites and cardiometabolic disease

The study, published in *Arteriosclerosis, Thrombosis, and Vascular Biology* (2022;42:e273-e288), was co-led by Stanley Hazen, MD, PhD, Co-Section Head of Preventive Cardiology and Rehabilitation at Cleveland Clinic and Chair of Cardiovascular and Metabolic Sciences in its Lerner Research Institute. It was prompted by mounting evidence over the past dozen years on the role of the gut microbiome in cardiometabolic disease — much of it published by Dr. Hazen, who discovered several pathways by which dietary nutrients such as carnitine and choline are used by microbes in the gut to produce metabolites. His Cleveland Clinic research team and others have shown in animal and human studies that these metabolites — namely, trimethylamine N-oxide (TMAO) and its related metabolites gamma-butyrobetaine and crotonobetaine — increase atherosclerotic burden and serve as mediators of plaque formation.

"These metabolites act in a manner similar to endocrine organs, exerting their effects by traveling through the circulation like hormones," Dr. Tang explains. "This can potentially promote diseases like atherosclerosis and lead to downstream cardiac events."

A large community-based cohort

For the current investigation, the researchers drew from the prospective, multicenter, community-based Cardiovascular Health Study, a longitudinal cohort study designed to evaluate risk factors for heart disease among older adults in four U.S. communities.

Participants, all aged 65 or older and healthy at the time of enrollment, were recruited from 1989 to 1993 and followed to 2015. Data on animal-source food intake was available from a validated self-reported food frequency questionnaire that participants completed at study enrollment and again several years later. Measurements of TMAO-related metabolites were made using frozen blood samples collected at enrollment and soon after administration of the second food frequency questionnaire. Using Cox proportional hazard models, the researchers analyzed these measures for their relationship to incident ASCVD — i.e., myocardial infarction, fatal coronary heart disease, stroke or other atherosclerotic death — adjudicated over median follow-up of 12.5 years.

Results in brief

After exclusion of participants without adequate diet and metabolite data and those with prevalent CVD at their first diet assessment/blood draw, 3,931 participants were included in the analysis. Mean age was 72.9 years, nearly two-thirds were female (63.5%) and 12.0% were nonwhite. Median follow-up was 12.5 years.

Key findings included the following (also see Figure):

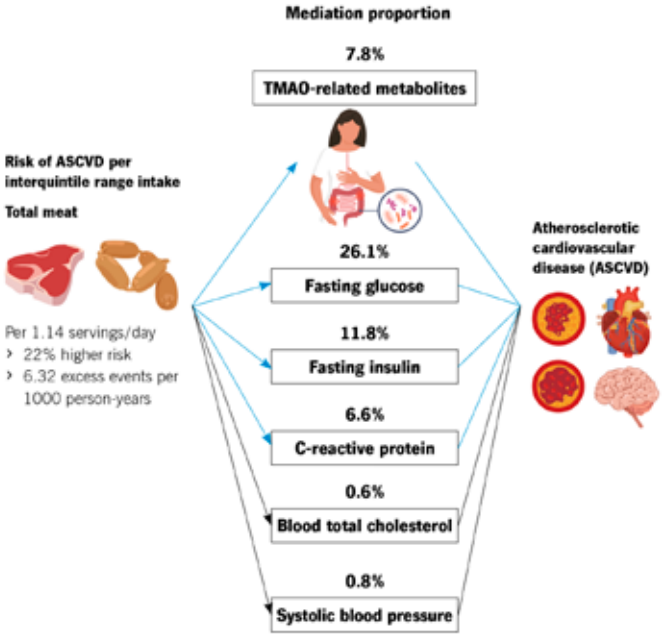
- At baseline, small but statistically significant correlations were observed between plasma TMAO levels and self-reported consumption of unprocessed red meat, total meat, fish and total animal-source food, but not processed meat, poultry or eggs. The TMAO-related metabolites gamma-butyrobetaine and crotonobetaine were significantly correlated with consumption of unprocessed red meat, processed meat, total meat and eggs.
- After multivariable adjustment, greater consumption of unprocessed red meat, total meat and total animal-source foods were each significantly associated with higher risk of incident ASCVD; intake of processed meat trended toward greater risk. In contrast, consumption of fish, poultry and eggs was not associated with elevated risk.
- Analysis showed that TMAO-related metabolites significantly mediated the associations between food intake and ASCVD, accounting for approximately 8% to 11% of excess risk.
- Among traditional risk factors for ASCVD, mediation analysis found that neither blood cholesterol nor blood pressure significantly mediated the associations between ASCVD and unprocessed red meat, processed meat or total meat. However, in addition to TMAO pathway-related metabolites, fasting blood glucose and insulin each significantly mediated these associations, and C-reactive protein significantly mediated the associations with processed and total meat.

Mechanistic links between meat, gut and ASCVD

"This is the first population-level study to explore the association of animal-source foods with ASCVD and potential mediation by TMAO-related metabolites generated by gut microbes," says Dr. Hazen, co-senior author of the study. "We observed linear dose-response relationships between higher unprocessed red meat and total meat consumption and both TMAO and ASCVD incidence over follow-up, with TMAO and its related metabolites remaining a major driver of the association."

The results support and advance an evolving understanding of the interplay between diet and atherosclerotic risk. The researchers write: "Our novel findings further suggest that L-carnitine- and choline-derived microbiome metabolites play a larger mediating role in meat-ASCVD associations than blood pressure or blood cholesterol levels. This result is consistent with, and may partly help explain, the neutral associations of saturated fat consumption with CVD, and it suggests that attention to other meat constituents and risk pathways is needed."

FIGURE — Schematic showing findings of the study's mediation analysis. Percentages in the middle column represent how much each factor accounted for excess ASCVD risk related to meat consumption. Reprinted, with permission, from Wang et al., *Arteriosclerosis, Thrombosis, and Vascular Biology* (2022;42:e273-e288). www.ahajournals.org/doi/10.1161/ATVBAHA. © 2022 American Heart Association.



They add that their observations support mechanisms associated with glucose-insulin homeostasis and with systemic inflammation (as reflected by C-reactive protein) as potentially important pathways by which meat consumption may impact ASCVD.

"This study provides insight into why some people may be more vulnerable to ASCVD than others, if the gut bacteria inside them can generate more metabolites that influence their hosts' organ functions," Dr. Tang observes.

"This study further validates the numerous lines of evidence linking dietary red meat to heightened cardiovascular disease risks, indicating that one portion a day translates to about a 20% increased risk," Dr. Hazen concludes. "And it further demonstrates the importance of the gut microbial TMAO pathway in accounting for these heightened risks."

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ADVANCES HAVE PUT CAROTID ARTERY STENTING ON PAR WITH SURGERY FOR STROKE PREVENTION

A multicenter, multidisciplinary call for CMS to update coverage decision

Outcomes of carotid artery stenting for stroke prevention in patients with carotid artery stenosis have reached parity with those of carotid artery surgery. So asserts a new *JACC* State-of-the-Art Review (*J Am Coll Cardiol.* 2022;80[2]:155-170), which attributes the parity to new techniques and devices, recent professional society statements promoting competency, and improved understanding of appropriate candidate selection.

The review — written by a multicenter, multidisciplinary team of experts from across the U.S. after a comprehensive review of the literature — calls for the Centers for Medicare & Medicaid Services (CMS) to provide equal coverage for stenting and surgery for stroke prevention in patients with carotid artery stenosis.

"Few medical procedures have undergone as much scrutiny as carotid artery stenting," says review co-author Sean Lyden, MD, Chair of Vascular Surgery at Cleveland Clinic. "Multiple randomized clinical trials involving more than 10,000 patients indicate that stroke and death rates associated with carotid artery stenting have decreased to levels similar to those seen with carotid endarterectomy."

Stenting has advanced over the past 25 years

Introduced as an alternative to carotid endarterectomy in the mid-1990s, carotid artery stenting has demonstrated steadily improved outcomes since the last relevant CMS coverage decision was made, in 2008. At that time, carotid artery stenting was regarded only as an alternative to patients deemed high risk for adverse perioperative outcomes with surgical intervention.

"CMS should not be putting Medicare patients at a disadvantage by favoring more invasive interventions, as it does with its current policy. It's time to bring coverage of carotid artery revascularization procedures in line with the evidence." — SEAN LYDEN, MD

The reviewers conclude that carotid artery stenting has now demonstrated equivalence or noninferiority to surgery in periprocedural outcomes, long-term stroke prevention and durability. They attribute carotid artery stenting improvements to advances in the following areas:

- **Technology.** New embolic protection devices, more stent options (e.g., dual-layered stents) and improved techniques have been developed.
- **Standards for operators and facilities.** Multiple expert groups have published recommendations for training and credentialing of interventionalists and have called for institutional collection of quality metrics data.
- **Patient selection.** Preoperative risk assessment with CT angiography and magnetic resonance angiography has become important for assessing procedure risk by evaluating the aortic arch and branch vessel anatomy. High-risk features include vessel and arch tortuosity and dense lesion calcification. Patients over age 75 are also deemed high risk for stenting.

"The evidence is now clear that carotid artery stenting is a reasonable and less invasive option than carotid endarterectomy for stroke prevention in patients with carotid artery stenosis," Dr. Lyden notes. "However, it's important that optimal strategies be employed, including the use of embolic protection devices, balloon sizing, efforts to ensure qualified operators, and appropriate candidate selection."

Intervention recommendations

The review also provides recommended treatment algorithms for carotid artery disease, including stenosis thresholds for carotid artery stenting. Thresholds are consistent with those of current FDA device approvals for patients with atherosclerotic bifurcation

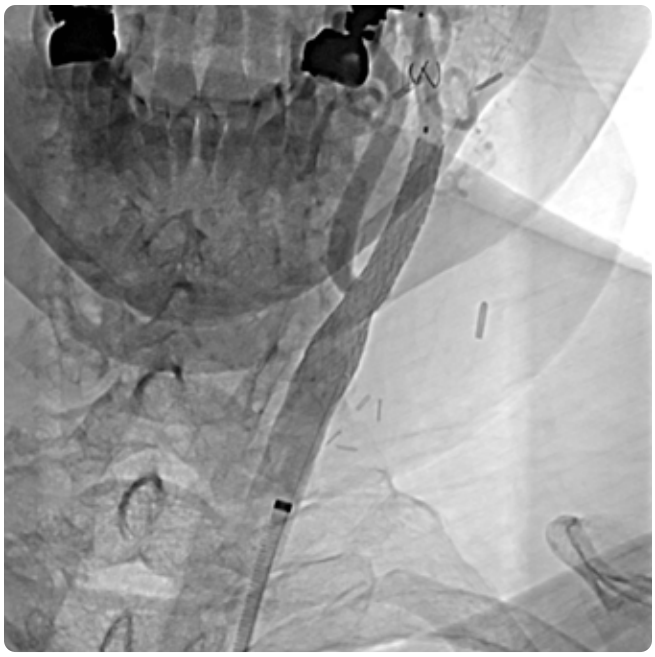

FIGURE — Angiogram showing a carotid artery stent. Authors of the new *JACC* State-of-the-Art Review note that carotid artery stenting is still evolving and that emerging developments in device technology, candidate selection and operator/facility standards can be expected to further lower risks of the procedure.

carotid disease at high and standard surgical risk, as follows:

- ≥ 50% to ≤ 99% for symptomatic patients
- ≥ 70% to ≤ 99% for asymptomatic patients

Multidisciplinary team input can be invaluable when assessing risk, the authors note. A table in the article provides a list of clinical and anatomic features that confer elevated risk for either stenting or surgery. Overall, the lowest-risk option should be chosen, and in cases for which risk is deemed equivalent, the patient should choose.

"We advise educating patients to understand the options — including the role of optimal medical therapy — so they can knowledgeably weigh in on their preference," Dr. Lyden observes.

What to watch for

Although about three-quarters of carotid artery revascularization procedures for primary stroke prevention are performed in asymptomatic patients, the benefit is not as well established in this group as in symptomatic patients. More evidence will be forthcoming from two large ongoing trials investigating outcomes for primary prevention in asymptomatic patients:

- ECST-2 (Second European Carotid Surgery Trial)
- CREST-2 (Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial)

The reviewers also emphasize that carotid artery stenting is still evolving — more so than carotid endarterectomy, which has been an established procedure for many years. Continued developments in carotid artery stenting device technology, as well as in appropriate candidate selection and establishment of operator and institutional standards, can be expected to further lower risk.

In the meantime, Dr. Lyden and his co-authors recommend that CMS update its coverage decision to reflect that carotid artery stenting is as safe and effective as surgery. "CMS should not be putting Medicare patients at a disadvantage by favoring more invasive interventions, as it does with its current policy," he says. "It's time to bring coverage of carotid artery revascularization procedures in line with the evidence."

An additional perspective

"This excellent *JACC* State-of-the-Art Review summarizes the progression of carotid artery stenting from open-cell self-expanding to dual-layered stents, covering single and double embolic protection device use, vascular access, optimal patient selection, institutional criteria for operators, optimization of guideline-derived treatment, and quality control for outcomes," notes Cleveland Clinic interventional cardiologist Aravinda Nanjundappa, MBBS, who was not involved with the review. "It highlights the importance of multidisciplinary input and patient counseling while making decisions on carotid endarterectomy versus carotid artery stenting. The evidence shows an equipoise in clinical outcomes of the two approaches."

Dr. Nanjundappa concludes: "In selected patients at high or average surgical risk for carotid endarterectomy, carotid artery stenting by experienced operators is a reasonable alternative to treat symptomatic and asymptomatic patients with carotid artery stenosis, consistent with FDA-approved stenosis thresholds. The CMS national coverage decision needs to be updated accordingly."

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Contact Dr. Lyden at 216.444.3581 and Dr. Nanjundappa at 216.445.5846.

PROTECTED TAVR TRIAL FINDS REDUCED RATE OF DISABLING STROKE WITH CEREBRAL EMBOLIC PROTECTION

Nuanced results from the largest randomized study of the technology to date

Use of a cerebral embolic protection (CEP) device during transcatheter aortic valve replacement (TAVR) significantly reduced the risk of disabling stroke, although not the overall risk of stroke, in the multicenter PROTECTED TAVR randomized controlled trial.

Results of the study — the largest randomized prospective trial of CEP use in TAVR to date — were presented in a late-breaking clinical science session at the Transcatheter Cardiovascular Therapeutics (TCT) conference by Samir Kapadia, MD, Chair of Cardiovascular Medicine at Cleveland Clinic, and published in the *New England Journal of Medicine* (2022;387:1253-1263).

"Given the reduction in disabling stroke demonstrated in this trial, along with the feasibility and safety of using the CEP device, CEP should be considered for all patients undergoing TAVR," says Dr. Kapadia, global principal investigator of PROTECTED TAVR and first author of the study.

He argues that this recommendation is justified despite the finding that the 21% relative reduction in the study's primary endpoint — periprocedural stroke — achieved with CEP did not reach statistical significance. He cites the 62% relative reduction in disabling stroke with CEP, noting that this is a critical component of the primary endpoint (although a secondary outcome) that is dreaded by patients — and therefore highly clinically meaningful. Moreover, the study authors conclude that "while a difference in periprocedural stroke with CEP use was not demonstrated, the results of the study do not exclude a possible benefit."

"This trial and previous experience have shown the CEP device to be extremely safe," Dr. Kapadia observes. "In light of that, this evidence of a significant reduction in disabling stroke — not to mention the remaining possibility of a reduction in overall stroke, as suggested by previous single-center and registry data — leaves cost as the only reason not to use CEP. While cost can be an important factor, it is not sufficient to exclude clinical consideration of CEP."

"It's important to practice medicine on a foundation of scientific data, and also to place this data in the context of experience and rationale," adds study co-author Amar Krishnaswamy, MD, Section Head of Interventional Cardiology at Cleveland Clinic. "It's telling that of the expert panel gathered for the PROTECTED TAVR trial presentation at TCT, all but one said they would want CEP used if their family member were undergoing TAVR."

An enduring need for cerebral embolic protection

The rationale for CEP is the embolization of debris from the valve or vasculature that occurs during TAVR, potentially causing periprocedural stroke and resultant morbidity and mortality. Although newer-generation TAVR devices have reduced the risk, stroke remains an important complication of TAVR, conferring mortality of roughly 16% at 30 days. "Understandably, patients continue to be troubled by the risk of stroke," Dr. Kapadia says.

To date, only one CEP device is commercially available in the U.S. — the Sentinel™ Cerebral Protection System, approved by the FDA in 2017. Although the pivotal trial showed the device to be safe and to capture debris in 99% of patients undergoing TAVR, it wasn't powered to assess the effect on stroke rates. While subsequent nonrandomized single-center studies and registry analyses have shown a significant reduction in stroke rates and mortality with CEP, definitive evidence from a large randomized trial had been lacking prior to PROTECTED TAVR.

PROTECTED TAVR at a glance

Investigators enrolled 3,000 patients at 51 centers in North America, Europe and Australia between February 2020 and January 2022. Patients were randomized to receive TAVR with (n = 1,501) or without (n = 1,499) the Sentinel CEP device. All underwent neurological examination before and after the procedure.

The primary endpoint was stroke within 72 hours of TAVR or discharge (whichever was first) in an intention-to-treat analysis. Secondary outcomes were disabling stroke, mortality, transient ischemic attack (TIA), delirium, acute kidney injury and major vascular complications at the CEP device access site.

The two treatment groups were statistically similar except for a larger share of female patients in the CEP group (42.0% vs. 37.8%).

Major results included the following:

- The CEP device was successfully placed in 1,406 of 1,489 attempted patients (94.4%).

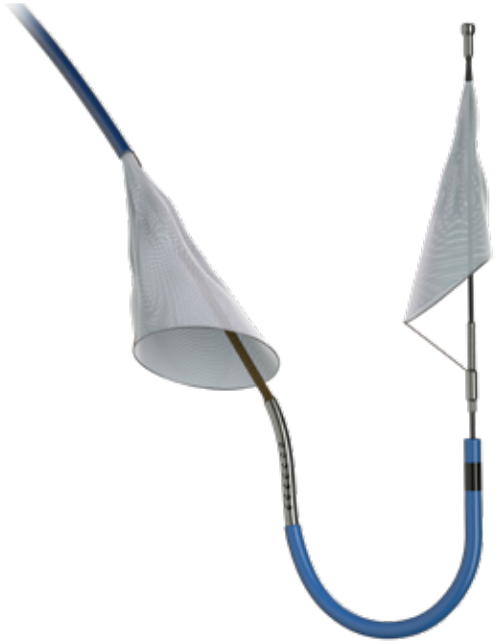

FIGURE — The Sentinel CEP device, shown here, was found to prevent one disabling stroke for every 125 TAVR patients in which it was used. Image © 2022 Boston Scientific Corporation or its affiliates. All rights reserved.

- The primary endpoint of stroke at discharge or 72 hours occurred in 2.3% of patients randomized to CEP and 2.9% of controls ($P = 0.30$).
- The secondary outcome of disabling stroke at discharge or 72 hours occurred in 0.5% of the CEP group versus 1.3% of the control group ($P = 0.02$). Subgroup analyses showed that this risk reduction with CEP was consistent across subgroups based on age, gender, operative risk, valve type and history of cardiovascular disease.
- There were no significant differences between the groups in mortality, acute kidney injury or the composite of stroke/TIA/delirium.
- One patient (0.1%) in the CEP group experienced an access-site major vascular complication.

Findings in context

The authors identify a few factors that may have contributed to the lack of a significant treatment effect on the study's primary endpoint of periprocedural stroke:

- A lower-than-expected stroke rate (2.6% overall), which limits the ability to detect differences in event rates
- A mean risk score for trial participants that was lower than in previous studies
- The fact that the studied CEP device does not protect the left vertebral artery, which limits complete cerebral coverage by this device but not necessarily by future CEP devices
- Inclusion of both ischemic and hemorrhagic stroke in the study's outcomes despite the fact that CEP cannot prevent hemorrhagic stroke

The authors note that of the eight patients in the CEP arm who had a disabling stroke, two had hemorrhagic strokes, leaving six disabling ischemic strokes — i.e., strokes that could be addressed by CEP. Of these six, one occurred in a patient in whom CEP could not be delivered (the study used intention-to-treat analysis), one in a patient with an embolized valve who also needed resuscitation during the procedure, and one in a patient with stroke-like clinical symptoms but in whom lesion localization was uncertain. Two other strokes occurred in the occipital lobes, which are not fully protected by the CEP device. "That leaves just one disabling ischemic stroke observed in the middle cerebral artery territory that the CEP device was designed to protect," Dr. Kapadia points out.

The authors report that the number needed to treat with CEP to prevent one disabling stroke is 125. "Given patient fears of disabling stroke, this is likely to be deemed important by many patients and caregivers," says Dr. Kapadia.

It is also deemed important by the TAVR team at Cleveland Clinic, where CEP use is routine for all TAVR patients. Dr. Kapadia says that practice will not change in the wake of this study. "CEP makes sense mechanistically, it is exceedingly safe, and it reduces disabling stroke and may still be shown to significantly reduce stroke overall," he says. "I would advise all TAVR teams to seriously consider it."

"We always discuss the risks of TAVR and surgical AVR frankly with our patients before either procedure," notes Cleveland Clinic cardiac surgeon James Yun, MD, PhD. "Patients and family members often are relieved to hear we have a CEP device for use with TAVR that has any potential to mitigate stroke risk."

More data coming

The next big development will be results from the British Heart Foundation's ongoing BHF PROTECT-TAVI randomized trial of the Sentinel device in nearly 8,000 patients. After that, a patient-level prospective meta-analysis of the combined PROTECTED TAVR and BHF PROTECT-TAVI data is planned.

The PROTECTED TAVR trial was funded by Boston Scientific, which markets the Sentinel device. Dr. Kapadia reports that he has not been compensated by Boston Scientific for his work on the trial.

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POST-TAVR CARDIAC SURGERY: GOOD OUTCOMES ACHIEVABLE DESPITE CHALLENGES

Study offers guidance on an increasingly common presentation

Cardiac operations after transcatheter aortic valve replacement (TAVR) are increasing in frequency, and the time between TAVR and subsequent cardiac surgery is shrinking. So finds a retrospective study out of Cleveland Clinic published in the *Annals of Thoracic Surgery* (2022;114:52-60).

Noting an increase in post-TAVR patients referred for heart surgery, Cleveland Clinic surgeons sought to determine the indications, frequency and outcomes of these operations performed at their institution. The study represents the largest investigation from a single center with multiple surgeons addressing this patient population.

"We found that most cases were complex operations with a high predicted mortality rate," says Cleveland Clinic cardiothoracic surgeon and first author James Yun, MD, PhD. "This brings to light the importance of considering potential future cardiac surgery when helping patients choose the best approach for initial aortic valve replacement (AVR). It's particularly important in younger patients with low or intermediate surgical risk who have a longer life expectancy. In these patients, accounting for future cardiac operations after TAVR, especially when the patient's cardiac pathology is not fully addressed by TAVR alone, is imperative."

Complexity increases risk

From January 2012 to July 2020, 59 patients underwent post-TAVR cardiac surgery at Cleveland Clinic; nearly two-thirds had undergone TAVR at another institution.

The frequency of post-TAVR surgery increased over time, with fewer than 10 such operations performed annually through 2018, in contrast to 18 performed in 2019 and nine in the first six months of 2020. The interval between TAVR and cardiac surgery decreased from seven years to less than one year over the course of the study period.

Median patient age was 70 years, and 71% were men. Forty patients (68%) underwent complex operations without a calculable Society of Thoracic Surgeons predicted risk of mortality (STS PROM); for the remainder, the median STS PROM was 5.5%. The TAVR valve was explanted in 46 cases (78%); only five (8.5%) were isolated surgical aortic valve replacements (SAVR), and 36 (61%) were redo sternotomies because of a history of prior open cardiac surgery.

Operative mortality was 8.5% — notably half of the 17% mortality reported in a recent analysis of surgical reoperation after TAVR using 2011-2015 data from the STS Adult Cardiac Surgery Database (*JACC Cardiovasc Interv.* 2020;13:1515-1525). Rates of other complications included the following:

- 20% required perioperative mechanical circulatory support
- 31% needed prolonged ventilation
- 10% experienced renal failure requiring new-onset dialysis
- 3.4% suffered a stroke

"These surgeries are complex. For the best results, an experienced surgical team needs to intervene at the right time," says Dr. Yun. "When patients are properly selected, reasonable outcomes are feasible."

"Because of the scope and complexity of such procedures, and because some patients have a heavy burden of comorbidities, the risk of morbidity and mortality is significant and higher than for isolated AVR," adds study co-author Faisal Bakaeen, MD, another Cleveland Clinic cardiothoracic surgeon. "That is why experience in cardiac reconstructive surgery and reoperations is a must for surgeons contemplating operating on patients who have undergone TAVR."

Indications for surgery

The leading indications for post-TAVR cardiac surgery were TAVR valve stenosis or regurgitation (58%), paravalvular leak (24%) and endocarditis (17%). In cases where the TAVR valve was not explanted, mitral regurgitation was the primary indication for surgery.

"Patients with significant mitral or coronary artery disease that was not addressed at the time of TAVR come in needing a valve or bypass in open surgery," notes Dr. Bakaeen. "When the issue is TAVR valve malfunction, it sometimes involves more than simply removing the valve; it may require a full root replacement because the TAVR valve has healed through the wall of the root. These are complex, multicomponent operations."

This [study] brings to light the importance of considering potential future cardiac surgery when helping patients choose the best approach for initial aortic valve replacement." — JAMES YUN, MD, PHD

Paravalvular leak is more common with TAVR than with SAVR, but the incidence has decreased as TAVR device manufacturers have added valve skirts and enhanced valve dilation and as heart teams have improved their ability to choose the correct valve size. Another complication more common with TAVR versus SAVR is heart block that requires a new permanent pacemaker, Dr. Bakaeen points out. "This complication also has decreased over time thanks to better TAVR deployment that minimizes risk of injury to the heart's conduction system," he says.

As the incidence of TAVR valve deterioration has fallen, rates of endocarditis are rising. Cleveland Clinic is currently analyzing the incidence of endocarditis in TAVR versus SAVR, with results expected soon. "Looking at the raw data, there doesn't appear to be a huge difference," says Dr. Yun.

Taking care in TAVR patient selection

At Cleveland Clinic, patients being considered for TAVR see both a surgeon and an interventional cardiologist, who discuss the pros and cons of TAVR and SAVR before making a recommendation.

"Because of our experience with post-TAVR surgery, we understand that if we can provide a surgical solution to a patient's problem at a younger age, we can focus on less-invasive options in older age," Dr. Yun notes. "Of course, there are some cases where a younger patient is at high surgical risk and should be treated less invasively, but as a heart team we determine what's best for an individual."

The answer is not always clear, due to lack of long-term data for TAVR. "One issue we debate is what the expected durability of a TAVR valve will be in, for example, a 64-year-old," Dr. Yun continues. "We expect the functional lifetime of a durable surgical aortic valve to be 12 to 15 years, on average, and the 10-year U.S. data for TAVR durability in low- and intermediate-risk patients will be very helpful when it becomes available."

Challenging, but far from hopeless

Since Cleveland Clinic surgeons are increasingly evaluating patients with previous TAVR for open-heart surgery, they plan to continue studying this population. "This clinical scenario is clearly part of the modern landscape," says Dr. Yun. "These cases can be challenging, but at centers like ours, reasonable outcomes are feasible."

FIGURE — The Cleveland Clinic retrospective analysis found that cardiac operations after TAVR are increasing and that the interval between TAVR and subsequent cardiac operations is shrinking.

"Due to the referral pattern at our institution, we likely see a skewed population," Dr. Bakaeen adds. "Nevertheless, these data are a warning sign that TAVRs can fail early. We should be selective and think twice before performing TAVR in healthy, young patients. Our SAVR results have traditionally been exceptional, with zero mortality in the past two years, and they serve as a benchmark."

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CASE STUDY IN COLLABORATION

THE VALUE OF AN OBSERVATIONAL VISIT TO CLEVELAND CLINIC'S HEART, VASCULAR & THORACIC INSTITUTE FOR AN ALLIANCE HOSPITAL

How a site visit helped Parkview Heart Institute expand its vascular services and improve operations

Hospitals are continually expanding service offerings and developing their programs. A comprehensive strategy is critical to this process.

The ability to forecast growth and its impact on personnel, space and resource requirements demands in-depth assessment and planning, as well as the capability to transition rapidly when needed. This was the case for Parkview Heart Institute (PHI) — a hospital in Fort Wayne, Indiana, that has had an alliance relationship with Cleveland Clinic's Heart, Vascular & Thoracic Institute (HVTI) since August 2019 — as PHI embarked on an expansion of its vascular program and growth of its vein clinic.

Parkview Heart Institute serves the cardiovascular needs of patients in northeast Indiana and northwest Ohio, providing high-quality, safe, patient-centric care that aligns well with HVTI's consistent focus on exceptional outcomes, continuous quality and process improvement, and innovation. The leadership at PHI recognized a steady increase in patient appointments for consultation and office-based procedures in the vein clinic, as well as a need to swiftly revise their strategy to address the increase in patient visits. It was clear that this would be another project on which the PHI team should work collaboratively with Cleveland Clinic.

Site visits as a cornerstone of collaboration

When a hospital or health system enters an affiliation or alliance relationship with Cleveland Clinic's HVTI, one of the many benefits is the opportunity to make in-person site visits to Cleveland Clinic. During a site visit, team members from the affiliate or alliance hospital have a chance to better understand Cleveland Clinic's clinical and business operations and management, observe processes in real time, and experience Cleveland Clinic team collaboration in person. These visits foster professional collaboration, learning and the sharing of best practices to optimize patient outcomes.

Site visits are tailored to the specific objectives outlined by participants, offering significant value through in-person meetings with key stakeholders, observation time and dedicated time for customized Q&A. Visits are typically multifaceted and comprehensive (see Table), making the experience maximally beneficial for affiliate and alliance organizations, as illustrated in the following case study.

The case for a site visit by PHI

Parkview Heart Institute's leadership discussed expansion of its vein clinic program with the HVTI Advisory Services team. A site visit was recommended, and planning immediately got underway. Five members of the PHI vein clinic team traveled to Cleveland in June 2022 to participate in a two-day visit that included time at Cleveland Clinic regional ambulatory vein center facilities. As the PHI vein clinic team was looking to procure new space and optimize its utilization, they requested the site visit to observe and share clinical best practices as well as strategies for effective patient scheduling, timely insurance authorization, optimization of patient throughput and maximization of resources for efficient caregiver workflow.

Focus Areas for On-Site Visits by Affiliate/Alliance Hospitals

Clinical practices
- Sharing best practices
- Clinical staff workflow
- New technologies

Observation
- Patient throughput
- Patient intake and triage
- Insurance preauthorization and registration practices
- Emergent care pathways (i.e., ST-elevation myocardial infarction)
- Appointment scheduling
- Surgeries and procedures
- Discharge process/follow-up

Business operations
- Business review meetings/dashboards
- Operating room/procedure room utilization
- Continuous improvement
  - Quality
  - Improved access
  - Efficiency

FIGURE — Dr. Anton (center, in blue scrubs) debriefs with the Parkview Heart Institute team after the case.

Day 1 of the visit

Most of the Parkview team spent their first day at Cleveland Clinic's East Side Vein Center, where they observed clinic-based procedures with vascular surgeon George Anton, MD, as well as outpatient throughput and office workflow. To get the most out of the experience, an advanced practice provider (APP) from PHI shadowed a Cleveland Clinic APP and observed and interacted with vascular surgeon Kathleen Boyle, DO, at the West Side Vein Center. The APP also worked with the office staff to gain better understanding of the center's scheduling and insurance pre-authorization processes.

"Our office-based models were designed to provide an integrated opportunity to schedule patient visits simultaneously with vascular lab imaging and assessment within the same office," explains Dr. Anton. "This provides a seamless care pathway allowing physician, nurse and vascular technologist to participate in the preoperative assessment and planning, interventional/surgical procedure and postoperative evaluation. Taking all of this into consideration up front allows our care to be delivered in a timely and efficient way, with increased attention to care accessibility, patient safety and overall patient satisfaction."

The group was then hosted by Sean Lyden, MD, Chair of the Department of Vascular Surgery, for a tour of the department on Cleveland Clinic's main campus. Dr. Lyden stressed the importance of multidisciplinary input from all caregivers in ensuring patient well-being, achieving the best possible outcome and maximizing patient satisfaction.

"We were thrilled to host the Parkview team," Dr. Lyden says. "Our goal is to share our processes with affiliate and alliance hospitals. We enjoy working collaboratively across our Heart, Vascular & Thoracic Institute — among vascular surgery, vascular medicine, cardiology and cardiac surgery — to provide optimal outcomes for our patients. We have integrated the vascular lab into our care of patients and work collaboratively in our vein centers with our ultrasound technicians to understand the pathology of the patient's venous disease and customize treatment plans."

Day 2 of the visit

The second day began with the entire PHI team observing a hospital-based procedure at Cleveland Clinic Hillcrest Hospital. Dr. Anton and PHI cardiothoracic surgeon David Sowden, MD, had a chance to discuss a case — including surgical approach, situational awareness and patient/caregiver safety — and debrief successes and opportunities afterward (see Figure).

"We discussed how the pre-procedural diagnostic vascular lab assessment is a critical step that provides the best opportunity to match a technology with a patient's specific anatomy in an unbiased fashion," Dr. Anton says. "We also explored how we work as a team with the patient to develop a shared mental model that we all comfortably agree upon."

The remainder of the day was spent at the West Side Vein Center with Douglas Joseph, DO, Director of the Vascular Medicine Outpatient Department, discussing vein clinic design to enhance the patient experience.

Reflections from the PHI team

"The Cleveland Clinic experience/partnership has assisted our vein clinic in focusing on the patient experience among our team," says PHI nurse practitioner Amber Glessner, who shadowed a Cleveland Clinic counterpart during the visit. "We took back the 'working as a unit' theory to ensure that all team members function together and consider everyone's contributions to reach the common goal of enhancing the patient's experience."

"The site visit to Cleveland Clinic exceeded our expectations," says PHI's Dr. Sowden. "We learned things that we can take back and put into clinical practice, such as the office pre-procedure timeout, as well as ideas for more efficient patient throughput. It gave us a good gauge of our program, including the things we do well and where we have some opportunities.

"The Cleveland Clinic team made us feel welcome," Dr. Sowden continues. "They listened to and offered solutions for issues we were experiencing in our practice. We have implemented into our daily routines many of the practices we learned during the visit. Since our visit we have noticed an improvement in quality and patient safety, which translates to overall better care for our patients. Our office is working more efficiently than ever before thanks to the staff at Cleveland Clinic."

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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

COURSE ON LIFELONG CARE OF ADULT CHD RETURNS TO CHICAGO THIS SPRING

Evidence-based updates on management advances and overcoming barriers to care

Comprehensive Care for the Lifetime Treatment of Adult Congenital Heart Disease: A Case-Based Approach

March 31-April 1, 2023

InterContinental Chicago Magnificent Mile
Chicago, Illinois

Information/registration: **ccfcme.org/achd23**

Patients with adult congenital heart disease (ACHD) are a rapidly growing and frequently underserved population. To equip clinicians to better meet their needs, Cleveland Clinic is returning to Chicago in spring 2023 to again offer this comprehensive 1.5-day CME course it introduced in Chicago last spring.

"Our goal is to update participants on clinical and research advances in the morphologies of congenital anomalies, the best diagnostic modalities and interventions, and the most appropriate management strategies for patients with ACHD," says course co-director Tara Karamlou, MD, MSc, a pediatric and adult congenital heart surgeon at Cleveland Clinic. "We aim to detail the highly complex ecosystem of congenital heart care in adults and describe how that care may be shaped by new approaches in management and recent guidelines."

30+ faculty over a day and a half

Over a full Friday and a Saturday morning, a faculty of more than 30 cardiologists, cardiothoracic surgeons and other clinicians with ACHD expertise from Cleveland Clinic and other top U.S. and international institutions will present practical, evidence-based updates on various aspects of ACHD care. After an opening session providing an overview of ACHD with patient perspectives, sessions will provide in-depth exploration of developments and innovations in the following:

- The pulmonary and tricuspid valves, including tetralogy of Fallot and Ebstein's anomaly
- Single-ventricle physiology
- The failing systemic right ventricle and systemic left ventricle
- Innovations in ACHD clinical care and research
- Special topics in the arc of care for ACHD

Each session includes presentations from multiple subspecialty perspectives, including imaging, diagnostic, surgical, interventional and electrophysiological.

"Recent advances have been made in various aspects of ACHD care, such as assessing and treating patients with pulmonary valve dysfunction and managing systemic right ventricular congenital disorders in adults, especially transposition of the great arteries," notes course co-director Hani Najm, MD, Chair of Pediatric and Congenital Heart Surgery at Cleveland Clinic.

"Moreover, as data mount on the management of adults who underwent Fontan surgery in infancy, the clinical care of these patients has improved," adds Joanna Ghobrial, MD, MS, Medical and Interventional Director of Cleveland Clinic's Adult Congenital Heart Disease Center. "However, not all clinicians are fully versed on these advances and insights, so we are focused on closing those knowledge gaps. We also will explore social and patient-perceived barriers that complicate the diagnosis and lifelong management of adult congenital heart disease."

New and notable this year

Notable this year are presentations devoted to ACHD and socioeconomic disparities, ACHD and women's health, and ACHD and sports. Other highlights include an overview of groundbreaking research trials in ACHD, a patient panel with patient experience videos, and a keynote address by eminent congenital heart surgeon Vaughn Starnes, MD, who will also take part in a "fireside chat" with course co-director Lars Svensson, MD, PhD, Chair of Cleveland Clinic's Heart, Vascular & Thoracic Institute.

"Lifelong surveillance is paramount for adults with congenital heart disease," says Dr. Svensson, "and recent advances in imaging, surgical repair and catheter interventions have improved outcomes for these patients. We want to make sure awareness and utilization of those advances is as broad as possible."

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Course and registration details are available at ccfcme.org/achd23.

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

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SAVE THE DATES FOR CME

25th Valve Disease, Structural Interventions and Diastology/Imaging Summit

Thu.-Sun., Feb. 2-5, 2023

Eden Roc Miami Beach, Miami Beach

Information/registration: ccfcme.org/echo

7th Annual Advances in Congenital Heart Disease Summit

Thu.-Sat., Feb. 16-18, 2023

Orlando World Center Marriott, Orlando

Information/registration: ccfcme.org/congenitalheart23

Comprehensive Care for the Lifetime Treatment of Adult Congenital Heart Disease

Fri.-Sat., March 31-April 1, 2023

InterContinental Chicago Magnificent Mile, Chicago

Information/registration: ccfcme.org/achd23
(see page 18 for a detailed preview)

Comprehensive, Lifelong, Expeditious (CLE) Care of Aortic Disease

Fri.-Sat., Sept. 22-23, 2023

Cleveland

Information/registration: ccfcme.org/aorticdisease

Global EP Summit 2023

Fri.-Sat., Sept. 29-30, 2023

Hilton Cleveland Downtown, Cleveland

Information/registration: ccfcme.org/globalep23

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

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