

CARDIAC CONSULT

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Heart, Vascular and Thoracic News

MITRAL VALVE SURGERY

Secrets to Success in Mitral Valve Repair — p. 5

Contending With Mitral Annular Calcification — p. 8

DEAR COLLEAGUES,

One of the greatest virtues of volume-based experience is that it benefits all patients, regardless of whether they need a common operation or a highly specialized procedure for an unusual and complex presentation.



This principle is illustrated well by the pair of articles related to our cover theme of mitral valve surgery.

The first piece, on page 5, details the various factors — both technical and cultural — that help explain how our mitral valve repair team recently surpassed 4,000 consecutive isolated mitral valve repairs without a mortality. Although mitral valve repair is a common operation with a mortality rate below 1% nationally, the vanishingly small operative risk represented by our team's long mortality-free stretch is of a different order of magnitude. This is due, in no small part, to having the highest mitral valve repair volumes in the nation.

Similarly, considerable mitral valve surgery volumes have rewarded our surgeons with expertise in contending with the challenge of removing mitral annular calcification in the setting of mitral valve replacement. As illustrated on page 8, deep experience in these complex cases has yielded insights that help achieve prosthetic valve sizing and seating that offer the best chance of favorable results.

If you have a patient in need of referral for either a common surgery or one tailored to unusually daunting circumstances, we would be honored to put our experience to work for their benefit.

Respectfully,



Lars G. Svensson, MD, PhD

Chair, Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute

AATS Taps Dr. Svensson as Its New President

In May, Cleveland Clinic Heart, Vascular & Thoracic Institute Chair Lars Svensson, MD, PhD, became the 104th President of the American Association for Thoracic Surgery (AATS) during the AATS annual meeting. Dr. Svensson previously served on the AATS Board and has chaired the AATS Guidelines Committee, among other roles with the association.

“I am honored to serve in this role,” Dr. Svensson says, “and I am humbled to follow in the footsteps of my Cleveland Clinic mentors who have served as presidents of AATS — namely, Drs. Floyd Loop, Toby Cosgrove and Bruce Lytle.”

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 — An illustration of the mitral valve, which figures prominently in two features in this issue. On page 5 we explore the factors contributing to a stretch of 4,000+ mitral valve repairs without an operative mortality. On page 8 we share tips on debridement of mitral annular calcification in the setting of mitral valve replacement.

FROM THE AMERICAN COLLEGE OF CARDIOLOGY (ACC) 2023 SCIENTIFIC SESSION

Cleveland Clinic staff played key roles in three late-breaking trials, recapped below

Bempedoic Acid Reduces Cardiovascular Events in Statin-Intolerant Patients

The non-statin lipid-lowering drug bempedoic acid (Nexletol®) demonstrated a significant reduction in the risk of cardiovascular events in the global CLEAR Outcomes study of statin-intolerant patients treated for primary or secondary cardiovascular prevention. Results were reported at the ACC meeting by Steven Nissen, MD, and published in the *New England Journal of Medicine*.

“These findings support bempedoic acid as an effective therapy for the 7% to 29% of patients who report statin intolerance,” says Dr. Nissen, Chief Academic Officer of Cleveland Clinic’s Heart, Vascular & Thoracic Institute and the study’s first author. “They establish this drug as an effective approach to ensure that this large group of patients can benefit from the protective effects of low-density lipoprotein cholesterol (LDL-C) reduction.”

Bempedoic acid — which was developed specifically for use in patients with statin intolerance — was approved by the FDA for LDL-C reduction in 2020, but its effects on clinical outcomes were not previously studied.

CLEAR Outcomes randomized 13,970 adults in a double-blind fashion to oral bempedoic acid 180 mg/day or placebo. Participants had a prior cardiovascular event or clinical features that put them at high cardiovascular risk. Prior to enrollment, all patients reported statin intolerance due to an adverse effect that resolved or improved after statin discontinuation.

Over median follow-up of 40.6 months, the primary endpoint — a composite of death from cardiovascular causes, nonfatal myocardial infarction (MI), nonfatal stroke or coronary revascularization — occurred in significantly fewer bempedoic acid recipients (11.7%) than placebo recipients (13.3%) (hazard ratio = 0.87; $P = 0.004$). This represents an absolute risk reduction of 1.6% and a relative reduction of 13%.

Statistically significant reductions were also seen with bempedoic acid versus placebo in three key secondary end points: (1) the composite of death from cardiovascular causes, nonfatal MI and nonfatal stroke; (2) fatal or nonfatal MI; and (3) coronary revascularization.

There were no clinically meaningful differences between treatment arms in overall or serious adverse events. Consistent with previous reports, bempedoic acid was associated with slightly higher rates of gout and gallstones and modest increases in serum creatinine, uric

acid and hepatic enzymes. Rates of muscle-related complaints were similar between the treatment groups.

“Bempedoic acid provides an important option for patients who cannot tolerate statins or who are maximized on their statin and cannot take PCSK9 inhibitors,” says study co-author Leslie Cho, MD, Co-Section Head of Preventive Cardiology at Cleveland Clinic.

The study was coordinated by the Cleveland Clinic Coordinating Center for Clinical Research (C5Research) and funded by Esperion Therapeutics, which markets Nexletol.

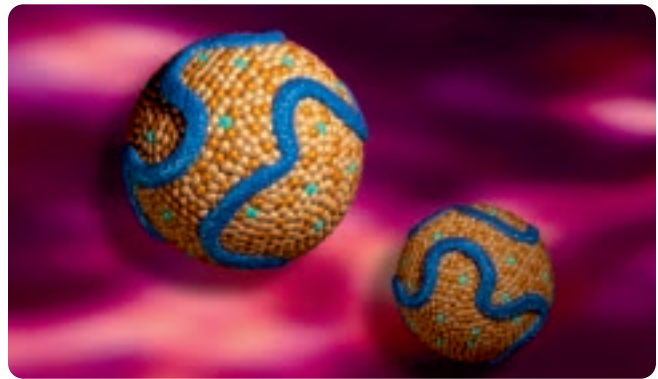


FIGURE 1 — Illustration of low-density lipoprotein (LDL) particles. The CLEAR Outcomes trial adds bempedoic acid to the group of LDL-C-lowering drugs that have shown improvements in clinical outcomes.

Targeting Inflammation Is Best Way to Curb Residual Risk in Statin-Treated Patients

Vascular inflammation is a stronger predictor of residual cardiovascular risk than LDL-C level among statin-treated patients with atherosclerotic risk, according to a pooled analysis of three large contemporary randomized controlled cardiovascular outcome trials.

“These data tell us that if we want to further reduce risk of cardiovascular events in patients on statins, we need to target inflammation,” says Cleveland Clinic’s Steven Nissen, MD, senior author of the analysis, which was presented at the ACC meeting and published in *The Lancet*. “Even after we’ve treated patients with very effective doses of statins, they still have some residual risk of major adverse cardiovascular events (MACE). We conducted this analysis to determine what is the best way to target that residual risk — by further lowering LDL-C or by reducing inflammation as measured by high-sensitivity C-reactive protein (hsCRP).”

Dr. Nissen was part of a multicenter team that pooled data from three recent randomized controlled trials assessing adjunctive lipid-lowering therapy in patients on maximally tolerated statin therapy for primary or secondary cardiovascular prevention: PROMINENT (N = 9,988), REDUCE-IT (N = 8,179) and STRENGTH (N = 13,078). These cohorts were chosen because they had levels of hsCRP and LDL-C representative of contemporary statin-treated populations, making them ideal for assessment of residual risk.

Among the studies' collective 31,245 patients, the researchers assessed increasing quartiles of baseline hsCRP, a biomarker of residual inflammatory risk, and of LDL-C, a biomarker of residual cholesterol risk, for their ability to predict future MACE, cardiovascular mortality and all-cause mortality.

Residual inflammatory risk was found to be highly associated ($P < 0.0001$) with all three primary end points. In contrast, the relationship of residual cholesterol risk to the primary end points was neutral for MACE and of lower magnitude (relative to residual inflammatory risk) for both cardiovascular and all-cause mortality.

The study authors write that "targeting LDL-C alone is unlikely to completely reduce atherosclerotic risk and that inflammatory pathways have yet to be fully exploited" to reduce cardiovascular outcomes. They add that combined use of potent lipid-lowering therapies and inflammation-inhibiting therapies may become a future standard of care for atherosclerotic disease.

Randomized trials have shown that targeted anti-inflammatory therapy with canakinumab or colchicine significantly reduces cardiovascular events in statin recipients in the absence of further LDL-C reduction. This new analysis might increase interest in colchicine, which is available in inexpensive generic forms, for reducing residual risk in this setting. "There are also interesting new therapies in development for this purpose, and we hope this study will accelerate those programs," Dr. Nissen adds.

TEER Benefits Persist Through 5 Years in Secondary MR

Outcome benefits from transcatheter edge-to-edge repair (TEER) of the mitral valve endure through five years in patients with heart failure (HF) and moderate-to-severe or severe secondary mitral regurgitation (MR) who remain symptomatic despite guideline-directed medical therapy, according to final results from the multicenter COAPT randomized trial.

The findings, which were presented at the ACC meeting and published in the *New England Journal of Medicine*, offer reassurance about TEER's longevity in this population, says Samir Kapadia, MD, one of the COAPT trial's lead investigators and a member of its steering committee.

"Given the severity of illness and comorbidities of symptomatic patients with HF and significant MR, it was uncertain whether the benefits with TEER at two years would remain meaningful out to

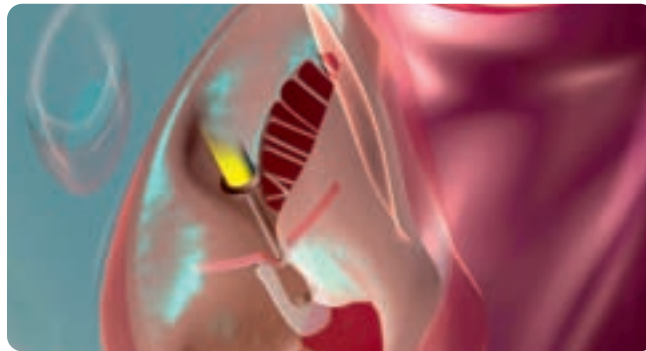


FIGURE 2 — Transcatheter edge-to-edge repair of the mitral valve, illustrated here, significantly reduced hospitalization for heart failure and all-cause mortality through five years in the COAPT trial.

five years," says Dr. Kapadia, Chair of Cardiovascular Medicine at Cleveland Clinic. "These are older patients with a very poor prognosis because of concurrent HF and valve dysfunction. The message from this trial is that TEER really helps these patients over a number of years."

Two-year COAPT results were published in 2018 and supported FDA approval of the TEER device used in the trial, MitraClip™, for treatment of symptomatic secondary MR in patients with HF. The open-label trial randomized 614 patients to TEER with MitraClip plus medical therapy or to medical therapy alone. After two years, patients in the control group who still met the study's enrollment criteria could cross over to TEER with MitraClip. Overall, 21.5% of patients in the control group ultimately underwent TEER, representing 44.9% of control patients who survived to two years.

After five years, annualized hospitalization for HF — the primary effectiveness end point — was 33.1% in the device group versus 57.2% in the control group (hazard ratio = 0.53; 95% CI, 0.41-0.68). Additionally, TEER was associated with significantly lower all-cause mortality and higher likelihood of being in NYHA functional class I or II throughout follow-up. Freedom from device-related complications at five years was 89.2%.

Among control patients who crossed over to device therapy, MR reduction and event rates after TEER were similar to those in patients initially assigned to the device group.

"These final COAPT results will likely increase use of TEER in this population," says Dr. Kapadia, "and fuel interest in new studies of TEER in patients at earlier disease stages, such as moderate MR."

The COAPT trial was sponsored and funded by Abbott, which markets MitraClip.

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SECRETS TO SUCCESS IN MITRAL VALVE REPAIR

The cultural and technical factors promoting repair durability and a mortality-free stretch of 4,000+ cases

Earlier this year, Cleveland Clinic completed its 4,000th consecutive isolated mitral valve repair without a perioperative death, continuing a mortality-free stretch that dates back to 2014.

While isolated mitral valve repair has come to be a relatively low-risk operation at most centers, the mortality rate nationwide remains near 1%, or 1 in 100 cases. In that context, the Cleveland Clinic rate of zero mortality across several thousand cases is of a different order of magnitude.

Cardiac Consult caught up with several members of Cleveland Clinic's mitral valve repair team to identify key factors, recapped below, that have contributed to this remarkable series of mortality-free operations and related success in the durability of mitral valve repairs.

Stats of Note from Cleveland Clinic's Mitral Valve Repair Program

> 4,200

consecutive isolated mitral valve repairs without an operative death through February 2023

99.4%

proportion of repairs in 2022 with mild (1+) or less residual mitral regurgitation

Experience and continual learning

"Mitral valve repair is a very specialized operation, and it requires a great deal of experience to become competent and then excellent at it," says A. Marc Gillinov, MD, Chair of Thoracic and Cardiovascular Surgery at Cleveland Clinic. "We perform well over 1,000 mitral valve operations per year, and that sort of experience leads to excellence."

"Our annual volumes of isolated mitral valve repair are the highest in the country, so there is virtually nothing we haven't seen before," adds Daniel Burns, MD, MPhil, staff surgeon and Assistant Professor of Surgery in the Department of Thoracic and Cardiovascular Surgery.

"This depth of experience goes back 35 or 40 years to when Toby Cosgrove, MD, helped pioneer many modern mitral valve repair practices here beginning in the 1980s," notes Brian Griffin, MD, Medical Director of Cleveland Clinic's Mitral and Tricuspid Valve Center. "From the start we've approached mitral valve repair with the view of continually learning as we go. From real-time imaging during repairs we've learned a lot about the underlying pathophysiological mechanisms that can make a repair look adequate intraoperatively when in fact it might not be adequate in a beating heart. One example is systolic anterior motion, which our surgeons have since developed ways to predict and deal with."

Judgment

Experience hones not only technical skill but also judgment. "Judgment is essential to our results, from knowing in whom to operate and which approach can be used most safely, to knowing how to achieve an excellent repair with a relatively short operation so that the patient's physiology is not stressed," observes Dr. Gillinov, who also serves as Surgical Director of the Mitral and Tricuspid Valve Center.

Such judgment has resulted in a rate of repair (versus replacement) of well over 99% for isolated degenerative mitral valve disease at Cleveland Clinic in recent years. It also guides the choice among robotically assisted mitral valve repair (Figure 1), other minimally invasive approaches, and partial or full sternotomy (Figure 2).

"Patients often come to Cleveland Clinic asking specifically for a robotically assisted repair, but not all are good candidates," says Dr. Burns. "Our job, regardless of what people are looking for, is to evaluate all facets of their presentation and then decide which operation is best for their individual situation. The priority determinant is whether a given operation will enable the valve to be repaired — and, specifically, be repaired safely. All other considerations come after that, including minimizing invasiveness, which we are readily prepared to do whenever it is safe."

For example, a patient with low-risk anatomical features is likely to be a good candidate for a robotically assisted operation, whereas a full sternotomy is usually best for a patient with suboptimal heart



FIGURE 1 — Photo of a robotically assisted mitral valve repair operation. Cleveland Clinic uses a homegrown screening algorithm to assess whether patients are good candidates for robotically assisted mitral valve repair. A recent study showed that 60% of screened patients qualified for robotic repair and that these patients' outcomes were as good as those of patients undergoing sternotomy.

function or with challenging body habitus, to ensure maximum visualization and safety. Partial sternotomy may be an ideal intermediate option for a patient who has one or two factors that rule out a robotic approach, such as poor suitability to peripheral cannulation, but who wants to avoid the longer recovery and larger scar associated with full sternotomy.

The team's judgment in choice of operation is guided by a Cleveland Clinic-developed screening algorithm used to assess patients' candidacy for a robotic procedure when undergoing repair for isolated degenerative mitral valve disease. The data-driven algorithm bases patient selection for robotic surgery on various features from transthoracic echocardiographic and CT evaluation, as well as established contraindications to robotic mitral valve surgery.

A recent study published in the *Journal of Thoracic and Cardiovascular Surgery* (2022;164:1080-1087) evaluated use of the algorithm across a 1,000-patient sample. It showed that 60% of screened patients qualified for robotic surgery and that these patients' postoperative outcomes were just as good as those of patients undergoing mitral valve repair with sternotomy. "These findings validate this screening approach," Dr. Gillinov notes.

"We have done a good job adhering to this algorithm rather closely," Dr. Burns adds. "I think that has been a contributor to Cleveland

Clinic's zero mortality for mitral valve repair over many years and our very high repair rate."

Prioritization of safety

The Cleveland Clinic mitral valve surgery team describes their screening algorithm for robotic procedures as "conservative" — without apology. "It is our philosophy that minimally invasive surgery is only appropriate when it can be offered without sacrificing safety or quality," they wrote in a recent commentary in *JTCVS Techniques* (2021;10[C]:82-83).

The team elaborated further in another recent paper, "The 10 Commandments for Mitral Valve Repair" (*Innovations [Phila]*. 2020;15:4-10), writing: "Surgeons may opt to 'push the envelope' and tackle a complex valve with a less invasive approach. This is a mistake and can result in extended cross-clamp times, limb ischemia (in the case of femoral perfusion), and adverse outcomes."

Beyond its priority role in choice of operative approach, safety is fundamental to other aspects of the Cleveland Clinic team's success. For instance, an insistence on preoperative CT of the chest, abdomen and pelvis before robotically assisted repairs helps ensure safe and effective femoral perfusion. "After instituting routine CT scanning for patients undergoing robotic mitral valve repair, we cut our stroke rate by more than half," Dr. Gillinov notes. "For borderline vessels, we expose the femoral vessels before chest incision and port placement. In rare instances, we may switch to sternotomy on that basis."

Bench depth and teamwork

As a former Cleveland Clinic advanced robotic and minimally invasive surgery fellow who joined the professional staff in 2018, Dr. Burns has firsthand knowledge of the depth of Cleveland Clinic's mitral valve surgery expertise. "Our large volumes have allowed us to develop a team of multiple surgeons who are mitral valve experts," he says. "We often operate with two highly experienced surgeons together, particularly if it's a complex case, to ensure that every patient gets an exemplary repair."

As intraoperative echo has assumed an increasingly important role in mitral valve repairs, partnership with the echocardiographer looms large as well. "Teamwork between the surgeons and the echocardiographer, typically a cardiothoracic anesthesiologist, is critical," Dr. Gillinov observes. "Without an expert doing the echocardiogram, excellent mitral valve repair would be extremely challenging."

"After instituting routine CT scanning for patients undergoing robotic mitral valve repair, we cut our stroke rate by more than half." — A. MARC GILLINOV, MD

“At 20 years there’s about a 10% risk of needing a reoperation, so [mitral valve repair] is a much more durable procedure than we ever thought.” — BRIAN GRIFFIN, MD

Dr. Burns concurs. “We rely heavily on intraoperative transesophageal echocardiograms from our anesthesiology colleagues,” he says. “They do a masterful job of initially pinpointing the valve pathology to precisely guide our repair with the maximum amount of information. Their images are exceptional — it’s almost like viewing the valve with our own eyes. Then, after we repair the valve, the same expert imagers are there in the operating room to do another echocardiogram to thoroughly assess the valve and confirm the repair quality.”

The importance of teamwork to mortality success continues in the postoperative setting, with support from intensivists, advanced practice providers and surgical trainees, “who are always available as first responders when issues arise,” Dr. Burns notes.

Giving repair durability its due

While operative survival is an obvious prerequisite for all other outcomes, good valve function over the long term is the reason patients undergo mitral valve repair in the first place.

“Twenty-five to 30 years ago, we thought these repairs would last an average of 10 to 15 years,” says Dr. Griffin. “Now we find that at 20 years there’s about a 10% risk of needing a reoperation, so it’s a much more durable procedure than we ever thought.”



FIGURE 2 — Photo of an open mitral valve repair operation. Although many patients ask for a robotic repair, not all are good candidates for it, and partial or full sternotomy is still used for a sizable share of patients in order to ensure maximal safety and repair quality.

He attributes the greater repair durability to a number of insights and advancements over the years, including routine placement of a prosthetic annuloplasty ring or band to reduce the size of the mitral annulus, which enlarges over time as a result of regurgitation. “This appears to be important for long-term valve durability,” Dr. Griffin notes. “Additionally, it seems that repair surgery may do more than just correct the regurgitation but perhaps also changes some biomechanical forces so that the valve essentially resets itself for a long period.”

Regardless of mechanisms, “a good long-term result is predicated on an excellent short-term result,” says Dr. Gillinov. “That means having the very highest standards in the operating room to get the repair as close to perfect as humanly possible,” with “perfect” defined as zero or close to zero mitral regurgitation.

This is where teamwork with the echocardiographer — to meticulously inspect the repair before the incision is closed — is most important. “Our expert imagers confirm whether the repair looks perfect,” Dr. Burns says. “If it looks anything but perfect, they help us understand the precise source of any residual regurgitation. We can then have a well-informed discussion about whether to do a second bypass pump run and revise the repair — and, if so, exactly what pathology we’re going after. We are aggressive about fixing repairs in this context, so it’s rare that we have more than trace residual mitral regurgitation when we leave the operating room. This ensures a remarkable success rate for repair quality.”

“Later, typically before the patient is discharged home, we perform another echocardiogram to ensure there has been no slippage,” Dr. Griffin adds.

“There is increasing evidence that small differences in the degree of residual mitral regurgitation — even mild versus none or moderate versus mild — result in long-term functional differences and potentially in long-term survival differences,” Dr. Burns says. “The implications for patients can be substantial.”

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MAC ATTACK: CONTENDING WITH MITRAL ANNULAR CALCIFICATION DURING MITRAL VALVE SURGERY

Surgical tips on debridement of calcification to optimize valve replacement

In the setting of mitral annular calcification (MAC) in a patient undergoing mitral valve replacement, addressing the calcium to achieve optimal sizing and seating of a prosthetic valve offers the best chance of favorable results. But special care must be taken to avoid releasing calcium fragments into the bloodstream or injury to the atrioventricular groove or the left circumflex coronary artery; these potential high-risk complications deter most surgeons from adequately addressing MAC.

Cleveland Clinic cardiothoracic surgeons have considerable experience with careful but sometimes aggressive handling of MAC, prompting an invited talk on the subject by Haytham Elgharably, MD, at the 2023 annual meeting of the Society of Thoracic Surgeons. In addition to discussing MAC assessment and tailoring the surgical approach to MAC severity, Dr. Elgharably provided procedural guidance for safely addressing this difficult situation.

“Removing MAC is technically challenging, but doing so often offers the best outcome by providing a smoother and more pliable surface for implanting an appropriate-size prosthesis that meets the patient’s requirements of adequate blood flow and cardiac output,” Dr. Elgharably says. “With careful attention to presurgical planning and intraoperative technique, it can be done safely at centers of expertise.” Highlights of his presentation are recapped below, along with perspectives from one of his cardiologist colleagues.

Know your enemy

MAC severity must be thoroughly evaluated preoperatively so that the strategy can be individually tailored and planned. A multimodality imaging assessment is recommended, including:

- › Cardiac CT to obtain precise anatomic details of MAC involvement, such as the amount, density, depth and extent of the disease as well as its proximity to important structures like the left circumflex coronary artery.
- › Transthoracic, and usually transesophageal, echocardiography for functional assessment of the valve, as MAC can lead to valvular stenosis and/or regurgitation.

“MAC is a highly heterogeneous disease,” notes cardiologist Serge Harb, MD, of Cleveland Clinic’s Section of Cardiovascular Imaging. “It can affect the annulus to varying degrees and may also extend to the mitral leaflets and surrounding myocardial tissue, resulting in various levels of functional impairment. To fully understand the

anatomical details and functional implications, a comprehensive preoperative assessment using multimodality imaging is necessary.”

He adds that in certain complex cases, 3D printing of the heart is done based on imaging studies, providing the operator with a realistic model of MAC distribution.

Dr. Elgharably explains that preoperative findings determine the surgical approach. In most cases:

- › Posterior MAC may need a transeptal (extended) approach for better exposure, especially in reoperative cases.
- › Circumferential MAC may require transaortic debridement of the anterior component of the calcification.
- › Anterior MAC that extends into the aorto-mitral curtain and the aortic valve may require a so-called Commando exposure, in which the incision in the aorta is extended into the roof of the left atrium, exposing both the aortic and mitral valves and the cardiac fibrous skeleton in between (Figure 1). Patients with radiation heart disease are particularly prone to developing this most severe involvement.

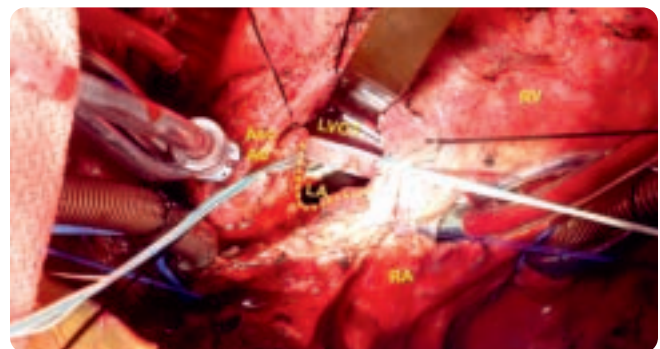


FIGURE 1 — Operative photo showing a Commando exposure. Asc Ao = ascending aorta; LA = left atrium; LVOT = left ventricular outflow tract; RA = right atrium; RV = right ventricle.

Other preoperative planning includes prosthesis type and sizing, taking into account the patient's body mass, functional status, symptoms, comorbidities and concomitant procedures.

Debride and reconstruct

Debridement starts with incising the posterior leaflet to expose the MAC, which is followed by sharp debridement of calcium fragments (Figure 2). After adequate debridement and sizing of the target prosthesis, reconstruction of the posterior annulus is necessary.

"The degree of reconstruction required is based on the magnitude of debridement, which depends on the defect size in the annulus, the density of MAC (as determined by tapercut needle if it can go through), the quality of tissues that can be used to support the reconstruction, and the type and size of prosthesis needed," Dr. Elgharably explains.

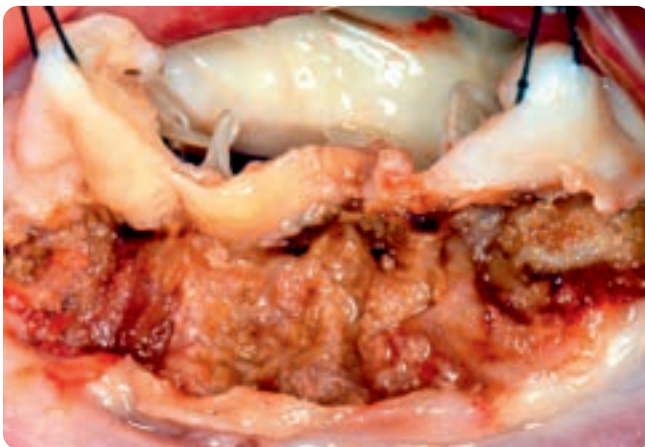


FIGURE 2 — Operative photo showing debridement of MAC.

Because the annulus may be weakened as a result, it may need to be reinforced to hold the prosthesis. In general, strategies for reconstruction include the following, according to MAC severity:

- Mild MAC: Native mitral leaflets can usually be used. After any thickening or calcification of the posterior leaflet is removed, it may be possible to reuse the rest.
- Moderate MAC: In some cases, the anterior leaflet can be flipped to cover the area of the posterior annular reconstruction or a felt strip can be placed.
- Severe MAC (Figure 3): A bovine pericardial patch may be required.

For the replacement valve, Dr. Elgharably prefers to use a low-profile prosthesis with short struts, as it is easier to seat and avoids obstruction of the left ventricular outflow tract (LVOT).

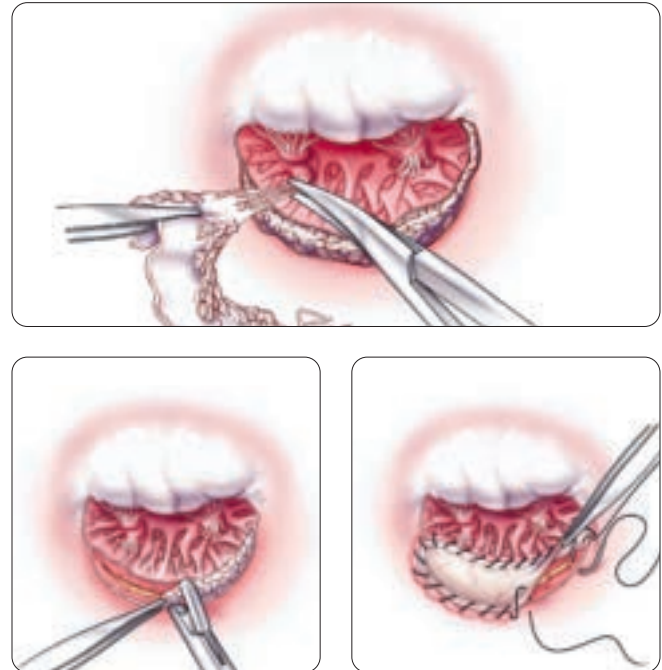


FIGURE 3 — Key steps in the surgical management of severe MAC.

Top: Excision of posterior leaflet that is too calcified to be spared.

Left: Calcium is debrided with care to avoid injury to the ventricular myocardium and coronary vessels. Calcium fragments must be completely aspirated from the field.

Right: In cases where calcification extends into the atrioventricular groove, a pericardial patch can be sewn on to cover the defect. Valve sutures should pass through the patch and out through the annulus to provide added support.

Dr. Harb says that a well-anchored and optimally positioned prosthetic valve can prevent complications such as paravalvular leaks and LVOT obstruction. The complications can be detected by echocardiography, which he notes is the preferred test for monitoring these patients.

"The margin of error during mitral valve surgery in patients with MAC is small," Dr. Elgharably concedes. "But as the U.S. patient population ages, MAC is becoming more of a problem, and having the ability to effectively address it grows more important."

Two detailed overviews of surgical techniques used at Cleveland Clinic to address MAC have been published, one in *Operative Techniques in Thoracic and Cardiovascular Surgery* (2003;8:2-13) and the other in the *Journal of Thoracic and Cardiovascular Surgery* (2013;146:233-235).

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SUGAR SUBSTITUTE ERYTHRITOL LINKED TO INCREASED CARDIOVASCULAR RISK

Human and animal studies show a rise in platelet reactivity, thrombosis and cardiac events

Erythritol — a commonly used artificial sweetener in processed foods — is associated with heightened risk of major adverse cardiovascular events (MACE), independent of traditional risk factors for cardiovascular disease.

So found an international team of investigators using U.S. and European cohorts, in addition to conducting in vitro studies on platelet activity using erythritol and animal model studies with erythritol at commonly ingested levels. The research was published in *Nature Medicine* (2023;29:710-718).

“Since sugar substitutes are often consumed at high levels, especially by people with obesity and diabetes, it is critical to ensure that they do not increase cardiovascular risk,” says the study’s senior author, Stanley Hazen, MD, PhD, Chair of the Department of Cardiovascular and Metabolic Sciences in Cleveland Clinic’s Lerner Research Institute. “Artificially sweetened products are actually recommended by some professional societies for those who are most vulnerable to their potential ill effects.”

Erythritol: considered safe, but is it?

Erythritol (see Figure) is a common additive used to sweeten as well as improve the taste and so-called mouthfeel of other artificial sweeteners. Because it is produced endogenously in human tissue and is present in fruits and vegetables, it is considered to be a “generally regarded as safe” (GRAS) ingredient by the U.S. FDA and the European Union, and its content need not be disclosed on food labels. However, common foods and drinks — such as artificially sweetened bakery products, “keto” products and many “zero calorie” products — may contain erythritol. When they do, erythritol is typically used in amounts thousands of times higher than natural levels.

While erythritol has undergone short-term toxicity tests (mainly evaluating mutagenicity) and human tolerance testing (to determine maximum levels ingested before acute adverse effects are observed), little is known about its possible long-term health effects. Epidemiological evidence has been mounting that links consumption of artificial sweeteners in general with weight gain, diabetes and cardiovascular mortality, but it is difficult to tease out bias from such data. Randomized clinical trials looking at long-term outcomes have not been performed.

Erythritol is a particularly worrisome ingredient, notes Dr. Hazen, who is also Co-Section Head of Preventive Cardiology at Cleveland

Clinic. It is only about 70% as sweet as sugar, so it is used in large quantities to achieve desired sweetness. “A ‘diabetic’ confection or bakery item may contain as much as 50% erythritol by dry weight,” he remarks.

Study design and results

The researchers conducted a series of diverse investigations to discover compounds linked to residual cardiovascular disease risks (after accounting for traditional risk factors), and they discovered erythritol as a lead compound in that search. They then designed numerous studies to evaluate the impact of commonly consumed quantities of erythritol on cardiovascular disease-relevant phenotypes. The studies are summarized below.

Initial untargeted metabolomics studies. This “discovery cohort” consisted of 1,157 patients undergoing cardiac assessment at Cleveland Clinic with at least three years of follow-up. Using untargeted mass spectrometry, the investigators identified compounds in these patients’ plasma that were associated with MACE, defined as death or nonfatal myocardial infarction or stroke over the three years following enrollment/sample collection. They found several artificial sweeteners to be associated with incident MACE risks, with erythritol being the most strongly predictive.

Targeted metabolomics analyses. Next came quantitative studies of erythritol using new cohorts of patients undergoing elective cardiac evaluation: one from Cleveland Clinic ($n = 2,149$) and one from Charité Hospital in Berlin, Germany ($n = 833$). Both of these quaternary referral centers cover large catchment areas, and patients had multiple cardiovascular risk factors. Findings included the following:

- › Plasma erythritol levels were higher among those with high prevalent cardiovascular disease and risk factor burden ($P < 0.0001$, each cohort).
- › High plasma levels of erythritol were associated with incident MACE over three years of follow-up ($P < 0.0001$, each cohort).
- › After adjusting for cardiovascular risk factors, higher erythritol levels were associated with higher risk of MACE (adjusted hazard ratio for fourth vs. first quartile = 1.80 [95% CI, 1.18-

2.77] in the U.S. cohort and 2.21 [95% CI, 1.20-4.07] in the European cohort).

- Associations between erythritol and MACE risk were found regardless of sex and presence of individual cardiovascular risk factors.

In vitro and ex vivo mechanistic studies in whole blood, platelet-rich plasma and isolated platelets from healthy volunteers. After adding erythritol to either whole blood, platelet-rich plasma or isolated platelets to achieve concentrations in the range observed among the previous cohorts, the researchers found that platelet aggregation and adhesion increased with increasing erythritol dose.

In vivo mechanistic studies using mice. In a murine model of arterial injury, increasing circulating erythritol across physiological levels led to faster clot formation.

Erythritol ingestion studies. Healthy volunteers (n = 8) were given an erythritol-sweetened drink (30 g erythritol), a load comparable to a single can of artificially sweetened beverage. Plasma erythritol levels increased 1,000-fold rapidly after ingestion. They remained elevated for more than two days at levels above the threshold that adversely affected platelet function in the mechanistic studies.

More research — and transparency — needed

These studies provide the strongest evidence to date of cardiovascular risk associated with an artificial sweetener. Dr. Hazen urges the following actions by food regulatory agencies:

- Require the food industry to conduct more safety studies of sugar substitutes, including long-term impacts and effects on cardiovascular disease.
- Reappraise food labeling requirements to better inform the public of ingredients.

“I tell my patients to stay away from artificial sweeteners and to instead modestly consume natural sweeteners, such as honey and sugar,” he adds.

Dr. Hazen’s group is continuing their research on artificial sweeteners and cardiovascular risk. “Our findings, together with other recent publications, have brought caution around the widely held belief that replacing sugar with some artificial sweeteners can provide benefits over the known risks of excess sugar consumption,” says study co-author W.H. Wilson Tang, MD, Research Director for Cleveland Clinic’s Section of Heart Failure and Cardiac Transplantation. “More rigorous investigations and methodologies are clearly needed in this important area of public health.”



FIGURE — Illustration showing the chemical structure of erythritol.

Although the compound is produced endogenously in human tissue and is present in fruits and vegetables, its use as an artificial sweetener in processed foods is typically in amounts thousands of times higher than natural levels.

“Artificial sweeteners have previously been suspected to be associated with obesity, diabetes and heart disease,” adds Dennis Bruemmer, MD, PhD, Director of Cleveland Clinic’s Center for Cardiometabolic Health. “This well-performed study provides important confirmation of increased cardiovascular risk from a commonly used artificial sweetener and sheds light on the reason underlying this relationship. One would hope the FDA will mandate disclosure to consumers of this increased cardiovascular risk associated with artificial sweeteners, to promote awareness and healthier food choices.”

Contact Dr. Hazen at 216.444.9426, Dr. Tang at 216.444.2121 and Dr. Bruemmer at 216.445.2332.

MASSIVE SPINE AND RETROPERITONEAL SARCOMA: A CASE STUDY IN SURGICAL COLLABORATION

Invasion of the lumbar spine and iliac vein made resection risky

A 51-year-old male general surgeon presented to an out-of-state institution for progressive low back pain of two months' duration. His past medical history was remarkable for testicular cancer treated 25 years earlier with orchiectomy and radiotherapy.

Imaging revealed a large mass invading the lumbar spine and left common iliac vein. Biopsy revealed it to be a spindle cell sarcoma, believed to be secondary to radiation changes following therapy for his testicular cancer. The patient came to Cleveland Clinic for evaluation.

The images in Figure 1 illustrate the complexity of potential management. Resection would risk damage to critical vasculature and require removal of a significant amount of spine.



FIGURE 1 — While the patient's 3D CT on the left shows a normal-appearing aorta and iliac vein segment, the axial view on the right reveals an apple-sized tumor (arrow) lifting up the left common iliac artery and displacing the left common iliac vein, with intimate involvement of the spine from the L3 to L5 vertebral bodies.

A course of neoadjuvant chemotherapy with doxorubicin and ifosfamide was initially pursued at the patient's local institution under guidance from Cleveland Clinic oncologists. The tumor showed modest progression after two cycles of treatment, which prompted multidisciplinary exploration of the feasibility of tumor resection.

Spine surgery staff consulted with multidisciplinary colleagues — among others, surgical oncology and vascular surgery, in view of the vascular involvement — to discuss treatment possibilities. Together with the patient, they decided to proceed with short-course preoperative radiation therapy followed by a two-stage surgical plan to first stabilize the patient's posterior spine and then to resect the tumor, reconstruct the venous system and further stabilize the spine from the front.

The first stage (Figure 2) was conducted by a team led by Center for Spine Health neurosurgeon Ajit Krishnaney, MD. Over nine hours, they performed T11-pelvis posterior instrumentation with iliac and S2 alar-iliac screw placement along with the following:

- > Laminectomies from L2 to S1
- > Complete resection of L2-3, L3-4, L4-5 and L5-S1 facets
- > Complete resection of L3-5 pedicles and transverse processes
- > Complete discectomies at L2-3 and L5-S1

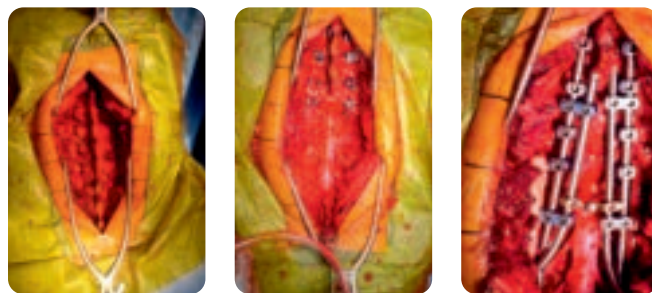


FIGURE 2 — Photos showing progressive steps in the first-stage operation. Left: Initial spine exposure. Middle: The spine after removal of posterior elements and screw placement. Right: Final construct.

Two days later, a multidisciplinary surgical team led by vascular surgeon Sean Lyden, MD, surgical oncologist Daniel Joyce, MBCh, and Dr. Krishnaney resected the tumor (Figure 3) using an anterior approach. In addition to removal of the tumor, the 14-hour operation involved the following:

- > Resection of the inferior vena cava (IVC) and left internal iliac vein, followed by reconstruction of the venous system (Figure 4) with a panel graft of bovine pericardium from the site of the resected IVC to the left iliac vein and then the right iliac vein, with an omental flap used to wrap the repair
- > Completion of discectomies at L2-3 and L5-S1
- > En bloc resection of the L3, L4 and L5 vertebral bodies

“There is not an off-the-shelf graft that could be used to reconstruct the vasculature we had to remove, so we took a sheet of bovine pericardium that’s used to patch arteries and we formed two long tubes to serve as the graft that was needed.” — SEAN LYDEN, MD



FIGURE 3 — Photo of the resected specimen, which included the tumor, the iliac vein and vertebral bodies L3-5.

- › Anterior cage placement and instrumented fusion for further spinal stabilization (Figure 5)

The patient fared well postoperatively. Despite the highly challenging tumor location, the team achieved a margin-negative (microscopic/RO) resection. It was decided to follow a course of active surveillance since the patient had received preoperative chemotherapy and radiation. He maintained his ability to walk safely despite removal of the three vertebral bodies, and there was minimal leg swelling. Imaging at three-month follow-up showed no recurrence of malignancy.

Perspectives on the case

Dr. Lyden, who led the vascular surgery aspects of the operation, says this case is notable for at least three reasons. First is the daunting challenges the resection posed and the multispecialty collaboration required to overcome them. “An extremely limited number of U.S. institutions would have taken on this surgery and been able to pull off the interdisciplinary coordination required by this case,” he says. “This tumor would be deemed unresectable by virtually everyone, with vascular surgeons citing the spine involvement and spine surgeons citing the veins involved.”

Another point of distinction was the sheer size of the tumor in this location. “Resecting this tumor required removing all the bone from a 6-inch segment in the middle of the patient’s body,” Dr. Lyden notes. “The fact that our spine surgery colleagues could create enough spinal stability that the patient is able to walk is simply remarkable.”



FIGURE 4 — Operative photo showing the reconstructed IVC.

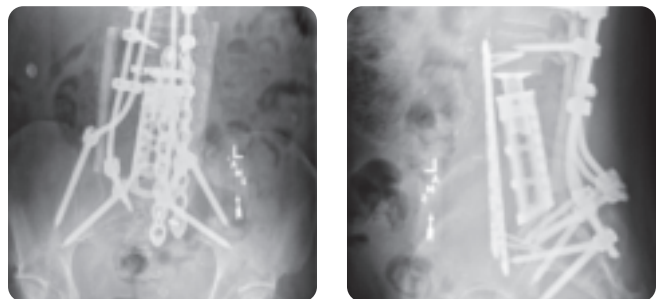


FIGURE 5 — Postoperative standing X-rays showing the final spinal reconstruction.

The case is also notable for the ingenuity it required on the vascular surgery front. “There is not an off-the-shelf graft that could be used to reconstruct the vasculature we had to remove,” Dr. Lyden says, “so we took a sheet of bovine pericardium that’s used to patch arteries and we formed two long tubes to serve as the graft that was needed. When you practice at an institution like Cleveland Clinic where you’re immersed in innovation, fashioning solutions like this comes fairly naturally.”

A slightly longer version of this case study, with additional images and perspectives from Drs. Krishnaney and Joyce, is available at ccf.org/massivesarcomacase.

Contact Dr. Lyden at 216.444.3581.

COMPREHENSIVE STEMI PROTOCOL EQUITABLY IMPROVES KEY CARE PROCESS METRICS

Black and white patients realize similar gains following adoption of new protocol

Implementation of a comprehensive protocol for management of ST-elevation myocardial infarction (STEMI) similarly benefits Black and white patients, suggesting that widespread protocol adoption could help reduce traditional racial disparities in STEMI care delivery. So found a study that compared STEMI care metrics between these two groups before and up to five years after Cleveland Clinic adopted a comprehensive STEMI protocol. The study was published in the *Journal of the American Heart Association*.

“This is the first study to show that a comprehensive STEMI protocol can successfully and equitably improve care for Black and white American patients,” says Umesh Khot, MD, Head of Regional Cardiovascular Medicine at Cleveland Clinic and corresponding author of the study. “Rapid identification of STEMI, development of standardized care protocols and procedural optimization were key components of the protocol, which yielded outcome gains across the board.”

A backdrop of racial disparities in healthcare

It is well recognized that Black Americans with STEMI tend to receive poorer care compared with white Americans, with studies documenting transfer delays, lower rates of revascularization and longer door-to-balloon times. Such differences are believed to contribute to poorer STEMI outcomes among Black patients.

In July 2014, Cleveland Clinic implemented a comprehensive STEMI protocol designed to standardize care to improve process metrics and clinical outcomes among all patients.

Protocol in brief

The comprehensive STEMI protocol includes the following major elements:

- › Standard criteria by which emergency department physicians can activate the catheterization lab

- › Use of a “STEMI safe handoff checklist,” which defines the roles of all involved caregivers
- › Immediate transfer to a catheterization lab
- › Use of a “radial artery first” approach for vascular access in primary percutaneous coronary intervention (PCI) for suitable candidates

Study design and findings

The study retrospectively examined medical records from consecutive patients with STEMI treated with PCI at Cleveland Clinic’s main campus, comparing those treated before the comprehensive STEMI protocol was adopted (Jan. 1, 2011, to July 14, 2014) with those treated after protocol adoption (July 15, 2014, to July 15, 2019). The cohorts’ racial makeup was as follows:

- › Pre-protocol: 208 Black patients and 479 white patients
- › Post-protocol: 271 Black patients and 793 white patients

Patients from other racial groups made up less than 1% of the identified population and were excluded.

Pre- and post-protocol cohorts were similar in age, sex and comorbidities, although fewer patients had a prior myocardial infarction in both post-protocol cohorts, and body mass index among white patients was higher in the post-protocol cohort.

Protocol adoption resulted in the following changes in key metrics among Black patients:

- › Administration of guideline-directed medical therapy prior to PCI increased from 71.6% pre-protocol to 81.9% post-protocol ($P = 0.01$).
- › Use of radial PCI increased from 14.4% to 73.8% ($P < 0.001$).
- › Median door-to-balloon time decreased from 90 to 70 minutes ($P < 0.001$).
- › Median fluoroscopy dose decreased from 1,610 to 1,147 mGy ($P < 0.001$).

“It’s encouraging that a single approach [to STEMI care] has been shown to reduce or eliminate disparities on three fronts — race, socioeconomic status and gender.” — UMESH KHOT, MD

TABLE — Cleveland Clinic STEMI Protocol Promotes Equity Across a Range of Care Disparities

Focus of Analysis	Publication	End Points of Interest	Key Findings
Sex disparities	<i>Eur Heart J Open.</i> 2021;1(3):oeab011	Use of GDMT, D2BT, use of transradial PCI, in-hospital mortality, MACCEs, net adverse clinical events	<ul style="list-style-type: none"> • Pre-protocol, care metrics and outcomes were statistically significantly better in male versus female patients on all measures except use of transradial PCI (which was statistically equivalent). • Post-protocol, differences between sexes were reduced to nonsignificant levels on all measures except use of transradial PCI, which favored males, and net adverse clinical events, which trended toward favoring males, largely due to a significantly higher rate of bleeding in females.
Socio-economic disparities	<i>J Am Heart Assoc.</i> 2021;10(24):e024540	In-hospital mortality, D2BT, use of GDMT, use of transradial PCI	<ul style="list-style-type: none"> • Care metrics and outcomes were analyzed by patients' neighborhood deprivation levels, classified by tertiles (high, moderate or low). • Post-protocol, in-hospital mortality was reduced significantly across the entire cohort, due mostly to reductions in the tertiles with high and moderate neighborhood deprivation. • Post-protocol, D2BT improved significantly in all three tertiles and reached statistical noninferiority between the high and low neighborhood deprivation groups. • Post-protocol, improvements in use of GDMT and transradial PCI were seen in all neighborhood deprivation groups.
Racial disparities	<i>J Am Heart Assoc.</i> 2023;12:e028519	Use of GDMT, use of transradial PCI, D2BT, fluoroscopy dose, contrast dose	<ul style="list-style-type: none"> • Pre-protocol, care metrics were statistically comparable between Black and white patients except D2BT, which significantly favored Black patients. • Post-protocol, all care metrics improved significantly in both racial groups, with no greater or lesser effect for either race.

STEMI = ST-elevation myocardial infarction; GDMT = guideline-directed medical therapy; D2BT = door-to-balloon time; PCI = percutaneous coronary intervention; MACCEs = major adverse cardiac and cerebrovascular events

› Median contrast dose decreased from 180 to 145 mL ($P < 0.001$).

Regression models developed for each key process metric revealed no significant interaction with race. “Race was not found to be a factor in the benefits achieved after adopting the comprehensive STEMI protocol,” observes study co-author Grant Reed, MD, MSc, Quality Improvement Officer in Cleveland Clinic’s Section of Invasive and Interventional Cardiology. “This indicates that gains from the protocol were equitable between Black and white patients.”

A protocol with multiple benefits

Previous analyses of the effects of the adoption of Cleveland Clinic’s comprehensive STEMI protocol found that it also achieved benefits among other traditionally underserved groups. One study, published in *European Heart Journal Open* (see Table), found that gains in key process metrics were made for men and women, eliminating the gender gap in most process and outcome metrics.

Another study, published in the *Journal of the American Heart Association* (see Table), found that adoption of the comprehensive STEMI protocol reduced socioeconomic disparities not only in care

process metrics but in clinical outcomes, most notably in-hospital mortality.

“These diverse studies on a single new approach to STEMI care indicate that standardizing healthcare delivery can benefit everyone, including traditionally underserved populations,” Dr. Khot observes. “Establishing and adopting a comprehensive STEMI protocol like ours should be a major priority of hospital systems, especially those that serve large Black or socioeconomically disadvantaged populations. It’s encouraging that a single approach has been shown to reduce or eliminate disparities on three fronts — race, socioeconomic status and gender.”

“Together, these studies suggest that taking a comprehensive, multifaceted approach to standardizing STEMI care has strong potential to level the playing field with regard to STEMI care disparities,” adds Samir Kapadia, MD, Chair of Cardiovascular Medicine at Cleveland Clinic and a co-author of all three studies. “We believe this protocol can be a model for other organizations aiming to improve the equity of their care delivery.”

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A PROCESS FOR IMPROVING SURGICAL SITE INFECTION PREVENTION BY CARDIAC SURGERY PROGRAMS

How our Advisory Services and Affiliate Program has helped hospitals drive down SSI rates

Preventing hospital-acquired conditions is a priority for healthcare providers, as these conditions cause unexpected harm to patients and are often preventable. Surgical site infections (SSIs) are hospital-acquired conditions that increase morbidity, mortality and hospital readmissions. Therefore, focusing on reducing and eliminating their occurrence is critical for patient safety and outcomes.

SSIs account for 20% of all hospital-acquired infections and are associated with a twofold to elevenfold increase in the risk of mortality, with 75% of SSI-associated deaths directly attributable to the SSI.¹ Furthermore, SSIs prolong hospital length of stay and have an adverse effect on patient-reported outcomes. Patients must be able to trust that hospitals will keep them safe while treating their medical conditions.

Prevention of SSIs — particularly deep sternal wound infections (DSWIs) — is one focus of the in-depth assessments offered to cardiovascular programs across the U.S. by the Advisory Services and Affiliate Program (ASAP) of Cleveland Clinic's Heart, Vascular & Thoracic Institute. The ASAP team's mission is to assist cardiovascular programs in improving their quality and operations in various areas. The team consists of physicians, nurses, a sonographer, quality and registry professionals, and continuous improvement and administrative experts who all have extensive experience in quality improvement, optimizing patient safety and continuous improvement.

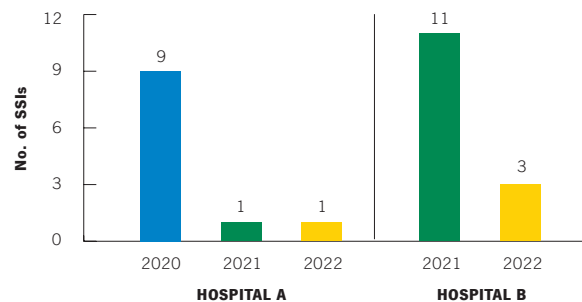
Over the years, the Cleveland Clinic ASAP team has provided several hospitals with a comprehensive review and analysis of their SSI prevention efforts and detailed recommendations for reducing DSWIs and other SSIs. These assessments have been highly successful, as shown in the Figure. This article outlines the importance of SSI prevention in cardiac surgery and how the ASAP team helps hospitals achieve it.

DSWIs: Uncommon but impactful

A DSWI is a devastating complication of cardiac surgery for patients as well as a challenging complication to treat. Additionally, hospitals are not reimbursed by the Centers for Medicare & Medicaid Services for costs associated with sternal wound infections, so these infections can have a negative financial impact.

The Society of Thoracic Surgeons defines a DSWI as an infection that meets the following criteria within 30 days after surgery:

FIGURE — Surgical site infections (SSIs) in cardiac surgery programs at two hospitals. Assessments by the Cleveland Clinic ASAP team corresponded with reductions in SSI rates at both hospitals. For both hospital A and hospital B, assessments began with a site visit in the first year shown in the graph, which was followed by a marked decline in SSIs in the subsequent year(s).



- > Wound opened with excision of tissue (I&D) or reexploration of mediastinum
- > Positive culture unless the patient was on antibiotics at the time of culture or no culture was obtained
- > Treatment with antibiotics beyond perioperative prophylaxis

Overall, SSIs are the No. 1 hospital-acquired infection and cost the U.S. healthcare system an estimated \$3.5 to \$10 billion annually,² with SSIs contributing the most (33.7%) to the overall costs of healthcare-associated infections.³ They also extend hospital length of stay by 9.7 days.¹ SSIs are the leading cause of hospital readmissions following surgery, and approximately 3% of patients who develop an SSI will die as a consequence.⁴ These various impacts have resulted in SSI reduction being identified as a top national priority in the U.S. Department of Health and Human Services' *National Action Plan to Prevent Health Care-Associated Infections*.⁵

Overview of the assessment process

In cardiac surgery, the most prevalent reported SSIs involve the sternum and incision sites for harvesting saphenous veins and radial arteries.

Prevention of SSIs starts before surgery even begins. The ASAP team has found that when surgical programs develop standards of care, there may be gaps in knowledge related to perioperative management, insufficient protocols to promote infection prevention and lack of process validation for patient safety strategies. It is essential to ensure that all perioperative team members are properly educated in SSI prevention and that care delivery is informed by proactive attention to prevent SSIs.

Assessment by the ASAP team involves a site visit and includes:

- › Review of risk factors for incisional infection prevention
- › Evaluation of preoperative processes for surgical preparation
- › Examination of intraoperative surgical techniques and strategies
- › Examination of postoperative prevention practices

Project focus and end results

The ASAP team has supported SSI assessments at several hospitals and identified modifiable opportunities at each. The team's consultants interview key stakeholders to gain perspective into current practices and challenges throughout the perioperative period. The project involves data analysis, a detailed assessment, real-time observations and evaluation of the cardiac surgical practice. The assessment is specifically focused on deep and superficial sternal wound infection prevention strategies, and it includes a comprehensive review of current clinical practice guidelines and protocols of the hospital's cardiovascular surgical program.

The team identifies and evaluates factors that contribute to DSWI. It also assesses adherence to evidence-based practice and registry recommendations. Patient profiles, cardiac procedure type and specific factors in the pre-, intra- and postoperative phases of care are included in the analysis, which also looks at modifiable and nonmodifiable risk factors. Workflows and processes are evaluated and benchmarked to the hospital policy.

Once an assessment is completed, the ASAP team provides a comprehensive report of findings and recommendations that identifies opportunities and suggests modifications to current practices. Assessment findings have highlighted perioperative risk factors and protocol deficiencies that increase patients' risk for infection. After identifying these factors, the ASAP team works closely with the perioperative teams to implement safeguards for infection prevention. The team's report also gives guidance to help hospitals sustain their newly implemented processes and promote ongoing improvement.

"SSIs, and specifically DSWIs, are dreaded complications of cardiac surgery," says Edward Soltesz, MD, MPH, Cleveland Clinic's Director

Testimonials from Affiliate Hospitals

"The site assessment you led was instrumental in identifying and helping to eliminate potential sources of infection in our cardiac OR and perioperative suites. Major changes to our processes and physical plant ensued. We also introduced a more proactive way of trying to reduce infection. Instead of asking for review when we have had an increase in infection, we have established a periodic review of the rooms and process by our infection control staff, allowing them to make observations and recommendations on a more continuous and preventive basis."

— Director of cardiothoracic surgery at a midsize
Midwestern affiliate hospital

"The insight from an experienced team such as Cleveland Clinic's was instrumental in reducing our wound complication rate."

— Cardiac surgeon at a midsize Midwestern affiliate hospital

of Cardiac Surgery Affiliate and Alliance Programs. "While there is a trove of guidelines and best practices for preventing SSIs in cardiac surgery, individual surgical programs often struggle with adopting and operationalizing generalized recommendations. The ASAP team is unique in its personalized approach to each program, focusing on the individual program's needs and unique circumstances. Rather than offering a generic set of recommendations, the ASAP team leverages its extensive experience to provide a site-specific set of recommendations and actionable steps for infection mitigation."

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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 Lesesky at leseska@ccf.org.

CME PREVIEW

EARLY AUTUMN BRINGS TWO UNIQUE CME OFFERINGS TO CLEVELAND

Can't-miss courses on aortic disease and advancing equitable cardiovascular care for all

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

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

InterContinental Cleveland

Information/registration: ccfcme.org/aorticdisease

This is the latest offering of a long-standing and popular CME course from Cleveland Clinic that takes its name quite seriously.

First, it is highly comprehensive, addressing every aspect of aortic disease care, from the role of genetics in cases related to connective tissue disorders through management in the chronic phase of disease. Along the way, the large interdisciplinary faculty covers emergency management of suspected aortic dissection, creation of a cardio-aortic triage unit, imaging options to confirm the diagnosis, mobilizing an on-demand OR team, the multiple stages of treating both acute ascending and acute distal dissections, and chronic care of dissection survivors. Each management stage is covered through various subtopics addressing nuanced caregiving challenges.

Second, it emphasizes lifelong care, with abundant presentations devoted to advising patients and their families before a dissection occurs and helping them thrive following dissection. Examples of the former include an overview of how clinical genetic care and family screening is done in Cleveland Clinic's Aorta Clinic and guidance on how to slow progression in the genetically vulnerable patient. Examples of the latter include talks on lifelong imaging follow-up, advising patients about strenuous activity and determining the best antihypertensive regimen in the chronic phase.

Third, the course dives deeply into expeditious management of acute dissection, with extensive multidisciplinary discussions of decision-making around surgical, endovascular and hybrid treatment. Distinct sessions are devoted to stages in treatment of both ascending and distal dissection, and several point/counterpoint sessions explore treatment controversies.

The entire curriculum highlights the importance of multidisciplinary teams, with staff from Cleveland Clinic's Aorta Center joined on the faculty by members of several other leading North American aorta centers. Case-based care is another emphasis, with a case study launching the panel discussion at the end of most sessions.

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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, Cleveland

Information/registration: ccfcme.org/cvdisparity23

This two-day CME course — presented by Cleveland Clinic in conjunction with the Association of Black Cardiologists Inc. (ABC) — is ambitious in design. Not only will it provide participants with a review of cardiology fundamentals and recent changes in the diagnosis and treatment of common cardiovascular (CV) conditions, but it will do so through the lens of addressing disparities in CV disease management in order to promote the highest quality of care across all patient communities.

More than two dozen expert faculty from Cleveland Clinic and ABC will survey the latest and most useful knowledge in preventive cardiology and health promotion, structural heart disease, heart failure and heart rhythm disorders. Additional sessions explore CV disease in special populations and targeted strategies for meeting the CV health needs of underserved communities. Content will be delivered in topical sessions that each comprise several 15- or 20-minute talks and culminate in a panel discussion and Q&A.

Discussions throughout will be attuned to prevention and management across various populations, addressing social determinants of health outcomes, race-specific CV disease and the impact of socioeconomic factors, as well as care disparities related to race, ethnicity and sex. Additional special populations — such as pregnant patients, athletes and the very old — will be covered as well.

The final session on Friday will focus on identifying and meeting the CV needs of underserved communities, including discussion of strategies to increase diversity in the CV workplace and to advance healthcare equity. It will conclude with a community leader roundtable forum.

Despite the “primary care” in the course title, general cardiologists were central to curriculum planning for this course and will glean much from the many cardiology subspecialists on the faculty along with experts in cardiac and vascular surgery, endocrinology, nephrology and geriatrics.

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



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SAVE THE DATES FOR CME

State-of-the-Art Topics in Cardiology

Fri.-Sun., Aug. 4-6, 2023
InterContinental Cleveland

Information/registration: ccfcme.org/cardiologysummit

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

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

Information/registration: ccfcme.org/aorticdisease

Global EP Summit 2023

Fri.-Sat., Sept. 29-30, 2023
Hilton Cleveland Downtown, Cleveland

Information/registration: ccfcme.org/global23

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, Cleveland

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/cardiocardiovascularAI23

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

Information/registration: ccfcme.org/aorticvalve

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