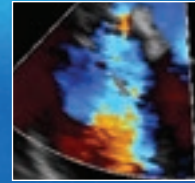




Pediatric  
Continuous-Flow  
Total Artificial  
Heart – p. 4



Simplified Frozen  
Elephant Trunk  
Repair: Midterm  
Outcomes – p. 10

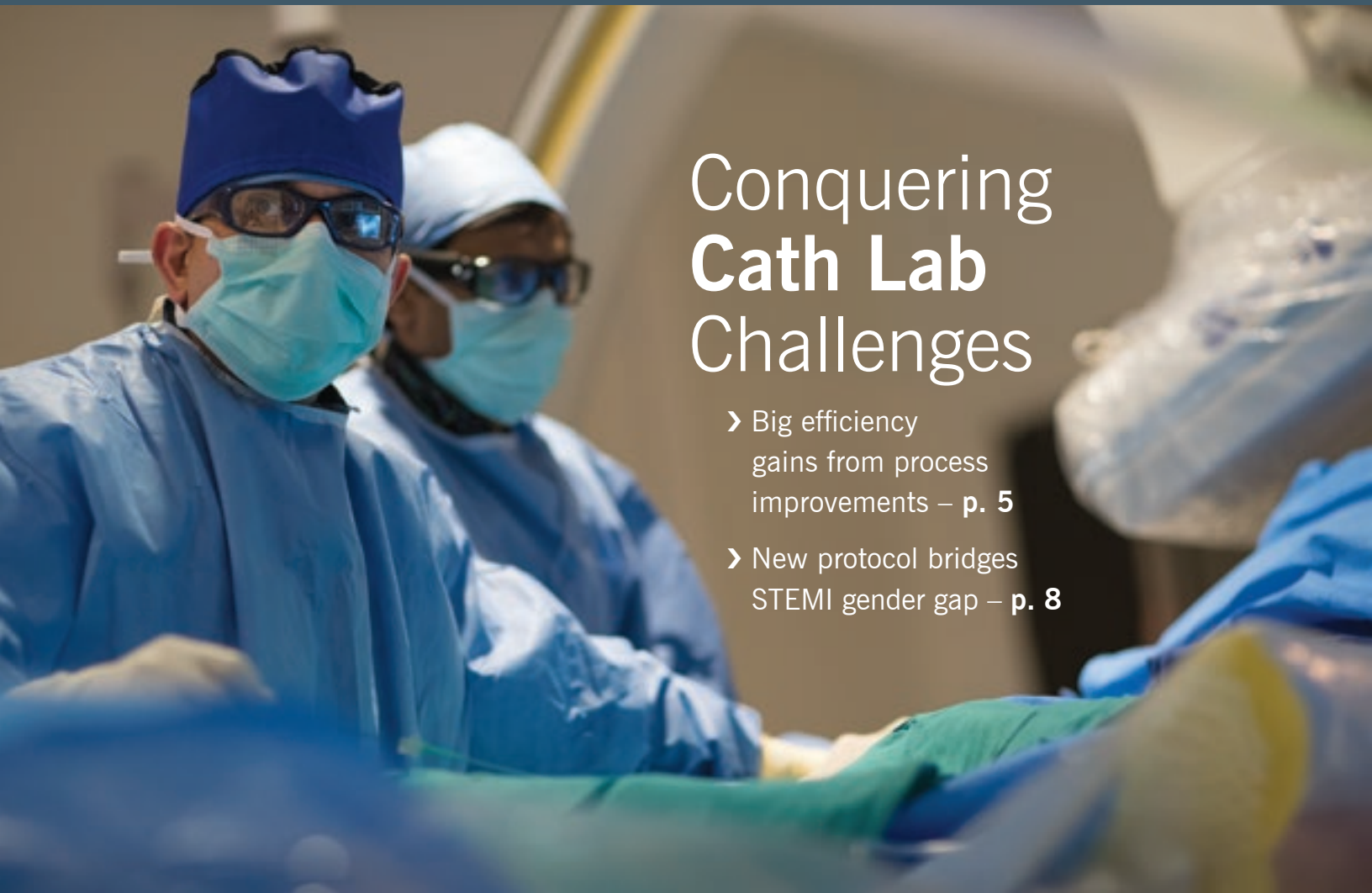


High-Risk Lead  
Extractions:  
Preparing for the  
Worst – p. 14



# Cardiac Consult

Heart and Vascular News from Cleveland Clinic | Spring 2018

A photograph of two surgeons in an operating room. They are wearing blue scrubs, blue surgical caps, and light blue face masks. They are looking down at a patient on the operating table. The background is slightly blurred, showing surgical equipment and lights.

## Conquering Cath Lab Challenges

- › Big efficiency gains from process improvements – p. 5
- › New protocol bridges STEMI gender gap – p. 8



## Dear Colleagues,

No matter how expert or technically adept providers may be, consistent success in healthcare delivery depends on supporting that expertise with systematic implementation of the best care processes and vigilance to continually improve them.

That's a theme that can't be missed in this issue of *Cardiac Consult*. The cover story profiles how a collection of process improvements in our catheterization lab yielded dramatic gains in cath lab efficiency and productivity while at the same time boosting caregiver satisfaction. A companion story on page 8 examines how introducing a comprehensive four-step protocol for managing ST elevation myocardial infarction (STEMI) not only improved patient outcomes overall but also went a long way toward closing the traditional gender gap in the quality of STEMI care. And the striking case study on page 14 illustrates one of the many times when our innovative protocol for performing high-risk lead extractions in a hybrid OR with surgical backup saved the day for a patient.

The article on page 12 showcases how we in Cleveland Clinic's Miller Family Heart & Vascular Institute work with outside affiliated provider organizations to help them benefit from this same systematic adoption of best practices — in this case, for continuous quality improvement in the echocardiography lab. We are always eager to collaborate in ways like this with you, our colleagues across the nation, as it invariably leads to higher-level care for all our patients and new insights for us as well as our partners. I welcome your inquiries and outreach.

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.

**Medical Editor**

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

**Managing Editor**

Glenn R. Campbell

**Art Director**

Michael Viars

**Marketing**

Jackie Riggle | Amy Wollmann | Colleen Burke

**Photography & Illustrations**

Cleveland Clinic Center for Medical Art & Photography  
Russell Lee Photography

*Cardiac Consult* is written for physicians and should be relied on for medical education purposes only. It does not provide a complete overview of the topics covered and should not replace the independent judgment of a physician about the appropriateness or risks of a procedure for a given patient.

© 2018 The Cleveland Clinic Foundation



# Vitals

## Heart & Vascular Vitals: Focus on Cardiovascular Medicine



A sampling of Cleveland Clinic Miller Family Heart & Vascular Institute outcome and volume metrics. This issue's focus is cardiology. For more outcomes data, visit [clevelandclinic.org/e15](http://clevelandclinic.org/e15) and [clevelandclinic.org/outcomes](http://clevelandclinic.org/outcomes).

### Transcatheter Aortic Valve Replacement (TAVR) in 2017

**469**

TAVR procedures (↑25% from 2016)

**84%** of cases done with monitored anesthesia care (vs. 50% in 2016)

**0.6%** in-hospital mortality

**0.4%**

rate of significant aortic insufficiency

**2 days** median post-procedure length of stay (vs. 3 days in 2016)

### Mechanical Circulatory Support in 2017

**91** durable LVADs placed (↑98% from 2016, highest annual count to date)

**68** temporary support devices placed (Impella or Centrimag/Rotaflow RVAD) (↑62% from 2016)

**100%** 1-month survival for primary LVADs (N = 64), vs. 95.5% INTERMACS benchmark\*

**93.9%** 12-month survival for primary LVADs (N = 16), vs. 83.3% INTERMACS benchmark\*

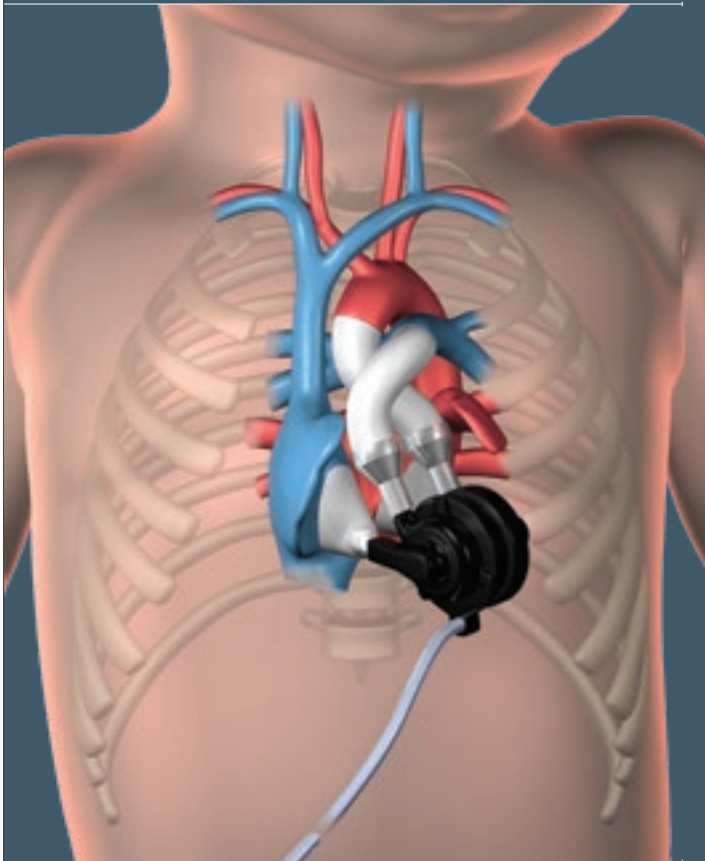
\*Survival rates are for primary prospective LVAD implants 1/1/16-9/30/17.

### Electrophysiology Procedures in 2017

MAJOR COMPLICATION RATES FOR PROCEDURES WITH BENCHMARKS		
PROCEDURE	Cleveland Clinic Complication Rate	Benchmark
Secondary pacemaker (with leads) (N = 30)	3.33%	5.88% Poole et al., 2010
Secondary pacemaker (without leads) (N = 83)	0%	2.27% Poole et al., 2010
Secondary ICD (with leads) (N = 86)	1.16%	17.4% Poole et al., 2010
Secondary ICD (without leads) (N = 193)	2.59%	5.80% Poole et al., 2010
Ventricular tachycardia ablation (LVEF < 50%) (N = 115)	0.87%	13.0% Stevenson et al., 2008
Pulmonary vein isolation (N = 960)	1.25%	4.56% Cappato et al., 2010



# Image of the Issue



## PEDIATRIC-SCALED CONTINUOUS-FLOW TOTAL ARTIFICIAL HEART IS FEASIBLE, IN VIVO STUDIES SHOW

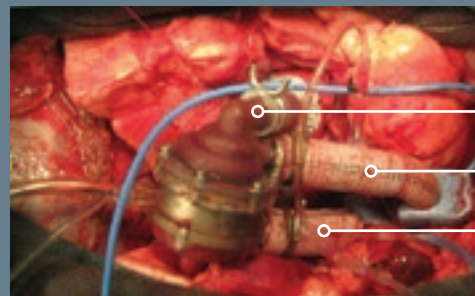
Cleveland Clinic researchers have been the first to demonstrate successful implantation of a pediatric continuous-flow total artificial heart (P-CFTAH) in an acute animal study. The results are from a report of implantations of the Cleveland Clinic-developed P-CFTAH in four healthy lambs, presented at the American Heart Association Scientific Sessions in November 2017.

The P-CFTAH is a downscaled version of Cleveland Clinic's previously reported CFTAH for adults, with size reductions of 30 percent in all dimensions to allow use in children and infants with a body surface area as small as 0.3 m<sup>2</sup>, or about 5 kg body weight.

The device features a dual-pump design (two valveless continuous-flow pumps) unified in a single, continuously rotating brushless DC motor and rotor assembly supported by a hydrodynamic bearing. Its sensorless design can produce pulsatile flow with speed modulation and automatically balance left and right circulations without electronic intervention.

The P-CFTAH's self-regulating performance — including pump speed, flow and current — was confirmed in all animals in the study (sample intraoperative photo shown below). Standard hemodynamic measures remained stable, and good left and right atrial balance was maintained in response to manipulations of systemic and pulmonary vascular resistance.

“Our early testing has validated feasibility of the dimensional scaling of this device in regard to size and performance,” says principal investigator Kiyotaka Fukamachi, MD, PhD, with Cleveland Clinic's Department of Biomedical Engineering. “The P-CFTAH's design allows for a significant size reduction while forgoing the use of valves or flow sensors for control.”



Right inflow cannula

Right outflow graft

Left outflow graft

“If durability is proven in clinical testing, the P-CFTAH could be used as a bridge to transplant and as destination therapy,” notes Hani Najm, MD, Chair of Pediatric and Congenital Heart Surgery at Cleveland Clinic. “That would help address unmet needs among children listed for heart transplantation, who face the highest waiting-list mortality in solid-organ transplant medicine.” ■

For more, see [consultqd.clevelandclinic.org/p-cftah](http://consultqd.clevelandclinic.org/p-cftah).

# CONQUERING CATH LAB CHALLENGES

Process Improvements Drive Dramatic Gains in Cath Lab Efficiency, Productivity

## How Cleveland Clinic got a handle on a universal challenge.

Five additional hours of procedure time each day. That's what Cleveland Clinic's catheterization lab achieved through improved start times and reduced turnaround times resulting from a collection of systematic process improvement initiatives designed to reduce inefficiencies. So reports a team of Cleveland Clinic clinicians in a new paper in *JACC: Cardiovascular Interventions* (2018;11:329-338).

*Continued next page >*



**“**This is one of the first and most comprehensive public reports of a quality improvement initiative in a large cath lab,” says the study’s corresponding author, Samir Kapadia, MD, Section Head of Interventional Cardiology and Director of Cleveland Clinic’s Sones Cardiac Catheterization Lab. “Our experience may serve as an example to others that process improvement initiatives like ours can lead to significant cath lab efficiency gains.”

#### A Pre/Post Look at Cath Lab Process Changes

The study examined the effects of new policies implemented in the cath lab in June 2014. The policies resulted from an analysis of cath lab workflow that included creating a process flowchart that outlined and time-stamped every step in a typical patient’s care. Cath lab leadership performed a comprehensive review of the process and identified systematic inefficiencies at several steps — along with changes to address them.

Among the most important changes were the following:

- Transition from a “block” to a “pyramidal” nursing schedule to ensure that more nurses would be available early in the day
- Increased use of an electronic scheduling system that is accessible on any computer and is displayed in each cath lab room, enabling immediate communication among team members
- Reducing barriers to patient transfer through increased use of a prep and recovery “holding” area

Additional changes (among others) included limiting sheath pulls in the cath lab, establishing a central supply system to reduce time spent searching for equipment, and downgrading future scheduling priority for attending physicians whose cases were not begun within 15 to 30 minutes of their being paged.

The changes were implemented in a stepwise manner across the cath lab at Cleveland Clinic’s main campus, which includes eight rooms and accommodates a single physician practice of about 20 employed cardiologists.



**“**Our experience may serve as an example to others that process improvement initiatives like ours can lead to significant cath lab efficiency gains.**”**

– Samir Kapadia, MD



## Cath Lab Process Revamp Brings Big-Time Efficiency Gains

In 2014, Cleveland Clinic adopted process improvements to curb inefficiencies in our cardiac cath lab. A new study reports the results, which include:

17 minutes	4.1 minutes	7.7% → 77.3%	5 hours/day
Improvement in procedure start times	Reduction in mean time between cases	Before/after change in the share of days at full cath lab utilization	Across the cath lab, these efficiencies added 5 hours of procedure time a day

Source: Reed GW, Hantz S, Cunningham R, et al. *JACC Cardiovasc Interv.* 2018;11:329-338.

### Results: Efficiency Gains, Plus Improved Satisfaction

The study evaluated all elective and urgent procedures performed from one year before to two years after implementation of the new policies. Diagnostic coronary angiograms, percutaneous coronary intervention (PCI) procedures, right heart catheterizations, myocardial biopsies, peripheral vascular interventions and structural heart interventions were included. Because emergent cases (e.g., primary PCI for ST elevation myocardial infarction) follow a separate workflow, they were excluded.

Comparison of metrics before and after implementation of the process changes revealed significant improvements across a range of measures. Among the key findings:

- Procedure start times improved by an average of 17 minutes, with the proportion of cases starting on time rising from 61.8 percent in the year before implementation to 81.7 percent in the subsequent two-year period ( $P = .0024$ ).
- Mean time between cases (i.e., room turnaround time) was reduced from 20.5 minutes before implementation to 16.4 minutes afterward ( $P < .0001$  for trend).
- The proportion of days at full lab utilization rose from 7.7 percent before implementation to 77.3 percent afterward ( $P < .00001$ ).

These improvements were achieved even as the number of cath lab employees declined from 2013 to 2016 despite steady case volume over the study period. Additionally, there was no increase in weekend, after-hours or overtime shifts, and improvements were observed in all measured aspects of cath lab employee experience, including employee satisfaction.

“Overall, our changes led to a gain of 5.1 to 5.6 hours per day in lab utilization resulting from improved start times and reduced turnaround times,” says Catheterization Lab Manager and study co-author Scott Hantz, MSN, MBA.

### The Efficiency and Quality Imperative

In an editorial accompanying the study in *JACC: Cardiovascular Interventions*, two cardiologists from UF Health at the University of Florida, Gainesville, wrote that the Cleveland Clinic authors “are to be congratulated for tackling some of the issues of inefficiency most catheterization laboratories deal with and approaching the task with scientific rigor.”

Indeed, translation of this approach is something Dr. Kapadia and his co-authors hope their study will engender. “We’re moving toward a reality where more and more cardiovascular care will be reimbursed through models like bundled payments that emphasize quality over quantity,” he says. “That makes utilizing resources as effectively and efficiently as possible — as we’ve aimed to do with our cath lab process improvements — a paramount consideration for all institutions.”

He adds that the team plans to continue this initiative and expand it to other services provided in the cath lab, such as electrophysiology, aortic endovascular and interventional radiology procedures. ■

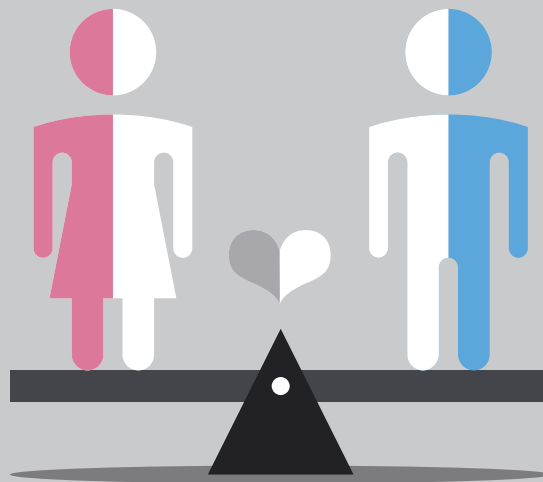
Contact Dr. Kapadia at [kapadis@ccf.org](mailto:kapadis@ccf.org)  
and Scott Hantz at [hantzs@ccf.org](mailto:hantzs@ccf.org).



# STEMI Protocol Bridges Gender Gap in Care, Outcomes

Gains from new STEMI care processes are especially pronounced in women.

A systems-based approach to minimize care variability in management of ST elevation myocardial infarction (STEMI) can significantly shrink the long-standing gender gap in STEMI care processes and clinical outcomes, according to a new Cleveland Clinic study.



“Despite important differences in biology and risk profiles between men and women with STEMI, we’ve shown that a standardized, systems-based approach to care can reduce entrenched gender disparities and significantly improve STEMI care and outcomes in women,” says Umesh Khot, MD, Vice Chair of Cardiovascular Medicine at Cleveland Clinic and senior author of the study, published by the *Journal of the American College of Cardiology* (2018 Mar 7 [Epub ahead of print]).

“After we implemented a comprehensive four-step STEMI care protocol, we saw improved clinical outcomes in all patients,” adds co-author Samir Kapadia, MD, Director of Cleveland Clinic’s Sones Cardiac Catheterization Laboratory. “Importantly, similar reductions in 30-day mortality were noted among men and women, as were similar rates of in-hospital adverse events.”

## What Prompted the Study

“It’s well established that STEMI care provided to women lags behind the care provided to men,” says Dr. Khot, noting that women generally are treated less rapidly and receive guideline-directed medical therapy at lower rates. These realities underlie in-hospital mortality rates from STEMI that are twice as high in women as in men, according to U.S. registry data. “This gender disparity has been identified as a public health priority, yet data on strategies to close this gender gap have been scarce.”

When Cleveland Clinic implemented a new care process for STEMI across its 10 hospitals and three free-standing emergency departments (EDs) in Northeast Ohio in July 2014, it had an ideal opportunity to obtain much-needed prospective data to address these issues. The aim of the new process was to minimize variability in STEMI care by introducing a comprehensive STEMI protocol featuring four key process changes:

- Standardization of criteria by which ED physicians can activate the cath lab
- Use of a “STEMI safe handoff checklist” delineating distinct roles for all caregivers involved
- Institution of a policy of immediate patient transfer to an immediately available cath lab at all times to avoid patient delays
- Transition to a “radial artery first” approach for vascular access in primary percutaneous coronary intervention (PCI) for all suitable candidates

To assess the protocol’s effect on care processes and clinical outcomes, the researchers studied 1,272 consecutive patients with STEMI treated with primary PCI from 2011 through 2016. Of those patients, 549 were treated after implementation of the STEMI protocol in July 2014 and constituted the protocol group. The other 723 were treated prior to the protocol and served as a control group.





**Results: Particularly Large Gains for Women**

The overall study population was 68 percent male and 32 percent female. In both the protocol and control groups, women were older than men and had significantly higher rates of diabetes, cerebrovascular disease and chronic lung disease.

In the control group (before the protocol), women received guideline-directed medical therapy prior to sheath insertion significantly less often than men did (69 vs. 77 percent of the time;  $P = .019$ ), and women had a longer door-to-balloon time (D2BT) (112 min [85, 147] vs. 104 min [79, 133];  $P = .023$ ).

Consistent with those process findings, women in the control group had significantly higher rates of in-hospital death and cardiovascular death, stroke, vascular complications, bleeding and transfusion requirements compared with men in the control group. In contrast, no adverse events occurred significantly more often in men than in women. “These control-group findings of worse outcomes in women compared with men are consistent with the prior literature,” observes Dr. Kapadia.

After implementation of the STEMI protocol, both process measures and clinical outcomes improved overall relative to those in the control period, with the biggest gains achieved among women. The result was that gender disparities in process measures ceased to be significant, as follows:

- Use of guideline-directed medical therapy was 84 percent in men versus 80 percent in women ( $P = .320$ ).
- D2BT was 89 minutes in men versus 91 minutes in women ( $P = .150$ ).

In keeping with those process measures, rates of in-hospital death and cardiovascular death in the protocol group were statistically similar between men and women, as were rates of stroke, vascular complications, bleeding and all other monitored adverse events.

The absolute gender difference in 30-day mortality declined from the control period, when it was 6.1 percent higher in women ( $P = .002$ ), to the period under the STEMI protocol, when it was 3.2 percent higher in women ( $P = .090$ ).

**More-Equal Care May Be at Hand**

“These findings convincingly show that this new STEMI care process has led to substantial improvements in the care of women,” says Dr. Khot. He cites improvements in the rate of appropriate medication use, time to reperfusion and use of radial artery catheterization as specific enhancements. “These improvements reduced the higher risk of serious complications in women compared with men.”

While noting that the findings warrant validation at other centers, Dr. Khot points out that no patients were excluded from this large prospective analysis and that the sample should reflect the STEMI population of any large U.S. urban STEMI referral center. “This strategy offers the promise of providing equal STEMI care regardless of patient gender,” he concludes. ■

Contact Dr. Khot at [khotu@ccf.org](mailto:khotu@ccf.org) and Dr. Kapadia at [kapadis@ccf.org](mailto:kapadis@ccf.org).

## Bridging the Gender Gap in STEMI Care and Outcomes

When Cleveland Clinic adopted a new care process for ST elevation myocardial infarction (STEMI), it did more than improve outcomes. It significantly shrank the well-established gender gap in STEMI care — to the benefit of women:

♀	BEFORE PROTOCOL		♂
	69%	Use of guideline-directed therapy	
112 min	Door-to-balloon time	104 min	
10.7%	30-day mortality	4.6%	
AFTER PROTOCOL			
80%	Use of guideline-directed therapy	84%	
91 min	Door-to-balloon time	89 min	
6.5%	30-day mortality	3.3%	



# Simplified Frozen Elephant Trunk Repair: Midterm Outcomes Underscore Its Safety

## Largest U.S. Study to Date of Extended Repair of Acute DeBakey Type I Dissection

Despite encouraging results elsewhere, uptake of frozen elephant trunk repair for acute DeBakey type I dissection has been slow in the United States. A new report of midterm outcomes with the procedure at Cleveland Clinic could help change that by demonstrating that a simplified approach to the technique is safe, promotes aortic remodeling and eases management of chronic aortic complications.

“Our experience shows that, at centers of excellence, frozen elephant trunk repair can be performed with mortality comparable to the conventional hemiarch repair strategy even in patients who present with ischemia,” says Cleveland Clinic cardiothoracic surgeon Eric Roselli, MD, lead author of the report, published as the cover feature of the March 2018 issue of *Annals of Thoracic Surgery* (2018;105:749-755).

### Evolving Approach to a High-Risk Challenge

The traditional approach to acute DeBakey type I dissection has been conservative, limiting repair to replacement of the ascending aorta and hemiarch. But recent years have seen refinement of operative techniques and the emergence of endovascular devices that make an extended initial repair possible with acceptable risk.

“At Cleveland Clinic, we’ve developed a simplified hybrid approach involving single anastomosis frozen elephant trunk repair,” explains Dr. Roselli, Surgical Director of Cleveland Clinic’s Aorta Center. “Since we published our initial experience with this technique (*J Thorac Cardiovasc Surg.* 2013;145[suppl 3]:S197-S201), we have refined the procedure to improve effectiveness and further disseminate its use” (see Figure 1).

### A Snapshot of 72 Cases

That refinement and the resulting outcomes are the focus of his team’s new report, which profiles the management of 72 patients with DeBakey type I dissection who underwent emergency simplified elephant trunk repair at Cleveland Clinic from 2009 to 2016.

The most common presentation was aortic insufficiency, followed by malperfusion, followed by rupture. Concomitant procedures included valve resuspension, root replacement, cusp repair and valve replacement. The first 39 patients were treated with modification of an early-generation stent graft, the next 16 patients received newer modified stent grafts, and the 17 most recent patients underwent the branched single anastomosis frozen elephant trunk repair (B-SAFER) technique with left subclavian stent grafting.

Primary outcomes in the study report were operative mortality and neurologic complications, including stroke and spinal cord injury.

### Key Results

Operative mortality was 4.2 percent (3 of 72 patients): Two patients were comatose at presentation without recovering, and the other died from coagulopathy complications.

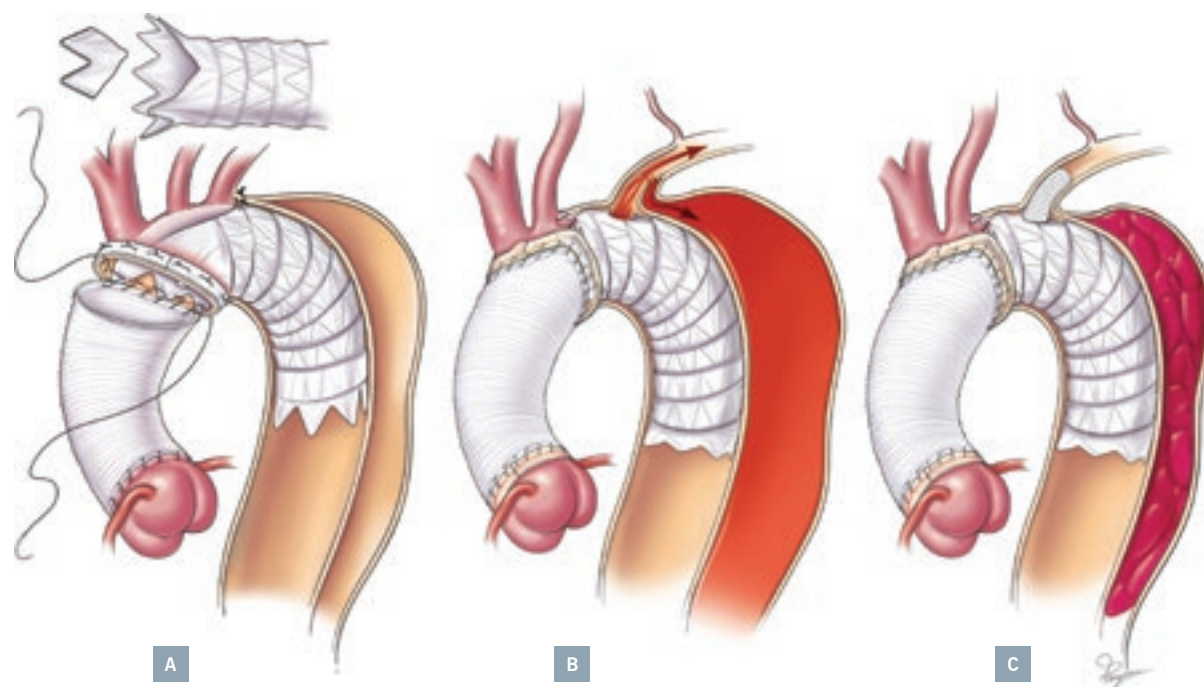
Morbidity included the following:

- Stroke (n = 3; 4.2 percent)
- Spinal injury (n = 3 [1 permanent]; 4.2 percent )
- Tracheostomy (n = 7; 9.7 percent)
- Renal failure (n = 2; 2.8 percent)

Over a median follow-up of 28 ± 25 months, survival was as follows:

- 92 percent at six months
- 92 percent at one year
- 89 percent at three years
- 80 percent at five years

**“Our modified single anastomosis strategy has maintained relatively low circulatory arrest times and enabled wider use among our team of surgeons.”** – Eric Roselli, MD



**Figure 1.** Evolution of the simplified frozen elephant trunk technique. (A) Intraoperative creation of fenestration by resection of a portion of proximal stent graft (2009). (B) Fenestration below the left subclavian artery (2012). (C) Direct branch vessel stent grafting (2015). Reprinted, with permission of The Society of Thoracic Surgeons, from Roselli et al., *Annals of Thoracic Surgery*. 2018;105:749-755. Permission conveyed through Copyright Clearance Center Inc.

Among the 63 surviving patients with follow-up imaging available, 92 percent demonstrated thrombosis in the false lumen of the treated segment. Complete reverse remodeling with shrinkage of the false lumen was seen in 54 percent of patients, with the mean total aortic diameter reduced from  $42 \pm 8$  mm to  $37 \pm 7$  mm.

Ten patients required 14 late reinterventions for aortic growth and progression of their dissection disease. Freedom from reintervention was as follows:

- 93 percent at six months
- 87 percent at one year
- 77 percent at three years
- 72 percent at five years

#### Support for More-Complete Arch Repair

“Our midterm outcomes show that the simplified frozen elephant trunk technique promotes false lumen thrombosis and reverse remodeling of the aorta in the treated segment,” says Dr. Roselli. “Our modified single anastomosis strategy has maintained relatively low circulatory arrest times and enabled wider use among our team of surgeons.”

He notes that he and his colleagues tailor their approach to acute ascending aortic dissection according to the aortic pathology, presentation and patient characteristics. “A minimally invasive approach with ascending thoracic endovascular aortic repair, or TEVAR, is reserved for exceptionally high-risk patients who aren’t candidates for open repair,” he adds.

In an invited commentary accompanying the report, T. Brett Reece, MD, of the University of Colorado noted that while only further follow-up will determine whether this technique will ultimately prevent late aortic reintervention, “the authors should be lauded for their perseverance and follow-up of these complex patients.”

Dr. Reece concluded as follows: “We are quickly approaching more complete replacements of the arch to not only allow patients to fight another day, but also with the ultimate goal of fighting independent of the need for further aortic intervention.” ■

Contact Dr. Roselli at [roselle@ccf.org](mailto:roselle@ccf.org).



# Bringing Consistency and Reproducibility to the Echo Lab

## How Cleveland Clinic helped an affiliated provider organization enhance its CQI process.

For echocardiography laboratories, a standardized continuous quality improvement (CQI) program is essential, as quality assessment and improvement strategies are critical to ensuring accuracy and reproducibility of echocardiography procedures. Although echo lab CQI programs are recommended by both the Intersocietal Accreditation Commission and the American Society of Echocardiography, adoption of a CQI plan is left to the discretion of individual echo labs, with no formal industry standardization and no required measures to evaluate performance.

The CQI program for Valley Health System's echocardiography lab was limited when the Ridgewood, New Jersey-based health system became an affiliate of Cleveland Clinic's Miller Family Heart & Vascular Institute in January 2017. Review and enhancement of affiliate organizations' CQI programs is an important component of services offered by Cleveland Clinic's Heart & Vascular Institute Affiliate Program, and CQI in the echo lab was a priority for Valley Health System.

### Quality Assurance Review

Early in the affiliation, key players from Cleveland Clinic's Section of Cardiovascular Imaging performed quality assurance (QA) on a portion of transthoracic and

transesophageal echocardiograms for Valley Health System. The peer-to-peer review was designed to provide a baseline quality assessment for Valley Health System's echo lab and offer recommendations for enhancements to the imaging and reporting capabilities. Peer-to-peer outcomes were provided through written formal feedback and conference calls between Valley Health System's cardiovascular imaging team and three Cleveland Clinic cardiovascular imaging specialists — Richard Grimm, DO; Brian Griffin, MD; and Suma Thomas, MD — as well as Cleveland Clinic consulting cardiac sonographer Kimberly Radigan, RDCS.

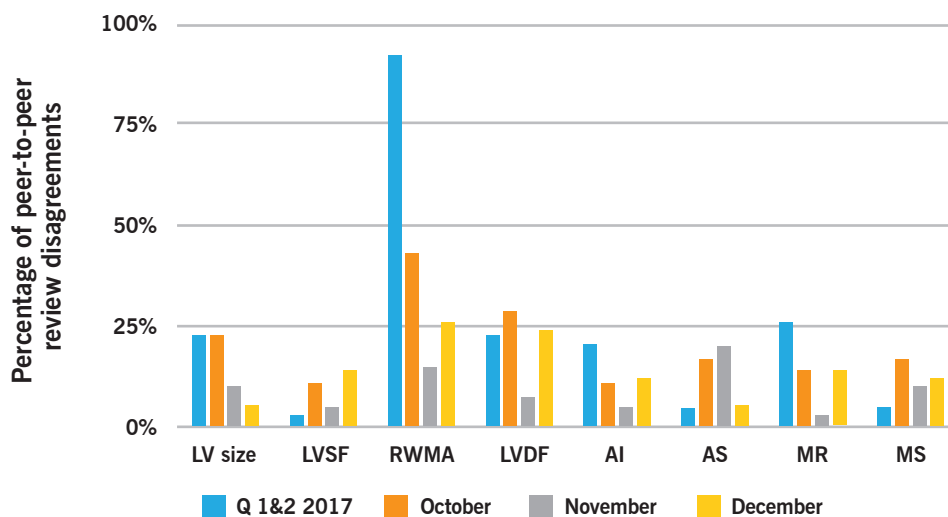
The QA process typically involves exposing the affiliate program to

Cleveland Clinic's internal echocardiography CQI program, to demonstrate the feasibility of a standardized, routine and structured peer-review process that has been incorporated into daily operations at a large tertiary referral hospital. The process is centered on constructive feedback and includes both sonographers and physician readers, with the goal of improving consistency in image acquisition by the sonographer and interpretation by the physician.

### Cleveland Clinic's CQI Program at a Glance

Cleveland Clinic's echocardiography CQI program has been in place for approximately five years. It is consistent and well-accepted and has proven

### Valley Hospital's peer-to-peer variability



**Figure 1.** Graph showing peer-to-peer variability in echocardiogram reviews before and after Valley Hospital's adoption of Cleveland Clinic's CQI program recommendations in the third quarter of 2017. LV = left ventricular; LVSF = LV systolic function; RWMA = regional wall motion abnormalities; LVDF = LV diastolic function; AI = aortic insufficiency; AS = aortic stenosis; MR = mitral regurgitation; MS = mitral stenosis.



feasible despite a relatively high volume of studies performed. Each business day, 2 to 5 percent of the completed echocardiographic studies are randomly selected for review. Experienced sonographers and readers perform the reviews, reporting their level of agreement/disagreement based on predefined fields. In cases of disagreement, the original sonographer/reader is notified. This process is followed up with monthly quality meetings at which sonographers and physicians participate in reviewing quality outcomes.

The peer-review process evaluates the technical quality of the images acquired and the interpretive accuracy of the reading physician. The percentage of agreement in the sonographer review process has been increasing with time in key areas — for example, agreement on contrast use rose from 83 to 97 percent. Similarly, the percentage of “no disagreements” in the reader review process has increased — from 50 to 62 percent — over the same period.

#### Implementation and Early Success

At the end of the QA review, the Cleveland Clinic team proposed a feasible peer-review process that could serve as the platform for a structured CQI program for the Valley Hospital echo lab. Valley Hospital adopted the proposal, much of which was adapted from Cleveland Clinic’s CQI program, and has continued to embrace quality improvement projects.

Implementation of the new process at Valley Hospital has met with considerable success. The imaging management team reports increased communication among physicians as well as between sonographers and physicians. Likewise, educational and quality meetings have been expanded in scope and increased in frequency to a monthly basis. Establishment of a physician-led peer-review process has reduced reporting discrepancies (Figure 1). The imaging management team has followed through on recommendations

to revise the standard comprehensive protocol while sonographers have enhanced and optimized equipment capabilities. The protocol and metrics set in place were derived from the initial feedback from Cleveland Clinic, but the driving forces behind the accomplishments outlined above have been Valley Medical Group physicians Michael Anshelevich, MD, and Howard Goldschmidt, MD, and the Valley Hospital echo lab management team.

To build on this success, Valley Hospital’s echo lab management team collaborates monthly with Cleveland Clinic’s imaging consultant to discuss the lab standards and areas of opportunity. Strategies to ensure quality metrics are discussed, along with innovation, educational opportunities and changes in American Society of Echocardiography guidelines. Innovative methodologies, such as myocardial deformation (strain), 3D acquisition and ultrasound enhancement agents, are highlighted topics of interest.

“The genesis of our new quality process is based on guidelines and recommendations shared by Cleveland Clinic during our assessment,” says Stacy Mack, MBA, Assistant Vice President, Heart and Vascular Institute, Valley Health System. “We have further reinforced the quality and improvement initiatives by incorporating two physician co-directors to oversee the process with Cleveland Clinic’s support.”

“Valley Hospital has truly embraced and leveraged its affiliation with our Heart & Vascular Institute and has consequently seen positive outcomes in both image acquisition and physician reporting, resulting in improved patient care,” observes Dr. Grimm, Director of Echocardiography Laboratories, Cleveland Clinic. ■

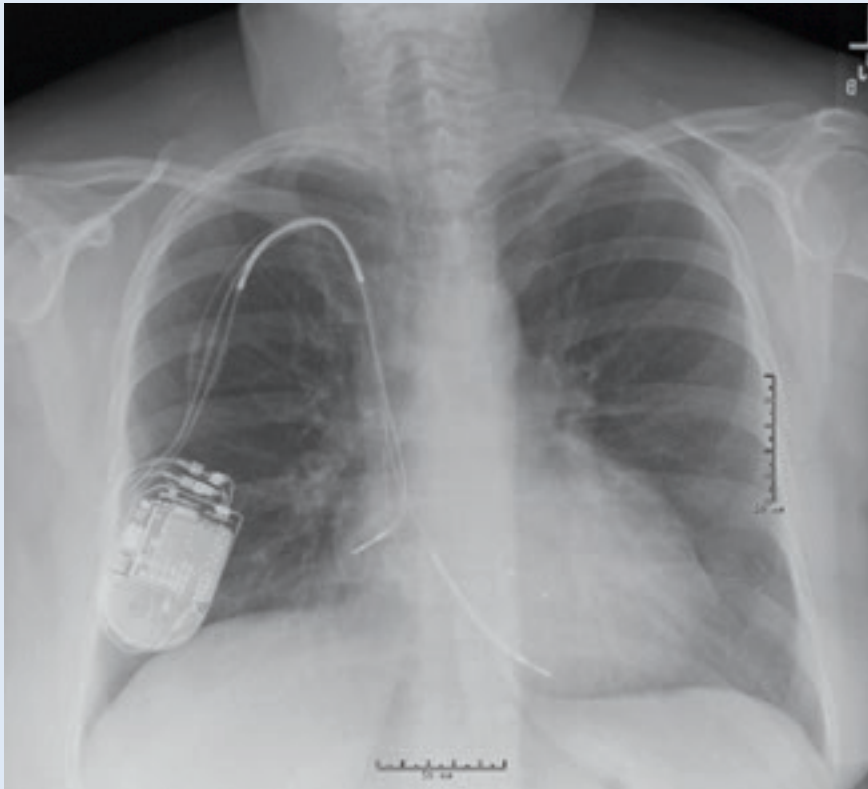
For details on affiliation opportunities with Cleveland Clinic’s Heart & Vascular Institute, visit [ahsproviders.com](http://ahsproviders.com).



# In High-Risk Lead Extractions, Preparing for the Worst Is Imperative

## Case Study: How a Protocol for Cardiac Surgical Backup Saved the Day in a Patient with SVC Injury

BY GOSTA PETTERSSON, MD, PHD; STEPHANIE MICK, MD; OUSSAMA WAZNI, MD; ALOK DASH, MD; AND ANDREW BAUER, MD



**Figure 1.** Preoperative chest radiograph showing right atrial, right ventricular and coronary sinus leads.

### Case Presentation

A 56-year-old woman presented to the emergency department with “vibrations” from her implantable cardioverter defibrillator (ICD). Such vibrations are a feature of ICDs designed to alert patients to changes in device function that may require a physician’s attention. She had a history of left mastectomy and nonischemic cardiomyopathy secondary to adriamycin and radiation therapy for breast cancer.

Preoperative chest radiography (Figure 1) showed three leads. Because of the patient’s left-sided breast cancer and disrupted lymphatic system, the ICD had been implanted on the right side.

Her cardiac resynchronization therapy (CRT) defibrillator generator had been changed five years earlier, with a retained

coronary sinus lead from which she did not benefit. The ICD lead had been recalled because of failures, so the patient was being followed, but extraction had been delayed because of patient anxiety about the procedure.

At the current presentation, interrogation revealed high right ventricular shocking impedance. Ejection fraction was 30 percent, but she was otherwise asymptomatic. The decision was made to transvenously extract and reimplant an ICD lead in a hybrid operating room (OR).

### Tamponade During Extraction

During the extraction procedure, the patient developed severe acute hypotension with tamponade. Echocardiogram showed a new pericardial effusion (Figure 2). She quickly became asystolic, and CPR was initiated. An emergency median

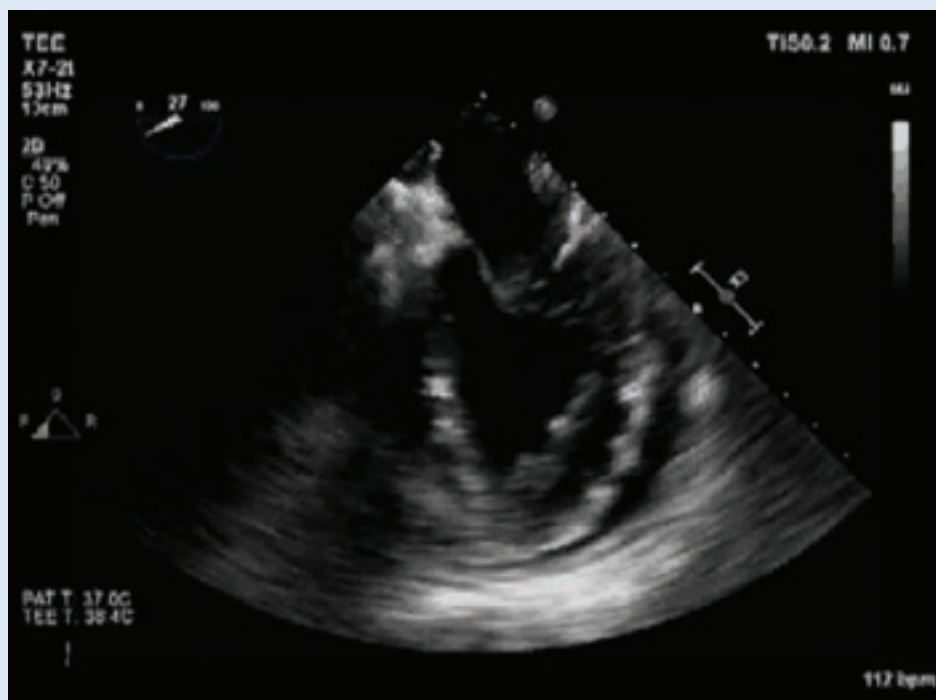
sternotomy was performed while another team member inflated the rescue balloon that was in place.

After the pericardium was open, the tamponade was relieved. Initially, the site of bleeding was unclear, but was soon localized to the superior vena cava (SVC). Digital pressure to the SVC temporarily abated the bleeding. At this point, echocardiography showed new tricuspid regurgitation (Figure 3).

Further inspection revealed a 4-cm posterior SVC wall tear from below the innominate vein and up to the subclavian and internal jugular vein confluence. Figure 4 depicts the normal venous anatomy.

### Reconstruction of a Friable, Difficult-to-Access SVC

A cardiothoracic surgeon was on hand for immediate cardiopulmonary bypass. The patient was heparinized, the ascending aorta was cannulated centrally, and the inferior vena cava and right atrium were cannulated. Cooling was started for possible deep hypothermic circulatory arrest, and the heart



**Figure 2.** Echocardiogram from the time of lead extraction showing new pericardial effusion.

was arrested with cardioplegia. All residual pacing leads were removed during cooling.

Access to the upper portion of the tear was very difficult and required periods of deep hypothermic circulatory arrest mixed with periods of low flow. The SVC, which was exceedingly thin and friable, was eventually reconstructed with autologous pericardium. The innominate vein was ligated. A large amount of calcium was noted and removed from the right atrium.

### Recovery and Follow-Up

The patient had an unremarkable postoperative course and was discharged home on postoperative day 11. Ejection fraction was still 30 percent, but she was asymptomatic and doing well at her most recent follow-up. She had no upper body edema, and a repeat postoperative CT demonstrated a patent but narrowed right SVC and good collaterals on the left side.

Although she never had an ICD shock during the 11 years of using the previous device, she still needs a defibrillator per guidelines but does not need pacing. She was subsequently implanted with a subcutaneous defibrillator to avoid endangering her repaired residual upper body venous system.

### Discussion: Why Did Injury Occur?

Over time, leads become more or less embedded in a sheath of scar tissue from chronic inflammation attached to the adjacent vascular wall and structures. This sheath eventually becomes calcified, which makes shearing off part of a vein

a serious risk with lead removal. Such injuries are common even if not always recognized clinically, as our group recently reported (*Heart Rhythm*. 2018;15:318-325).

The excessive calcium deposition in this patient, probably a result of her radiation therapy, contributed to the difficulty of the lead extraction.

Injuries around the SVC are notoriously challenging because of the complexity of circulation, as the confluence of veins results in force vectors in multiple directions. What may start as a small laceration can quickly get bigger and result in tamponade and circulatory collapse.

Acute hypotension during a procedure that doesn't resolve within a few seconds is probably due to an injury. In our experience, the most common sites of injuries requiring emergency surgical or endovascular intervention are:

- SVC-right atrial junction (36 percent)
- SVC (20 percent)
- Right ventricle (12 percent)
- SVC-brachiocephalic vein junction (8 percent)

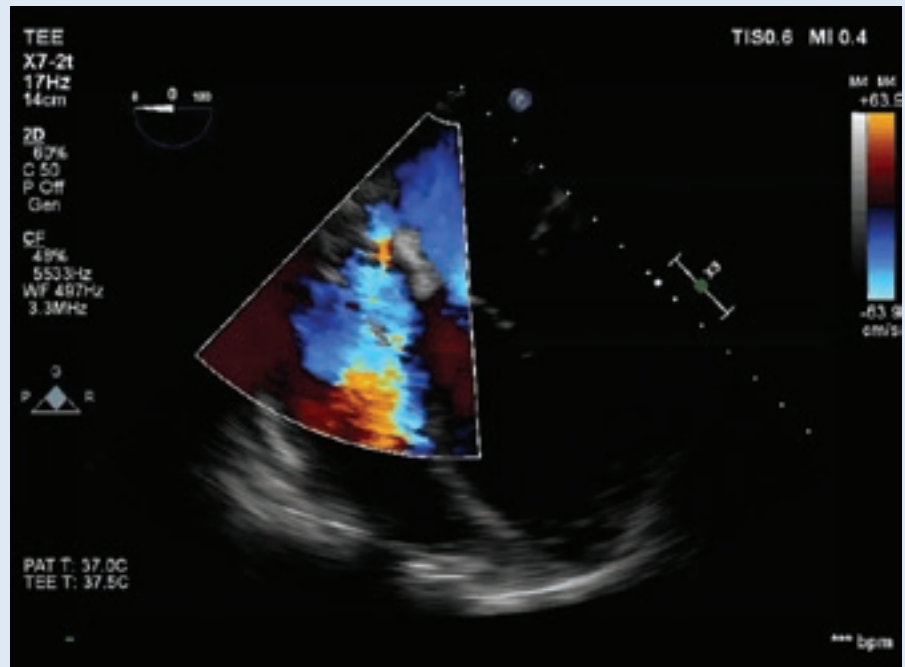
### The Imperative for a Surgical Backup Protocol

Performing lead extraction in a hybrid OR can be critical. If we hadn't had the capability to inflate the balloon and institute immediate cardiopulmonary bypass and surgery, the patient in this case would not have survived.

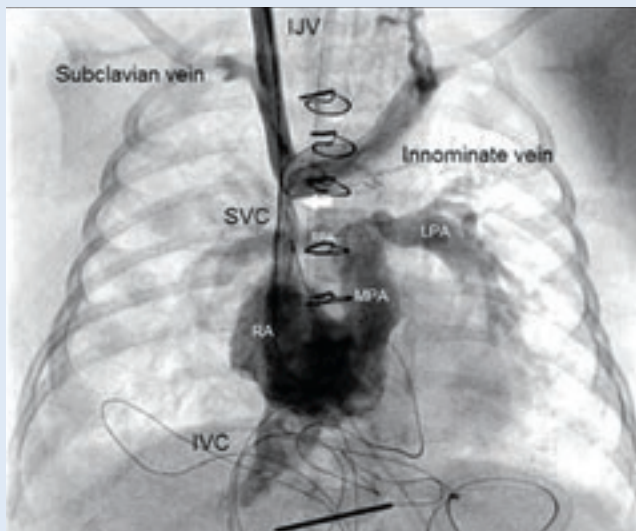
*Continued next page >*



**Figure 3.** Echocardiogram showing tricuspid regurgitation with fluid compressing the right atrium and fluid around the left ventricle.



Cleveland Clinic instituted a protocol in 2014 for high-risk lead extractions that requires formal cardiac surgical backup. It was roughly modeled on our protocol for cardiac surgery/interventional cardiology collaboration during transcatheter aortic valve replacement (TAVR) in response to Centers for Medicare & Medicaid Services national coverage requirements for TAVR. This protocol is designed to minimize time to intervention in the event of a catastrophic complication from attempted transvenous extraction. High-risk cases are performed in a hybrid OR with surgical and cardiopulmonary bypass equipment on standby and a cardiac surgery team physically present until the “all clear” is given.



**Figure 4.** Venogram with injection of contrast bilaterally depicting the normal venous anatomy (not from the case patient).

High-risk patients are evaluated by cardiac surgery before extraction to determine whether they are candidates for surgical backup in the hybrid OR. Candidates are generally selected because they are defined as high risk for perforation due to lead age (> 5 years) or because of previous cardiac surgery that would make surgical rescue more challenging.

For rescue candidates, a customized surgical plan is made, which may involve a full sternotomy or thoracotomy, depending on history, and appropriate pre-emptive measures are taken (e.g., wire access is placed for emergency peripheral cannulation). For those not deemed rescue candidates due to low probability of successful rescue (e.g., patients with very low ejection fraction, very advanced age or multiple prior cardiac surgical procedures), extraction proceeds without surgical backup if it is essential.

### Benefits in Outcomes and Beyond

In our first three to four years of operating under this protocol, multiple patients have been rescued when central vascular injury has occurred and resulted in tamponade. The protocol has also increased the degree of interdisciplinary cooperation in lead extraction cases, which almost invariably leads to a higher level of patient care and safety. ■

**Drs. Petterson ([petterg@ccf.org](mailto:petterg@ccf.org)), Mick ([micks@ccf.org](mailto:micks@ccf.org)) and Dash ([dasha@ccf.org](mailto:dasha@ccf.org)) are with the Department of Thoracic and Cardiovascular Surgery. Dr. Wazni ([waznio@ccf.org](mailto:waznio@ccf.org)) is Head of the Section of Electrophysiology and Pacing. Dr. Bauer ([bauera@ccf.org](mailto:bauera@ccf.org)) is with the Department of Cardiothoracic Anesthesiology.**





### › Trimming Reperfusion Time for In-Hospital STEMI

Implementing a comprehensive protocol for in-hospital ST elevation myocardial infarction (STEMI) yielded a 45 percent decrease in ECG-to-balloon time and doubled the percentage of patients treated within the guideline-recommended 90-minute time window. So finds a Cleveland Clinic analysis presented at the American College of Cardiology's 67th Scientific Session. "Patients with STEMI during hospitalization are a high-risk, vulnerable population who tend to experience delays in reperfusion relative to STEMI patients who present to the emergency department," says co-author Umesh Khot, MD.

Recognizing this, he and colleagues implemented a comprehensive STEMI protocol for hospitalized patients at Cleveland Clinic in July 2014 and compared process measures for several years before and after implementation. Use of radial access for primary PCI rose from 17 percent before the protocol to 71 percent afterward, and median ECG-to-balloon time declined from 107 to 60 minutes over the same period. "We welcome opportunities to exchange insights with others to define best practices for addressing this population's unmet needs," notes Dr. Khot. More at [consultqd.clevelandclinic.org/inpatientstemi](http://consultqd.clevelandclinic.org/inpatientstemi).

### › Size Matters in Embolism Risk from Endocarditis Vegetations

Vegetations larger than 10 mm confer significantly increased odds of embolism and death in patients with infective endocarditis, a large meta-analysis by Cleveland Clinic researchers confirms. The systematic review of the literature through May 1, 2017, identified 21 investigations — randomized controlled trials or observational studies — evaluating the association of vegetation size greater than 10 mm with embolic events in adults with infective endocarditis. The studies included 6,646 unique patients with 5,116 vegetations with available size data.

Compared with those who had vegetations smaller than 10 mm, patients with vegetations larger than 10 mm had significantly increased odds of both embolic events (odds ratio = 2.28) and death (odds ratio = 1.63). The associations were independent of age, sex and valve type involved. "Clinicians must balance the risk of embolism with the risk of surgery in infective endocarditis patients," says co-author Milind Desai, MD. "Our findings will help promote more-effective risk stratification." The study appears in *JAMA Internal Medicine*. More at [consultqd.clevelandclinic.org/sizematters](http://consultqd.clevelandclinic.org/sizematters).

### › Smartwatch Tech Detects Atrial Fibrillation Prior to Cardioversion

A new FDA-approved smartwatch accessory can record heart rhythm and successfully differentiate atrial fibrillation (AF) from normal sinus rhythm through an automated algorithm, finds a Cleveland Clinic study in the *Journal of the American College of Cardiology*. The results suggest the wearable technology, KardiaBand™, can help screen patients before presentation for elective cardioversion (CV) to avoid unnecessary procedures.

Consecutive patients with AF presenting for CV underwent pre-CV ECG along with a KardiaBand recording. If CV was performed, a post-CV ECG was obtained along with a KardiaBand recording. KardiaBand interpretations were compared with physician-reviewed ECGs.

Of 169 simultaneous ECG and KardiaBand recordings, 57 were noninterpretable by the KardiaBand algorithm. In the remaining recordings, KardiaBand interpreted AF with 93 percent sensitivity and 84 percent specificity. Accuracy improved further when KardiaBand was supported by physician review. "This study shows that KardiaBand can provide excellent sensitivity and good specificity in identifying AF," says co-author Khaldoun Tarakji, MD. More at [consultqd.clevelandclinic.org/smartwatch](http://consultqd.clevelandclinic.org/smartwatch).

### › PRECISION Substudy: Aspirin Use Shaves Celecoxib's Safety Edge

When the multicenter PRECISION trial was published in 2016, it found the selective COX-2 inhibitor celecoxib to be noninferior to the nonselective NSAIDs naproxen and ibuprofen in cardiovascular safety and superior in gastrointestinal and renal safety among 24,000 patients with arthritis and elevated cardiovascular risk. All patients were on long-term NSAID therapy, but the analysis didn't address effects of concurrent use of low-dose aspirin ( $\leq 325$  mg/d) in nearly half the study's population.

Now a prespecified subanalysis of PRECISION has been published in the *Journal of the American College of Cardiology* to address the safety of adding aspirin to chronic NSAIDs. Among the 12,935 patients who didn't take aspirin, celecoxib demonstrated a more favorable overall safety profile than both naproxen and ibuprofen. Among the 11,018 patients who took concurrent aspirin, celecoxib was still associated with lower rates of the primary composite safety end point relative to ibuprofen but was merely noninferior to naproxen. "The relative cardiovascular and overall safety of NSAID therapy is modified by concurrent aspirin use," notes senior author Steven Nissen, MD. More at [consultqd.clevelandclinic.org/precisionaspirin](http://consultqd.clevelandclinic.org/precisionaspirin).



# CME Preview: Upcoming Courses Worth Making Time For

## State-of-the-Art Echocardiography

Fri.-Sun., Sept. 14-16, 2018

Hilton Cleveland Downtown | Cleveland, Ohio  
[ccfcme.org/echocardio](http://ccfcme.org/echocardio)

This comprehensive 2.5-day CME event covers just about everything there is to know about effective use of echocardiography in contemporary clinical practice.

A faculty of nearly three dozen Cleveland Clinic experts — cardiologists as well as cardiac sonographers — will use case-based formats to provide guidance on the optimal use of echo across a broad range of cardiovascular care. Full sessions are devoted to various aspects of each of the following:

- Aortic stenosis
- Mitral regurgitation
- Echo guidance in device therapy for heart failure
- Endocarditis
- Adult congenital heart disease
- Cardiomyopathy
- Structural heart disease

An additional session is focused on special topics including diastolic dysfunction, strain imaging, echo's role in cardio-oncology and contrast use in echocardiography. Optional workshops are offered the first day of the course on the following:

- 3-D image reconstruction and cropping
- How to employ strain and 3-D volumes/ejection fraction in clinical practice
- Transthoracic and transesophageal echo in an echocardiography simulation lab

"Attendees will also learn about the latest relevant research studies, get updates on the newest ACC and ASE valve disease guidelines, and be privy to expert assessment of technical innovations and fast-evolving areas such as multimodality imaging, 3-D imaging, strain and point-of-care ultrasound," says course co-director Richard A. Grimm, DO, Director of Echocardiography at Cleveland Clinic.

"We've put a premium on assembling a faculty with multidisciplinary expertise," adds co-director Brian Griffin, MD, Section Head of Cardiovascular Imaging. "Panels of cardiovascular specialists with deep experience in fields such as structural heart interventions, heart failure, electrophysiology and critical care will debate management of challenging cases."

If the substance of this course isn't enough of a lure, American Society of Echocardiography members qualify for reduced fees, and participants may earn up to 20.5 ABIM Maintenance of Certification (MOC) points in addition to CME credit. The early-registration discount ends Aug. 17.

## 3rd Annual Advances in Pediatric and Congenital Heart Summit: Atrial Isomerism — the Road to Survival

Thu.-Sat., Sept. 27-29, 2018

InterContinental Hotel & Conference Center | Cleveland, Ohio  
[ccfcme.org/pediatricheart18](http://ccfcme.org/pediatricheart18)

The third annual offering of this tour de force summit on pediatric and congenital heart disease will convene world experts from Cleveland Clinic and around the nation to focus on management of the rare defect known as atrial isomerism (heterotaxy syndrome).

The 2.5-day course will dive deeply into all aspects of the condition's natural history and management, including:

- How misaligned cardiac embryological development leads to cardiac manifestations of heterotaxy syndrome
- Current surgical and catheterization lab approaches to venous, valvular and other cardiac lesions in left and right atrial isomerism
- Mechanisms of bradycardias and tachycardias in heterotaxy syndrome
- The impact of noncardiac anomalies on patient outcomes in isomerism

"We have enlisted a premier faculty of world experts for one of the most in-depth explorations of this rare condition to date," says course director Hani Najm, MD, Chair of Pediatric and Congenital Heart Surgery at Cleveland Clinic. "We will focus on how recent advances in 3-D modeling, surgical repair and catheter interventions have improved outcomes for patients with atrial isomerism and related congenital heart diseases."

Highlights include specialized workshops on echo, ECG, surgical management, interventional management and nursing.

This summit is complemented by a pre-symposium, **General Pediatric Cardiology/Cardiovascular Update**, on Thursday, Sept. 27, designed to provide an update on the current standard of care in management of pediatric cardiovascular disease.

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

*For more live cardiovascular CME from Cleveland Clinic, see the back cover of this issue.*

## RESOURCES FOR PHYSICIANS

### Stay Connected with Cleveland Clinic's Heart & Vascular Institute

#### Consult QD — Heart & Vascular

News, research and perspectives from Cleveland Clinic experts:  
[consultqd.clevelandclinic.org/cardiovascular](http://consultqd.clevelandclinic.org/cardiovascular)

 [facebook.com/CMEClevelandClinic](https://facebook.com/CMEClevelandClinic)

 [@CleClinicMD](https://twitter.com/CleClinicMD)

 [clevelandclinic.org/heartlinkedin](http://clevelandclinic.org/heartlinkedin)

 [clevelandclinic.org/cardiacconsult](http://clevelandclinic.org/cardiacconsult)

#### 24/7 Referrals

855.REFER.123

[clevelandclinic.org/heartreferrals](http://clevelandclinic.org/heartreferrals)

Outcomes Data: [clevelandclinic.org/outcomes](http://clevelandclinic.org/outcomes)

CME Opportunities: [ccfcme.org](http://ccfcme.org)

#### 50 Years of Heart Health:

View our multimedia timeline of cardiovascular advances at [cle.clinic/2fcvBg2](http://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 urology care.



# Cardiac Consult



## Live CME Events from Cleveland Clinic

### 19th Annual Intensive Review of Cardiology

Sat.-Wed., Aug. 18-22, 2018

InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration: [ccfcme.org/cardioreview](http://ccfcme.org/cardioreview)

### 3rd Annual Heart Rhythm Care in the 21st Century: Allied Professional Regional Conference

Fri.-Sat., Sept. 14-15, 2018

InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration: [ccfcme.org/heart-rhythm](http://ccfcme.org/heart-rhythm)

### State-of-the-Art Echocardiography

Fri.-Sun., Sept. 14-16, 2018

Hilton Cleveland Downtown | Cleveland, Ohio

Information/registration: [ccfcme.org/echocardio](http://ccfcme.org/echocardio)

(see course overview on page 18)

### 3rd Annual Advances in Pediatric and Congenital Heart Summit: Atrial Isomerism — the Road to Survival

Thu.-Sat., Sept. 27-29, 2018

InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration: [ccfcme.org/pediatricheart18](http://ccfcme.org/pediatricheart18)

(see course overview on page 18)

### Mastering the Mitral Valve: A Case-Based Approach

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

JW Marriott Essex House | New York, New York

Information/registration: [ccfcme.org/mitralmasters](http://ccfcme.org/mitralmasters)

*For more cardiovascular CME from Cleveland Clinic, both live and online, visit [ccfcme.org](http://ccfcme.org).*

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

**For a deeper dive into CME, see page 18.**