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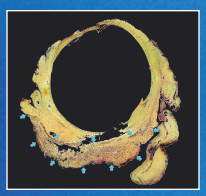

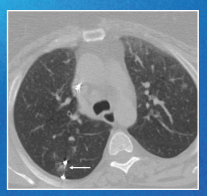

Cleveland Clinic

Cardiac Consult

Heart and Vascular News from Cleveland Clinic | Winter 2018

Finding New Clarity in Aorta and Aortic Valve Care

Dear Colleagues,

The great vessel can pose great challenges. That's clear from the story on page 4 of this *Cardiac Consult* issue outlining the Cleveland Clinic-led multiparty collaboration called MATADORS formed to overcome some of those challenges. The project aims to enhance understanding of the pathogenesis of aortic diseases and develop criteria for testing much-needed endovascular devices for use in the ascending aorta. The first findings are due out soon, and we're excited about where this collaboration may lead.

The aorta's challenges extend to the aortic valve itself, and two more stories here showcase progress on that front. On page 8 we profile a review of our recent experience with aortic valve repairs — the largest series published to date — and report heartening findings on the durability of this appealing but not widely offered alternative to aortic valve replacement. And on page 7 we report some of the first U.S. implantations of the Inspiris Resilia aortic valve following its FDA approval last year. This new device promises to be a more-durable bioprosthesis option for younger patients requiring aortic valve replacement — and is designed to facilitate future valve-in-valve procedures if needed.

This issue also shares news and insights beyond aortic care, from our success at driving down heart failure readmissions with an innovative EMR-embedded checklist for discharge preparedness (page 11) to our experience with a novel approach to resection of nonpalpable lung nodules (page 14). Whatever your interests or needs across the spectrum of cardiology and cardiothoracic surgery, we welcome the opportunity to partner with you.

Respectfully,

Lars G. Svensson, MD, PhD

CHAIRMAN | Sydell and Arnold Miller Family Heart & Vascular Institute

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

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Vitals

Heart & Vascular Vitals: Focus on Cardiothoracic Surgery

A sampling of Cleveland Clinic's Miller Family Heart & Vascular Institute outcomes and volumes. This issue's focus is cardiothoracic surgery. For more outcomes data, visit **clevelandclinic.org/outcomes**.

4,607

Number of cardiac surgery cases in 2017

>50%

Proportion of our case mix that requires procedures more complex than those rated by the Society of Thoracic Surgeons (STS)

Yet that daunting case mix doesn't prevent delivery of standard-setting outcomes:

3 for 3 in STS Adult Cardiac Surgery Database

Cleveland Clinic achieved a 3-star (highest) rating in 3 categories of the STS Adult Cardiac Surgery Database for the 3-year period ending June 2017:

- Coronary artery bypass graft surgery (CABG)
- Aortic valve replacement (AVR)
- AVR + CABG

Outcomes in common procedures for which the STS requests data continued to be exemplary throughout 2017. Examples:

	Operative mortality	STS predicted mortality
CABG (N = 835)	0.8%	1.6%
AVR (N = 364)	1.1%	1.8%
AVR + CABG (N = 181)	1.1%	3.2%
MV repair (N = 402)	0.0%	0.6%
MV repair + CABG (N = 83)	2.4%	4.9%

Those outcomes were matched in procedures for which STS doesn't report risk-adjusted benchmarks. Examples (full-year 2017 data):

	Operative mortality
Other valve surgery* (N = 636)	3.8%
Aorta surgery (N = 882)	2.4%
Septal myectomy (N = 177)	0.6%

*Other than AVR or mitral valve (MV) repair/replacement or those surgeries combined with each other or with CABG. Visit clevelandclinic.org/e15 for more.

MATADORS:

Novel Partnership Rises to Challenges of the Ascending Aorta

A distinctive multistakeholder partnership spearheaded by Cleveland Clinic is aiming to improve the odds for patients with acute aortic dissection and other diseases of the thoracic aorta.

The Multidisciplinary Study of Ascending Tissue Characteristics and Hemodynamics for the Development of Novel Aortic Stentgrafts (MATADORS) brings together Cleveland Clinic surgeons and biomedical engineers with R&D leaders from the top five endovascular stent graft medical device companies and with U.S. Food and Drug Administration (FDA) staff.

The project, which began in 2016, has two goals:

- To closely study and better understand the tissue architecture and molecular changes involved in the pathogenesis of aortic dissection and aneurysms
- To develop optimal criteria for testing new endovascular devices to treat the ascending aorta, as no such devices are currently approved by the FDA

Focusing Multiple Experts on the Same Solution

"MATADORS is a study that has brought together many of us from different disciplines with the understanding that we have a host of unanswered questions about aortic disease, which is a growing epidemic of often fatal problems," says Eric Roselli, MD, Surgical Director of Cleveland Clinic's Aorta Center.

The partnership is orchestrated by Kelly Emerton, PhD, Senior Director of Product Development and Commercialization at Cleveland Clinic Innovations, the commercialization arm of Cleveland Clinic. She explains the project's genesis as follows: "In the past, when I would meet with clinicians to move their ideas forward, I would note that we have prototyping capabilities for R&D and we have researchers in biomedical engineering. The thought was that we could cohesively work across various Cleveland Clinic institutes to drive a project forward, given our internal expertise, and then marry that with FDA and industry, thereby bringing all parties to the table. The concept behind MATADORS was to orchestrate an unprecedented alliance to better design endovascular treatments and develop better verification and validation testing parameters for devices used to treat ascending aortic diseases."

Acute Aortic Dissection Poses Unmet Needs

Indeed, there is a great unmet need for new approaches to thoracic aortic diseases, which are estimated to kill more than 40,000 people in the U.S. annually. The incidence appears to be rising, although this may be due in part to increased detection via wider use of chest CT scans.

About 5,000 open surgical repairs are performed annually in the U.S. for acute aortic dissection specifically, but that's thought to represent only about half of the total need. It's unknown how many people die at home with the condition undiagnosed, but data suggest acute aortic dissection may account for 8 to 10 percent of sudden deaths, Dr. Roselli says.

Even when patients do reach the hospital, many are deemed unsuitable for open corrective surgery, which involves putting the patient on cardiopulmonary bypass, excising the damaged tissue and replacing it with a graft.

Cleveland Clinic's outcomes in acute aortic dissection are superior to U.S. and world averages, with a mortality rate of about 5 to 10 percent following emergency surgery compared with nearly 20 percent elsewhere. And at Cleveland Clinic,

"If we are putting in devices without cutting out tissue, we need to really understand how the stent will interact with the tissue, including how strong it needs to be." – Eric Roselli, MD

only about 7 to 8 percent of candidates are deemed unfit for the open procedure, typically for reasons such as coma, cardiac arrest, extreme comorbidities or extensive gut gangrene.

"But we can still do better," Dr. Roselli notes. "We don't operate on all patients. The disease process, combined with the need for a major emergency operation, is a serious problem. In elective situations, surgical mortality is less than 1 percent. If we had a less invasive way to treat dissection in dire situations, we could perhaps bridge patients during the acute emergency and then do an elective operation later."

Dr. Roselli and the Aorta Center team have published heavily in this area, and Cleveland Clinic's Department of Thoracic and Cardiovascular Surgery is deeply vested in accruing clinical data for better care of patients with dissection.

Study Underway, First Data Due Soon

MATADORS has already enrolled more than 60 of a planned 400 patients who fall into one of the following arms:

- Patients with ascending dissection (study population)
- Patients with ascending aneurysm (disease control group)
- Transplant recipients or patients needing root replacement without aneurysm (non-disease control group)

Ultrasound images are taken intraoperatively while the chest is open, to directly examine in situ biomechanical properties of the ascending aorta. Resected specimens are analyzed in detail for biomechanical, histologic and hemodynamic properties. Genetic information is also being analyzed.

Such information will be essential for device development. "If we are putting in devices without cutting out tissue, we need to really understand how the stent will interact with the tissue, including how strong it needs to be," Dr. Roselli explains.

The project is exploiting what's likely to be a short time window, he notes: "We're moving more and more to endovascular approaches for treating various segments of the aorta, but we're still doing open surgery on the ascending aorta. So as long as we're cutting out pieces of tissue, we might as well study them from as many perspectives as possible."

Continued next page ›

Snapshots of a few of the study methods employed in MATADORS

Top left: Computational modeling of simulated flow and compliance of the ascending aorta. **Top right:** Uniaxial testing of extracted specimens to compare in vivo and ex vivo mechanical properties of ascending aortic tissue in acute dissection versus nondissected tissue. **Bottom left:** Analysis of resected samples from aortic dissection and aneurysm patients to evaluate histopathology and biomechanical properties of ascending aorta regions. **Bottom right:** Histopathologic evaluation of dissected tissue to assess proteoglycan/glycosaminoglycan content and ratio within treatment groups and within regions of the aorta.

The team has submitted for publication a manuscript on two novel proteins discovered in the aortic wall among the first 60 MATADORS patients. That will be followed by another on results from biomechanical testing showing varied behavior of tissues in different aorta segments, as well as a manuscript on the team's in vivo epiaortic imaging findings.

"We're just starting to scratch the surface," Dr. Roselli says. "I think we'll see an abundance of other really important research as this effort grows."

New Model for Device Development?

Dr. Emerton notes that device industry leaders have joined the collaboration to identify commonly adopted end points for their device development while still guarding their respective proprietary information. "All the participants will design their devices independently," she explains, "but they'll uniformly use these data to drive better design inputs and to determine, in conjunction with the FDA, the best methods for testing safety and efficacy."

She describes the initiative as a new model to be applied to any number of clinical challenges: "We plan to get the key parties together at the table to design better regulatory testing to evaluate and get these devices out the door faster, more efficiently and better designed to help patients." ■

Contact Dr. Roselli at roselle@ccf.org and Dr. Emerton at emertok@ccf.org.

New Aortic Bioprosthesis Designed for Durability Makes Its U.S. Debut

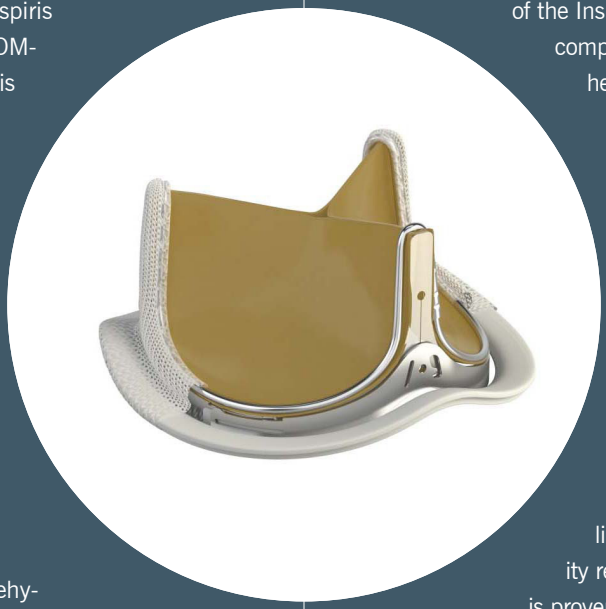
Cleveland Clinic among first users of the Inspiris Resilia valve

Cleveland Clinic has performed some of the very first commercial U.S. implantations of the Inspiris Resilia aortic valve following the device's FDA approval last year. The successful operations, performed in several patients in mid-January, follow Cleveland Clinic's investigational use of the bovine pericardial bioprosthesis in numerous patients as part of the ongoing multicenter COMMENCE trial, whose two-year results formed the basis for FDA approval (see consultqd.clevelandclinic.org/resilia). Cleveland Clinic investigators plan to soon report three-year results of the COMMENCE trial, which remain positive.

"We are proud to be among the very first U.S. centers to offer this promising new bioprosthesis to appropriate surgical aortic valve replacement (AVR) patients outside of a research context," says cardiothoracic surgeon Lars Svensson, MD, PhD, Chairman of Cleveland Clinic's Miller Family Heart & Vascular Institute.

Dr. Svensson performed Cleveland Clinic's first commercial implantations of the Inspiris valve and is an investigator with COMMENCE. He says the new prosthesis is notable in several ways:

- **Use of dry-storage technology developed at Cleveland Clinic.** This aspect of the valve's novel Resilia tissue technology makes transporting the valve less costly and may give it longer shelf life.
- **New anti-calcification properties.** These also derive from the valve's Resilia tissue technology and involve additional steps to dehydrate the valve tissue and reduce fat content. The aim is to enhance durability relative to other bioprostheses. "If this valve resists deterioration over time, we see tremendous potential for its use in younger patients," says Dr. Svensson.
- **An expandable frame.** This aspect, designed to enable pliability similar to that of the older Edwards model 2700 (Perimount) valve, promises enhanced potential to facilitate a later valve-in-valve transcatheter AVR procedure if needed. "Until now, this hasn't been possible with the newer valves, which are more rigid," Dr. Svensson explains.



That pliability enabled Dr. Svensson to combine use of the Inspiris prosthesis with placement of a composite valve graft in one of the cases he performed in mid-January — the first time the new prosthesis has been used in such a combination. The composite valve graft was needed to address an aortic root aneurysm with valve stenosis.

He notes that while this pliability and the resulting option for later valve-in-valve procedures are welcome, the new device's greatest prospective benefit lies in its potential for longer durability relative to other bioprostheses. "If it is proven over the long term, it would be a game changer for younger patients," he says.

On that score, the latest COMMENCE results — through three years of follow-up — remain encouraging. "The clinical outcomes and freedom from structural failures observed at two years have been maintained," Dr. Svensson says. ■

Photo of Inspiris Resilia valve courtesy of Edwards Lifesciences.

Aortic Valve Repair: Durability Demonstrated in Largest Series to Date

Shown to be effective, durable option for regurgitation at experienced centers

Only 1 in 10 patients undergoing surgical aortic valve repair required reoperation within a decade after surgery, report investigators with the largest series of aortic valve repairs published to date. Durability was particularly strong for patients undergoing repair with annular support and those receiving commissural figure-of-8 suspension sutures.

"We've shown that, at experienced centers, valve repair is effective and durable for treating aortic regurgitation," says principal investigator Lars Svensson, MD, PhD, Chairman of Cleveland Clinic's Miller Family Heart & Vascular Institute. "But only a handful of centers across the U.S. will attempt aortic valve repairs, as these procedures require a steady number of cases to maintain expertise and skills."

One of those centers is Cleveland Clinic, where all 1,009 aortic valve repairs in this new series were conducted. The report was published by *Annals of Thoracic Surgery* (2017 Dec 11 [Epub ahead of print]).

When Replacement Isn't Always Ideal

While valve replacement is the standard of care for patients with severe aortic valve dysfunction, the less-common approach of aortic valve repair holds several advantages for appropriate patients with aortic regurgitation. First there's the potential for extended durability, particularly for patients younger than 65. There's also freedom from the need for lifelong anticoagulation required with mechanical valves and a reduction in the risks of stroke and infection with repair versus replacement.

"We perform aortic valve repairs as minimally invasive keyhole operations, and previous data from our group have shown that hospital mortality in these procedures is very low," Dr. Svensson notes. "For instance, mortality was just 0.41 percent in our study of 728 patients undergoing repair of a bicuspid aortic valve [*Ann Thorac Surg.* 2014;97:1539-1547], which occurs in 1 to 2 percent of the population. So we knew that repair was safe, and much progress has been made in avoiding early repair failure."

He explains that the current study was undertaken to address the scarcity of data on late outcomes from aortic valve repair and to better inform guidelines on patient selection and repair durability.

Study Essentials

Dr. Svensson and colleagues reviewed records for all 1,124 patients scheduled for elective primary aortic valve repair at Cleveland Clinic from January 2001 to January 2011. Most patients had aortic regurgitation (75 percent), followed by aortic stenosis (6 percent), and both regurgitation and stenosis (3.4 percent). The remaining 15 percent had miscellaneous indications.

Ten percent of patients had their planned repair aborted and underwent replacement; significant risk factors for conversion to replacement were more-severe aortic regurgitation and valve calcification. The remaining 1,009 patients underwent repair via various techniques, including cusp repair with commissuroplasty in nearly half of cases (48 percent) as well as commissural figure-of-8 suspension sutures, debridement, free-margin plication or resection, and annulus repair with resuspension, root reimplantation or root remodeling.

In-hospital outcomes among these 1,009 patients included death in 1.2 percent, stroke in 1.3 percent and reoperation for valve dysfunction in 1.4 percent.

Immediate postoperative aortic regurgitation grade was none/mild in 94 percent of patients, moderate in 5 percent and severe in 1 percent. At 10 years post-repair, aortic regurgitation grade was none in 20 percent, mild in 33 percent, moderate in 26 percent and severe in 21 percent.

Long-term outcomes were as follows:

- Freedom from aortic valve reoperation was 97 percent at one year, 93 percent at five years and 90 percent at 10 years.
- Survival was 96 percent at one year, 92 percent at five years and 83 percent at 10 years.

"While survival during the first year is somewhat less than for the matched general population," says Dr. Svensson, "these results show that aortic valve repair can be done safely and with early mortality and morbidity similar to those with valve replacement."

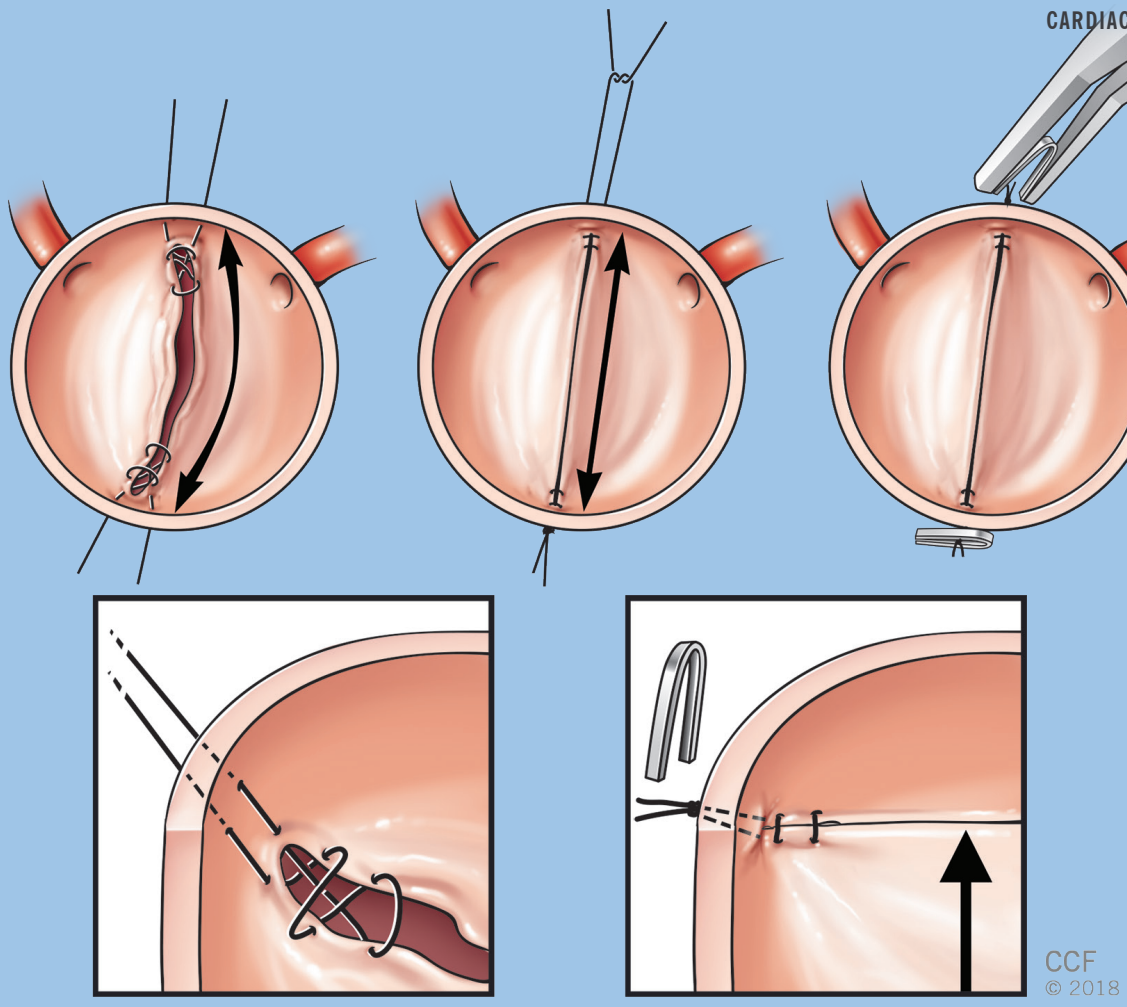


Figure. Illustration of aortic valve repair with figure-of-8 (Svensson) suspension sutures, which were associated with reduced reoperative risk in the study. This stitch increases the area of apposition for valve leaflets and elevates them to achieve more tension. The result is greater contact area and apposition, which may provide redundancy if the leaflets stretch over time.

He noted several important additional findings:

- Aortic valve cusp repair was more durable when performed with an annulus-stabilizing root procedure than when performed alone. "We found that having support for the valve is important, just as it is in mitral valve repair," he says.
- Among cusp procedures, the commissural figure-of-8 suspension suture (see Figure), which Dr. Svensson developed, was associated with the lowest risk of reoperation, whereas commissuroplasty was associated with the highest risk.
- A comprehensive approach to all components of the aortic valve using the CLASS scheme — for commissure, leaflet (cusps), annulus, sinus and sinotubular junction — appears to be needed to ensure a durable repair.

Pinpointing Repair Candidates

Dr. Svensson says the best candidates for aortic valve repair versus replacement include patients with a three-leaflet valve with an enlarged aortic root as well as younger patients with a bicuspid valve with no perforations and without calcification. "I now offer repair to about 70 percent of patients with a bicuspid valve and to about 90 to 95 percent of those with a three-leaflet valve with an enlarged aortic root," he explains.

Rates of aortic valve repair may increase further if current explorations of transcatheter aortic valve repair via a transfemoral approach pan out. "But for now," Dr. Svensson concludes, "surgical repair allows experienced centers to offer appropriate patients survival rates and repair durability that match what we see with bioprosthetic aortic valve replacement — without some of the potential downsides of replacement." ■

Contact Dr. Svensson at svenssl@ccf.org.

Image of the Issue

VENOUS INJURIES FROM LEAD EXTRACTION: MORE COMMON THAN RECOGNIZED

This image shows a transverse section of a fibrous cuff dissected from around an extracted lead of a cardiac implantable electronic device (CIED) with evidence of transmural venous injury. All three layers of the vein are present (between the arrows) along with evidence of thermal injury from use of a laser-powered sheath.

The image illustrates findings from a new Cleveland Clinic study reported in *Heart Rhythm*, the first large investigation to characterize the histopathology of extracted CIED leads. It found that microscopic venous injuries during transvenous lead extraction (TLE) are common but may go unrecognized clinically.

"As CIED use expands, we've encountered more cases where CIED leads need to be removed, due to infection, lead malfunction or other indications," says lead author Khaldoun Tarakji, MD, MPH, a Cleveland Clinic electrophysiologist.

Lead extraction is usually done transvenously, with a 1 to 2 percent rate of major complications such as venous laceration.

While that low rate is welcome, it makes identifying predictors of complications a challenge. So Dr. Tarakji and colleagues set out to define the incidence and extent of venous injuries after TLE on a microscopic level and compare them with the rate of clinically documented venous lacerations.

Among 861 lead extractions done at Cleveland Clinic over the 30-month study period, venous injury was seen at a microscopic level in 9.3 percent of extractions despite a much lower rate of clinical adverse events (1 percent). Predictors of vein injury included older age of lead, defibrillator (vs. pacemaker) leads and use of laser-powered sheaths for extraction.

"Venous injuries with lead extraction happen more frequently than we observe clinically," says Dr. Tarakji. "This was a wake-up call." He adds that these findings can help inform decisions around whether to remove or abandon a lead, especially in noninfectious indications for extraction. ■

For more, see consultqd.clevelandclinic.org/venousinjury or contact Dr. Tarakji at tarakjk@ccf.org.

Heart Failure Checklist

Tames HF Readmissions, Garners National Health IT Honor

If heart failure (HF) readmissions are to be prevented, the time to make a difference is during in-hospital discharge preparation or transitions at discharge.

That was the hypothesis behind Cleveland Clinic's Heart Failure Checklist when it was conceived in 2011. The real-time electronic checklist — one of the first in the nation to be fully integrated into the electronic medical record (EMR) — has since borne out that hypothesis in two big ways.

First it enabled Cleveland Clinic to achieve its lowest-ever 30-day HF readmission rates — and to sustain those rates for three years and counting. And now it has helped Cleveland Clinic win the 2017 HIMSS Enterprise Davies Award from the Healthcare Information and Management Systems Society (HIMSS). The award, the highest honor from HIMSS and the only one granted to healthcare providers, recognizes outstanding achievement by an organization in using health information technology (IT) to substantially improve patient outcomes and value.

"The Heart Failure Checklist leverages analytics from the EMR and uses clinical decision support to ensure that every patient with HF is identified while in the hospital and then receives appropriate multidisciplinary care," says Umesh Khot, MD, Vice Chair of Cardiovascular Medicine, who spearheaded the project.

"The checklist does this with real-time data inputs at the point of care that reflect the true multidisciplinary coordination of care involved in managing patients with HF," adds Randall Starling, MD, MPH, Medical Director of Cleveland Clinic's Kaufman Center for Heart Failure and part of the leadership team behind the project. "It ultimately leads to an electronic 'hard stop' in the EMR to ensure that all checklist items are completed for the patient before discharge can proceed."

Continued next page ›

The Backstory

The project was a long time coming, notes heart failure cardiologist Corinne Bott-Silverman, MD, another member of the project's leadership team. "Programs to reduce HF readmissions at our organization had been attempted with little success, from discharge follow-up calls to telemonitoring and other approaches," she explains. "After much data analysis, we found that preventable readmissions tend to occur early."

That observation spurred the hypothesis that success in reducing HF readmissions would lie in interventions during patients' hospital stay and in transition at discharge. "So we proposed an HF discharge checklist and corresponding in-hospital care metrics," notes Dr. Khot.

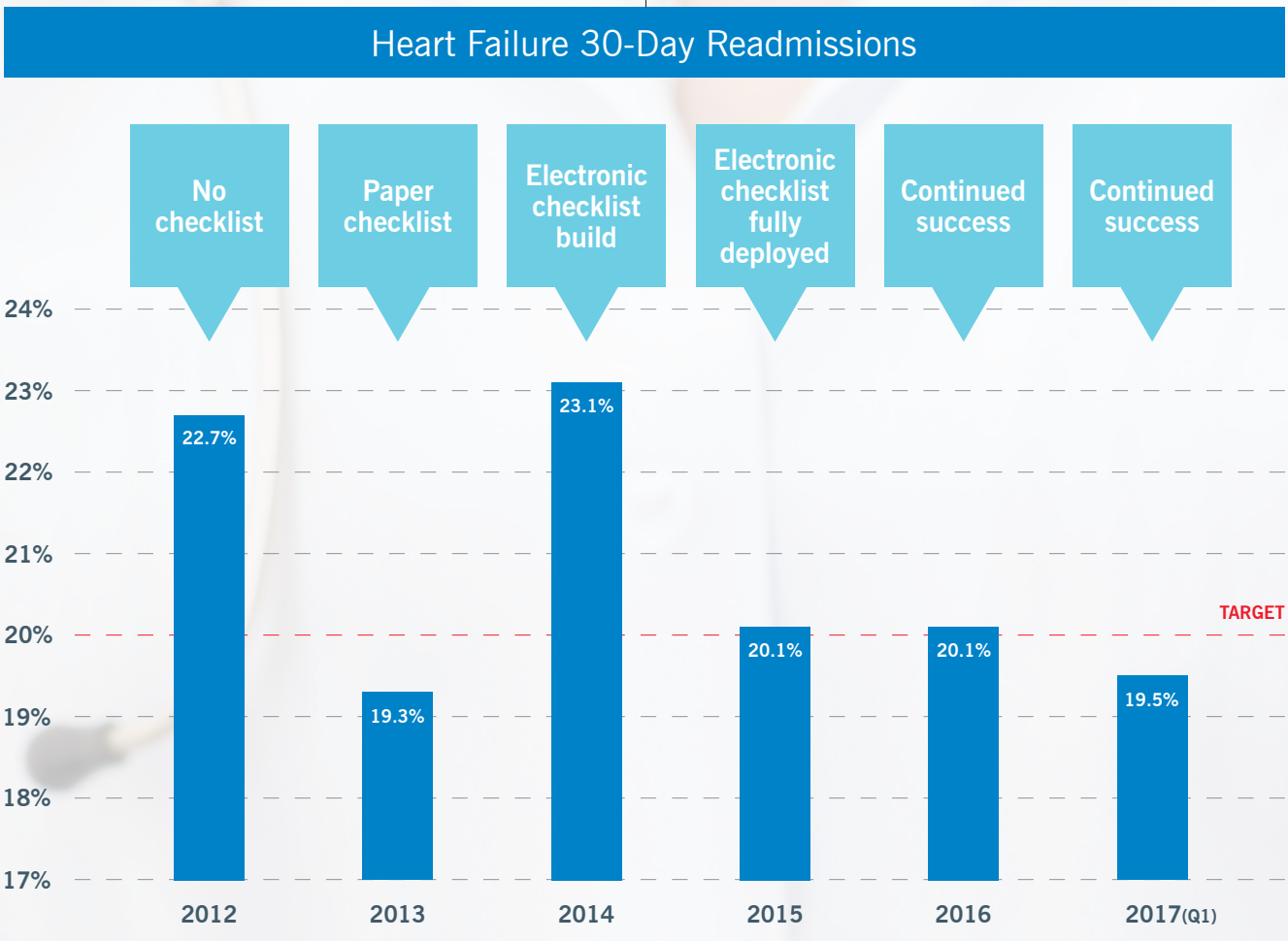
The checklist was first developed in paper form and called for information on patient readiness for discharge to be supplied by nursing, pharmacy, nutrition care management, and the physician or advanced practice provider. The aim was to bring all discharge-relevant information together in one place for easy tracking.

Proof of Concept

The paper checklist was tested in a 12-week pilot study with two services on a heart failure unit. Patients managed with the checklist had a 14.6 percent 30-day readmission rate, which compared favorably with the 22.1 percent rate for HF controls managed without the checklist and the unit's 25 percent readmission rate from the prior year. "Patients managed with the checklist had one of the lowest HF readmission levels we had seen," says Dr. Starling. "These results grabbed our attention."

The concept was further validated when readmissions for the unit's patients spiked when checklist use was temporarily stopped after the pilot — and again when rates went back down to pilot levels when checklist use was resumed.

"We had proven the concept, but we needed to take it to a larger scale," observes Dr. Khot. Yet the checklist's paper format made that a huge challenge, as it required labor-intensive manual completion and had limited reporting and analysis capabilities.



From Paper to Electronic

So the project team created a governance structure to transition the HF discharge checklist from paper to electronic form and secured funding for contracted resources. They then identified the key roles from the paper checklist and where documentation for each would be discretely captured in the EMR for the electronic checklist. This was done by a multidisciplinary team — representing nursing, quality, IT, nutrition, pharmacy and care management — formed with the clinical leadership.

Key features of the resulting electronic checklist included:

- **Real-time updating of the checklist report** as any of the multiple users completes data entry. The result is "unified electronic documentation" where physicians, nurses, nutritionists, pharmacists and care managers enter updates in a single report at the point of care.
- **Multilevel inclusion criteria capabilities** that scan EMRs throughout the institution to identify patients with an HF diagnosis across all services while excluding inappropriate patients, such as those admitted with observation status.
- **Real-time checklist visualization**, including an electronic hard stop to ensure checklist compliance by requiring completion of any remaining tasks before the patient can be discharged.

Realities of Implementation

After more than 13 months developing the paper checklist into its electronic version, the team was ready to take the electronic tool live in November 2014.

But implementation presented its own challenges. Chief among them was insufficient awareness of the checklist among many front-line caregivers and/or lack of awareness of the institutional priority that had been given to reducing HF readmissions. Manifestations included excessive use of the checklist on patients who didn't need it, concern that checking boxes was being prioritized over care delivery, and refusal to use the checklist because of misunderstanding about the motivations behind it.

"We had focused too much on the technology at the expense of human factors," observes IT project manager Tim Sobol, MS. "It became clear that we needed to educate front-line caregivers on why we were doing this and engage them in the process."

So the team created a simple infographic explaining the "why, who and what" behind the checklist, with supporting details. This served as the centerpiece for a new round of education supporting the checklist's launch. "Our education emphasized that this was about ensuring care coordination across the various disciplines involved in HF care," explains Kathleen Kravitz, a quality director with Cleveland Clinic's Miller Family Heart & Vascular Institute. "We also stressed that readmission prevention is a process that starts at admission and informs all aspects of normal clinical care, not just the portion right before discharge."

Rollout and Success

With this additional educational push, the checklist was embraced and implemented for more than 1,500 patients with HF over the first six months of rollout. As detailed in the graph on page 12, 30-day HF readmission rates have been at or below the 20 percent target level for each year since introduction of the electronic checklist in late 2014.

Beyond the clear patient benefits from fewer readmissions, the checklist has already more than offset its contracted resource cost through reductions in CMS penalties for excess HF readmissions at Cleveland Clinic's main campus hospital alone.

Words of Advice

"The Heart Failure Checklist has been a technical and operational success that's now been in place for several years, with 100 percent implementation across our Heart & Vascular Institute," says Dr. Khot. "We've seen significant decreases in our readmissions locally and in public reporting, and there's been a significant return on investment for the project."

For other organizations considering a similar initiative, he offers two key pieces of advice:

- **Transitioning from paper to an electronic checklist is not as easy as it may seem.** "In our case, it was only possible because of at least 10 other incremental IT initiatives dating back to 2011 that enabled this project to succeed," he notes. These included things like introducing listings of discrete diagnoses in the EMR, establishing follow-up appointment orders in the EMR and providing "tableau" reporting of performance metrics for easy data visualization. "I call these foundational initiatives, and they don't happen overnight."
- **Don't underestimate the importance of the human/technology interface.** "Front-line caregivers need to be thoroughly educated about the reasons and benefits behind new IT initiatives," Dr. Khot says. "This is something we're much more cognizant of as a result of this project." ■

Contact Dr. Khot at khotu@ccf.org, Dr. Starling at starlir@ccf.org and Dr. Bott-Silverman at bottsic@ccf.org.

Microcoil Localization: A Novel Way to Guide Resection of Nonpalpable Lung Nodules

The use of CT to screen for lung cancer has enabled detection of lesions at increasingly smaller sizes. Yet that positive development brought along with it a clinical conundrum: "Until recently, patients with very small lesions were told that their only option was to wait until the lesion could be palpated before having it removed," says Cleveland Clinic thoracic surgeon Daniel Raymond, MD.

That was before the advent of an innovative procedure that's rapidly changing the diagnostic and treatment picture for patients with very small nodules and ground-glass lung lesions. The procedure, known as microcoil localization or by several alternate names (nodule localization, needle localization, fiducial localization), allows thoracic surgeons to accurately resect these lesions in a minimally invasive fashion.

"We're no longer dependent on lesions being palpable to pinpoint their location," notes Dr. Raymond. "Wire localization enables us to localize questionable areas, remove them thoracoscopically and make a diagnosis."

It Takes a Team

Percutaneous nodule localization is a complex technique offered at Cleveland Clinic and a small number of other U.S. centers. It requires close teamwork between a radiologist, who locates the nodule and places the microcoil, and a thoracic surgeon, who removes the lesion.

"We're no longer dependent on lesions being palpable to pinpoint their location. Wire localization enables us to localize questionable areas, remove them thoracoscopically and make a diagnosis."

– Daniel Raymond, MD

The primary team at Cleveland Clinic — consisting of Dr. Raymond, thoracic surgeon Sudish Murthy, MD, PhD, and thoracic radiologist Jason Lempel, MD — has performed the procedure on approximately 60 patients since February 2015. All Cleveland Clinic thoracic surgeons and one additional thoracic radiologist have since been trained in details of the procedure.

"Microcoil localization isn't the first attempt at developing a technique to enable pinpointing of small lesions, but we've found it to be the best and most accurate option," says Dr. Lempel.

How It's Done

Percutaneous microcoil localization and subsequent video-assisted thoracoscopic surgery (VATS) resection is performed in two stages:

- Using CT guidance, the radiologist inserts a needle (preloaded with a soft, fiber-coated platinum thread) through the chest, into the lung and then into the target nodule. When the needle tip reaches the nodule, the thread is pushed out into the lung, allowing it to conform to its natural coil shape and thereby marking the location of the nodule. The radiologist then retracts the needle into the pleural space and deploys the coil's opposite end at the edge of the lung before pulling the needle out of the body. The final configuration (Figure 1) resembles a dumbbell, with one end of the coil anchored along the nodule and the other in the pleural space connected by a metallic thread.
- After the coil is placed, the surgeon makes an incision for a thoracoscope and deflates the lung. The surgeon locates the coil in the pleural space and resects it along with a wedge of tissue (Figure 2).

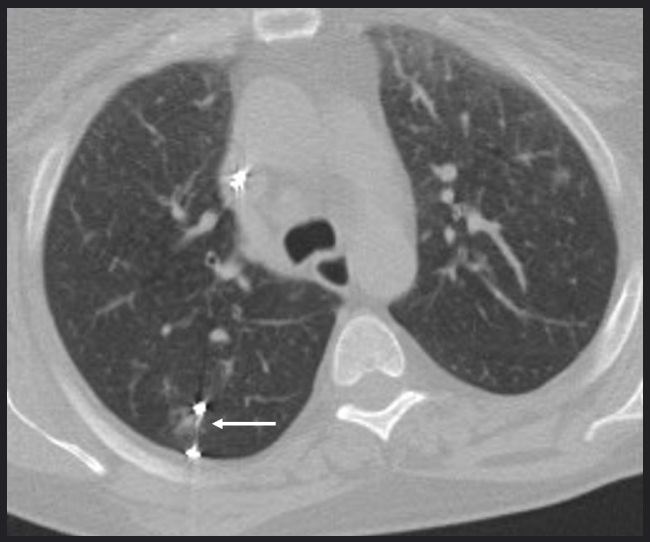


Figure 1. CT localization image showing a ground-glass nodule with a localizing microcoil (arrow) extending from the nodule back to the pleural surface and marking the nodule for subsequent VATS resection.

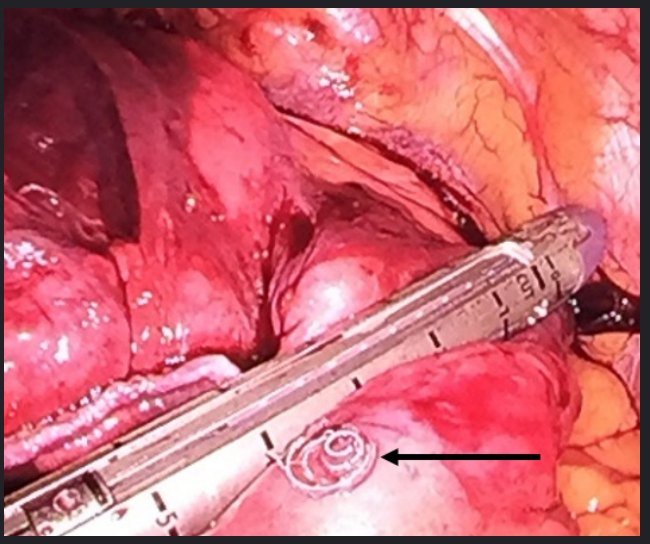


Figure 2. Intraoperative photograph showing a coil along the pleural surface (arrow) guiding the surgeon to the precise location for wedge resection.

At Cleveland Clinic, the resection is usually done without fluoroscopic assistance, as the radiologist tells the surgeon how many centimeters from the surface of the lung the distal end of the microcoil is located.

"We could use fluoroscopy to confirm that the cut is around the deep end of the coil, but it's preferable to limit radiation exposure to the patient and surgical staff whenever possible," Dr. Lempel explains.

In fact, a review of the team's first 20 cases confirmed a 100 percent success rate in retrieving the target lesion with clear margins.

Where It's Done

The optimal environment for this complex procedure is still being worked out. The team has tried two protocols. In one, the patient is placed under conscious sedation and the localizing coil is inserted in the radiology suite. The patient is then transferred to the OR and anesthetized for the resection.

The alternate method — and the team's preference — is to perform both stages of the procedure in one of Cleveland Clinic's hybrid ORs. This allows the patient to be anesthetized for the entire procedure, with the anesthesiologist controlling ventilation to obtain minimal motion of the lung during the procedure.

Advantages over Lobectomy

No matter where needle localization is performed, its advantages are clear:

- The need for biopsy is often eliminated. "It can be difficult to obtain enough tissue from a small nodule to do a biopsy," explains Dr. Raymond. "By removing the entire nodule in a wedge resection, we can get the information we need to determine whether additional treatment is required and what that should be."
- It decreases OR time and the patient's time under anesthesia.
- It lowers the risk of conversion to open thoracotomy.

As the team continues to accrue experience with microcoil localizations, Dr. Raymond is cautiously optimistic about its long-term outcomes. "The classic treatment is lobectomy," he says. "However, the probability of lymph node disease with these very small lesions is low, so a wedge resection may be all that's necessary."

"I believe microcoil localization will eventually eliminate the need for lobectomy and conversion to open thoracotomy in many of these situations," adds Dr. Lempel. "We're achieving clean margins with the minimal amount of tissue resected." ■

Contact Dr. Raymond at raymond3@ccf.org and Dr. Lempel at lempelj@ccf.org.

Consultation and Collaboration Reduce Prolonged Post-CABG Ventilation Rates

Cleveland Clinic helps a Midwestern academic center revamp its approach to early extubation.

When Froedtert & the Medical College of Wisconsin Froedtert Hospital entered into an affiliate relationship with Cleveland Clinic's Miller Family Heart & Vascular Institute in early 2016, a comprehensive assessment of the Milwaukee-based academic medical center's cardiovascular services was a key part of the process. That assessment revealed that one aspect of Froedtert Hospital's cardiac surgery service was not up to its broader standards — specifically, the rate of prolonged mechanical ventilation in patients following coronary artery bypass graft surgery (CABG).

The extent of the opportunity for improvement was clear from Froedtert Hospital's incidence of prolonged ventilation time (i.e., > 24 hours) following CABG for the first three quarters of 2016: 9.7 percent. This was higher than the Cleveland Clinic rate (6.5 percent) and the benchmark of 7.9 percent from the Society of Thoracic Surgeons (STS) national database.

The Froedtert & Medical College of Wisconsin (MCW) cardiovascular leadership saw the issue as a priority since early extubation after cardiac surgery reduces length of stay in both the ICU and the hospital and lowers patients' risk of developing pneumonia and other infectious complications. In response, they set out to improve the prolonged postoperative mechanical ventilation metric in their 20-bed adult cardiovascular ICU (CVICU) by following a plan-do-study-act model with assistance from Cleveland Clinic.

The Consultation Process

Early in the process, a Cleveland Clinic cardiothoracic anesthesiologist and a clinical consultant from Cleveland Clinic's Heart & Vascular Institute Affiliate Program analyzed Froedtert Hospital's postoperative ventilation data with the hospital's postoperative care team, underscoring the importance of this metric to the hospital's overall STS rating for CABG procedures. Key members of the Froedtert & MCW cardiovascular team made a site visit to learn from processes in place at Cleveland Clinic. Monthly conference calls were also held between the Froedtert & MCW cardiovascular team and Cleveland Clinic consultants before and after the site visit.

These efforts led to the formation of a CVICU interprofessional team at Froedtert Hospital to guide and champion efforts to change practice in support of early extubation following CABG. The team included nurse leaders, CVICU staff RN Quality Council co-chairs, critical care anesthesiology providers, respiratory therapists, a physical therapist and a pharmacist.

The Intervention: Empowerment Through Early Extubation Protocol

The interprofessional team drew on Cleveland Clinic recommendations and a literature review to develop a post-cardiac surgery early extubation protocol providing guidance to all caregivers for management during the preoperative, intraoperative, handoff (OR to CVICU) and postoperative phases of care. The protocol was designed to facilitate early identification of patients eligible for early extubation and to empower nurses and respiratory therapists to drive the early extubation process in appropriate cases.

Among the protocol's notable aspects:

- The postoperative portion is subdivided into assessments and actions specific to (1) the first six hours after surgery, (2) hours six to 24, (3) the time of extubation and (4) the period after extubation.
- Identification of candidates for early extubation and related communication are encouraged from the OR-to-CVICU handoff phase through the various postoperative phases.

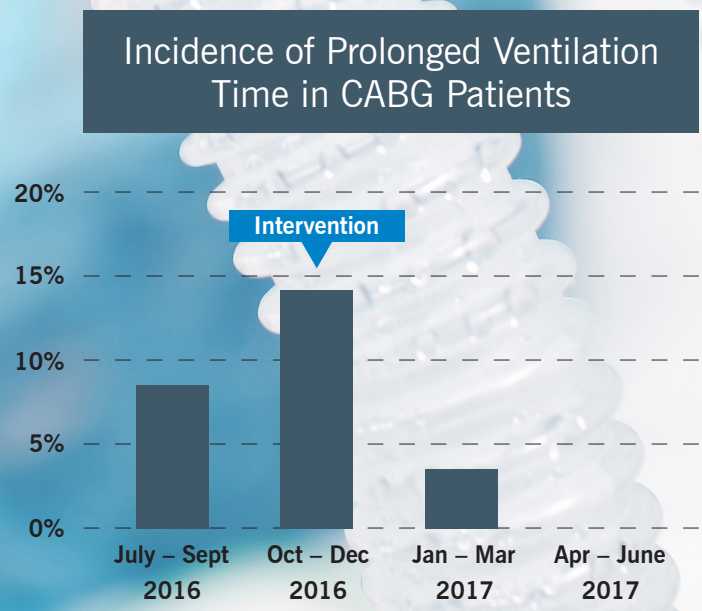


Figure. Graph showing the percentage of CABG patients with prolonged postoperative ventilation times at Froedtert Hospital over time. Requirements for prolonged ventilation plummeted after implementation of an early extubation protocol in the fourth quarter of 2016.

> "Success like this underscores the importance of data review, clinical protocols and collaboration, which is the foundation of our affiliate program." – Jeffrey Rich, MD

Results and Reflection

Following implementation of the protocol in the fourth quarter of 2016, Froedtert Hospital's rate of CABG patients with prolonged ventilation times plummeted in the subsequent two quarters — to 3.7 percent in the first quarter of 2017 (based on a sample of 27 CABG patients) and to 0 percent in the second quarter of 2017 (sample of 30 CABG patients) (Figure).

"The success we have seen in driving down post-CABG prolonged ventilation could not have been achieved without the efforts of a multidisciplinary team," says Froedtert & MCW cardiothoracic surgeon Paul Pearson, MD, PhD. "This team, including cardiovascular staff and providers, inpatient nursing, anesthesiologists and respiratory therapists, collaborated to achieve marked improvement in this critical patient safety measure. This achievement is a testament to our focus on improving quality using external benchmarks, and it further illustrates the value our partnership with Cleveland Clinic brings to patients in southeastern Wisconsin."

"Success like this underscores the importance of data review, clinical protocols and collaboration, which is the foundation of our affiliate program," adds Jeffrey Rich, MD, Chair of Strategic Operations for Cleveland Clinic's Heart & Vascular Institute Affiliate Program. "We congratulate the Froedtert team on a phenomenal effort to reduce the incidence of prolonged ventilation." ■

For details on affiliation opportunities with Cleveland Clinic's Heart & Vascular Institute, visit ahsproviders.com.

Research Roundup Quick Takes on Recent Cardiovascular Studies of Note

Enlarged Aortas Are Widespread in Former NFL Players

Middle-aged former National Football League (NFL) players are twice as likely as controls from the general population to have an enlarged ascending aorta — independent of age, body size, race and risk factors for aortic dilation. So finds a cross-sectional cohort study led by Cleveland Clinic researchers and published in *Circulation: Cardiovascular Imaging*. The study also showed that mean ascending aortic diameter was 12 percent greater in the retired athletes overall (n = 206) than in a well-matched male control group (n = 759).

"Even after adjusting for risk factors, former NFL athletes had a twofold higher prevalence of aortic dilation [aortic dimension > 40 mm]," says principal investigator Dermot Phelan, MD, PhD, Director of Cleveland Clinic's Sports Cardiology Center. "The players' aortic enlargement was observed despite their having a lower cardiovascular risk profile." While these results must be considered hypothesis-generating, he says they call for "caution and regular monitoring of elite athletes until further studies explore potential clinical implications."
More at consultqd.clevelandclinic.org/nflaorta.

LV Strain Promises Prognostic Utility in Obstructive HCM

Abnormal left ventricular global longitudinal strain (LV-GLS) appears to help identify at-risk patients with obstructive hypertrophic cardiomyopathy (HCM) who may benefit from earlier myectomy. That's the upshot of a large observational study by Cleveland Clinic researchers to determine whether LV-GLS offers incremental prognostic utility in the setting of obstructive HCM with preserved LV ejection fraction.

The study, published by the *Journal of the American Heart Association*, analyzed echocardiograms from 1,019 adults with documented HCM and preserved LV ejection fraction evaluated at Cleveland Clinic over a 10-year period. Echoes underwent LV-GLS measurement retrospectively. Over mean follow-up of 9.4 years, the primary end point — a composite of cardiac death or appropriate ICD discharge — was significantly associated with worsening LV-GLS and rose exponentially when strain worsened below about –7 percent. "If validated prospectively, these findings suggest we may be able to identify at-risk patients with obstructive HCM who stand to benefit from earlier myectomy, before onset of symptoms or LV dysfunction," says principal investigator Milind Desai, MD.
More at consultqd.clevelandclinic.org/strainhcm.

Pharmacomechanical Thrombolysis Doesn't Curb Post-Thrombotic Syndrome

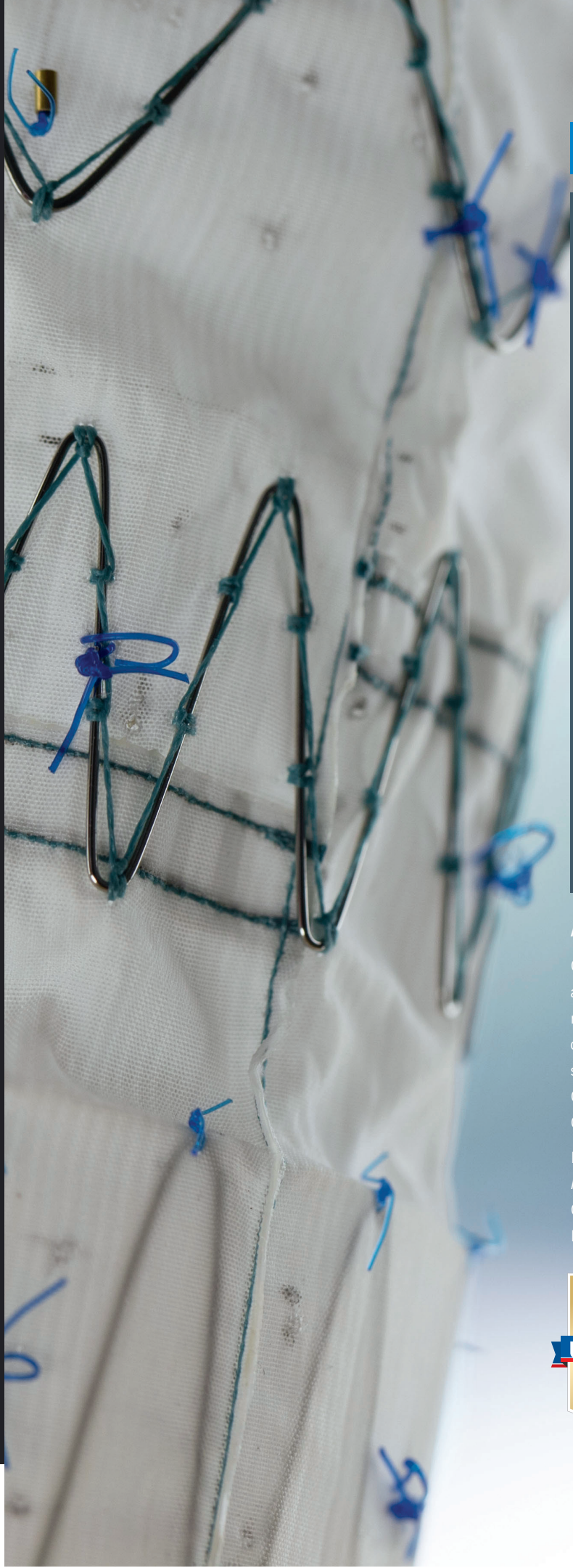
Pharmacomechanical catheter-directed thrombolysis to manage deep vein thrombosis (DVT) does not reduce the risk of post-thrombotic syndrome over anticoagulation alone, but it does raise the risk of major bleeding. That's the conclusion of the multicenter phase 3 ATTRACT trial, published in the *New England Journal of Medicine.*

Nearly 700 patients with acute proximal DVT involving the femoral, common femoral and/or iliac veins were randomized to either anticoagulation and compression stockings alone (control) or the control therapy plus pharmacomechanical thrombolysis (intervention). Whereas similar numbers of patients (about half) in the two groups developed post-thrombotic syndrome six to 24 months after treatment, major bleeding within 10 days of treatment occurred significantly more often in the intervention group. "The ATTRACT trial shows that first-line therapy for most patients with DVT should remain anticoagulation without pharmaco-mechanical thrombolysis," says study co-author and Cleveland Clinic cardiologist Heather Gornik, MD.
More at consultqd.clevelandclinic.org/attract.

EchoCRT Revisited: A Role for CRT Despite Narrow QRS Complex?

When the EchoCRT trial was halted in 2013, cardiologists largely abandoned the goal of extending cardiac resynchronization therapy (CRT) to a broader range of heart failure (HF) patients beyond the minority who had wide QRS intervals and met guidelines for this lifesaving therapy. But now researchers led by Cleveland Clinic's Niraj Varma, MD, PhD, have taken a second look at the EchoCRT data. They've identified a subgroup of patients with QRS duration of less than 130 ms who may benefit from CRT — specifically, those with a high ratio of QRS duration to left ventricular end-diastolic volume.

The new data come from a post hoc analysis of EchoCRT presented at the European Society of Cardiology 2017 Congress, so they require validation in a prospective trial. But Dr. Varma says they suggest "the door isn't shut" on the idea of applying CRT more broadly. If the findings pan out, an additional 20 percent of HF patients might qualify for CRT beyond those currently eligible by virtue of long QRS duration.
More at consultqd.clevelandclinic.org/echocrt.



RESOURCES FOR PHYSICIANS

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50 Years of Heart Health:

View our multimedia timeline of cardiovascular advances at **cle.clinic/2fcvBg2**

About Cleveland Clinic

Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,500 physicians and researchers represent 140 medical specialties and subspecialties. We are a main campus, more than 150 northern Ohio outpatient locations (including 18 full-service family health centers and three health and wellness centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada and Cleveland Clinic Abu Dhabi.

In 2017, Cleveland Clinic was ranked the No. 2 hospital in America in *U.S. News & World Report*'s "Best Hospitals" survey. The survey ranks Cleveland Clinic among the nation's top 10 hospitals in 13 specialty areas, and the top hospital in heart care (for the 23rd consecutive year) and urologic care.

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Cardiac Consult

Can't-Miss CME from Cleveland Clinic

Managing Valvular and Thoracic Aortic Disease: What Every Cardiologist Should Know in 2018

Fri., March 9, 2018, 7-9:30 p.m.
(complimentary dinner symposium)
Hilton Orlando | Orlando, Florida

An independent certified session at the ACC's 67th Scientific Session (ACC.18)

Info/registration: ccfcme.org/aorticacc

Managing Complex Challenges in Heart Failure: Integrating Advances in Therapies from Multiple Disciplines

Fri., March 9, 2018, 7-9:30 p.m.
(complimentary dinner symposium)
Rosen Centre | Orlando, Florida

An independent certified session at the ACC's 67th Scientific Session (ACC.18)

Info/registration: ccfcme.org/ephfacc

Multidisciplinary Master Class in Endocarditis and Other Cardiovascular Infections

Thu.-Fri., Apr. 12-13, 2018

InterContinental Hotel & Conference Center
Cleveland, Ohio

Over 30 expert faculty in ID, cardiac surgery, cardiology, radiology, neurosurgery, neurology, nephrology and behavioral health share insights in the first comprehensive interdisciplinary U.S. symposium on cardiovascular infections.

Info/registration: ccfcme.org/endocarditis18

Advanced EP Concepts: The Cleveland Clinic Perspective

Tue., May 8, 2018, 6:30-9 p.m.
(complimentary dinner program)
Boston, Massachusetts
(location TBD — see URL below)

An official educational satellite session at Heart Rhythm 2018 (not sponsored or endorsed by the Heart Rhythm Society)

Info/registration: ccfcme.org/hrsep18

Lead Management 2018: The Pursuit of Efficiency, Safety and Excellence

Wed., May 9, 2018, 6:30-9:30 p.m.
(complimentary dinner program)
Boston, Massachusetts
(location TBD — see URL below)

An official educational satellite session at Heart Rhythm 2018 (not sponsored or endorsed by the Heart Rhythm Society)

Info/registration: ccfcme.org/hrsleadmgt18

Mastering the Mitral Valve: A Case-Based Approach

Fri.-Sat., Nov. 30-Dec. 1, 2018

JW Marriott Essex House | New York City

Info/registration: ccfcme.org/mitralmasters

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17-HRT-4722