

# CardiacConsult

Heart, Vascular and Thoracic News from Cleveland Clinic | 2021 | Issue 1

› CARDIAC CONSULT FEATURE

## Preemptive Hemodynamic Support for VT Ablation

– p. 4



CLEVELAND CLINIC'S HEART, VASCULAR & THORACIC INSTITUTE:

# Who We Are by the Numbers

148 Cardiologists/vascular specialists

28 Cardiac surgeons (adult and pediatric)

19 Vascular surgeons

6 Thoracic surgeons

1,304 Nurses

496 Nursing support staff

132 Advanced practice providers

113 Residents and fellows

Numbers are as of year-end 2020.



**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 Riggle | 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 2020-21, as well as the No. 1 hospital in cardiology and heart surgery for the 26th consecutive year.

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### Dear Colleagues,

One hundred years ago, Cleveland Clinic was founded as a group practice — a novel concept at the time — by four Ohio physicians. Their aim was to deliver healthcare modeled on the team-based approach to care they had experienced as part of military medical units during World War I.

Their mission has endured for a century now, transforming the modest practice they started in February 1921 into one of the world's great medical centers. In no realm has that mission proved as fruitful as it has in cardiovascular care.

Although Cleveland Clinic was not known for particular expertise in cardiovascular care during its first few decades, that began to change with the landmark development of coronary angiography by cardiologist F. Mason Sones, MD, in 1958. This and Sones' subsequent pioneering work here in cardiac catheterization paved the way for many of the advancements in myocardial revascularization that followed in the next two decades.

Chief among them was the development of coronary artery bypass grafting (CABG) as a planned, consistent approach to the treatment of coronary artery disease. That effort was led by Cleveland Clinic cardiac surgeon Rene Favoloro, MD, who in 1967 completed the first successful attempt at coronary vein grafting with an interposed saphenous vein graft. By the early 1970s, Cleveland Clinic surgeons led by Floyd Loop, MD, standardized the use of internal thoracic artery (ITA) grafts in CABG, ultimately establishing ITA grafting as the standard of care in a landmark 1986 *New England Journal of Medicine* study.

The impact of the rise of CABG on all of U.S. healthcare is hard to overstate. Together with the creation of Medicare a few years earlier, it fueled explosive growth in hospitals in the last few decades of the 20th century, creating the infrastructure of modern U.S. healthcare.

CABG was also the first treatment that began to draw large numbers of international patients to Cleveland Clinic. Soon the health system's reputation for unparalleled expertise expanded to other cardiovascular services, making Cleveland Clinic a destination for complex patients and setting the stage for its

run as the top-ranked U.S. center for cardiology and heart surgery by *U.S. News & World Report* for the past 26 years.

Other innovations contributed to that status, from early development of stopped-heart surgery by Donald Effler, MD, in the mid-1950s, to creation of the world's first computerized data registry for cardiac diagnosis and treatment in 1972, to the first minimally invasive mitral valve operations led by Toby Cosgrove, MD, in the mid-1990s, among others. Cleveland Clinic surgeons and cardiologists also played pioneering roles in the development of everything from heart transplantation to intravascular ultrasound to transcatheter aortic valve replacement.

The reputation built by these advancements has made cardiovascular services singularly essential to Cleveland Clinic's success and growth over its first century. At the same time, our Heart, Vascular & Thoracic Institute could not have achieved what it has without the excellence, support and multidisciplinary collaboration of the overall Cleveland Clinic enterprise. That enterprise has been guided at every turn by the mission of the four Cleveland Clinic founders: *caring for life, researching for health and educating those who serve.*

This three-part mission will remain the light that guides us into Cleveland Clinic's second century, as providers everywhere grapple with growing case complexity and demands for greater efficiency as healthcare financing further evolves. Our Heart, Vascular & Thoracic Institute will continue its tradition of adaptation and innovation to meet new patient needs, conduct practice-shaping investigations and train tomorrow's master clinicians — all in the service of high-value care with untouchable patient outcomes. We thank you for your enduring confidence and collaboration.

**Lars G. Svensson, MD, PhD**

CHAIR

Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute



# Preemptive Hemodynamic Support

*for Improving the Safety and Efficacy of*

## **VT Ablation**

- ▶ Cleveland Clinic has adopted a novel multidisciplinary approach for improving the management of ventricular tachycardia (VT). The strategy involves management by a multidisciplinary heart care team to determine whether preemptive hemodynamic support can be provided to safely make VT ablation possible in patients who would otherwise be deemed too vulnerable to the procedure's potential complications.



### Rationale for the preemptive strategy

VT occurs due to scar that develops following myocardial infarction or a slew of other possible etiologies, such as infection, inflammation and other types of nonischemic cardiomyopathy. Affected patients often require implantation of cardiac defibrillators for treatment of life-threatening VT. While defibrillators are relatively effective, the electrical shocks they deliver can cause pain, psychological trauma and other harmful effects.

In response, VT ablation was developed as a percutaneous, catheter-based procedure that aims to eliminate sites critical for development of VT, thereby reducing the risk of recurrent VT and defibrillator shocks. The procedure often requires induction of VT to allow accurate identification of those critical sites before they can be targeted with ablation. While VT can be induced safely in patients with milder heart failure and stable arrhythmias, induction is less safe in those with advanced heart failure and/or more complex arrhythmias. In these patients, induction of VT can lead to hemodynamic collapse and increased risk of complications, including death.

For years, a range of pumps have been used to provide temporary mechanical hemodynamic support to the failing heart during VT ablation, mitigating the risk of periprocedural acute hemodynamic failure. This practice has been limited, however, by insufficient circulatory support from the relatively small pumps that were available and their selective use in only the sickest patients. The past few years have seen development of larger and more effective pumps that can completely replace the function of the heart for periods of time. These pumps have been used at Cleveland Clinic for the past two years, including use to support VT ablation in critically ill patients (*Circ Arrhythm Electrophysiol.* 2020;13:e007669).

### Extending ablation's benefits more broadly

When electrophysiologist Elad Anter, MD, joined Cleveland Clinic in 2020 to lead its VT program, he recognized that about 90% of the institution's patients with VT were referred or transferred after failed ablation attempts or because they were considered too sick to undergo ablation. He saw an opportunity to formalize a VT program comprising experts from multiple disciplines in addition to electrophysiology, including cardiac surgery, interventional cardiology, advanced heart failure and cardiovascular imaging.

Dr. Anter led the establishment of the multidisciplinary program, whose aim is to evaluate patients with VT and develop an optimal treatment plan for each patient. The plan may include changes to the medical regimen, ablation using a variety of hemodynamic support devices tailored to the individual's heart conduction, and advanced heart failure therapies, including left ventricular assist device implantation or heart transplantation.

"VT usually occurs in patients with heart failure and should be addressed in the context of the overall heart condition and the patient's well-being, plans and wishes," explains Dr. Anter, Associate Section Head of Cardiac Electrophysiology.

### Choosing the right pump

As a leader in the development and application of mechanical support devices, Cleveland Clinic has embraced the full range of Impella and ventricular assist pumps to support patients in heart failure, undergoing VT ablation or undergoing high-risk coronary artery bypass grafting. Familiarity with each model's advantages allows the heart team to customize device selection to each patient.

*Continued next page >*



“Our new program facilitates collaboration among various subspecialists to provide effective and safe hemodynamic support during complex VT ablation procedures.” — Elad Anter, MD

When a patient has mildly reduced heart function and relatively simple VT, the Impella CP® — a pump that is placed through a catheter in the groin and delivers about 4 liters of blood per minute — may be sufficient. In contrast, patients who have more severe heart failure and/or complex arrhythmias require the larger Impella 5.0® or Impella 5.5®, both of which deliver more blood per minute. The size of the latter devices precludes catheter-based delivery and requires a minimally invasive incision in the shoulder. In some patients with right ventricular failure, a pump supporting the left ventricle may not be sufficient and an additional right ventricular support pump is needed.

In October 2019, the Impella 5.0 was replaced by the 5.5 version, which incorporated a key design change — removal of the curled “pigtail” tip of the device. “This made it easier to place surgically,” says Edward Soltesz, MD, MPH, Surgical Director of Cleveland Clinic’s Kaufman Center for Heart Failure Treatment and Recovery. “Without a pigtail irritating the ventricle, it is also less arrhythmogenic.”

Cleveland Clinic was the first U.S. center to implant the Impella 5.5 and is the top user of the Impella family of pumps in the U.S., having implanted more than 350 by the end of 2020. “Use of these pumps mitigates the risk of a disaster occurring during the ablation,” Dr. Soltesz notes.

### Defining success

In the electrophysiology lab, the electrophysiologist maps the heart to pinpoint the origin of the arrhythmia and ablates the location. Attempts to induce VT are made. If these attempts fail, the procedure is considered successful, and the patient is transferred to intensive care for observation.

After confirmation that the patient is stable and is maintaining good heart function, the Impella is removed. This may be done a few hours to two days after surgery. No anesthesia is required. If the patient has an implantable cardioverter defibrillator, it is left in place for backup.

### Decidedly multidisciplinary decision-making

Cleveland Clinic’s VT program provides a multidisciplinary platform for preemptively strategizing the treatment plan for each patient. This includes determining whether hemodynamic support is needed and which type is appropriate.

“Every patient referred for VT therapy is thoroughly evaluated by a team of electrophysiologists, interventional cardiologists, cardiac surgeons and cardiac intensivists to ensure that treating the arrhythmia is the right decision — and, if so, how it will be best accomplished,” says Dr. Anter. “Our new program facilitates collaboration among these subspecialists to provide effective and safe hemodynamic support during complex VT ablation procedures.”

“This preemptive approach is an excellent option, as it plays a major role in managing these critical patients,” notes Ousama Wazni, MD, Section Head of Cardiac Electrophysiology.

“This form of advanced life support enables VT ablation to be well planned and successfully accomplished by our heart team,” adds Samir Kapadia, MD, Chair of Cardiovascular Medicine and an interventional cardiologist on the VT ablation team.

“VT ablation is a high-risk procedure due to the need to repeatedly induce VT to map the heart and identify the arrhythmogenic substrate,” Dr. Anter concludes. “As a result, many patients are told they are not candidates for it. However, this is the best solution for some patients with VT, and we need to make sure we can perform ablation in the safest, most effective fashion possible.” ■

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Contact Dr. Anter at 216.444.4293, Dr. Soltesz at 216.444.5680, Dr. Wazni at 216.444.2131 and Dr. Kapadia at 216.444.6735.

# Carotid Endarterectomy and the High-Risk Patient



Carotid endarterectomy (CEA) remains a safe treatment option for severe carotid artery stenosis even in patients at high surgical risk, concludes a large retrospective study from Cleveland Clinic in the *Journal of Vascular Surgery*.

While CEA has been the gold standard for carotid disease since the 1950s, it has been joined more recently by minimally invasive transfemoral carotid artery stenting and transcatheter artery stenting, termed “TCAR” for transcatheter artery revascularization.

Patients with anatomic or physiologic conditions that put them at high surgical risk are often referred for these endovascular alternatives as the least invasive — and presumably safest — procedures. But is there evidence to support this practice? Cleveland Clinic researchers sought to find out by evaluating their institution’s 10-year experience with high-risk patients undergoing traditional CEA.

“We focused on high-risk patients who were considered for CEA or transfemoral carotid artery stenting but ultimately underwent CEA,” says vascular surgeon Francis Caputo, MD, the study’s lead author. “We found that patients with one or more high-risk factors can undergo CEA and end up with stroke rates comparable to those with transcatheter artery revascularization.”

## Study in brief

The analysis focused on 1,347 consecutive patients who underwent CEA at Cleveland Clinic between 2008 and 2018. Of these, 1,152 met inclusion criteria for the analysis. These patients were separated into high-risk and standard-risk categories based on whether they had any of various physiologic and anatomic risk factors.

Physiologic risk factors were an ejection fraction < 30%, severe pulmonary disease or an abnormal stress test. Anatomic risk factors were prior head/neck radiation, prior ipsilateral neck surgery, contralateral nerve palsy, redo CEA, prior ipsilateral stenting, contralateral occlusion, contralateral CEA, nasotracheal intubation or a requirement for digastric muscle division.

Initial analysis revealed 450 patients who had one or more high-risk factors. When propensity score matching was used to pair these patients with those without high-risk factors, adequate matches were found for 424 high-risk patients (94%), of whom 173 met at least one physiologic high-risk criterion and 293 met at least one anatomic high-risk criterion.

When the high-risk and standard-risk groups were compared on the primary outcome — a composite of stroke, myocardial



infarction (MI) or death at 30 days — there were no significant differences in the composite endpoint or any of its components. Notably, the stroke rate was 1.9% in standard-risk patients versus 1.4% in high-risk patients. Moreover, results were comparable between patients with one high-risk factor and those with multiple high-risk factors.

## Still an option worth considering

“Since the establishment of high-risk criteria, there have been studies to both support and question the safety of CEA in high-risk patients,” says study co-author Sean Lyden, MD, Chair of Vascular Surgery. “Our findings support the safety of high-risk CEA in centers of excellence.”

The authors note that rates of stroke, MI and 30-day mortality among high-risk CEA patients in their study were comparable to rates among standard-risk patients who received TCAR in a recent review of the Vascular Quality Initiative database (*J Vasc Surg*. 2018;67:1752-1761). They write that while their study showed high-risk patients to be significantly more likely than standard-risk patients to have a cranial nerve injury, most such injuries were temporary.

“From this analysis,” says Dr. Caputo, “we conclude that CEA remains an effective and safe surgical solution for high-risk patients. Whereas the emergence of transcatheter artery revascularization will reduce demand for transfemoral carotid artery stenting, CEA continues to be a viable option for high-risk patients who fall outside the indications for transcatheter artery revascularization.” ■

**Contact Dr. Caputo at 216.445.9580 and Dr. Lyden at 216.444.3581.**



# RHAPSODY Reveals Unprecedented Reduction of Recurrent Pericarditis With Riloncept

Phase 3 trial may lead to first FDA approval for the indication.

Targeting interleukin-1 (IL-1) may represent a paradigm shift in the treatment of patients with recurrent pericarditis, suggest results from the phase 3 RHAPSODY trial published late last year in the *New England Journal of Medicine*.

The multicenter study evaluated riloncept, an IL-1 $\alpha$  and IL-1 $\beta$  cytokine trap, in patients with recurrent pericarditis. It found that the agent was associated with rapid resolution of active recurrent pericarditis episodes and a significantly reduced risk of pericarditis recurrence compared with placebo.

“Interleukin-1 has been implicated as an important mediator of recurrent pericarditis, a highly disabling disease with a huge clinical and economic burden and no therapies currently approved by the FDA,” says lead study author Allan Klein, MD, Director of Cleveland Clinic’s Center for the Diagnosis and Treatment of Pericardial Diseases. “Riloncept represents a new targeted approach to recurrent pericarditis. Results of this pivotal study indicate this type of IL-1 blocker may be a game changer in the management of patients with this disease.”

## An event-driven randomized withdrawal trial

The phase 3 RHAPSODY trial built on findings of a successful phase 2 study of riloncept for recurrent pericarditis presented by Dr. Klein at the American Heart Association’s 2019 Scientific Sessions.

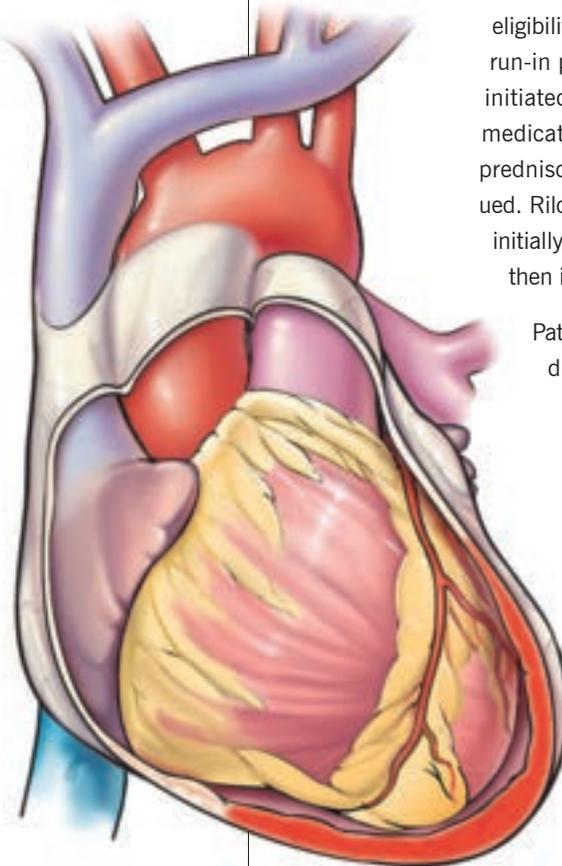
RHAPSODY was designed as a double-blind, placebo-controlled, randomized withdrawal trial to determine time to first recurrence in the withdrawal period. It enrolled patients with symptomatic recurrent pericarditis and systemic inflammation from Australia, Israel, Italy and the United States, with Cleveland Clinic’s academic research organization, C5Research, serving as the study’s coordinating center.

Patients aged 12 years or older were eligible for inclusion if they presented with acute symptoms during at least a second recurrence of pericarditis despite treatment with NSAIDs, colchicine and/or glucocorticoids. A pain score of at least 4 on a validated 10-point scale was required, as was a C-reactive protein (CRP) level  $\geq 1$  mg/dL within seven days of study treatment initiation.

After an initial screening period to confirm eligibility, patients underwent a 12-week run-in period in which riloncept was initiated and background pericarditis medications (NSAIDs, colchicine and prednisone) were tapered and discontinued. Riloncept was given subcutaneously, initially in a loading dose of 320 mg and then in a weekly dose of 160 mg.

Patients who had a clinical response during run-in (prespecified as a CRP level  $\leq 0.5$  mg/dL and a weekly average pain score  $\leq 2$  without a recurrent pericarditis episode) were randomized on a 1:1 basis to continued riloncept (160 mg) or matching placebo, each administered once weekly. The study’s event-driven design specified that this randomized withdrawal period would end upon observation of 22 adjudicated first recurrence events of pericarditis, with time to first recurrence serving as the primary endpoint.

After closure of the randomized withdrawal period, participants were offered the option of receiving up to 24 months of open-label riloncept therapy in the study’s long-term extension phase (which remains ongoing).





“This suggests that rilonacept can replace the use of steroids in the future and allow tapering of standard-of-care anti-inflammatories such as NSAIDs, colchicine and prednisone.” — Allan Klein, MD

### Efficacy results

Of 141 patients assessed for eligibility, 86 were enrolled in the trial's run-in period, with more than one-third of participants enrolled at Cleveland Clinic. Mean patient age was 44.7 years; 57% were women. The cause of pericarditis was idiopathic in 85% of patients, with the remaining cases representing post-cardiac injury pericarditis. Roughly half of patients were taking glucocorticoids when they had their qualifying pericarditis episode.

During the run-in phase, median time to pain resolution or near resolution was five days (95% CI, 4-6), and median time to CRP normalization was seven days (95% CI, 5-8). Manifestations of pericarditis that were present at baseline (pericardial effusion, pericardial rub or ECG changes) resolved by the end of the run-in phase in all but one of the 86 patients.

A total of 61 patients entered the study's event-driven randomized withdrawal phase, during which pericarditis recurrence occurred in two of 30 patients in the rilonacept group (7%) versus 23 of 31 in the placebo group (74%). This translated to a significantly lower risk of recurrence with rilonacept (hazard ratio = 0.04; 95% CI, 0.01-0.18;  $P < 0.0001$ ). This result was consistent regardless of patients' baseline use of glucocorticoids. Notably, no patient who was switched to open-label bailout rilonacept therapy experienced a pericarditis recurrence in the remainder of the randomized withdrawal period.

Secondary efficacy endpoints — maintenance of clinical response, days with minimal or no pain, and percentage of patients with minimal or no pericarditis symptoms — were assessed at week 16 of the randomized withdrawal period. The rilonacept group showed significantly superior outcomes versus the placebo group on all these outcomes ( $P < 0.001$ ).

### Safety consistent with current labeling

In the trial's run-in period, four patients (5%) had adverse events that led to study discontinuation. The most common events with rilonacept throughout the study were injection-site

reaction and upper respiratory tract infection. The drug's adverse event profile was consistent with its FDA-approved labeling for treatment of cryopyrin-associated periodic syndromes.

### A likely new era in recurrent pericarditis care

“These results show rapid and sustained reductions in pain and CRP levels, as well as resolution of pericarditis manifestations, with rilonacept therapy,” says Dr. Klein, who served as one of the trial's two co-principal investigators. “Rilonacept monotherapy reduced the risk of pericarditis recurrence by 96%, and each of the two recurrence events in the rilonacept arm occurred during temporary interruptions of drug administration.”

“Rilonacept also supported corticosteroid tapering and discontinuation, as all patients on corticosteroids at the start of the study successfully transitioned to rilonacept monotherapy during the run-in period,” adds Cleveland Clinic cardiologist and RHAPSODY co-investigator Paul Cremer, MD.

“This suggests that rilonacept can replace the use of steroids in the future and allow tapering of standard-of-care anti-inflammatories such as NSAIDs, colchicine and prednisone,” says Dr. Klein, noting that each of these therapies has limitations for use in recurrent pericarditis. “IL-1 targeting may be a paradigm shift in treatment of this disease.”

He adds that for cases intractable to medical therapy, pericardiectomy remains an option. A Cleveland Clinic team led by cardiac surgeon Douglas Johnston, MD, has one of the world's largest experience bases in surgery for pericardial disease.

A supplemental biologics license application for use of rilonacept in recurrent pericarditis was granted priority review by the FDA in late 2020. ■

**Contact Dr. Klein at 216.444.3932, Dr. Cremer at 216.444.6765 and Dr. Johnston at 216.444.5613.**



# MIDCAB:

## A CASE STUDY IN ITS BENEFITS, AND CONSIDERATIONS FOR PATIENT SELECTION

### Case vignette

In August 2020, a 62-year-old male triathlete arranged a virtual visit with clinical cardiologist Tamanna Singh, MD, Co-Director of Cleveland Clinic's Sports Cardiology Center. After hearing Dr. Singh on a podcast on heart health and running, he became concerned that his recent jaw pain and decline in stamina might be atypical symptoms of heart disease. Based on the virtual visit, Dr. Singh recommended that he have a cardiac catheterization done locally. When it revealed a severely diseased left anterior descending artery (LAD) and diseased circumflex artery, he came to Cleveland Clinic for an in-person evaluation.

Because the patient had a history of pericarditis, Dr. Singh ordered a cardiac MRI to rule out active inflammation or constriction effect on the heart; she also ordered a repeat catheterization to confirm the location and extent of his coronary artery disease. The catheterization, performed by interventional cardiologist Jaikirshan Khatri, MD, included pressure-wire interrogation of the circumflex. When this was negative, Dr. Khatri confirmed that the patient's disease was confined to the LAD.

Since revascularization via coronary artery bypass grafting or stenting would be necessary, Drs. Singh and Khatri met with cardiothoracic surgeon Faisal Bakaeen, MD, to discuss treatment options. A significant intramyocardial segment of LAD identified by Dr. Khatri on catheterization made stenting unwise. Dr. Bakaeen felt the patient would be an excellent candidate for minimally invasive direct coronary artery bypass (MIDCAB) grafting and would derive greater benefit from bypass grafting than stenting, owing to his age and activity level and the large myocardial territory at risk. The patient agreed to proceed with MIDCAB so long as all attempts would be made to avoid sternotomy.

The patient was anesthetized and prepared for off-pump surgery. Dr. Bakaeen made a small left thoracotomy incision, harvested the internal thoracic artery (ITA) and connected it to the LAD distal to the obstruction.

Graft flow was measured with a flowmeter and found to be ideal. After heparin was reversed, graft flow was rechecked and continued to be excellent. The wound was closed, and the patient was sent to the ICU. Two days later, graft patency was confirmed by coronary CT angiogram. The patient's recovery was uneventful, and he was discharged home on postoperative day three. He was pleased with the limited extent of his scar.

### Considerations behind the case

Although single-vessel disease is often treated medically or with stenting, MIDCAB offers many advantages for appropriately selected patients with suitable anatomy.

In this patient, borderline findings of disease in the circumflex artery seen on the first angiogram were ruled out with a second catheterization and pressure-wire interrogation. Concerns about potential constriction due to pericarditis were eliminated with an MRI.

Although the patient was leaning toward stenting to avoid a sternotomy, the team explained that because a segment of his LAD was buried in the myocardium, a stent would not be optimal due to risk of continued symptoms and an increased risk of sudden cardiac death.

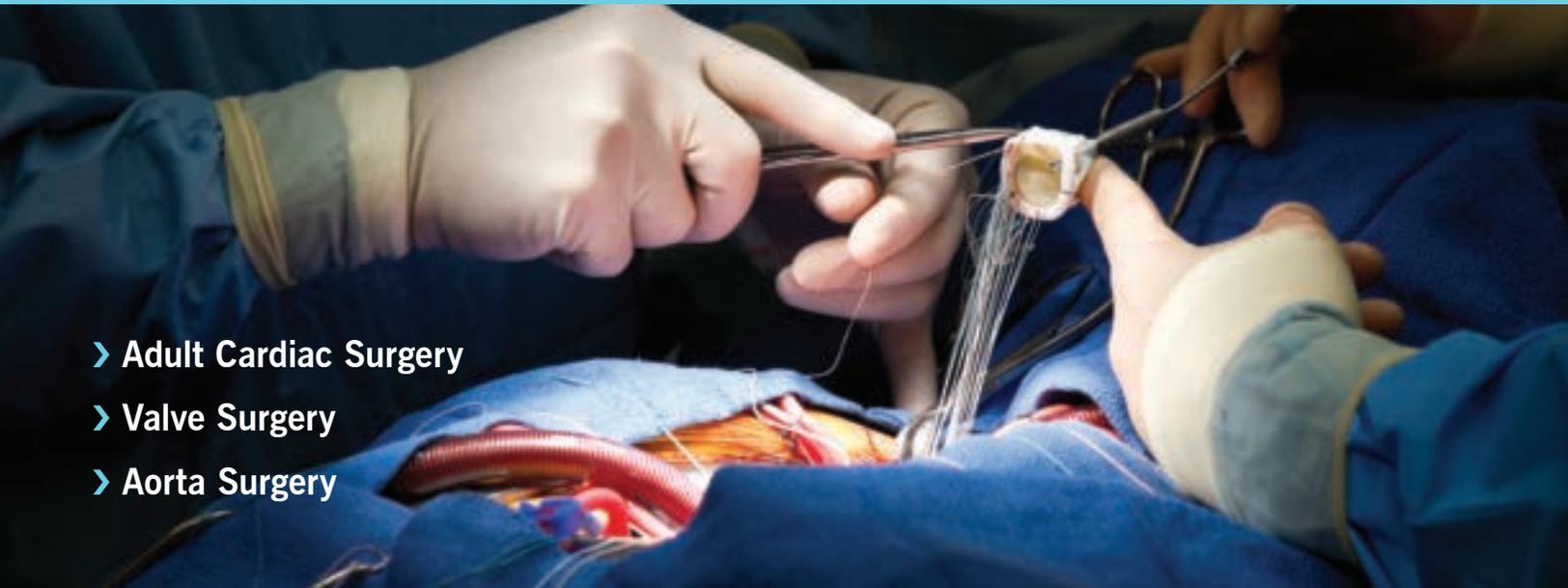
MIDCAB would be a better option, they noted, since an ITA graft to the LAD is likely to stay open in perpetuity.

HEART, VASCULAR & THORACIC

# Vitals

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

- › Adult Cardiac Surgery
- › Valve Surgery
- › Aorta Surgery



# Adult Cardiac Surgery

Cleveland Clinic's Overall Composite Quality Ratings in STS Adult Cardiac Surgery Database\*



CABG



AVR



AVR + CABG



MVRR



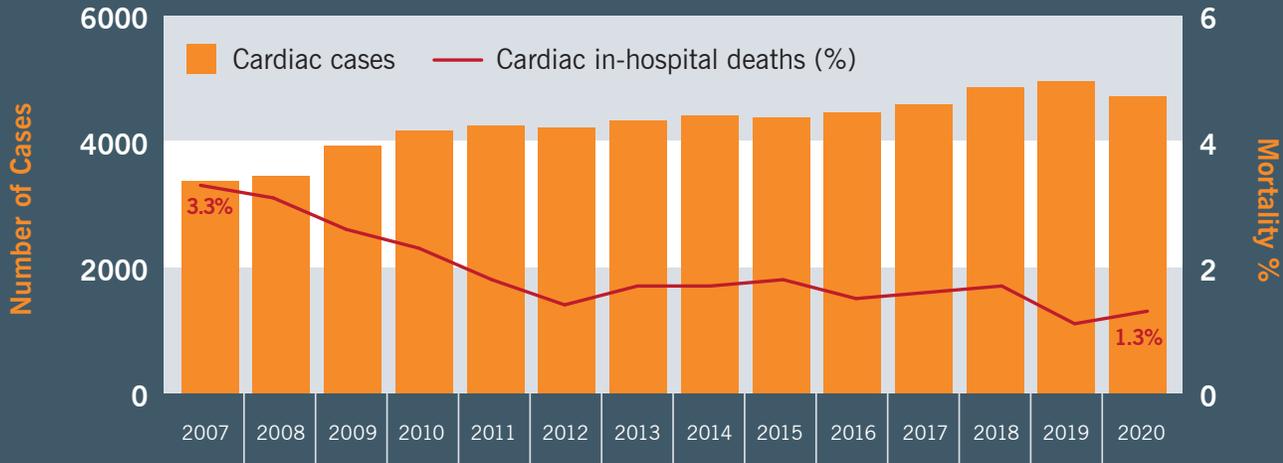
MVRR + CABG

\*For 7/1/17-6/30/20 for all categories but CABG, which is for 7/1/19-6/30/20.

STS = Society of Thoracic Surgeons; CABG = coronary artery bypass grafting; AVR = aortic valve replacement; MVRR = mitral valve repair/replacement

# Adult Cardiac Surgery

## Adult Cardiac Surgery Mortality Declines Even as Volume and Case Complexity Increase



Over the past 14 years, mortality has trended downward even as case complexity increases, with 57% of patients in 2020 requiring operations more complex than those classified by the Society of Thoracic Surgeons.

## Aortic Valve Replacement (AVR)

### SURGICAL AVR

**0.6%** operative mortality for isolated AVR in 2020 (N = 331)

(vs. 1.3% STS predicted mortality)

**0%** operative mortality for AVR + CABG in 2020 (N = 150)

(vs. 3.0% STS predicted mortality)

### TRANSCATHETER AVR

**0.7%** procedural mortality in 2020 (N = 677)

(no predicted rate available)

## Mitral Valve Repair and Replacement

### ISOLATED MITRAL VALVE REPAIR

**0%** operative mortality among 2,960 cases from 2014 through 2020

(vs. 0.7% STS predicted mortality)

### ISOLATED MITRAL VALVE REPLACEMENT

**2.8%** operative mortality in 2020 (N = 145)

(vs. 4.5% STS predicted mortality)

## Aorta Surgery\*

**1.9%** operative mortality in 2020 (N = 1,008)

(no predicted rate available)

**1.1%** operative mortality for elective cases in 2020 (N = 715)

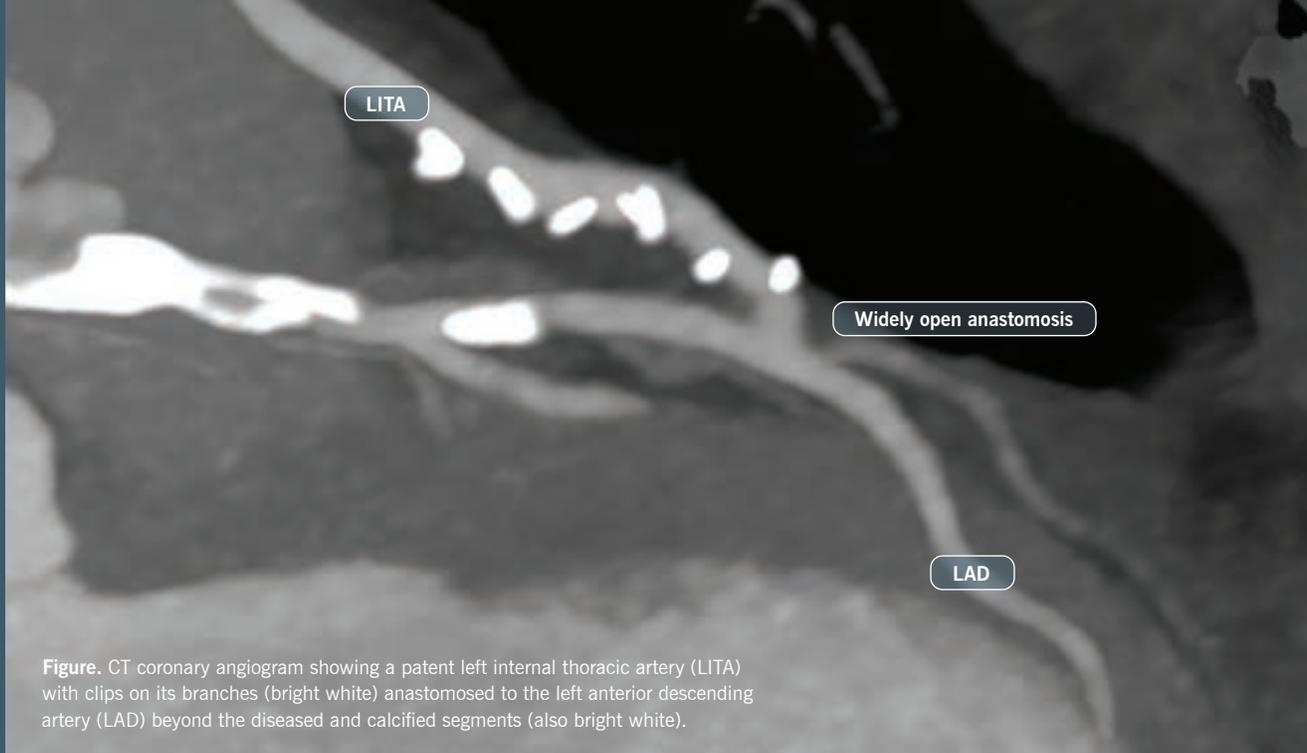
(no predicted rate available)

\*Aorta surgery data are from STS Adult Cardiac Surgery Database and thus do not include vascular surgery cases.

STS = Society of Thoracic Surgeons;  
CABG = coronary artery bypass grafting

For more data like this, visit [clevelandclinic.org/hvtioutcomes](https://clevelandclinic.org/hvtioutcomes) and [clevelandclinic.org/e15](https://clevelandclinic.org/e15).





**Figure.** CT coronary angiogram showing a patent left internal thoracic artery (LITA) with clips on its branches (bright white) anastomosed to the left anterior descending artery (LAD) beyond the diseased and calcified segments (also bright white).

### MIDCAB advantages

Cleveland Clinic performs about 20 off-pump ITA-to-LAD graft procedures per year, and some are done through this mini-thoracotomy MIDCAB approach. In addition to being durable, MIDCAB offers advantages over traditional on-pump coronary artery bypass grafting, such as less scarring, shorter length of stay, less pain and quicker recovery. Because the operation is typically done off pump, patients experience less bleeding and potentially fewer complications and have lower risk of atrial fibrillation and stroke.

With a sternotomy, strenuous activity and heavy lifting are restricted for eight weeks as the sternum heals. With MIDCAB, those restrictions are loosened and governed by pain levels.

“Patients can gradually increase their activity,” says Dr. Bakaeen. “Once they feel no pain, they can generally perform most activities with few limitations.”

### Patient selection, quality control

A key initial consideration for MIDCAB candidacy is making absolutely certain the patient has single-vessel LAD disease, says Dr. Khatri. “MIDCAB is not technically feasible if the patient has multivessel disease,” he explains. Other important considerations are the patient’s chest anatomy and the location and quality of the LAD target.

In addition to careful patient selection and input from

a multidisciplinary heart team, successful MIDCAB requires quality control. At Cleveland Clinic, this is done by measuring graft flow in the operating room and often verifying graft patency with CT coronary angiography prior to discharge (Figure).

“This gives us a look at graft functionality and anatomy and provides confidence the graft is working well,” Dr. Bakaeen explains.

### Safety first

As with other minimally invasive procedures, use of MIDCAB cannot always be guaranteed. Sometimes the patient’s anatomy or condition prevents carrying out the approach as planned. When this occurs, the surgeon makes adaptations to ensure the patient has the best outcome.

“We always start with a very small incision between the ribs,” says Dr. Bakaeen, “but if the LAD cannot be adequately exposed or if other factors preclude a safe or effective MIDCAB approach, then we have no hesitation to convert to sternotomy with or without use of a heart-lung machine. We never compromise safety or outcomes.”

In this case, the MIDCAB went as planned. “MIDCAB was a fantastic option for this patient, and he was very happy with the outcome,” notes Dr. Singh. ■

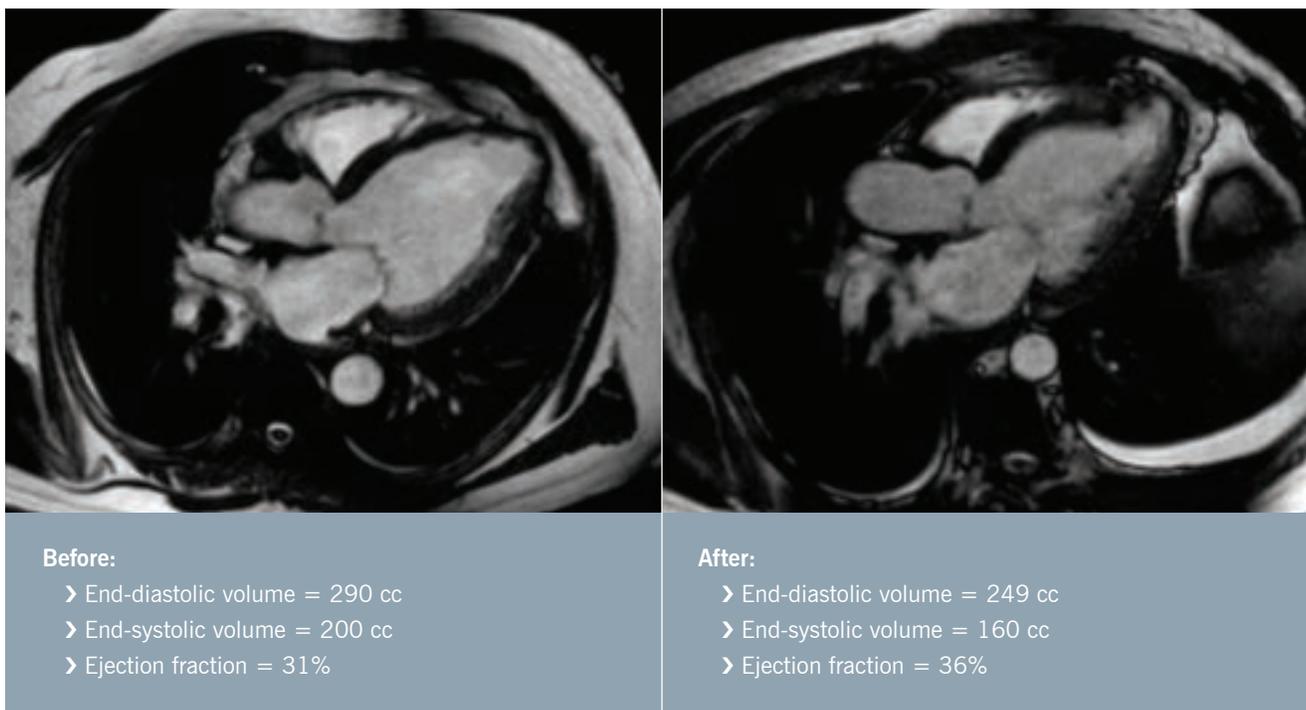
.....  
**Contact Dr. Singh at 216.445.5323, Dr. Khatri at 216.445.3991 and Dr. Bakaeen at 216.444.0355.**



# ALIVE Trial Offers Hybrid Approach for Ischemic Cardiomyopathy With Residual Scar

## Reshaping the heart with a minimally invasive percutaneous/surgical procedure

The multicenter ALIVE (American Less Invasive Ventricular Enhancement) trial is underway to evaluate the safety and efficacy of the Revivent TC™ Transcatheter Ventricular Enhancement System for heart failure patients with left ventricular scarring. The system requires a cardiac surgeon and an interventional cardiologist working together simultaneously to reshape the heart to a more normal size, with the goal of improving pumping efficiency.



**Figure.** Axial MRIs taken before (left) and after (right) the Revivent procedure.

“Interventional heart failure therapies are the next frontier of invasive cardiology,” says Cleveland Clinic interventional cardiologist Rishi Puri, MD, PhD, the trial’s local principal investigator. “The Revivent system has the capacity to alter the treatment paradigm for a population of patients with heart failure who have very limited treatment options.”

### Few choices for patients not ready for end-stage options

According to Edward Soltesz, MD, MPH, Surgical Director of Cleveland Clinic’s Kaufman Center for Heart Failure and Recovery, many patients with heart failure have poorly controlled symptoms despite medical therapy but do not yet have disease severe enough to warrant a heart transplant or left ventricular assist device. For such patients, left ventricular reconstructive

surgery using the Dor procedure may be indicated, requiring open-heart surgery and cardiopulmonary bypass.

“We are optimistic that the ALIVE trial will lead to a better alternative for these patients whom we are hesitant to recommend for highly invasive surgery,” says Dr. Soltesz. “It’s anticipated that the system used in this trial will slow cardiomyopathy progression and improve quality of life.”

Less Invasive Ventricular Enhancement (LIVE™ Therapy) using the Revivent system was approved for use in Europe in 2016. Evidence indicates that it increases ejection fraction, reduces ventricular volume and improves New York Heart Association (NYHA) functional class and exercise capacity. Long-term outcomes data are not yet available.



### A minimally invasive hybrid approach

The Revivent procedure is performed off pump and without a ventriculotomy. It involves placement of the following:

- Internal micro-anchors into the interventricular septum of the right ventricle by an interventional cardiologist with transcatheter access via the internal jugular vein
- External micro-anchors in the outer wall of the left ventricle below the scar tissue by a cardiac surgeon via a 4-cm mini-thoracotomy

Usually three pairs of internal/external micro-anchors are needed. When the micro-anchor pairs are drawn toward each other with a wire, the newly shaped left ventricular wall consists of functioning tissue and is of a more normal size and shape. Patients typically remain in the hospital three to four days after the procedure.

### Study design

The trial is anticipated to enroll 126 patients in up to 30 sites in the U.S., with 84 patients in the intervention arm and 42 controls who do not undergo the procedure.

Enrollment criteria include (1) contiguous acontractile scar involving the septum and/or anterior, apical or anterolateral regions of the left ventricle; (2) left ventricular ejection fraction < 45%; (3) left ventricular end-systolic volume index  $\geq 50$  mL/m<sup>2</sup>; and (4) NYHA functional class III to IV (ambulatory).

Exclusion criteria include having a cardiac resynchronization therapy device placed within 60 days, peak systolic pulmonary artery pressure > 60 mm Hg, myocardial infarction within 90 days or chronic renal failure (serum creatinine > 2.5 mg/dL or glomerular filtration rate < 30 mL/min). Patients with prior pericardiectomy, left thoracotomy or open-heart surgery do not qualify for the intervention but may enroll as control subjects.

Patients are followed for 12 months. Efficacy is being evaluated in terms of:

- Hospital readmission for heart failure
- Minnesota Living with Heart Failure Questionnaire quality-of-life score
- Six-minute walk distance
- NYHA classification

Safety is being assessed in terms of:

- A composite primary safety endpoint through 30 days consisting of all-cause death, placement of a mechanical support device, emergency cardiac surgery, prolonged mechanical ventilation, renal failure and clinically important stroke. Patients in the intervention group are compared with patients from the Society of Thoracic Surgeons database who underwent surgical left ventricular aneurysm or scar repair.
- A composite secondary endpoint for post-procedure months 1 to 12 consisting of all-cause death, mechanical support or operation for heart failure, bleeding or tamponade. Patients in the intervention group are compared with the trial's control group.

Preliminary results are anticipated at the end of 2021.

### Pooling expertise for a new treatment paradigm

The investigators expect this trial will be definitive for this method of scar elimination.

They note that the high degree of procedural collaboration between interventional cardiologist and cardiac surgeon required by the Revivent approach is unusual in cardiac therapy. They add that Cleveland Clinic's Kaufman Center for Heart Failure Treatment and Recovery is well suited for such collaboration, given that it already serves as an umbrella structure under which multidisciplinary subspecialists routinely work together to optimize patient outcomes.

Cleveland Clinic completed the procedure in one ALIVE trial enrollee in late 2020 (Figure) and anticipates enrolling several additional patients this year.

"The Revivent procedure offers a minimally invasive treatment option to patients with symptomatic heart failure without obviating advanced heart failure treatment options in the future," adds the ALIVE trial's national co-principal investigator, Jerry Estep, MD, Medical Director of Cleveland Clinic's Kaufman Center for Heart Failure and Recovery and Section Head of Heart Failure and Transplantation. "If the trial results are positive, this will be a game changer and will add to our heart failure therapeutic armamentarium." ■

**Contact Dr. Puri at 216.444.6731, Dr. Soltesz at 216.444.5680 and Dr. Estep at 216.444.7646.**



# Revisiting Registry Reporting Practices Boosts Quality Metrics for an Allied Hospital

The Parkview Heart Institute (PHI) at Parkview Regional Medical Center, Fort Wayne, Indiana, is the only dedicated heart hospital in its region. Beginning in August 2019, PHI entered into an alliance with Cleveland Clinic's Heart, Vascular & Thoracic Institute to advance care quality and efficiencies for its cardiovascular patients.

## A focus on registry submissions

An early focus of the alliance was PHI's processes for data collection, coding and management for the various cardiac registries in which PHI participates. The PHI registry team was highly engaged and qualified, but the hospital's performance on some registry quality metrics wasn't satisfactory. Initial consultation from a clinical analyst with Cleveland Clinic Heart and Vascular Advisory Services identified registry data submission as a likely contributing factor to performance shortfalls.

In response, PHI committed to providing oversight of all cardiac registries and ensuring high-quality data abstraction and reporting. "Robust data collection and registry management are key to driving quality improvement," says Megan Gibas, BS, CPHQ, the data quality metrics manager who leads the PHI registry team. "Early discussions with Cleveland Clinic Heart and Vascular Advisory Services staff revealed that we had opportunities to restructure and adopt some best practices to facilitate efficient, real-time data abstraction and reporting for our cardiac registries."

## Review reveals opportunities for improvement

Gibas and the PHI registry team worked closely with a Cleveland Clinic clinical analyst to conduct a thorough review of the abstraction and reporting processes for all PHI registries. They started with the ICD Registry™ of the American College of Cardiology's (ACC) National Cardiovascular Data Registry (NCDR®) and discovered crucial abstracting practices that were impacting PHI's data reporting and influencing its performance on the registry's device-based therapy guideline metrics.

**Example 1.** For instance, PHI ranked below the 50th percentile of all registry participants on ICD Registry guideline metrics. Yet when PHI's electrophysiology physician champion reviewed the records of patients identified as not meeting indications for ICD implantation, he determined that they did indeed meet the indications.

Detailed review revealed that most of these patients were classified as not meeting indications because they were coded as not having ventricular tachycardia (VT). Further review showed that this was because patients with certain special circumstances that qualify for coding as VT — such as ventricular fibrillation arrest — were not being coded as VT. A previous frequently asked question (FAQ) from the NCDR registry provided clarification and proper instruction on how to capture this data point moving forward.

**Example 2.** Another issue discovered was that data elements required by the ICD Registry were sometimes missing from physician charting of cases. While PHI's electronic medical record (EMR) offered structured reporting, utilization was not required. At Cleveland Clinic's recommendation, PHI physician leadership made use of structured reporting mandatory for device implantation cases. The policy not only ensured accurate documentation for the EMR but also supplied many of the missing elements required by the registry.

As a result of these and other changes to the data collection and abstracting process, PHI's quarterly adherence rate for ICD Registry guideline metric 25 improved from 63.9% to 100% in less than a year, and the quarterly adherence rate for metric 26 rose from 53.3% to 100% in the same period. Gibas presented these and other positive results from the initiative in a poster at the virtual ACC Quality Summit in October 2020.

## Learnings applied to additional registries

The Cleveland Clinic and PHI teams have subsequently reviewed PHI's practices for other cardiac registries to ensure accurate and timely abstraction. The initial review of the ICD Registry prompted the PHI team to conduct more frequent data submissions to the NCDR, which allows them to review any metric fallouts and thoroughly review data ahead of submission deadlines.



The result has been improved outcomes in all NCDR registries. For example, PHI saw an improvement in the class I/class II guideline requirement in the AFib Ablation Registry™ as well as more accurate capture of complications. In the coming year, a thorough review of abstraction and reporting for the Society of Thoracic Surgeons Adult Cardiac Surgery Database will be undertaken.

### Collaboration continues

Cleveland Clinic and PHI teams continue to hold quarterly quality meetings via videoconference for various specialty areas, including cardiac surgery, the catheterization lab, electrophysiology and, beginning in 2021, transcatheter aortic valve replacement. These meetings include data reviews and discussion of clinical best practices, and they involve physicians, clinical consultants and the clinical analyst from Cleveland Clinic's Heart, Vascular & Thoracic Institute as well as physicians, nurse leaders, administrators, and data and registry managers from PHI.

"The collaboration between the Cleveland Clinic and Parkview teams allowed for the creation of a timely workflow for abstraction to national registries with improved accuracy to reflect the high-quality care Parkview provides to the Fort Wayne community," says Christopher Bajzer, MD, one of the Cleveland Clinic cardiologists involved in those meetings.

"This alliance has been instrumental in our registry and quality program development," adds PHI's Gibas. "Implementing best practices shared by Cleveland Clinic has created a robust quality program at Parkview Heart Institute that will continue to ensure the best patient care and outcomes."

"Our collaboration with Cleveland Clinic is oriented to the direct improvement and advancement of patient care," says Roy Robertson, MD, President, Parkview Heart Institute. "Our joint efforts around data collection and registry management have provided information to help our teams advance the level of care to new heights. Working alongside Cleveland Clinic has facilitated many best practices and prompted some helpful restructuring. We look forward to continued collaboration." ■

**For information on affiliation and alliance opportunities with Cleveland Clinic's Heart, Vascular & Thoracic Institute, email Amanda Lesesky at [leseska@ccf.org](mailto:leseska@ccf.org).**

## Cleveland Clinic Heart and Vascular Advisory Services at a glance

### COLLABORATIVE RELATIONSHIPS OFFERED

- Advisory services: > 60 assessments completed for health systems, hospitals, physician practices and outpatient offices
- Affiliations and alliances: 14 affiliate or alliance relationships as of year-end 2020

### HISTORY AND SCOPE

- Established 2003
- Provider-based advisory services driven by Cleveland Clinic Heart, Vascular & Thoracic Institute (HVTI) physicians, supported by a team with multidisciplinary expertise
  - 20-member core team: HVTI physician leaders plus dedicated full-time administrators, clinical consultants, continuous improvement specialists, quality analysts, project managers
  - All HVTI physicians and surgeons support the core team

### AVAILABLE ADVISORY SERVICES

Optimizing clinical quality, operational efficiency | Strategy development and enhancement | Resource allocation | Development of existing programs and expansion of services | Advice and education on patient care, strategic planning and clinical innovation

### TO LEARN MORE

Contact Amanda Lesesky, Director, Outreach Programs, [leseska@ccf.org](mailto:leseska@ccf.org)



# Higher Positioning of SAPIEN 3 Reduces Conduction Abnormalities and Pacemaker Requirements

**Novel TAVR deployment technique improves outcomes without compromising safety.**

Among patients undergoing transfemoral transcatheter aortic valve replacement (TAVR), implanting the balloon-expandable Edwards SAPIEN 3 valve with higher placement — in a position just 1.5 mm under the noncoronary cusp — led to greater than 50% reductions in rates of conduction abnormalities and 30-day permanent pacemaker implantation compared with conventional valve deployment.

So found a study comparing outcomes in more than 1,000 patients who underwent TAVR at Cleveland Clinic before or after transition to the new deployment method. The results were published in *Circulation: Cardiovascular Interventions* (Epub 12 Jan 2021).

“As TAVR use increases among patients with longer life expectancy, finding new ways to improve the procedure is especially important,” says the study’s senior author, Samir Kapadia, MD, Chair of Cardiovascular Medicine. “We found that the high deployment technique for aortic valve implantation appears to be a significant step forward, as outcomes improved without compromising procedural safety or valve hemodynamics.”

## Conventional TAVR puts conduction tissue at risk

Although TAVR is considered a safe alternative to surgery for severe, symptomatic aortic valve stenosis in patients at any level of surgical risk, it is well known to be associated with risk of new-onset conduction disturbances and permanent pacemaker requirement. Conventional deployment of the balloon-expandable SAPIEN 3 valve results in a ratio of valve frame in the aorta to left ventricular outflow tract of 70:30 or 80:20, a level that may put pressure on conduction tissue at and below the annular plane (see Figure).

In April 2017, Cleveland Clinic TAVR operators started to use a novel high deployment technique to achieve higher implantation of the SAPIEN 3 valve, with the goal of reducing impairment of the conduction system. From January 2018 on, all TAVR procedures using the SAPIEN 3 valve performed at the institution employed the high deployment technique.

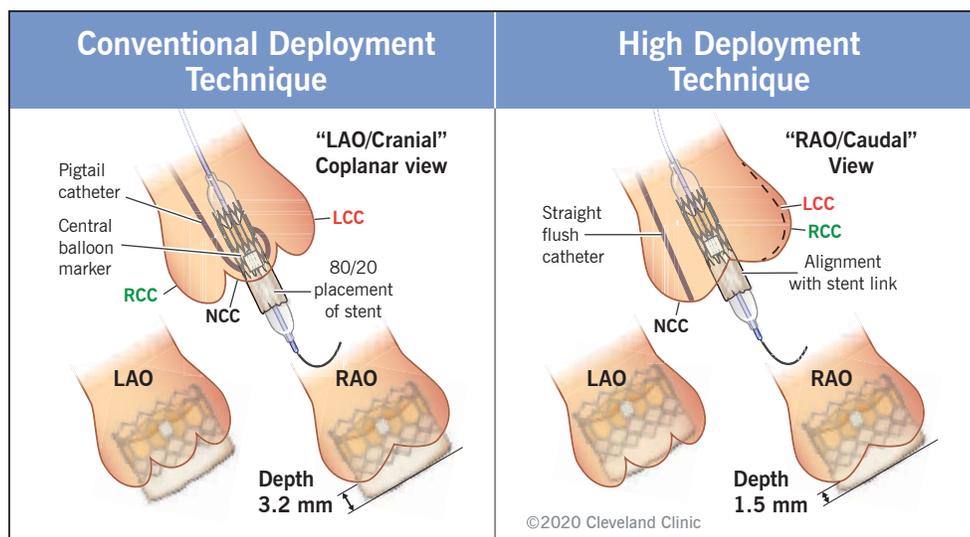
## Study design

All consecutive patients who underwent transfemoral TAVR with the SAPIEN 3 valve at Cleveland Clinic between April 2015 and December 2018 were included in this retrospective study. Of the 1,028 total patients, 622 (60.5%) underwent the conventional deployment technique and 406 (39.5%) underwent the high deployment technique. Overall, the median patient age was 82.7 years, and the median Society of Thoracic Surgeons risk score was 4.9 (interquartile range, 3.6-7.3).

Patients with a preexisting permanent pacemaker were included in the overall analysis but were excluded from the endpoint analyses of the need for a new permanent pacemaker and new onset of conduction abnormalities.



“As a result of our experience, we recommend that high deployment of the SAPIEN 3 valve be adopted to decrease implantation depth and improve patient outcomes after TAVR.” — Samir Kapadia, MD



**Figure.** Differences between the conventional and high deployment techniques for placing the SAPIEN 3 valve. LAO = left anterior oblique; RAO = right anterior oblique; LCC = left coronary cusp; RCC = right coronary cusp; NCC = noncoronary cusp.

## Results

Key changes observed with adoption of the high deployment technique included the following:

- *Implantation depth into the left ventricular outflow tract was significantly reduced.* Specifically, the mean depth declined from  $3.2 \pm 1.9$  mm with the conventional deployment technique to  $1.5 \pm 1.6$  mm with the new technique ( $P < 0.001$ ). Although implantation depth using the conventional technique declined significantly over the course of the study, the mean depth remained larger than with the high deployment technique.
- *30-day permanent pacemaker requirements significantly fell.* The rate decreased from 13.1% with conventional deployment to 5.5% with high deployment ( $P < 0.001$ ).
- *Conduction abnormalities became significantly less frequent.* Rates of complete heart block dropped from 11.2% to 3.5% ( $P < 0.001$ ), and rates of new-onset left bundle branch block declined from 12.2% to 5.3% ( $P < 0.001$ ).

Additional key outcomes were similar between the two techniques:

- *Successful implantation occurred in both groups.* There was no conversion to open-heart surgery, no second valve implantation within the first TAVR and no coronary occlusion during TAVR. One patient in the high deployment group (0.2%) had valve embolization ( $P = 0.216$ ). There was no difference in mortality between the two groups, and 30-day stroke rates were comparable.

- *Hemodynamic measures were comparable.* No significant differences were found in mild or moderate-to-severe aortic regurgitation at one year. Although the high deployment technique resulted in slightly higher one-year mean and peak gradients that reached statistical significance, the differences were not clinically meaningful, and the Doppler velocity index was similar between the two groups.

## Careful placement is critical

The study report describes the technique for achieving high valve deployment. The technique was applied to all types of aortic root anatomy, in different angulations and with varying degrees of the valve being centered in the annulus. The authors share the following tips:

- Make sure the valve is in the appropriate position according to the noncoronary cusp (usually the deepest of the sinuses) in the right anterior oblique/caudal projection.
- Optimize fluoroscopic angles to remove any parallax from the valve.
- Identify the coplanar view on intraoperative angiography, which is achieved by pre-procedural planning using contrast-enhanced multidetector CT of the aortic root.
- Position the valve based on the superior aspect of the most proximal (or inferior) set of stent struts, seen as a radiolucent line on the crimped SAPIEN 3 valve.

“As a result of our experience, we recommend that high deployment of the SAPIEN 3 valve be adopted to decrease implantation depth and improve patient outcomes after TAVR,” concludes Dr. Kapadia. ■

Contact Dr. Kapadia at 216.444.6735.



# Artificial Intelligence Looms Large in New Studies of Heart Transplant Rejection and Noncompaction Cardiomyopathy

Two multicenter heart failure-related research projects involving artificial intelligence (AI) are underway at Cleveland Clinic — one for better predicting heart transplant rejection and the other for characterizing noncompaction cardiomyopathy. Each recently received funding of \$3 million from the National Institutes of Health (NIH) over a four-year period to apply advanced computer analytics to image assessment to better evaluate risks and ultimately improve therapeutic decisions.

“Cardiovascular care is very dependent on diagnostic studies, and their interpretations may vary by expertise,” says W.H. Wilson Tang, MD, staff cardiologist and Research Director in Cleveland Clinic’s Section of Heart Failure and Transplantation. “The promise of AI is that it may be able to identify pathologic features more accurately and consistently, and thereby improve evaluation and management.”

Dr. Tang, a physician-scientist and translational researcher interested in applying AI to clinical cardiology, is actively involved in both projects, profiled below.

## 1) CACHE: Predicting heart transplant rejection

Cardiac allograft rejection surveillance and diagnosis are currently done primarily by histological grading of endomyocardial biopsy. But the grading standard has poor prognostic accuracy and limited ability to discern mechanisms of rejection. As a result, management decisions put patients at risk for inappropriate treatment.

The CACHE (Computer-Assisted Histologic Evaluation of Cardiac Allograft Rejection) project will use computational image analysis to assess endomyocardial biopsy specimens,

comparing morphologic biomarkers with clinical outcomes. New biomarkers of rejection-related injury — including immunologic markers — are expected to be discovered with the help of immunofluorescence panels.

“The computer algorithms may capture features we don’t detect visually,” Dr. Tang explains. “Some of these may be evidence of rejection that have yet to be appreciated.”

The CACHE investigational team is led by researchers from the University of Pennsylvania and Case Western Reserve University who previously developed and evaluated computer algorithms that identify novel morphological features in histologic specimens to improve upon the accuracy of classifying failing versus nonfailing hearts. With the new NIH grant, CACHE will be further refined using cardiac biopsy samples from three major transplant centers in the U.S., with Dr. Tang overseeing research activities at the Cleveland Clinic site in collaboration with researchers from the University of Pennsylvania and Cedars-Sinai. Samples obtained retrospectively will be compared against clinical outcomes, and then accuracy of the optimized model will be validated in a multicenter prospective cohort.



“While artificial intelligence may not replace clinicians, it has the potential to make us smarter by helping us manage our patients with greater insight.” — W.H. Wilson Tang, MD



“Our goal is to develop an accurate, consistent and informative system for diagnosing allograft rejection that correlates with patients’ clinical trajectories,” says Dr. Tang. “This technique is expected to be applicable to other organ transplants as well.”

“One of the most significant risks of heart transplantation is the body’s response to reject the donor heart,” says Jerry Estep, MD, Cleveland Clinic’s Section Head of Heart Failure and Transplantation. “Improving diagnostic accuracy to detect this complication may position providers to offer earlier and enhanced treatment. Research like this that incorporates AI analysis is a step in the right direction to improve post-transplant outcomes.”

## 2) NONCOMPACT: Characterizing LV noncompaction cardiomyopathy

Left ventricular (LV) noncompaction is a rare congenital cardiomyopathy involving a layer of loose myocardial tissue that appears on MRI as prominent trabeculations and deep recesses extending from the LV cavity to the subendocardial surface of the ventricular wall. The disorder is poorly understood and highly heterogeneous, as some patients have a benign course while others develop heart failure, embolic stroke from blood clots in these recesses, arrhythmias and sudden cardiac death. It is estimated that about half of LV noncompaction cases are inherited and have a genetic component.

LV noncompaction currently is diagnosed by criteria based on echocardiography and MRI. With the widespread use of these imaging studies, the condition is increasingly recognized and diagnosed. But that does not necessarily mean it’s being appropriately treated, notes Dr. Tang, who has a special interest in the condition (see *Heart*. 2013;99:681-689).

“It’s often difficult to differentiate pathological from benign hypertrabeculation with current imaging techniques,” he observes. “This leads to potential excessive use of implantable cardioverter-defibrillators and anticoagulation therapies, as many patients may have been diagnosed with LV noncompaction yet may not have a malignant clinical course.”

Dr. Tang is co-principal investigator of a study of LV noncompaction that recently received the second of the NIH grants mentioned above. The investigation, known as the International Consortium for Multimodality Phenotyping in Adults with Noncompaction (NONCOMPACT), is the first international effort to collect comprehensive clinical, genetic, structural and functional information for detailed computer analysis with the goal of differentiating pathological from benign patterns of noncompaction.

A large cohort of adults with suspected LV noncompaction will be investigated at Cleveland Clinic, Stanford University and the University of Pennsylvania, as well as at centers in the Netherlands and South Korea, with up to three-year follow-up. Associations between myocardial structure by MRI and contractility by echocardiography will be investigated, with advanced imaging expert Deborah Kwon, MD, Director of Cardiac MRI at Cleveland Clinic, playing a key collaborative role in this regard. In addition, a subset of patients will undergo high-resolution cardiac CT for detailed structural characterization of the myocardial wall.

Novel analytical methods will be developed to characterize the 3D architectural complexity using deep learning techniques. Machine learning-based analytics will then be used to create predictive models of risk, which can be compared with current models and treatment criteria.

### Augmented clinical acumen through AI

“Both of these research projects are bringing 21st-century technology to diagnostics,” says Dr. Tang. “While artificial intelligence may not replace clinicians, it has the potential to make us smarter by helping us manage our patients with greater insight. The responsibility and opportunity for clinicians is to harness its potential.” ■

Contact Dr. Tang at 216.444.2121 and Dr. Estep at 216.444.7646.

# Cardiac Consult



## Continuing Education Opportunities for Today and Tomorrow

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[clevelandclinic.org/cvupdate](https://clevelandclinic.org/cvupdate)

Complimentary archived videos of this livestreamed CME event from October 2020

Get up to date on most major aspects of general cardiovascular care in this collection of 20-minute talks and panel discussions from top Cleveland Clinic cardiologists. The popular two-day course is presented as seven webcast-style videos corresponding to the event's seven topical sessions. These include three sessions on various aspects of cardiovascular disease prevention and management; sessions on structural heart disease, heart failure and heart rhythm disorders; and a special session on "clinical conundrums in your clinic."

*Note: These archived videos are not certified for CME credit.*

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

[clevelandclinic.org/mitralmasters2020](https://clevelandclinic.org/mitralmasters2020)

Complimentary archived videos of this livestreamed CME event from December 2020

In late 2020, Cleveland Clinic convened many of the nation's leading experts in mitral valve disease for a livestreamed version of this 1.5-day course. Now the course content is available as 39 focused videos from the event, most of them under 15 minutes. They explore the full range of mitral valve management issues with plenty of case-based examples. A few videos cover emerging technologies in transcatheter mitral valve repair and replacement. *Note: These archived videos are not certified for CME credit.*

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