

CardiacConsult

Heart, Vascular and Thoracic News from Cleveland Clinic | 2020 | Issue 2

> CARDIAC CONSULT FEATURE

A Close-Up Look at Surgical Outcomes — p. 5



Dear Colleagues,

As this issue of *Cardiac Consult* goes to press, the COVID-19 pandemic continues to evolve. Thus far, Cleveland Clinic has found itself well prepared for the challenges the pandemic has brought to the communities we serve. Over many weeks we prepared for a potential large surge of COVID-19 patients by postponing nonessential procedures, cross-training our caregivers in the use of ventilators and post-intubation management, and creating a temporary surge hospital on our main campus, among other measures. While we continue to care for patients with COVID-19, our communities have contained the virus enough to allow us to resume safely offering surgery and other procedures to patients beyond those needing immediate intervention.

In the meantime, we have vastly expanded our use of virtual visits and other forms of telemedicine to continue caring for patients in whatever setting is best suited to their needs and concerns. And we have collaborated with colleagues around the nation and the world on research to better understand how the SARS-CoV-2 virus impacts the cardiovascular system and how to ensure the best outcomes for patients with COVID-19. One example of such research is featured as the first story in this issue.

We are excited to be getting back to what we do best: taking full and proper care of our fellow citizens with cardiovascular and thoracic disease. While there may be bumps along the way to our country's full return to its healthcare capacity, our profession's resiliency in the past few months suggests we have a bright future ahead.

Respectfully,

Lars G. Svensson, MD, PhD

CHAIRMAN | Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute



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

Medical Editor

Lars G. Svensson, MD, PhD
Institute Chair
svenssl@ccf.org

Managing Editor

Glenn R. Campbell

Art Director

Michael Viars

Marketing

Jackie Riggie | Colleen Burke | Suzanne Anthony

Photography & Illustrations

Cleveland Clinic Center for Medical Art & Photography
Russell Lee Photography



Cleveland Clinic was named a top U.S. hospital in *U.S. News & World Report's* "Best Hospitals" rankings for 2019-20, as well as the No. 1 hospital in cardiology and heart surgery for the 25th consecutive year.

© 2020 The Cleveland Clinic Foundation

Stay Connected



consultqd.clevelandclinic.org/cardiovascular



clevelandclinic.org/cardiaccsult



@CleClinicMD



clevelandclinic.org/heartlinkedin



clevelandclinic.org/cardiaccsultpodcast

24/7 Referrals

855.REFER.123 | clevelandclinic.org/heartreferrals

Outcomes Online

clevelandclinic.org/hvtioutcomes

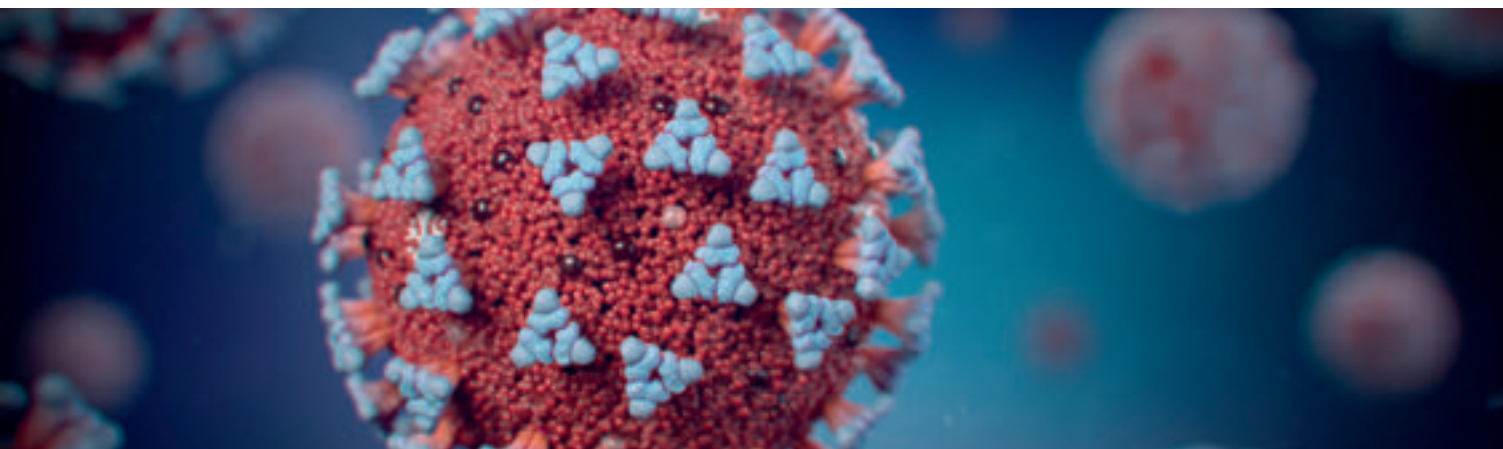
Clinical Trials

clevelandclinic.org/clinicaltrials



Cleveland Clinic Registry Study Finds No Link Between ACEI/ARB Use and COVID-19 Risk

Findings offer some reassurance amid an evolving evidence base.



A retrospective cohort study from Cleveland Clinic has found no association between use of angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin II receptor blockers (ARBs) and testing positive for COVID-19. A secondary analysis among COVID-19-positive patients showed no association between use of these medications and risk for mechanical ventilation.

The findings, reported in *JAMA Cardiology* on May 5, “add to rapidly evolving evidence related to the role of ACEIs and ARBs in the setting of COVID-19 and support current guidance from professional societies to not discontinue these medications during the pandemic,” says senior author Mina Chung, MD, of Cleveland Clinic’s Department of Cardiovascular Medicine.

Backdrop to the study

The study was spurred by controversy over whether ACEIs and ARBs are helpful or harmful in the context of COVID-19. The controversy arose from the fact that COVID-19’s causative virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), binds to the ACE2 receptor to gain entry into host cells. Some animal models have shown that ACEIs and ARBs upregulate ACE2 expression, prompting speculation that this could increase risk of SARS-CoV-2 infection and worsen COVID-19 outcomes. Others have postulated that upregulation of ACE2 could improve outcomes in the setting of lung injury induced by SARS-CoV-2 infection.

In the absence of clinical data or randomized trials demonstrating either benefit or harm with background use of ACEIs or ARBs in COVID-19 patients, the American Heart Association, American College of Cardiology and Heart Failure Society of America recommended in March that ACEI and ARB therapy be continued in patients currently taking these

drugs for proven indications, including heart failure, hypertension and ischemic heart disease. At the same time, the professional societies called for “much more detailed research” on this question.

Study design

In keeping with that call, Cleveland Clinic undertook a retrospective analysis of a prospective registry of all patients tested for COVID-19 at its locations in Ohio and Florida from March 8 to April 12, 2020. The exposures of interest were ACEI or ARB use as shown in the electronic medical record at the time of COVID-19 testing (done by naso-/oropharyngeal swab).

The primary outcome was a positive COVID-19 test. A secondary analysis was conducted to ascertain clinical outcomes among COVID-19-positive patients in terms of hospital admission, ICU admission and use of mechanical ventilation. Because comorbidities are more likely among patients prescribed ACEIs or ARBs, propensity-score weighting was performed to adjust for potential confounding.

Results

Overall cohort. The analysis comprised 18,472 individuals tested for COVID-19, with a mean age of 49 ± 21 years. Subjects were predominantly female (60%) and white (69%).

Continued next page >



Testing for COVID-19 was positive in 1,735 patients, or 9.4% of the total sample. Among test-positive patients, 421 (24.3%) were hospitalized, 161 (9.3%) were admitted to an ICU and 111 (6.4%) were placed on a ventilator.

Patients on ACEIs or ARBs. Among the overall cohort of tested subjects, 2,285 individuals (12.4%) were on an ACEI (n = 1,322) and/or an ARB (n = 982). Among the 1,735 patients positive for COVID-19, 116 (6.7%) were taking an ACEI and 98 (5.6%) were taking an ARB.

Patients taking an ACEI or an ARB were significantly more likely than the rest of the cohort to have each of the following comorbidities: obesity, diabetes mellitus, coronary artery disease, hypertension, chronic obstructive pulmonary disease and heart failure.

Comparative test results and outcomes. Overlap propensity-score weighting showed no significant association of ACEI and/or ARB use with test positivity. Specifically, the weighted test positivity rate was 8.6% in patients taking an ACEI versus 9.5% in those not on an ACEI and 10.0% in patients taking an ARB versus 9.3% in those not on an ARB.

Similarly, overlap propensity-score weighting among test-positive patients showed no significant association between ACEI or ARB use and ventilator requirement — a finding observed in both pooled and separate analyses for ACEIs and ARBs. Although ICU admission among patients on an ACEI was significantly more likely than in patients not on an ACEI (24% vs. 15%; odds ratio = 1.77; 95% CI, 1.07-2.92), the investigators note that findings from secondary analyses are largely exploratory at this time.

Reassurance, but not the final word

“This analysis found no association between ACEI or ARB use and COVID-19 test positivity,” says Cleveland Clinic cardiologist Ankur Kalra, MD, the study’s corresponding author. “These medications are important tools in the management of coronary artery disease, heart failure, diabetes and hypertension. As there may be a risk to withdrawing these agents, our findings support current professional society guidelines to not discontinue ACEI or ARB therapy in the context of the COVID-19 pandemic.”

The authors note, however, that further study is needed to yield more definitive answers, particularly on the question of whether and how ACEI or ARB therapy may impact COVID-19 severity.

“Our findings with regard to clinical outcomes and measures of COVID-19 severity while on ACEI or ARB therapy give some reassurance,” notes Dr. Chung, “but they must be interpreted with caution, due to the small sample size and the limits of observational studies. They require replication and reanalysis in larger patient samples later in the course of the pandemic.” ■

Contact Dr. Chung at 216.444.2290 and Dr. Kalra at 330.344.7400.

Research Responses to COVID-19

Cleveland Clinic COVID-19 Research Registry — In mid-March, Cleveland Clinic launched the COVID-19 Research Registry to expedite COVID-19-related clinical research across its health system. Drawing on data from all patients who undergo COVID-19 testing, the prospective registry is using predictive analytics to address three broad questions: (1) Who tests positive? (2) Why do some patients become sicker from COVID-19? (3) Which available treatment options are effective against COVID-19?

Data collection is enabled in Cleveland Clinic’s EMR system, and outcomes to be assessed include mortality, hospitalization, ICU stay, need for ECMO and need for mechanical ventilation. In addition to fueling data research to aid individualized risk prediction, the registry is supporting clinical trials and collection and analysis of specimens for Cleveland Clinic’s enterprise-wide biorepository.

The registry includes workstreams to coordinate ideas and efforts within and across therapeutic areas. Proposals submitted to its Cardiovascular Research Workstream involved topics ranging from the use of echocardiography to predict outcomes to questions around the role of cardiovascular medications that act on the ACE2 receptor.

Cleveland Clinic is involved in numerous national studies of proposed treatments for COVID-19. Among notable efforts coming out of its Heart, Vascular & Thoracic Institute is an investigator-initiated study of the IL-1 antagonist canakinumab for acute myocardial injury in patients hospitalized for COVID-19 with elevated troponin, C-reactive protein and brain natriuretic peptide.

COVID-19 coordinating center for national research initiative — In early May, the American Heart Association (AHA) awarded funding to Cleveland Clinic to serve as the coordinating center for the AHA’s new rapid response research initiative on COVID-19’s effects on the body’s cardiovascular and cerebrovascular systems. A Cleveland Clinic team led by Mina Chung, MD, will collect results from the initiative’s various fast-tracked research projects and coordinate dissemination of all study findings.



A CLOSE-UP

LOOK AT SURGICAL OUTCOMES:

› What Steady Improvements Across a Range of Procedures Add Up to Over Time

Expanded public reporting of procedural outcomes has been one of the most positive developments in the cardiovascular and thoracic specialties over the past decade. Public reporting focuses care teams on outcomes that ultimately matter most to patients and their families — whether and how long they survive, and how well their quality of life is maintained or improved.

Yet as helpful as public reporting may be in continually driving care quality, providers must take care not to let it turn outcomes analysis into a purely abstract exercise. Numbers and percentages alone may dictate Society of Thoracic Surgeons (STS) star ratings, but they do not properly capture what the underlying procedures mean to individual patients.

Continued next page >



Translating outcomes to lives saved

To keep focused on the impact of overall surgical outcomes at this patient level, staff in Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute did an extra round of number crunching early this year when looking back at their adult cardiac surgery and thoracic surgery volumes and outcomes in 2019 and the preceding years.

As illustrated in the graph below, Cleveland Clinic's in-hospital mortality rates for these major surgical categories have shown a cumulative and largely steady decline over the past 13 years. For adult cardiac surgery, mortality has been slashed by two-thirds, from 3.3% in 2007 to 1.1% in 2019. Thoracic surgery mortality dropped even further over the same period, from 4.4% to 1.2%.

These improvements in mortality were achieved even as surgical volumes steadily increased in the case of adult cardiac surgery and even as case complexity increased for both thoracic and adult cardiac procedures. In fact, 60% of adult cardiac surgery patients in 2019 required operations more complex than those classified by STS.

The additional number crunching mentioned above focused on how these continuing improvements in mortality translated in terms of actual patient lives saved, and calculations showed that the changes in mortality saved approximately 1,500 lives in the 10 years from 2010 through 2019 alone.

"This is a humbling number to consider, and it helps affirm for all caregivers why we chose the calling we did," says Lars Svensson, MD, PhD, Chair of the Heart, Vascular & Thoracic Institute. "Over time, we have also reduced rates of wound

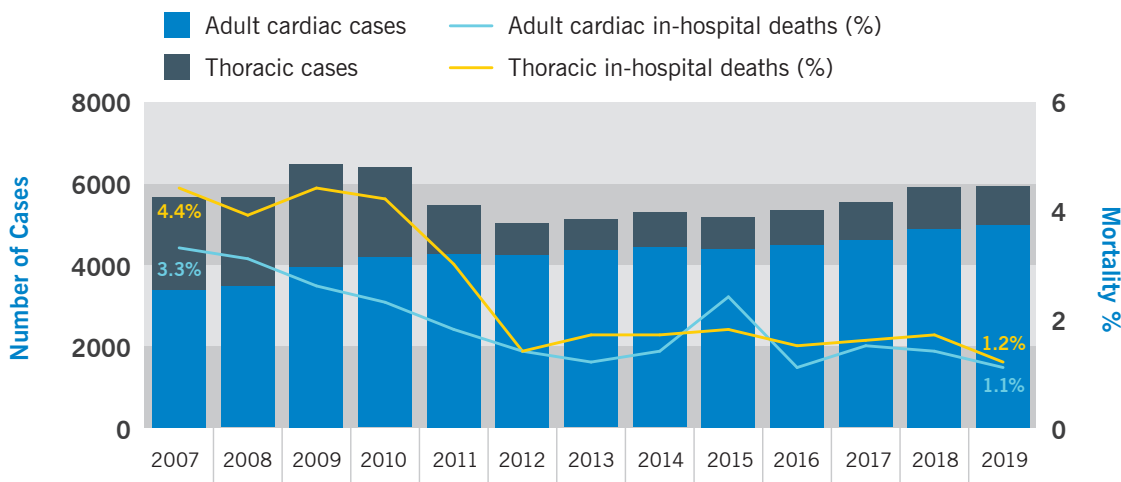
infection, renal failure, GI complications and, for some procedures, stroke. These improvements translate to better quality of life — in addition to longer life — for countless patients."

Most operations are more complex than the mainstays

A sizable share of the operations included in these data are the mainstays of adult cardiac surgery and thoracic surgery for which the STS evaluates hospitals and health systems with its star rating system. In the latest reporting periods for the STS Adult Cardiac Surgery Database and General Thoracic Surgery Database, Cleveland Clinic received the highest (three-star) composite quality rating in all categories assessed, as detailed in the table below.

Adult Cardiac Surgery Categories	STS Rating
Coronary artery bypass grafting (CABG)	★ ★ ★
Aortic valve replacement (AVR)	★ ★ ★
AVR+CABG	★ ★ ★
Mitral valve repair/replacement (MVRR)	★ ★ ★
MVRR+CABG	★ ★ ★
General Thoracic Surgery Categories	
Lobectomy for lung cancer	★ ★ ★
Esophagectomy	★ ★ ★
For the three-year periods ending Dec. 31, 2018.	

Surgical Mortality Declines Even as Volume and Case Complexity Increase



Case complexity increased over this period, with 60% of adult cardiac surgery patients in 2019 requiring operations more complex than those classified by the Society of Thoracic Surgeons.



At the same time, these mainstay operations represent less than half of the overall adult cardiac surgery and thoracic surgery procedures performed at Cleveland Clinic. As a result, most of the surgeries included in the mortality graph on the opposite page are procedures for which the STS doesn't report risk-adjusted benchmark rates, often because of relative rarity or substantial complexity.

For example, 1,129 of the adult cardiac surgeries performed at Cleveland Clinic in 2019 — over 21% of the total — were reoperations. Other operations in the cardiothoracic surgical mix are uncommon procedures not offered widely elsewhere and requiring volume-based expertise. The rest of this article profiles a small sampling of such operations — and the difference that Cleveland Clinic's expertise can make for individual patients needing these procedures.

Aortic Root Replacement With Valve Reimplantation

While efforts to repair the aortic valve date back several decades, the breakthrough in valve-sparing aortic root aneurysm repair came in the early 1990s with cases first reported by Tirone David, MD, who completed his general surgery residency at Cleveland Clinic.

The so-called David reimplantation procedure involves mobilizing the aortic valve, inserting it within a polyester tube graft, attaching coronary buttons, and then replacing the aneurysmal root and ascending aorta. The operation demonstrated good durability, but a number of complications — including fistulas, mitral valve tears and aortic valve leakage over time — prompted efforts to further refine the technique.

Among those leading these efforts was Cleveland Clinic's Lars Svensson, MD, PhD, who visited Dr. David later in the 1990s to learn the procedure. Dr. Svensson soon began to develop several modifications to the David operation, including the following:

- Use of pledgeted sutures to reduce the risk of sutures pulling through the tissue in patients with fragile tissue, which results in fistulas and leaks.
- Reduction of annulus size through customized choice of a Hegar's dilator to better match the patient's anatomy based on body surface area. The aim was to achieve more durable repair.
- Introduction of figure-of-8 suspension sutures in cases where the valve leaflets require repair to prevent prolapse.

These modifications were described by Dr. Svensson in a 2003 paper (*Ann Thorac Surg.* 2003;76:1751-1753), and the modified operation has been called the Svensson or LGS reimplantation procedure. It had been performed in over 990 Cleveland Clinic patients through the end of 2019, giving Cleveland Clinic the world's largest experience in aortic root replacement with valve reimplantation.

"About 90% of those cases have been elective operations, and the mortality rate in these elective cases is 0.14%," Dr. Svensson notes. "Mortality in emergency and urgent cases has been low as well, at 3.0%."

Despite the growth of valve-sparing aortic root replacement at Cleveland Clinic, where it is done by a number of staff cardiothoracic surgeons, the operation remains a relative rarity in much of the rest of the U.S., with only two other centers performing the procedure on a regular basis.

Dr. Svensson says that while late outcomes of valve-sparing aortic root replacement have not been thoroughly examined, recent analysis of such outcomes among Cleveland Clinic patients suggests that earlier intervention promises equal or better outcomes compared with watchful waiting. These data have been submitted for publication, he notes.

An Aggressive Take on Pericardiectomy

Pericardiectomy has long been viewed as a high-risk operation for which a limited anterior "phrenic to phrenic" off-pump approach has been advocated. Surgeons at Cleveland Clinic have developed a systematic approach focusing on radical resection and routine use of cardiopulmonary bypass in this procedure for patients with constrictive or chronic recurrent pericarditis.

"Anterior resection from phrenic nerve to phrenic nerve via a thoracotomy approach achieves symptom improvement, but some patients still have progressive constriction of the remaining pericardium that requires redo pericardiectomy," says Cleveland Clinic cardiothoracic surgeon Douglas Johnston, MD. "Recent evidence demonstrates superior survival and functional outcome with a complete pericardiectomy."

As a result, since 2008 Cleveland Clinic surgeons have switched to an approach performed via median sternotomy with routine use of cardiopulmonary bypass to achieve radical resection of the pericardium and "pedicalization" of both phrenic nerves. "Pedicalization involves completely removing the pericardium from the phrenic nerve, leaving a small amount of fat," explains Cleveland Clinic cardiothoracic surgeon Shinya Unai, MD.

Continued next page >



In a recent review of radical pericardiectomy for pericardial diseases (*Curr Cardiol Rep.* 2019 Feb 12;21:6), Drs. Johnston and Unai reported Cleveland Clinic's experience with pericardiectomy in 601 patients from 1977 to 2013. Overall in-hospital mortality was 6%, with mortality for patients with idiopathic pericarditis as low as 1.2% in operations performed since 2000.

"Even with aggressive resection and the use of cardiopulmonary bypass, the rate of reoperation for bleeding was only 3.8%," notes Dr. Unai. "And advances in postoperative management kept requirements for intra-aortic balloon pump and extracorporeal membrane oxygenation at 2.6% and 1.7%, respectively."

"Short-term outcomes of pericardiectomy have improved substantially at experienced centers that select patients carefully," says Dr. Johnston. "We favor aggressive removal of the entire pericardium, particularly for patients with relapsing pericarditis, as it doesn't increase operative risk. We recently presented our data showing long-term survival is improved with this approach as opposed to performing a partial resection." (Barrios et al., American Association for Thoracic Surgery annual meeting 2019, abstract 202)

Rise of Robotics for Thoracic Procedures

Cleveland Clinic thoracic surgeons were among the earliest adopters of robotic technology for general thoracic surgery. Today they use video-assisted thoracic surgery (VATS) or robotic assistance for the following procedures, among others:

- Most lobectomies for lung cancer (over 90% of cases of stage I disease), including for complex segmentectomies and bronchial and vascular sleeve resections
- Treatment of complex esophageal, thymus and chest wall tumors
- Procedures for benign esophageal diseases, including achalasia, reflux, paraesophageal hernias and giant gastric hernias

"Taking advantage of this technology is critical to our goal of treating disease with as little collateral injury as possible," says Sudish Murthy, MD, PhD, Section Head of General Thoracic Surgery. "Patients can reap the benefits of outcomes equivalent to those with open surgery but with less treatment-associated morbidity."

Snapshot of Vascular Surgery Outcomes

While coordinated national public reporting efforts are handled differently for vascular surgery than for cardiothoracic surgery, Cleveland Clinic's Department of Vascular Surgery is building and enhancing its ongoing outcomes analysis and reporting efforts. What follow here are longitudinal data from one key procedural area within that department: open surgery for infrarenal repair of nonruptured abdominal aortic aneurysms (AAAs).

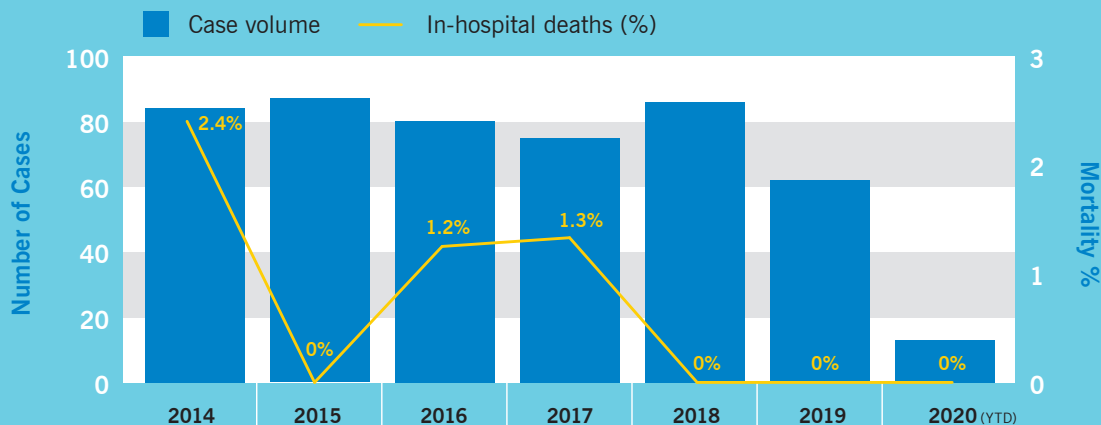
438

Total open infrarenal procedures for nonruptured AAA, January 2014-April 2020

0.8%

In-hospital mortality (n = 4) for those 438 cases, vs. a Vascular Quality Initiative benchmark of 10% for 2019

Open Surgery for Nonruptured AAA, 2014-2020 (through April 8)





Very small incisions are needed for robotically assisted surgeries, he notes, and deep tissues can gently be pushed out of the way with the robotic arms instead of cut, causing less internal damage. This results in less blood loss and reduced postoperative pain. Scarring is also minimized, which is an important advantage if an additional surgery is needed.

“We believe our judicious use of minimally invasive VATS and robotically assisted techniques is an important contributing factor to our consistent three-star composite quality ratings from STS for lung cancer and esophagectomy,” says Dr. Murthy.

Moreover, patient recovery times are shorter with robotic and VATS procedures, with fewer days spent in the hospital. This is borne out by Cleveland Clinic’s steadily declining median length of stay (LOS) for lobectomy patients, which was reduced to 3 days in 2018. Robotic and VATS procedures have driven the decline, as they were associated with median LOS values 1 to 2 days shorter than their open-procedure counterparts in 2018 across various types of lobectomies.

“We are increasing our use of minimally invasive techniques for more complex operations while simultaneously instituting perioperative protocols designed to hasten recovery,” notes thoracic surgeon Usman Ahmad, MD. “We are finding that such initiatives allow our patients to resume their normal activities more quickly without compromising safety.” ■

A Few Other Procedural Stats of Note

696

Number of TAVR procedures performed in 2019

0%

In-hospital mortality for those 696 TAVRs

158

Number of heart transplants/LVAD implantations performed in 2019

94.6%

1-year patient survival for heart transplant recipients, vs. 91.3% national benchmark

87.0%

3-year patient survival for heart transplant recipients, vs. 84.7% national benchmark

(Source: Scientific Registry of Transplant Recipients program report of 1/7/20)

91.5%

12-month post-implant survival among continuous-flow LVAD recipients for destination therapy, vs. 87.0% STS Intermacs survival

(Source: STS Intermacs report for 1/1/19-12/31/19)

192

Number of septal myectomies performed in 2019

0.5%

In-hospital mortality for those 192 myectomies

2,333

Number of consecutive isolated mitral valve repairs without a mortality (through the end of 2019, and dating back to 2014)

TAVR = transcatheter aortic valve replacement; LVAD = left ventricular assist device



Beta-Blockers' Efficacy May Be Partly Explained by Newly Discovered Gut Microbial Metabolite

A Cleveland Clinic-led investigation published in *Cell* (2020;180:862-877.e22) has identified a new gut microbial metabolite that acts via adrenergic receptors and is linked with cardiovascular disease and major adverse cardiovascular events, including myocardial infarction, stroke and death.

The findings suggest that some of the benefits of beta-blockers may be related to prevention of activity linked to the newly identified metabolite, known as phenylacetylglutamine (PAG).

New metabolite drives cardiovascular disease

The researchers, led by Stanley Hazen, MD, PhD, found that when the amino acid phenylalanine — found in animal- and plant-based foods such as meat, beans and soy — is broken down by microbes in the gut, PAG is one of the plasma by-products that ultimately result.

This finding came from a research approach known as untargeted metabolomics performed on plasma from an initial discovery-based study in a cohort of 1,162 patients undergoing elective diagnostic cardiac evaluation. Candidate molecules whose levels predicted future development of cardiovascular events were identified. Then, after structural identification and after a more-specific assay was established, the relationship between PAG and incident cardiac risks was confirmed in an independent validation cohort of 4,000 stable patients. The researchers also found that PAG levels in blood were elevated among subjects with type 2 diabetes.

"These findings are consistent with animal model and microbe transplantation studies that suggest this gut microbe-derived metabolite may play an important role in driving cardiovascular disease," says Dr. Hazen, Chair of Cardiovascular and Metabolic Sciences at Cleveland Clinic and Co-Section Head of Preventive Cardiology and Rehabilitation.

Twofold contribution to elevated risk

The research showed that PAG contributes to cardiovascular risk in at least two ways. After analyzing whole blood cells, platelet-rich plasma and isolated platelets from patient samples to understand how PAG affects cell processes, the researchers used mouse models of arterial injury to explore how these cellular changes manifest. They found that PAG enhanced platelet reactivity and thrombosis potential. They also discovered that PAG interacts with G-protein coupled receptors (GPCRs), including three adrenergic receptors present on platelets: alpha-2A, alpha-2B and beta-2. Using genetic and



pharmacological studies, the researchers then showed that PAG exposure to GPCRs on platelets in general — and these three adrenergic receptors specifically — leads to a cascade of cellular events that contribute to disease.

"Our discovery of PAG is particularly interesting because it binds to the same receptors as beta-blockers, which are associated with reduced risk for cardiovascular mortality and the treatment of various cardiovascular diseases," explains Dr. Hazen.

Administering beta-blockers in a mouse model of elevated PAG was shown to reverse adverse cardiovascular events driven by PAG; additional genetic studies showed that adrenergic receptors were critical to promoting adverse cardiovascular phenotypes caused by elevation of PAG. The team also found that using gene editing technology on gut microbes could alter PAG generation and significantly reduced thrombotic activity in animal models.

"Our findings suggest that some of the benefits of beta-blockers may be attributed to preventing the activity of the gut microbe-generated metabolite PAG," notes Dr. Hazen. "Despite the extensive use and study of beta-blockers, this is the first time, to our knowledge, that this mechanism has been suggested as an explanation for some of their benefits. PAG appears to serve as an allosteric modulator of adrenergic receptors." ■



In CABG with Bilateral ITAs, Tailor Target Vessel Choice to Myocardial Mass

Survival following coronary artery bypass graft surgery (CABG) using bilateral internal thoracic artery (ITA) grafts is substantially influenced by the proportion of total myocardial mass perfused by the targeted vessels, finds a Cleveland Clinic study in the *Journal of the American College of Cardiology* (2020;75:258-268).

“Our findings support a bilateral ITA approach that maximizes the myocardium supplied by the ITAs and steers clear of less-important targets,” says Cleveland Clinic cardiothoracic surgeon Faisal Bakaeen, MD, lead author of the large retrospective analysis.

Distinguishing ‘important’ and ‘less important’ targets

Whereas a survival benefit is well established for use of an ITA versus a saphenous vein bypass to the left anterior descending coronary artery (LAD), strong evidence is lacking for use of a second ITA graft rather than a vein graft for non-LAD targets.

So Dr. Bakaeen and colleagues reviewed 6,127 patients who underwent bilateral ITA grafting at Cleveland Clinic from 1972 to January 2011. Of this group, 2,551 received one ITA graft to the LAD and had an assessable preoperative coronary angiogram.

Among these patients, the researchers set out to determine the survival effect of grafting to a dominant LAD — i.e., one wrapped around the left ventricular apex — as well as to non-LAD target vessels. They scrutinized the angiograms to categorize non-LAD targets on the basis of their terminal reach toward the apex, with targets having > 75% reach graded as important (n = 1,698) and targets with ≤ 75% reach graded as less important (n = 853).

Mean follow-up was 14 ± 8.7 years, and multivariate analysis was used to pinpoint risk factors for mortality over time.

Key findings

Analysis showed that patients in whom less-important additional target vessels were used were more likely to have a dominant LAD than were patients with important target vessels (51% vs. 35%; $P < 0.0001$). Overall, 179 patients (7.0%) had a second ITA grafted to multiple targets, and 43% of these cases involved multiple important targets.

While unadjusted survival wasn’t influenced by the importance of the second ITA target, multivariate analysis showed that grafting a second ITA to multiple important non-LAD targets was associated with significantly improved long-term survival relative to using a second ITA to only one important

target or to nonimportant targets ($P = 0.005$). In patients with a nondominant LAD, grafting a second ITA to a less-important vessel was associated with higher operative mortality relative to grafting to an important vessel (2.4% vs. 0.51%; $P = 0.007$).

Saphenous vein grafts had no effect on long-term survival among recipients of bilateral ITAs, regardless of target importance.

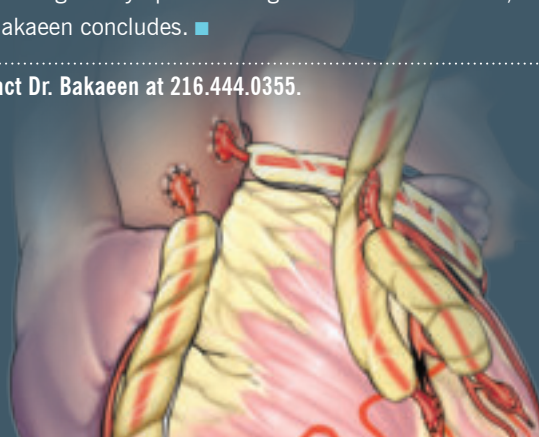
Takeaways for practice

“Among patients who receive bilateral ITA grafts, choosing an anatomically important vessel for the second ITA is associated with lower surgical mortality in patients with a nondominant LAD,” notes Dr. Bakaeen. “Additionally, bypassing multiple important target vessels is associated with improved long-term survival. Think of it as a dose-response relationship between the mass of cardiac muscle supplied by the ITA and survival. The best survival is achieved when all important targets are bypassed with ITAs when possible.”

The researchers translate their findings to two practical recommendations for formulating a bilateral ITA strategy: (1) use ITAs (or arterial grafts) to revascularize the greatest myocardial mass, and (2) when the LAD is nondominant, give priority to grafting the second ITA to all important targets that reach toward the heart’s apex.

“Our findings suggest that objective methods for quantifying the share of total myocardium perfused by each potential arterial target may optimize long-term CABG outcomes,” Dr. Bakaeen concludes. ■

Contact Dr. Bakaeen at 216.444.0355.





Concomitant Carotid Endarterectomy and Carotid Artery Stenting Can Safely Treat Tandem Lesions

A series of 22 high-risk patients supports the hybrid approach in well-chosen candidates.

Hybrid treatment of tandem carotid artery lesions with carotid endarterectomy and ipsilateral carotid artery stenting can be safely performed in appropriately selected patients if careful attention is paid to distal carotid clamping before stenting. So finds a retrospective review of Cleveland Clinic's experience with the approach, which revealed no perioperative deaths and a low risk of myocardial infarction (MI) and neurological events. The study was published in the *Journal of Vascular Surgery* (2020;71:1579-1586).

"We use a hybrid carotid procedure that combines the best of both worlds of open and endovascular approaches," says corresponding author Christopher Smolock, MD, a Cleveland Clinic vascular surgeon. "Our experience demonstrates a low rate of adverse events despite this being a high-risk cohort."

How best to treat this difficult condition?

Tandem lesions of the internal carotid artery and proximal arch branch vessels are uncommon. This leaves uncertainty about the safest treatment approach, with mixed results reported in the literature. While open reconstruction of arch branch vessels is invasive, endovascular reconstruction is not always feasible.

Cleveland Clinic vascular surgeons use a hybrid approach that employs concomitant open carotid endarterectomy and proximal ipsilateral carotid artery stenting. Their recent study assesses the Cleveland Clinic experience with the procedure in 22 patients from its adoption in December 2007 through April 2017.

Cohort characteristics

The 22 patients were predominantly men (68%) and had a mean age of 70.0 ± 6.1 years. They had a high rate of multiple comorbidities, with the most common being hypertension (86%), chronic obstructive pulmonary disease (56%) and diabetes mellitus (31%). In addition, 15 patients (68%) had a prior neurologic event and 12 (55%) were currently symptomatic. All patients were either current (36%) or former smokers.

Many of the cases posed additional technical challenges. Nine patients (41%) had prior carotid endarterectomy or carotid artery stenting, with three having undergone prior neck radiation and three having had reoperative carotid surgeries.

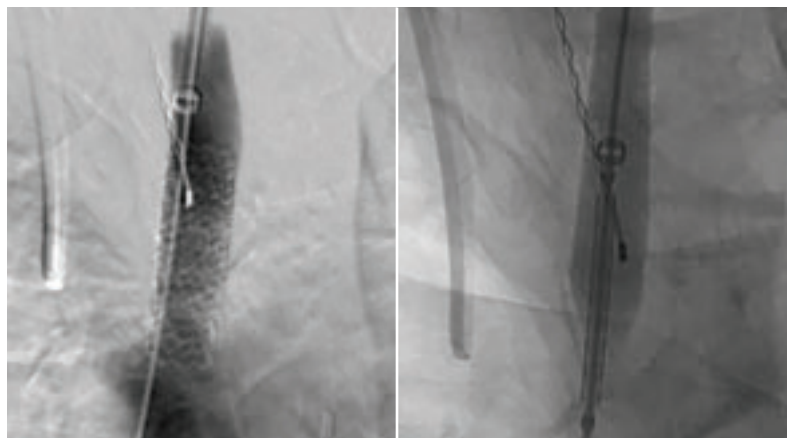
Results

Short-term outcomes. Technical success was 100%. Mean length of hospital stay was 2.6 ± 2.0 days. Adverse events were as follows:

- 1 perioperative stroke (4.5%), which was contralateral
- 1 postoperative MI (4.5%), which occurred on postoperative day 1
- 2 cranial nerve injuries (9.1%)
- 1 death within 30 days (4.5%)

The death occurred in a 74-year-old man with end-stage renal disease on dialysis who had diabetes, chronic obstructive pulmonary disease and a prior MI.

Long-term outcomes. Average follow-up of the cohort was 2.8 years. Seven patients (32%) developed more than 50% restenosis, two of whom (9%) underwent reintervention due to symptoms. Survival was 89.5% at one year and 83.1% at three years. For deceased patients whose cause of death was known, death was secondary to conditions other than stroke.



X-rays showing retrograde proximal common carotid artery stenting with a balloon-expandable stent via carotid bifurcation endarterectomy patch access.

“We use a hybrid carotid procedure that combines the best of both worlds of open and endovascular approaches. Our experience demonstrates a low rate of adverse events despite this being a high-risk cohort.” – Christopher Smolock, MD

Steps to optimize success

The authors note that because this hybrid procedure is rarely performed, evidence of its safety and efficacy is limited to small series in which single events have a significant impact on outcomes data. Still, this single-center review indicates that the procedure can be performed successfully and safely by following the principles outlined below.

1) Select candidates carefully. In general, the procedure should be undertaken only in symptomatic patients. Otherwise, a more conservative approach with aggressive medical management is recommended. The patient in this series who had a perioperative contralateral stroke had a contralateral common carotid artery occlusion, which meta-analyses of carotid endarterectomy have shown to be a recognized risk factor for stroke and death. In many cases, however, risk is higher without treatment. Patients with end-stage renal disease are at particularly high perioperative risk of stroke and death relative to life expectancy, and most should be managed medically, especially if they have asymptomatic common and/or internal carotid artery disease.

2) Keep distal embolic protection foremost in mind.

The following steps are recommended perioperatively:

- Perform carotid endarterectomy first in the usual fashion.
- After endarterectomy, clamp the common carotid artery for distal protection prior to retrograde common carotid access and wire manipulation. Additionally, this allows flow to be reestablished from the external to the internal carotid artery during retrograde stenting.
- Perform retrograde stenting of the proximal common carotid artery with a balloon-expandable stent in the usual fashion.
- After stenting, flush potential debris into the field and the external carotid artery and “back bleed” the internal carotid artery while again flushing the carotid access site with heparinized saline prior to arteriotomy access repair.

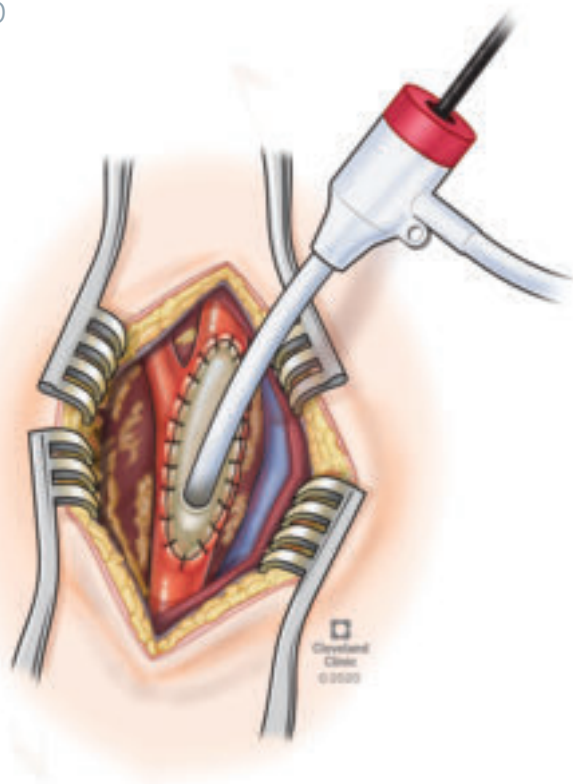


Illustration showing carotid patch retrograde sheath access in the context of the hybrid procedure.

3) Intervene for restenosis only in symptomatic patients.

Restenosis can be expected, as patients with tandem lesions have advanced disease and those with a history of smoking are more likely to have recurrence. As with original candidate selection, symptoms should be more of a consideration than degree of stenosis when deciding whether to intervene.

A reasonable option for a challenging population

“This patient population — with multiple comorbidities and risk factors — is at high risk both from their disease and from intervention,” comments Dr. Smolock.

“In contrast to other institutional single-center data,” adds Sean Lyden, MD, Cleveland Clinic’s Chair of Vascular Surgery, “our data show that with careful patient selection and targeted techniques to lower the risk of distal embolization, tandem carotid lesions can be addressed with acceptable risk.” ■

Contact Dr. Smolock at 216.445.4787 and Dr. Lyden at 216.444.3581.



Realizing Operational Efficiencies in the EP Lab Through a Fresh Look at Staffing Schedules

How we helped an allied hospital keep pace with growing case volumes.

Over the course of 2018 and 2019, St. Luke's Hospital in greater St. Louis, Missouri, saw swift and steady growth in its electrophysiology (EP) program. In little more than a year, the hospital's two EP labs — each with EP-dedicated nursing/tech staff — went from an average of fewer than 50 cases per month to nearly 100 cases per month (Figure 1). The growth exerted stress on the system, creating long days for EP providers, increasing overtime costs and contributing to provider burnout.

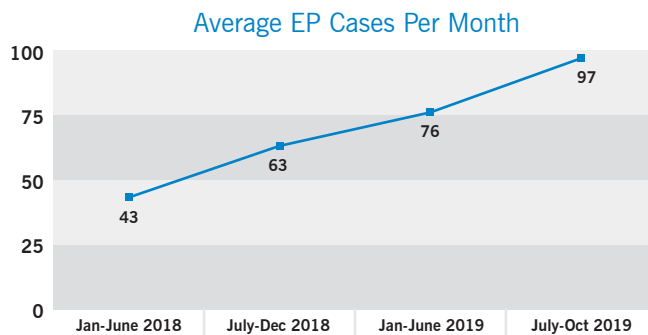


Figure 1

To help meet the increasing demand for EP services while managing these stresses, St. Luke's turned to its alliance relationship with Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute, which has been in place since 2016 to promote sharing of best practices in clinical care, quality improvement and operational efficiency.

Under the alliance, Cleveland Clinic makes its Continuous Improvement Service (i.e., CI team) available to advise partner organizations on operational challenges. Jeanne Secrest, BSN, RN, nurse manager of St. Luke's cardiac catheterization and EP laboratories, engaged with this team and Cleveland Clinic's EP clinical consultant for alliances and affiliations. "Our primary goal was to identify opportunities to enhance the EP labs' ability to run more efficiently, increase productivity and lower overtime utilization," says Secrest. "We believed that improvement in these areas would reduce provider burnout as well."

Starting with a data deep-dive

Cleveland Clinic's CI team and EP clinical consultant worked with Secrest to establish and track operational efficiency metrics in the EP labs, reviewing the time stamps to be captured for each case, essential key metrics to establish and goals to work toward. This type of data-driven approach increases

visibility into daily operations and provides a clear focus on where areas of opportunity exist.

Once refined data collection was underway in response to this review, the CI team used the data gathered by Secrest's team to perform baseline and updated operational efficiency analyses of the EP labs. The following operational metrics were analyzed:

- Lab/room utilization
- Staffing utilization relative to actual caseload
- Turnaround time
- Start times for first case of the day
- Overtime and weekend cases

The baseline efficiency analysis was presented in April 2019 to the nurse manager, EP lab medical director and vice president of St. Luke's cardiovascular service line. This led to development of a plan to address the opportunities identified through the analysis. The plan and its rationale were presented to physician and nursing staffs to gain buy-in and support of the changes. Opportunities identified included improvements in room turn-around time, first case start times and, most importantly, lab and staffing utilization rates relative to actual caseload.

A shift in nursing shifts

Prior to completion of the updated efficiency analysis by the CI team in June 2019, EP lab nurses were scheduled for five 8-hour shifts, Monday through Friday, and the EP labs' operating hours were 8 a.m. to 4 p.m. four days a week. However, because of the increase in case volume — especially the consistent supply of add-on cases late in the day — nursing staff were regularly working 10-hour shifts. This contributed to high rates of overtime and low staff morale. Moreover, some physicians' EP cases were being scheduled months out, due to the growing volume, daily add-ons and staff scheduling issues.

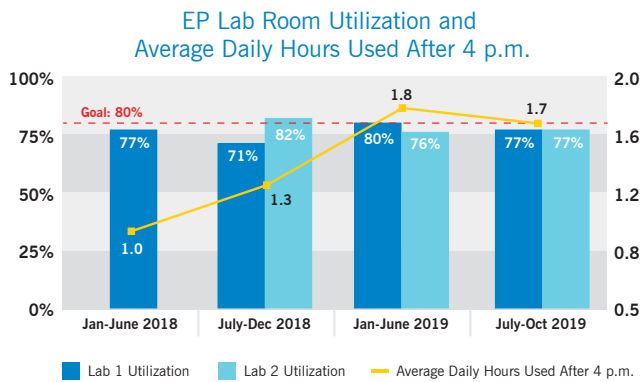


Figure 2

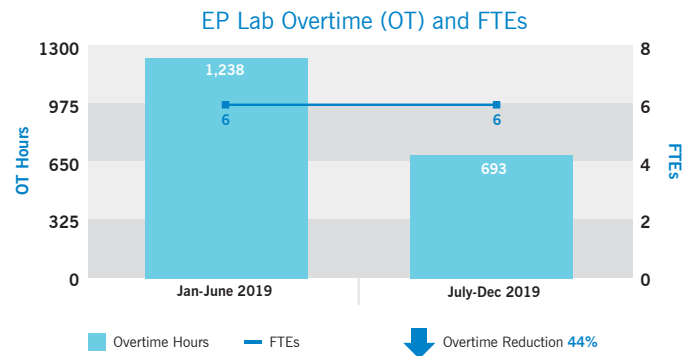


Figure 3

One focus of the efficiency analysis was how much procedure time was taking place after 4 p.m., the nominal “closing” hour, relative to overall lab utilization. As shown in Figure 2, during each of the time periods of volume growth, the labs had between 75% and 80% utilization (which is the goal, in order to leave 20% available for urgent cases or unassigned block time) and grew to consistently have cases until almost 2 hours beyond the primary operating hours.

The analysis identified an opportunity to adjust the EP nursing staff’s shifts from 8 hours across 5 days to 10 hours across 4 days to align with the actual length of lab days. This would reduce utilization of overtime and expand the EP labs’ collective available procedure time by 25% weekly.

In July 2019, St. Luke’s EP leadership implemented Cleveland Clinic’s recommendation of four 10-hour shifts, with nurses working 7 a.m. to 5:30 p.m. or until the last case is done. This allowed one EP lab to be fully run five days a week while the second EP lab is staffed three days a week to align with physicians’ scheduled lab and office time.

Swift results seen

The above changes proved impactful: Over the first six months of moving the nursing staff to the 10-hour shift model, overtime utilization decreased by 44%, reducing the overtime payout by 44% as well. This was achieved even as the total number of full-time equivalent (FTE) employees stayed constant (Figure 3) and the total individual procedure volume increased slightly.

St. Luke’s EP leadership team attributes these significant improvements in operational efficiency to collaboration among the nurse management team, hospital leadership, physicians and Cleveland Clinic’s CI team.

“Everyone had to work together to understand the importance of collecting data, tracking time, monitoring efficiency metrics and using data to drive decisions,” says Secrest. “The data analysis provided by the Cleveland Clinic team made clear to us that the day-to-day demands on our team needed to change. The transition to four 10-hour shifts has led to a healthier work-life balance for the EP nursing staff, which has resulted in increased job satisfaction.”

Further steps toward even greater efficiency

These results prompted the St. Luke’s team to identify further opportunities to streamline the daily workflow in the EP lab setting, promote operational efficiency, improve staff morale, reduce labor costs and improve resource utilization. A second Cleveland Clinic recommendation — a monthly clinical and business review meeting — has been implemented to support these ongoing improvement efforts and enhance the transparency of daily EP lab operations. The monthly meetings are used to discuss quality, efficiency, productivity and cost reduction strategies.

The St. Luke’s EP program will continue to work with Cleveland Clinic’s EP clinical consultant and CI team to support ongoing efficiency efforts, specifically:

- Balancing the schedule throughout the week
- Aligning first-case start schedules with anesthesiologist availability
- Improving EP lab room turnaround time
- Reassessing staffing support as volume incrementally grows

For information on affiliation and alliance opportunities with Cleveland Clinic’s Heart, Vascular & Thoracic Institute, visit clevelandclinic.org/heartaffiliates or email HVI_Strategic_Operations@ccf.org.



FOR SUCCESS IN MITRAL VALVE REPAIR, FOLLOW THESE

10 Commandments

Editorial lays out best practices from three Cleveland Clinic surgeons.

With a variety of options available to address a prolapsed mitral valve, repair is feasible in more than 95% of cases and yields better outcomes than replacement. In a new editorial, “The 10 Commandments for Mitral Valve Repair,” published in *Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery* (2020;15:4-10), three Cleveland Clinic cardiothoracic surgeons detail critical recommendations for successful repair.

“Mitral regurgitation from degenerative disease can be repaired equally well via a variety of surgical techniques,” says lead author A. Marc Gillinov, MD, Chair of Thoracic and Cardiovascular Surgery at Cleveland Clinic. “But whichever technique is chosen, the surgeon must follow certain guidelines to ensure a safe and successful repair.”

The editorial's 10 commandments are briefly recapped below.

1 Scrutinize the intraoperative, pre-repair echocardiogram

Together, the surgeon and echocardiographer should evaluate the baseline transesophageal echocardiogram for the following:

- Mechanism(s) of mitral regurgitation
- Risk of systolic anterior motion (SAM)
- Left ventricular function
- Tricuspid valve function

Complete interrogation of the mechanism of regurgitation is most important, with evaluation including two- or three-dimensional echocardiography with and without color flow.

2 Choose the safest chest wall approach

The choice between a full sternotomy or a less-invasive option depends on patient anatomy and physiology as well as the surgeon's skill and comfort level. “Safety is the first priority,” says editorial co-author Daniel Burns, MD, MPhil. “It is crucial to remember that as the approach becomes less invasive, control over the operation is necessarily relinquished. Early

in a surgeon's experience, it is unwise to tackle a complex valve repair with a minimally invasive approach for the sake of pushing the envelope, as this can prolong cross-clamp time and may risk limb ischemia and other adverse events.”

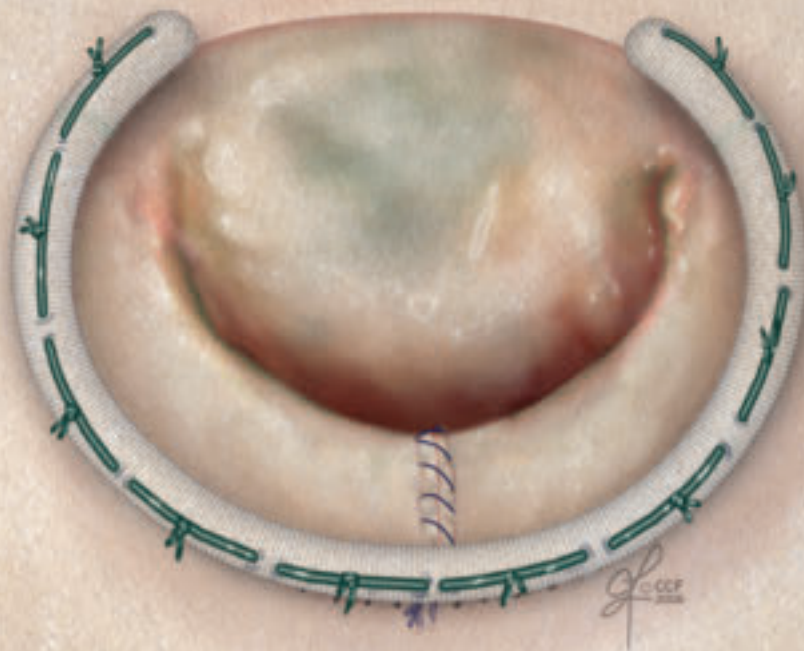
The authors recommend a sternal approach for patients with aortic insufficiency greater than 1+, severe mitral annular calcification, left ventricular dysfunction or dilatation, pulmonary hypertension, aorto-iliac atherosclerosis or femoral artery diameter less than 7 mm.

3 Obtain good valve exposure

While robotic surgery nearly always provides excellent exposure, patients with obesity or a severe pectus excavatum should undergo standard sternotomy. In general, a left atriotomy provides the best valve exposure. However, for challenging cases (e.g., a small left atrium), a trans-septal approach may be a justified trade-off for optimal visualization despite the increased risk for postoperative dysrhythmia and need for a permanent pacemaker.

4 Place annuloplasty sutures first

For nonrobotic approaches, placing the annuloplasty sutures first — with the first one placed wherever is easiest — enhances exposure for a more complete valve inspection. Directing needle tips toward the valve/ventricle when placing sutures in the annulus near the orifice of the left atrial appendage and left fibrous trigone avoids damaging the circumflex coronary artery.



5 Perform a detailed valve inspection

With the echocardiogram findings in mind and valve exposure optimized, inspection should include detecting leaks (using a saline test), identifying areas of prolapse and ruptured chordae, and noting indentations, clefts and areas of leaflet restriction. A tall posterior leaflet is associated with SAM and requires preventive measures.

6 Choose repair techniques that work for you

“For isolated posterior leaflet prolapse, either resection or creation of artificial chords will lead to good outcomes, so surgeons should choose techniques they are comfortable with,” urges editorial co-author Per Wierup, MD, PhD. For anterior leaflet prolapse, however, he recommends artificial chordae creation.

Assessing chordal length is cited as the biggest challenge in creating artificial chordae. The loop technique enables pre-measurement to the length of the native chordae; if chordae are constructed freehand, the final length should be adjusted after the annuloplasty has been secured.

7 Use a prosthetic annuloplasty

A prosthetic annuloplasty should be inserted for all repairs for degenerative disease, but the choices of ring versus band and rigid versus flexible are a matter of preference. The authors favor a flexible band for most cases. While sizing should be determined based on the surface area of the anterior leaflet, a relatively large band or ring is appropriate for most patients.

8 Avoid SAM

“Although there is no way to completely avoid the risk of SAM in mitral valve surgery, efforts should be made to minimize it,” says Dr. Gillinov. This begins with evaluating the preoperative echocardiogram for the following:

- Excess leaflet tissue
- A septal bulge
- A small hyperdynamic ventricle

If any two of these features are present, preemptive surgical measures are needed to move the point of coaptation posteriorly by avoiding too small of an annuloplasty and reducing posterior leaflet height.

9 Delay repair assessment until ventricular function returns

Full ventricular recovery must take place before final weaning from cardiopulmonary bypass. This requires time, a high systemic blood pressure and, in some cases, inotrope administration.

10 Don't accept a bad repair!

Anything higher than mild (1+) mitral regurgitation following repair is almost always unacceptable, the authors assert. And even that level should prompt careful study of the echocardiogram and a possible second pump run to identify problems for immediate correction.

“Good long-term outcomes start with good short-term results,” concludes Dr. Gillinov. “These preoperative and intraoperative ‘commandments’ optimize success for our patients.”

Contact Dr. Gillinov at 216.445.8841, Dr. Wierup at 216.445.1652 and Dr. Burns at 216.444.5104.



► CME PREVIEW

EP's Fundamentals and Future Are on Tap at Virtual CME Summit in September

Virtual Global EP Summit 2020

Livestreamed Friday, Sept. 11, 2020

(complimentary registration)

ccfcme.org/globalep2020

This September, physicians and other providers around the world will have free access to a faculty of international experts for a comprehensive review of the latest in electrophysiology (EP), thanks to a virtual offering of Cleveland Clinic's Global EP Summit 2020. The CME course, which is co-sponsored by the Heart Rhythm Society, was initially scheduled as a live event but will be livestreamed instead due to the COVID-19 pandemic. There is no registration fee, and CME credit will still be offered.

"Like last year's inaugural offering of this summit, this year's event will connect cardiac electrophysiologists and allied health specialists who are eager to discuss EP research and what's on the horizon for EP practice," says course co-director Walid Saliba, MD, Director of Cleveland Clinic's Electrophysiology Lab. "Our aim remains helping to drive innovation and collaboration in our field worldwide."

The course boasts a prestigious international faculty, including 25 members of Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute. Guest faculty hail from leading medical centers across the U.S. as well as Canada, Croatia, France and Germany.

Comprehensive sessions

Over the course of the daylong summit, participants will have real-time access to sessions on:

- Atrial fibrillation (AF) ablation
- Stroke prevention in AF
- Ventricular arrhythmia management
- Device infection
- Surgical EP
- Innovation in pacing and autonomic dysfunction

There will be ample time for open discussion at the end of each session via the livestream.

"Not only will participants learn the latest in ambulatory recording methods, catheter ablation procedures and stroke-prevention therapies, they will learn how to best appraise His-bundle pacing options and cardiac devices such as leadless pacemakers, subcutaneous ICDs and wearable defibrillators," says course co-director Khaldoun Tarakji, MD, MPH, Associate Section Head of Electrophysiology at Cleveland Clinic.

"Everyone will come away with new information, guidance and tips they can use immediately in their practice," adds course co-director Oussama Wazni, MD, MBA, Section Head of Electrophysiology at Cleveland Clinic. "This course should provide a valuable opportunity to stay current in light of reduced course offerings and society meetings since the pandemic began."

From fundamentals to the future

In addition to providing a fresh take on EP fundamentals, presentations will offer innovative insights. Among the notable forward-looking topic titles:

- Pulsed-Field Ablation: Is This the Future of AF Ablation?
- Recorded New-Generation Left Atrial Appendage Closure Devices
- Neuromodulation for Ventricular Tachycardia and Ventricular Fibrillation
- Artificial Intelligence and Innovation in EP

For more details and registration, visit ccfcme.org/globalep2020.

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

Research Roundup

Recent Electrophysiology Studies of Note

► Trio of Studies Showcase Catheter Ablation Advances

Highlights of the 2020 virtual scientific sessions of the Heart Rhythm Society included three studies of advances in catheter ablation reported by Cleveland Clinic electrophysiologist Elad Anter, MD, and colleagues.

One was a late-breaking study of a novel lattice-tip catheter that toggles between delivery of radiofrequency ablation (RFA) and pulsed-field ablation (PFA) for patient-specific tailoring. In this first-in-human single-arm trial, the catheter was used in 76 patients with paroxysmal or persistent atrial fibrillation (AF). Patients underwent pulmonary vein isolation (PVI) and additional linear ablation using either PFA posteriorly and RFA anteriorly, or PFA throughout. PVI was successfully and rapidly achieved in all patients, and linear lesions were acutely successful and achieved in relatively short duration. There were no major complications. "This technology combines PFA and RFA in a single platform, capitalizing on the improved safety of PFA and the many years of experience with RFA," says Dr. Anter.

Results of the Physio-VT study were also presented, demonstrating that a new method for mapping and ablation in patients with scar-related ventricular tachycardia (VT) may improve clinical outcomes. The methodology involves mapping the heart from multiple directions during activation to increase sensitivity and specificity, in contrast to the standard technique of mapping from a single direction. Physio-VT was a prospective, single-arm study of 85 patients with refractory infarct-related VT. It showed that left ventricular mapping from multiple directions identified an additional ~30% of areas exhibiting slow activations that were responsible for an additional 25% of VT circuits that could not be identified during activation from a single direction. Over follow-up of 3.6 years, only 16.5% of patients had VT recurrence. "The physiological observations and impressive clinical outcomes from this pivotal study may signal a paradigm shift in VT treatment," notes Dr. Anter.

The third study compared a strategy of high-power (50 W), short-duration (8-15 sec) RFA during PVI with conventional moderate-power (30-40 W), moderate-duration (20-30 sec) RFA in patients with symptomatic AF. Results from 112 patients who underwent the high-power, short-duration approach were compared with those in 112 patients who underwent the conventional approach. The high-power, short-duration strategy resulted in significantly lower rates of acute and chronic pulmonary vein reconnection and shorter total ablation time. However, it was less effective for ablation in thicker tissue. More on all three studies is at consultqd.clevelandclinic.org/virtualhrs.

► Direct Pacemaker Monitoring via Smartphone Boosts Transmission Rates

Empowering patients with implanted cardiac pacemakers to use a smart device app for remote monitoring resulted in a significantly higher rate of scheduled transmission success compared with traditional manual and automatic bedside monitoring technologies, reported investigators with the international BlueSync Field Evaluation. They also found a comparable rate of transmission success among patients using the new technology outside the study, suggesting a similar experience in real-world use.

"This is the first large assessment of smartphones or tablets for direct monitoring of pacemakers," says principal investigator Khaldoun Tarakji, MD, MPH, a Cleveland Clinic electrophysiologist who presented the findings as a late-breaking trial at the virtual meeting of the Heart Rhythm Society. "Its encouraging findings have the potential to reshape monitoring of patients with pacemakers and other cardiac implantable electronic devices." More at consultqd.clevelandclinic.org/bluesync.

► Bailout Ablation for Cardiogenic Shock and Refractory VT in Patients on Mechanical Support

Of 21 consecutive patients with refractory ventricular tachycardia (VT) in cardiogenic shock, 81% could be successfully weaned off mechanical support following radiofrequency ablation. So reported Cleveland Clinic clinicians in a case series published in *Circulation: Arrhythmia and Electrophysiology*. All patients had previously been unable to be removed from mechanical support despite anti-arrhythmic drug therapy.

Patients' median left ventricular ejection fraction was 20%, their median PAINESD score was 18 out of 35, and 81% had ischemic cardiomyopathy. The ablation procedures targeted clinical VTs and premature ventricular contractions in addition to empiric scar modification. At the end of the procedures, 91% of patients had no inducible VTs. Among the 17 patients (81%) successfully weaned off mechanical support, 15 (71%) were discharged from the hospital, with 13 (62%) alive at one-year follow-up.

This is the only known study investigating VT bailout ablation in this high-risk setting. "Managing this critically ill group of patients is extremely challenging," says senior author Ayman Hussein, MD. "Ablation as a last resort proved to be a viable option, allowing liberation from mechanical hemodynamic support shortly afterward." More at consultqd.clevelandclinic.org/bailoutablation.

Cardiac Consult



20-HV-1845930

Keep Current With **Live Virtual CME** from Cleveland Clinic

21st Annual Intensive Review of Cardiology

Sat.-Wed., Aug. 15-19, 2020

Offered virtually via livestream

Information/registration:

ccfcme.org/cardioreview20

Global EP Summit 2020

Fri., Sept. 11, 2020

Offered virtually via livestream

(complimentary registration)

Information/registration:

ccfcme.org/globalep2020

(see page 18 for more detail)

Fetal and Congenital Cardiac Care: Lifelong Commitment to the Continuum of Care

Fri., Sept. 11, 2020

Offered virtually via livestream

Information/registration:

ccfcme.org/congenitalheartdisease2020

State-of-the-Art Echocardiography 2020

Fri.-Sun., Oct. 2-4, 2020

Offered virtually via livestream

(complimentary registration)

Information/registration:

ccfcme.org/echocardio20

Cardiovascular Update for the Primary Care Provider

Thu.-Fri., Oct. 15-16, 2020

Offered virtually via livestream

(complimentary registration)

Information/registration:

ccfcme.org/cardioupdate20

The Unpartitioned AV Connection: 5th Annual Advances in Pediatric and Congenital Heart Summit

Fri.-Sat., Oct. 16-17, 2020

Offered virtually via livestream

Information/registration:

ccfcme.org/congenitalheart20

A Case-Based Approach to Mastering the Mitral Valve: Imaging, Innovation & Intervention

Fri.-Sat., Dec. 4-5, 2020

Offered virtually via livestream

(complimentary registration)

Information/registration:

ccfcme.org/mitralmasters

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



Cardiac Consult

Is Now a Podcast Too




Listen at clevelandclinic.org/cardiacconsultpodcast or subscribe from your favorite podcast source.

HEART, VASCULAR & THORACIC

Vitals

Volumes and outcomes from a sampling of
centers in Cleveland Clinic's Miller Family
Heart, Vascular & Thoracic Institute

- 
- › Heart Failure & Recovery
 - › Electrophysiology

Heart Failure & Recovery

158 Number of heart transplants ($n = 57$) and LVAD implantations ($n = 101$) performed in 2019

411 Number of patient referrals for advanced heart failure in 2019, up 20% from 2018

94.6% 1-year patient survival for heart transplant recipients, vs. 91.3% national benchmark

87.0% 3-year patient survival for heart transplant recipients, vs. 84.7% national benchmark

35% Our reduction in 1-year risk of graft failure vs. national benchmark

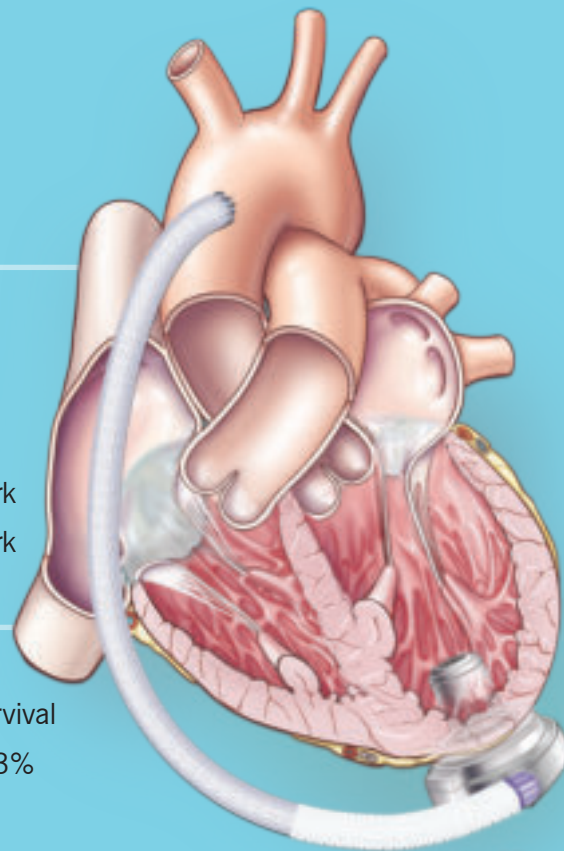
13% Our reduction in 3-year risk of graft failure vs. national benchmark

(Source: Scientific Registry of Transplant Recipients program report of 1/7/20)

91.5% 1-year post-implant survival among continuous-flow LVAD recipients for destination therapy, vs. 87.0% STS Intermacs survival

90.8% 1-year post-implant survival among LVAD recipients, vs. 88.3% STS Intermacs survival

(Source: Society of Thoracic Surgeons [STS] Intermacs report for 1/1/19-12/31/19)



Electrophysiology (EP)

28,530 EP lab procedure volume, 2015-2019

6,290 EP lab procedure volume, 2019

897 Lead extraction procedures, 2015-2019, with total of 1,705 leads extracted

97.9% Clinical success rate for lead extractions

1.7% Major complication rate for lead extractions, vs. benchmark of 1.8% (Kusumoto et al., *Heart Rhythm*. 2017)

5,141 Atrial fibrillation (AF) ablations, 2015-2019

1.5% Major complication rate for AF ablations, vs. benchmark of 4.5% (Cappato et al., *Circ Arrhythm Electrophysiol*. 2010)

655 Ventricular arrhythmia ablations in patients with LVEF < 50%, 2015-2019

1.7% Major complication rate for these ablations, vs. benchmark of 10% (Cronin et al., *Heart Rhythm*. 2020)

480 Placements of Watchman™ device for LAAO procedures (EP and interventional cases), 2015-2019 (post-March 2015 FDA approval)

1.7% Major complication rate within 7 days of Watchman implant, vs. benchmark of 2.7%-8.7% in published Watchman studies (Boersma et al., *Eur Heart J*. 2016)

LVEF = left ventricular ejection fraction; LAAO = left atrial appendage occlusion

For more data like this, visit clevelandclinic.org/hvtioutcomes and clevelandclinic.org/e15

