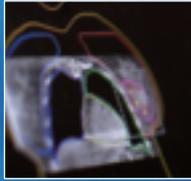




Total Aortic Replacement for Post-Dissection Aneurysm – p. 8



Radiation-Associated Heart Disease – p. 10



Surgical Cure for Chronic Thrombo-embolic Pulmonary Hypertension – p. 15



Cardiac Consult

Heart and Vascular News from Cleveland Clinic | 2019 | Issue 4

> CARDIAC CONSULT FEATURE

ROBOTICS

in the Cath Lab – p. 4



Dear Colleagues,

The essence of excellence lies in a commitment to always do better for our patients. That reality is particularly well reflected in this issue of *Cardiac Consult*.

The feature on page 10 outlines guidance on how to better care for a subset of patients whose heart disease poses especially vexing challenges — those with radiation-associated heart damage — from an expert scientific panel on which several of our staff served. The feature on page 12 relates how we are championing the POCMA methodology with our affiliated heart programs around the country to enhance surgical quality by going beyond the standard morbidity and mortality review. And our Image of the Issue on page 15 depicts the result of aggressive use of pulmonary thromboendarterectomy to cure a case of chronic thromboembolic pulmonary hypertension that some might have given up on.

Yet excellence also involves striving to always do better for our fellow caregivers as well. That's a message of the cover story on our adoption of a robotic system for use in one of our cath labs. A key impetus for adopting the system was to reduce operators' occupational risks related to radiation exposure. At the same time, the technology also promises potential patient benefits in terms of greater precision in stent deployment and the possibility of offering interventions remotely through "telestenting."

The story illustrates an important truth: Doing what's best for our colleagues usually also means doing what's best for our patients, and vice versa. We look forward to continuing to work with you toward both of these never-ending goals.

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

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Research Roundup

Quick Takes on Recent Cardiovascular Studies of Note

Stroke Rates in TAVR: Low but Stubbornly Stable

Postprocedure stroke occurred in just 2.3% of patients undergoing transcatheter aortic valve replacement (TAVR) in the first five years after the procedure's FDA approval, but this rate remained notably constant throughout the period despite increasing operator experience and improved device technology. So finds an analysis of the Transcatheter Valve Therapy Registry from November 2011 to May 2017 reported in *JAMA* (2019;321:2306-2315) by a Cleveland Clinic-led research team.

"One-month stroke risk after TAVR was low during the first five years of the procedure's clinical use, but because of stroke's potentially devastating consequences, it is imperative to identify how to improve," says senior author Samir Kapadia, MD, Chair of Cardiovascular Medicine at Cleveland Clinic. "The lack of improvement in stroke rates over time indicates that we have more work to do to refine stroke prevention strategies." More at consultqd.clevelandclinic.org/tavrstroke.

Machine Learning-Derived Biomarker Boosts Cardiac Risk Prediction

A novel biomarker derived via machine learning can predict cardiac risk better than currently available risk prediction methods, according to a collaborative study by researchers at the University of Oxford and colleagues in Germany and at Cleveland Clinic. Using artificial intelligence, the researchers analyzed both tissue and imaging features to identify markers of perivascular fat remodeling, connect those markers to cardiac risk and then develop a single value to express that risk.

The study builds on the CRISP-CT study by the same team, which established a perivascular fat attenuation index (FAI) that can predict all-cause and cardiac mortality above and beyond clinical risk factors and current coronary CT angiography interpretation methods. The new study adds perivascular fat fibrotic and microvascular changes to the inflammation quantified by the FAI to achieve a fat radiomic profile. "This type of artificial intelligence-based technology could represent a big step forward in personalized care for people predisposed to future coronary events," says Cleveland Clinic co-author Milind Desai, MD. The study was published in the *European Heart Journal*. More at consultqd.clevelandclinic.org/machinebiomarker.

Opioid-Sparing Strategy After LVAD Surgery Curbs Chronic Use

Use of an opioid-sparing regimen for postoperative pain management after left ventricular assist device (LVAD) implantation resulted in pain control comparable to that achieved with an opioid-based regimen while significantly reducing subsequent chronic opioid use. These findings, from a retrospective chart review at Cleveland Clinic, were presented at the Heart Failure Society of America's 2019 annual meeting.

The charts of all 196 adult LVAD recipients at Cleveland Clinic from 2014 through 2017 were reviewed to compare pain control and opioid use between those who received LVADs before versus after Cleveland Clinic's June 2016 adoption of an opioid-sparing regimen for LVAD patients. The opioid-sparing approach was associated with a significant decrease in need for opioid prescriptions at discharge and with sustained freedom from chronic opioid use 18 months after surgery. "This study suggests that approaches like this can consistently yield significant reductions in patients' opioid use following LVAD surgery," says co-investigator Edward Soltesz, MD, MPH, Surgical Director of Cleveland Clinic's Kaufman Center for Heart Failure and Recovery. More at consultqd.clevelandclinic.org/lvadopioids.

Pre-Ablation Bariatric Surgery Cuts AF Recurrence

Patients with morbid obesity who have symptomatic atrial fibrillation (AF) should be considered for bariatric surgery before undergoing AF ablation, concludes a retrospective Cleveland Clinic study. The study, published in *Europace*, evaluated outcomes among 239 consecutive patients with morbid obesity who underwent ablation between 2010 and 2016. It found a greater than threefold reduction in AF recurrence over three years in those who underwent bariatric surgery prior to ablation (n = 51) compared with control patients who received standard medical therapy for weight reduction. It also identified three pre-ablation factors that significantly increased the risk of AF recurrence after ablation: elevated epicardial fat volume, little or no weight reduction, and little or no improvement in glycated hemoglobin levels.

"It is well established that bariatric surgery leads to many short- and long-term cardiovascular benefits," says senior author Walid Saliba, MD, Director of Cleveland Clinic's Atrial Fibrillation Center. "This study indicates that such surgery can also help reduce recurrence of atrial fibrillation following ablation." More at consultqd.clevelandclinic.org/barisurgeryablation.



ROBOTICS



- ▶ For most providers, the Hippocratic oath's dictate to "first do no harm" is sacrosanct in its intended application to patient care. Yet providers are not always so diligent about extending this principle to themselves in their professional lives, particularly in the catheterization lab.



in the Cath Lab:

A LONG-OVERDUE TECHNOLOGY IS POISED TO RESHAPE PRACTICE

“Radiation exposure in the cath lab is what interventional cardiologists tend to worry about most,” says Jaikirshan Khatri, MD, a staff physician in Cleveland Clinic’s Section of Invasive and Interventional Cardiology. “Rates of left eye cataracts and left-side brain tumors within our subspecialty are alarming. The risks from radiation exposure are real.”

And the most widely used means to protect against that exposure — a lead apron — is not without major drawbacks of its own in terms of orthopaedic strain and injuries. “I’m not sure I know an interventional cardiologist who doesn’t have back problems from standing for hours on end with a lead apron on,” notes Dr. Khatri.

These occupational safety concerns are a key reason Cleveland Clinic installed a robotic system — the Corindus CorPath® GRX Vascular Robotic System — in one of its cath labs in June 2019. Cleveland Clinic has used the system for coronary interventions in patients since July, and Dr. Khatri is now using it for about 80% of his caseload.

“The robotic system reduces the operator’s radiation exposure by 95% and liberates him or her from lengthy standing with the lead apron on,” he says. “No other solution on the market addresses both of these major challenges to operators’ health.”

How it works

The system allows the operator to remotely control the equipment essential to percutaneous coronary and peripheral vascular interventions — i.e., guidewire, balloon and stent platforms, and the guide catheter — from the safety of a radiation-shielded cockpit (see next page). This is done via a remote control panel in the cockpit with a joystick and touchscreen pad to guide an articulated robotic arm mounted to the cath lab table. Attached to the arm is a disposable sterile cassette (photo at right) to which the guide catheter is connected and through which intravascular tools are advanced and retracted.

The robotic arm is maneuverable for both radial and femoral access. Notably, however, while the current system is compatible with rapid-exchange designs, its cassette cannot be used with over-the-wire equipment.

The CorPath GRX is the second-generation robotic system from Corindus, which built on the initial CorPath 200 system by introducing the ability to control the catheter. “That refinement was key to making the technology usable in a wide range of coronary interventions,” says Dr. Khatri.

While other robotic technology systems have been used for endovascular peripheral and aortic vascular procedures, the two CorPath systems are the only ones approved for coronary interventions in the U.S.

How we’re using it

Dr. Khatri and his colleague Rishi Puri, MD, PhD, were the first Cleveland Clinic interventional cardiologists to gain proficiency in robotically assisted procedures, but others are expected to be trained soon. These two physicians currently use the robotic system for the full range of coronary interventions, from straightforward to highly complex lesions, including chronic total occlusions (CTOs).

Dr. Khatri had treated about a dozen CTOs with the robotic system within the first two months of using it. “Most CTO cases need to be started manually because they require over-the-wire equipment, but they typically can be completed with the robot,” he says, adding that the same is true of cases involving atherectomy. Likewise, some cases with highly complex coronary anatomy need to be converted to manual procedures near the end because the needed equipment simply cannot be delivered by the robot.

Continued next page >





The ability to handle over-the-wire equipment is the main enhancement that Dr. Khatri expects from the next generation of robotic systems. “That’s the one thing that forces us to plan around the robot,” he explains. “If we could manage over-the-wire equipment, we could do pretty much all cases robotically from start to finish.”

Indeed, being able to weigh in on the next generation of robotic systems was a key impetus for Cleveland Clinic to acquire the robotic system at this time. “The technology isn’t yet quite where it ultimately needs to be, so we wanted to be able to offer our experiences and opinions to shape its future development,” Dr. Khatri says.

To that end, Cleveland Clinic has started a database to collect and evaluate its experience with the technology and share it with developers and the larger interventional cardiology community.

Peripheral vascular applications too

While Cleveland Clinic had not yet used the robotic system for endovascular treatment of peripheral vascular disease as of early autumn 2019, expansion along those lines is anticipated soon.

“The arteries involved in those procedures are typically nice and straight, so it’s even easier for the robot to work well in these cases,” says Dr. Khatri, who also performs peripheral vascular procedures. And because peripheral vascular interventions tend to involve more radiation exposure, he says there’s even more potential benefit for operator safety in this setting. “This is going to be a growing area that may even surpass use for coronary interventions. There’s a range of peripheral interventions that appear to be amenable to a robotic approach — below-the-knee, above-the-knee, carotid, renal and mesenteric interventions.”

What does the robot mean for patients?

At this point, the evidence base for robotically assisted interventions has largely been limited to the noncontrolled trials that supported regulatory approval of the first robotic systems, including the PRECISE and CORA-PCI studies in the case of percutaneous coronary intervention (PCI) and the RAPID trial in the case of peripheral vascular intervention (PVI).

Collective evidence from these trials and registry data to date indicate that both short-term outcomes and cardiovascular event rates at one year with robotically assisted PCI and PVI appear to be equivalent to those with manual PCI and PVI. “There has



been no signal of a disadvantage in patient safety or other clinical outcomes to date,” Dr. Khatri says, though he points out that no head-to-head comparisons have been conducted.

He adds that a limited body of data suggests that operators can more accurately measure lesion length with the robot, which may allow more reliable deployment of just the right length of stent. “The more precisely you can match stent length to lesion length, the better it is for the patient,” he explains. “So this represents a potential benefit to patients, but it needs to be more thoroughly investigated and confirmed.”

More patient benefits may be in store

Other potential patient benefits may be on the horizon. One involves “telestenting,” or the use of robotic interventions and telemedicine to broaden access to interventional cardiology care in areas that currently lack it. With appropriate real-time video and audio communication equipment, an experienced operator can perform a case from the remote control cockpit regardless of whether the table is on the other side of a glass wall or hundreds of miles away, so long as the table is equipped with a robotic arm and staffed by an on-site cardiologist or experienced technician. The feasibility of telestenting has already been demonstrated in small published series such as the REMOTE-PCI study.



Dr. Khatri in the cockpit during a case. Though he’s shielded from radiation, he may keep his lead apron on while seated in the cockpit for complex cases in the event he needs to return to the table to manually perform a portion of the case because over-the-wire equipment is required.

“I think robotics is going to become the way interventional cardiology is done pretty much everywhere over the next 10 to 15 years.” – Jaikirshan Khatri, MD

“Interventions offered remotely via telestenting are not a far-fetched idea and may start to be adopted in the not-too-distant future,” says Dr. Khatri. “This concept can offer real value to patients in rural or remote areas, who will be able to access tertiary center expertise without long-distance travel.”

Another possible benefit that Dr. Khatri foresees is the ability to extract metadata from the robotic devices for development of algorithms to improve the treatment of certain types of lesions.

A coming ‘robot first’ reality

“I think robotics is going to become the way interventional cardiology is done pretty much everywhere over the next 10 to 15 years,” Dr. Khatri concludes. “It’s going to take some additional development of the technology, but the likely future landscape looks clear.”

He says he’s already near a “robot first” approach in his own practice, as he offers a robot-assisted procedure to virtually all patients whose lesions don’t exclude it because of over-the-wire requirements. He notes that robotic procedure time is “pretty close” to that of manual procedures and that he’s encountered essentially no resistance to robotic procedures from patients, despite the lack of a clear patient benefit at this point.

And he sees real interest in robotics from his fellow interventionalists at Cleveland Clinic and beyond. “Once you demonstrate to your colleagues that this approach is feasible and effective, it’s just a matter of comparing your radiation badge reading to theirs,” he observes. “It quickly becomes a no-brainer.” ■

Contact Dr. Khatri at 216.445.3991.



Total Aortic Replacement for Post-Dissection Aortic Aneurysm: Case-Based Insights

Residual dissection requires lifelong surveillance.

BY CASSANDRA BECK, DO, AND FRANCIS CAPUTO, MD

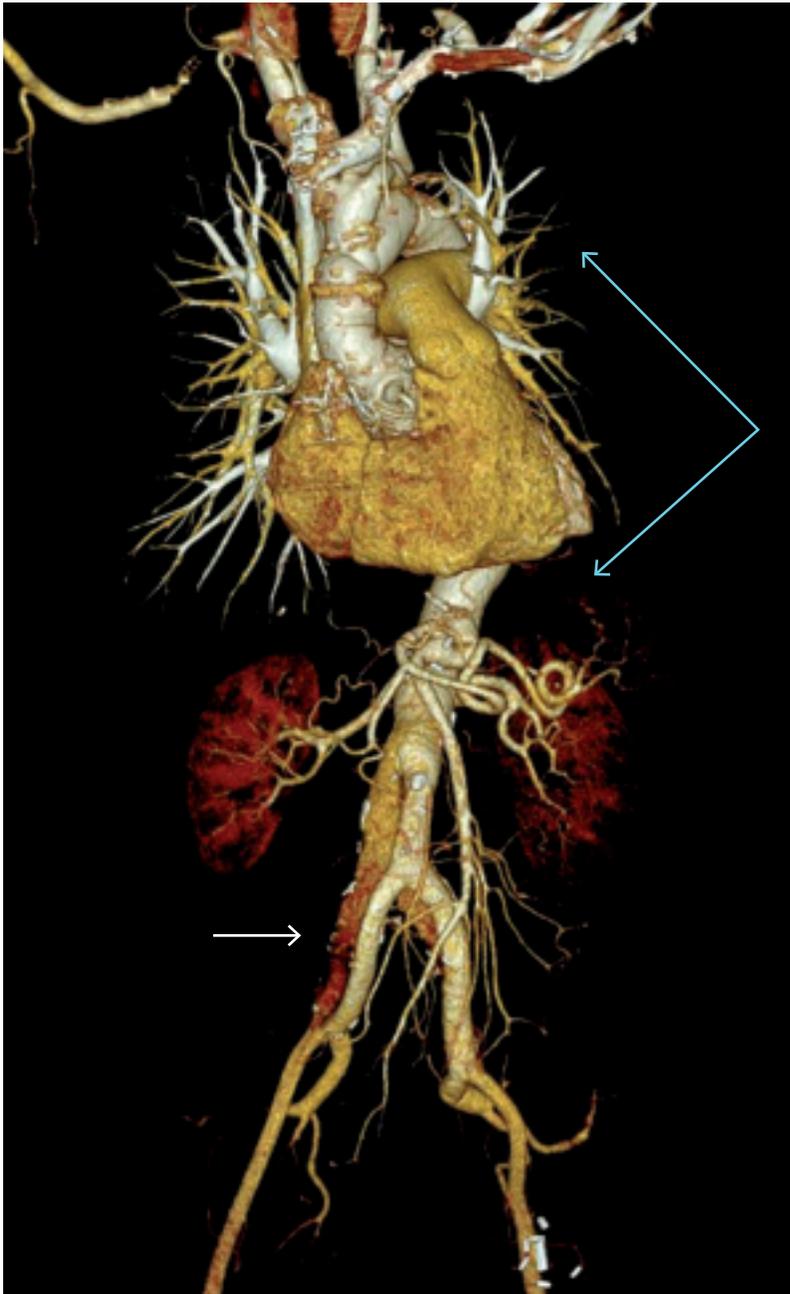


Figure 1. Volume-rendered three-dimensional CT reconstruction of contrast-enhanced images demonstrating intact surgical repair of the ascending aorta, aortic arch and thoracoabdominal aorta to the level of the renal arteries (blue arrows) and residual chronic dissection with aneurysmal degeneration of the infrarenal aorta and bilateral common iliac arteries (white arrow).

Open proximal aortic repair remains the standard of care for treatment of acute type A aortic dissection (ATAAD). Even when repair is successful, the distal false lumen may remain patent and lead to progressive aneurysmal degeneration of the involved residual aorta. Patients with residual dissection following type A repair often undergo multiple reoperations for disease progression. Chronic post-dissection thoracoabdominal aortic aneurysms (TAAAs) present substantial therapeutic challenges due to the significant morbidity and mortality associated with repair.

Patients can be treated with open surgical, endovascular or hybrid techniques, depending on the complexity of the anatomy, patient factors and operator experience. Cleveland Clinic's Aorta Center has become a national and international referral center for patients requiring complex aortic repairs such as the one profiled below, which ultimately represented total aortic replacement.

Case vignette

A 58-year-old woman with a past medical history of acute repair of type A aortic dissection presented for a surveillance CT angiogram. Her initial repair was done at age 43 at an outside institution, and at age 55 she further required a staged arch and TAAA open repair, which was performed by a cardiothoracic surgery team in Cleveland Clinic's Aorta Center.

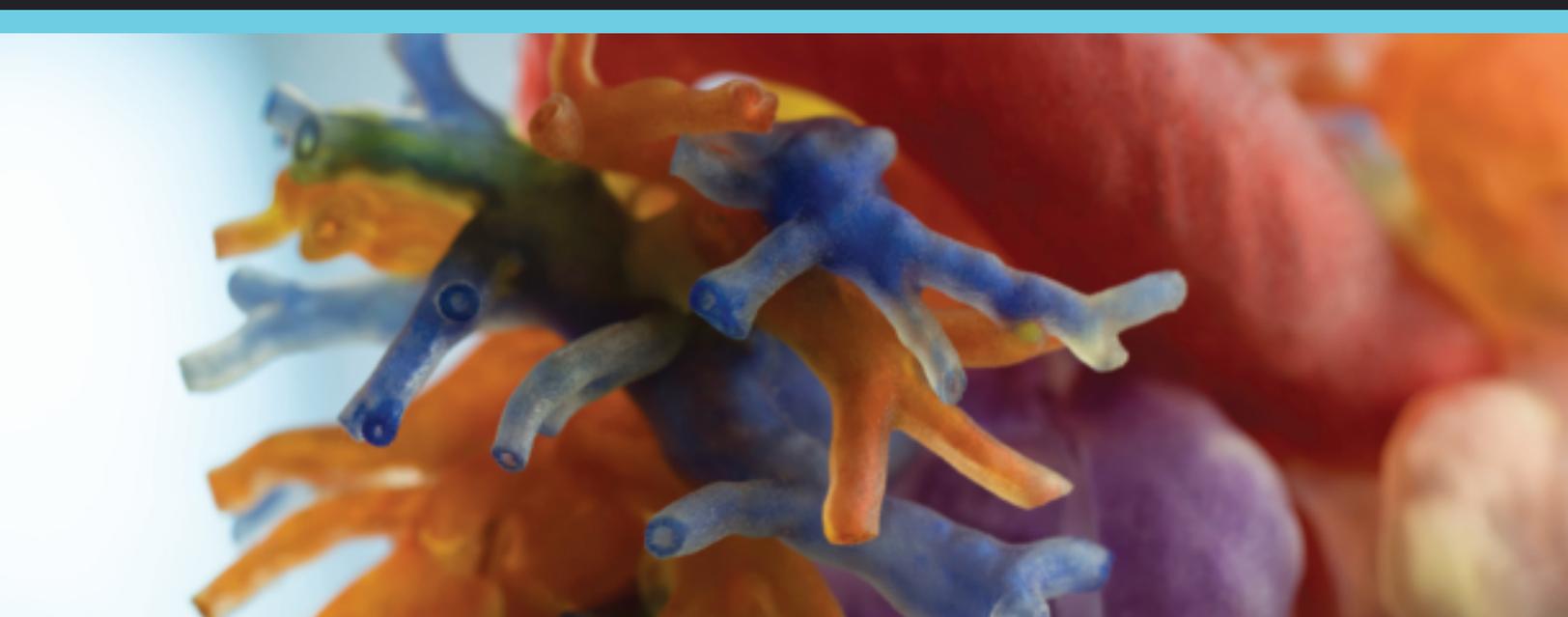
CT angiography at her current presentation demonstrated progressive aneurysmal degeneration of the chronically dissected untreated segments of the infrarenal aorta and bilateral common iliac arteries (Figure 1). She was referred for evaluation by Aorta Center vascular surgery staff, who recommended open aortoiliac repair.

HEART & VASCULAR

Vitals



A sampling of volumes and outcomes
from selected centers in Cleveland Clinic's
Miller Family Heart & Vascular Institute



Adult Cardiac Surgery

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

★ ★ ★
CABG

★ ★ ★
AVR

★ ★ ★
AVR + CABG

★ ★ ★
MVRR

★ ★ ★
MVRR + CABG

*For 7/1/16-6/30/19 for all categories but CABG, which is for 7/1/18-6/30/19.

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

1 of 3 Cleveland Clinic is 1 of only 3 STS Adult Cardiac Surgery Database participants out of more than 1,000 across the U.S. to achieve a 3-star (highest) rating in all 5 categories assessed

Ischemic Heart Disease — Surgical Treatment

1,476 CABG (coronary artery bypass graft surgery) volume in 2018

- › **852** isolated CABG | 624 CABG + other
- › **159** (10.8%) were reoperations

In-Hospital Mortality, Isolated CABG

Year	Cleveland Clinic Observed	STS Expected
2018 (N = 852)	0.7%	1.3%
2017 (N = 834)	0.8%	1.6%

In-Hospital Mortality, CABG + Other

Year	Cleveland Clinic Observed	UHC Expected
2018 (N = 624)	3.4%	6.7%
2017 (N = 671)	3.9%	5.8%

STS = Society of Thoracic Surgeons; UHC = University HealthSystem Consortium

Sources: (1) STS Adult Cardiac Surgery Database. (2) Vizient Clinical Data Base/Resource Manager™. Used by permission of Vizient. All rights reserved.

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

Vascular Disease

In-Hospital Mortality for Various Vascular Surgery Procedures

Mortality	Procedure	Time Frame/Sample
0%	Iliac stenting	2016-2018 (N = 380)
0.5%	Lower-extremity percutaneous interventions	2016-2018 (N = 1,135)
0.6%	Femoral endarterectomy with stenting	2015-2018 (N = 157)
0.6%	Lower-extremity bypass*	2015-2018 (N = 329)
1.5%	Carotid stenting**	2014-2018 (N = 198)
0.3%	Carotid endarterectomy**	2014-2018 (N = 575)

*Rate for lower-extremity bypass is 30-day mortality, not in-hospital mortality. **2018 mortality for these procedures was 0%.

Comparative Mortality Rates*

0.6% vs. 5.2% Observed vs. expected in-hospital mortality for elective open abdominal aortic aneurysm repairs, 2014-2018 (N = 357)

0.50 Observed-to-expected ratio for risk-adjusted mortality for 1,096 vascular surgery cases for “recent year” through Q3 2018 (among like-size academic centers)

*Source for expected rates: Vizient Clinical Data Base/Resource Manager™, used by permission of Vizient. All rights reserved.

Volume Snapshots

7,368 Vascular surgery procedures performed in 2018 in greater Cleveland region

48,895 Noninvasive vascular lab ultrasound studies performed in 2018 in greater Cleveland region

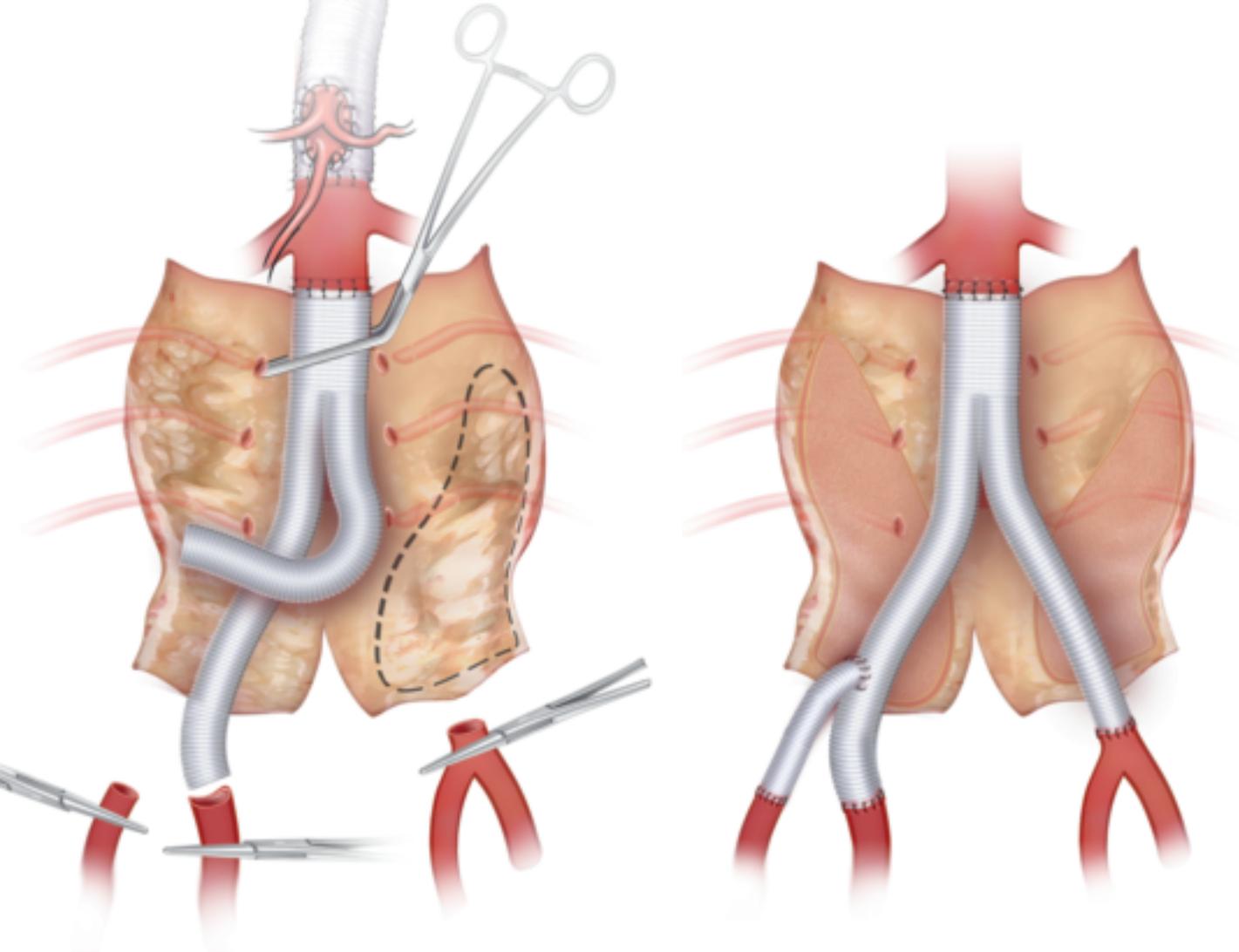


Figure 2. Illustrations demonstrating open repair of the infrarenal aorta with resection of the intimal flap and bypass to the right internal and external arteries and left common iliac artery bifurcation.

The patient underwent a final open infrarenal aortic repair with bypass to the right internal and external iliac arteries and to the left common iliac artery bifurcation (Figure 2). She recovered without complications and neurologically intact.

Takeaways

We have described a case of multidisciplinary, multistage open total aortic replacement for aneurysmal degeneration of the residual chronically dissected thoracoabdominal aorta and bilateral common iliac arteries after emergency repair of ATAAD more than a decade earlier. This case highlights the following important points:

- Lifelong imaging surveillance is required for patients with residual dissection following type A repair to identify progressive aortic dilation and prevent rupture.
- Open distal aortic repair can be performed with acceptable morbidity and mortality at experienced institutions with specialized Aorta Centers.
- Multidisciplinary teams with collaboration between cardiothoracic and vascular surgery staff are essential to provide optimal care for patients with extensive and complex aortic disease. ■

.....
Dr. Beck is a fourth-year resident and Dr. Caputo (216.445.9580) is a vascular surgeon in Cleveland Clinic's Department of Vascular Surgery.



Radiation-Associated Heart Disease: Management Pearls from a New Expert Review

JACC panel gives guidance on nuanced care of a complex disease.

Radiation-associated cardiac disease (RACD) — which typically arises years or decades after a cancer patient undergoes radiation therapy to the chest — should be systematically screened for and monitored, with care delivered by an experienced multidisciplinary team of cardiovascular specialists. So recommends a new review of RACD from an expert scientific panel convened by the *Journal of the American College of Cardiology*, which also calls for especially careful consideration in the timing and planning of cardiovascular surgery or transcatheter intervention.

The review (*J Am Coll Cardiol.* 2019;74:905-927) is a consensus effort by an international group of seven experts based on their experience with RACD over the past 20 years. It covers at-risk groups, clinical manifestations, screening recommendations, and management and surgical considerations.

“Radiation-associated heart disease can have diverse presentations that overlap with other cardiac conditions, and it may arise so long after the radiation exposure that clinicians don’t think of it,” says cardiologist and lead author Milind Desai, MD, one of three physicians from Cleveland Clinic’s Miller Family Heart & Vascular Institute on the expert panel. “But recognizing it is important, as management considerations are paramount to a patient’s quality of life and long-term survival.”

Who’s at risk?

The review drew mostly on available data from patients who received radiation therapy for breast cancer or Hodgkin’s lymphoma, although those who have received radiation for other cancers in the thorax are also at risk.

Identified factors conferring higher risk include:

- Age younger than 50 at time of radiation therapy
- Existing cardiovascular risk factors or disease
- Lack of shielding, or cobalt as the radiation source
- High cumulative dose (>30 Gy) or high dose of radiation fractions (>2 Gy/day)
- Tumor in or next to the heart
- Anterior or left chest radiation
- Concomitant chemotherapy, particularly with anthracyclines or trastuzumab

Manifestations of RACD

The wide range of cardiac complications associated with RACD — as well as pulmonary damage from radiation —

makes diagnosis particularly challenging. The main cardiac manifestations include:

- **Myocardial dysfunction**, which is likely related to diffuse fibrosis and which may manifest as impaired functional capacity without heart failure or as heart failure with preserved ejection fraction
- **Valvular disease** presenting as progressive valve thickening and calcification that results in valve stenosis and/or regurgitation, with left-side valves more often affected
- **Pericardial disease**, including pericarditis and sometimes chronic pericardial inflammation with resulting constriction that can be difficult to distinguish from restriction caused by underlying myocardial fibrosis
- **Vasculopathy** typically marked by long, tubular, concentric and frequently noncalcific lesions; resulting porcelain aorta may preclude percutaneous intervention or surgery
- **Conduction system dysfunction** related to fibrosis, with many patients requiring a pacemaker

Pulmonary fibrosis is another common consequence of radiation therapy, usually manifesting after many years. “The possibility of radiation-associated pulmonary disease should be an important consideration when weighing cardiac surgery for RACD,” says Cleveland Clinic cardiac surgeon Douglas Johnston, MD, another co-author of the review. “Pulmonary complications are a major source of perioperative morbidity and mortality.”

Screening of cancer survivors

The review recommends the following surveillance strategy for patients with a history of chest radiation therapy:

- Annual history and physical exam with a focus on signs and symptoms of RACD. If signs and symptoms are present, testing as needed to evaluate.



- Screening echocardiography to assess structural abnormalities, ventricular performance and valvular disease. Initially at five years after exposure in high-risk patients (10 years in others), with reassessment every five years.
- Functional noninvasive stress testing to screen for coronary artery disease (CAD). Initially at five to 10 years after exposure in high-risk patients, with reassessment every five years.

Specialized imaging plays a role in enhanced evaluation and preoperative assessment and planning. It should be assumed that patients suffered radiation injury to the aorta, ventricles, pericardium, lungs and chest wall. Among tests to consider:

- Multidetector cardiac CT for preoperative evaluation and planning; full assessment of aortic, valvular and intravalvular calcium; and, in some cases, noninvasive coronary angiography
- Nuclear scintigraphy to assess myocardial ischemia
- Cardiac MRI to assess myocardial fibrosis and pericardial constriction and as an adjunct to echocardiography in some cases
- Left and right heart catheterization with simultaneous pressure measurements to distinguish constrictive pericarditis from myocardial restriction
- Extracardiac vascular ultrasonography of the carotid and subclavian arteries
- Pulmonary function testing

“Significant radiation exposure is a critical risk factor that doesn’t show up in standard preoperative risk stratification scores,” notes cardiologist Patrick Collier, MD, PhD, Co-Director of Cleveland Clinic’s Cardio-Oncology Center. “For truly informed consent, these patients require more-detailed preoperative testing to better assess comorbidity, procedural risk and optimal treatment strategies.”

Team management, timing of intervention

The review provides specific management guidance, starting with the recommendation that patients be cared for by a multidisciplinary team. Medical therapy should follow standard guidelines, as no RACD-specific therapies have been identified and validated. However, most patients with significant symptoms eventually require invasive therapies.

The authors recommend that surgery generally be delayed to later in the disease course than would be the case without prior radiation therapy. Radiation injury to the lungs and pleura with resultant lymphatic dysfunction predisposes to intrathoracic fluid retention after surgery, hampering recovery and diminishing long-term quality of life.

“Avoiding redo surgery should be paramount,” says Dr. Johnston. “All issues, such as replacing multiple valves, should be taken care of during the first operation if at all possible.”

Systematic preoperative planning is critical, as is flexibility in dealing with unexpected reconstruction problems. An aggressive approach to double valve replacement is recommended due to RACD patients’ tendency to have extensive calcification and a small aortic root and mitral annulus. Because radiation-damaged valve tissue tends to thicken and scar over time, replacement is preferred over repair, especially for the mitral valve.

“Surgery for RACD often involves resection of extensive calcium and reconstruction of multiple areas of the heart, including the aorta and the annuli of the mitral and aortic valves,” says Dr. Johnston. “Our team’s experience with other complex multivalve surgery, in the setting of reoperation or endocarditis, has been essential to success in RACD.”

For RACD patients with CAD as the primary manifestation, percutaneous coronary intervention is usually preferred unless concomitant valvular disease can be addressed simultaneously with surgery.

Regarding transcatheter aortic valve replacement (TAVR), aortic valve disease more frequently involves extensive calcification of the valves and blood vessels, as well as severe conduction abnormalities, posing potential complications. With extensive planning, TAVR is still the preferred strategy for severe isolated aortic stenosis in this setting, particularly if transfemoral access can be safely used. “Careful evaluation of other valvular lesions is needed, and if there is evidence of advanced multivalvular disease (with or without concomitant CAD), surgery might be the preferred option,” says Dr. Desai.

Postoperative considerations

The article identifies a number of postoperative problems that tend to occur in this population: chronic pleural and pericardial effusions; conduction system disturbances, often requiring longer temporary pacing; prolonged postoperative diuresis, sometimes for weeks; and fibrosis-induced limitation of cardiac output, requiring avoidance of beta-blocker overuse and consideration of higher pacemaker rates.

Minimizing future risk

The review notes that improvements in radiotherapy protocols mean that patients now undergoing radiation therapy are expected to be at less risk for RACD in the future.

“The oncology community has made considerable progress in minimizing unwanted exposures,” says co-author Brian Griffin, MD, Cleveland Clinic’s Section Head of Cardiovascular Imaging. “But efforts in this arena are still a priority, as significant practice variations in radiation delivery remain and many questions are unanswered.” ■

Contact Dr. Desai at 216.445.5250, Dr. Johnston at 216.444.5613, Dr. Collier at 216.444.8429 and Dr. Griffin at 216.444.6812.



Rethinking Mortality Review in Cardiac Surgery by Looking for Triggers Across Phases of Care

Why and how we encourage phase-of-care mortality analysis among our affiliated programs

The morbidity and mortality review (M&M) has served the healthcare community well over the years, but is it the best tool for detecting patterns behind the triggers of potentially avoidable surgical deaths?

That question spurred a team from the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) a few years ago to develop a new approach to mortality review called phase-of-care mortality analysis (POCMA) (*Ann Thorac Surg.* 2012;93:36-43).

Surgeons in Cleveland Clinic's Department of Thoracic and Cardiovascular Surgery were impressed by the POCMA methodology, and by 2016 they adopted it with modest modifications into their own mortality review process. In the fall of 2016, this phase-of-care analysis platform was adopted by affiliate and alliance provider organizations participating in Cleveland Clinic's Cardiac Surgery Affiliate Program.

"POCMA represents a new, standardized way of doing mortality review," says cardiothoracic surgeon Edward Soltesz, MD, MPH, Director of the Cardiac Surgery Affiliate Program. "It has proved successful in helping hospitals implement center-specific systemwide protocols to enhance patient safety and improve outcomes, so we felt our affiliate and alliance partners would be eager to share our use of it."

POCMA vs. traditional M&M

The premise of POCMA is that each mortality is rooted in a single event that culminates in either immediate death or deterioration and eventual failure to recover after cardiac surgery.

The POCMA model was developed from a collaborative interrogation of all postsurgical mortalities over a 4.5-year period among Michigan institutions participating in the MSTCVS. The objective was to provide a reproducible, structured platform for mortality review with the aim of identifying the root cause by focusing on a seminal event that may have triggered a cascade of events leading to death.

The MSTCVS interrogation classified the specific phase and subcategory of care responsible for each mortality, identifying five phases of care and several categories of potential mortality triggers within each phase, as outlined in the figure. The POCMA process is designed to examine the seminal event in the context of the phases of care, and then to categorize the

root cause as either avoidable or unavoidable — and, if avoidable, to determine what system changes can be implemented to prevent similar events. The process allows for nuance, recognizing that a case may have more than one mortality trigger and that more than one phase of care may be involved.

The ultimate objective is to better identify areas of care that may be amenable to strategic interventions to reduce mortality and improve overall quality. The focus on triggers is a key difference from a standard M&M review, with POCMA emphasizing identification of where the system of care did not work and how to fix it.

One partner's experience with POCMA

Ridgewood, New Jersey-based Valley Health System is an alliance partner that has worked with Cleveland Clinic since 2015 and has enthusiastically embraced the POCMA process — not just for cardiac surgery but across other cardiovascular services as well. Exceptional high-quality care is an ongoing priority for The Valley Hospital, and this tool was an obvious process enhancement that the leadership team and physicians eagerly adopted and immediately found to be valuable.

"POCMA provides a defined system of analysis for each case event," says Mary C. Collins, RN, MSN, APN-BC, Director of Cardiac Specialty/Cardiac Surgery Programs, The Valley Hospital. "It promotes a comprehensive evaluation across the continuum of care, looking at how each phase of care may have contributed to the event. This helps us uncover areas for modification and improvement."

"The POCMA system encourages the surgeon to broaden analysis beyond the OR suite to improve results," adds Valley Health System cardiac surgeon Alex Zapolanski, MD.

Chief learnings from the POCMA process

Dr. Soltesz identifies at least two benefits that many cardiothoracic surgery programs are likely to reap from the POCMA process, regardless of program size.



The first is heightened recognition of the importance of the preoperative phase of care, particularly regarding complete and accurate presurgical risk assessment. “Too often surgeons may rush to a decision to operate without having all the necessary data on a patient’s comorbidities and appropriateness for surgery,” Dr. Soltesz observes. “POCMA has helped us and others realize how often mortalities begin in the preoperative phase, with the workup not being complete enough to reveal that a patient was too ill to be operated on.”

A second frequent benefit is greater impetus to prioritize myocardial protection during the intraoperative phase of care, he adds.

Rolling out POCMA to partner organizations

With these insights from Cleveland Clinic’s own use of POCMA, the Cardiac Surgery Affiliate Program team has integrated the methodology into its recurring quality meetings with affiliate and alliance programs. Whereas these meetings used to review only hard outcomes, they now include reviews of cases involving mortalities, which are done through the prism of POCMA.

Those reviews sometimes reveal a problem in a particular area, such as myocardial protection, that others have grappled with, allowing the team to share recommendations based on the experience and learnings of other affiliate and alliance partners.

All about the system, not the surgeon

While it may seem difficult for a program to have an external program direct a review of its mortality-related outcomes, the Cardiac Surgery Affiliate Program team notes that most partner programs take to it well over time. One reason is that they recognize that Cleveland Clinic has seen all kinds of case outcomes itself — both successes and failures — by dint of the very large number of cardiac surgery patients it treats every year and that insights can be gleaned from that experience.

Perhaps even more important is that POCMA is designed to objectify mortality review, and involving an outside program reinforces that. “POCMA encourages surgeons to take a step back and try to understand where a mortality trigger occurred,” says Dr. Soltesz. By standardizing the mortality review and introducing an outside reviewer, the POCMA process compels surgeons to carefully look at all phases of care and discourages premature assumptions about root causes.

“It’s not a review of the surgeon; it’s a review of processes and protocols — the system — and it’s based on phases of care,” Dr. Soltesz emphasizes. “It’s not about blame but rather about what the system might have missed, and why. Many affiliate and alliance programs have realized the value of this, and it becomes a win-win, because we continue to learn what does and doesn’t work across programs of various sizes.” ■

For information on affiliation and alliance opportunities with Cleveland Clinic’s Heart & Vascular Institute, visit clevelandclinic.org/heartaffiliates.

Figure. The five phases of care from the POCMA form.

Pre-Operative Phase

Cardiac risk factor profile, e.g.:

- Cardiogenic shock
- Myocardial viability

Noncardiac risk factor profile

- Renal failure on dialysis
- COPD
- Cirrhosis
- Combination

Judgment

- Timing of surgery
- Risk > benefit

Patient preparation

- Medical optimization failure

Patient evaluation

- Functional class
- ID occult disease(s)

Other: _____

Intra-Operative Phase

Anesthesia

- Technical (lines, TEE, ET)
- Pharmacologic management
- Recognition/treatment of decompensation

Surgeon

- Judgment
- Technical (Iacs, grafts, emboli)
- Myocardial protection

Cardiopulmonary bypass

- Parameters (Hct, MAP, mVO₂)
- Fluid management

CVA

Catastrophic event (specify): _____

Other: _____

Post-Op ICU Phase

Hemodynamic management

- Inotrope titration
- Adequate O₂ delivery

Respiratory care

- Prevent lung injury and VAP
- Appropriate support plan

ICU care

- (Keystone criteria)
- DVT/PE prophylaxis
- Sepsis prevention/treatment
- Nutritional support

Multisystem organ failure

Failure to thrive

Surveillance/recognition/ Rx of decompensation

Catastrophic event (specify): _____

Other: _____

Post-Op Floor Phase

Pharmacologic management

- Coumadin
- Other

Pulmonary embolism

CVA

Dysrhythmia (atrial or vent)

Surveillance/recognition/ Rx of decompensation

Sepsis prevention/ treatment

Catastrophic event (specify): _____

Other: _____

Discharge Phase

Appropriate disposition, e.g.:

- Nursing home/ECF vs. home

Pharmacologic details

Adequate instruction and support network

Catastrophic event (specify): _____

Other: _____

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Save a Spot in Your ACC.20 Itinerary for This Update on CVD Essentials

Prevention and Management of Cardiovascular Risk and Disease: Old Problems, Novel Approaches and New Evidence

Friday, March 27, 2020, 7-9:15 p.m.

(complimentary dinner symposium)

InterContinental Hotel, Chicago, Illinois

› ccfcme.org/cvprevention

An independent certified session at the American College of Cardiology Scientific Session (ACC.20)

After plummeting by more than 70% from 1950 to 2010, the U.S. death rate from cardiovascular disease (CVD) has nearly plateaued since, declining by just 4% from 2011 to 2018.

These numbers help illuminate the objective of this free CME-certified symposium at the start of the upcoming ACC.20 meeting in Chicago — i.e., to empower cardiologists to leverage new evidence and approaches to make more of a dent in lingering challenges in CVD care.

“As the population continues to age, we are seeing more and more patients presenting with cardiovascular risk or established cardiovascular disease,” says symposium co-director Steven Nissen, MD, Chief Academic Officer of Cleveland Clinic’s Miller Family Heart & Vascular Institute.

“This symposium is laser-focused on the latest strategies for preventing, delaying, diagnosing and managing these patients across several distinct realms of widespread cardiovascular disease and risk,” adds co-director Samir Kapadia, MD, Chair of Cleveland Clinic’s Department of Cardiovascular Medicine.

The program consists of six 15-minute presentations by Cleveland Clinic staff who are national leaders in their subspecialty:

- **The Complex and Disparate Effects of Obesity and CVD.** Dr. Nissen will review the nuances of the latest evidence on the role of obesity in CVD and sort through evidence that substantial weight loss can reduce the risk of major cardiovascular events in patients with both obesity and diabetes.

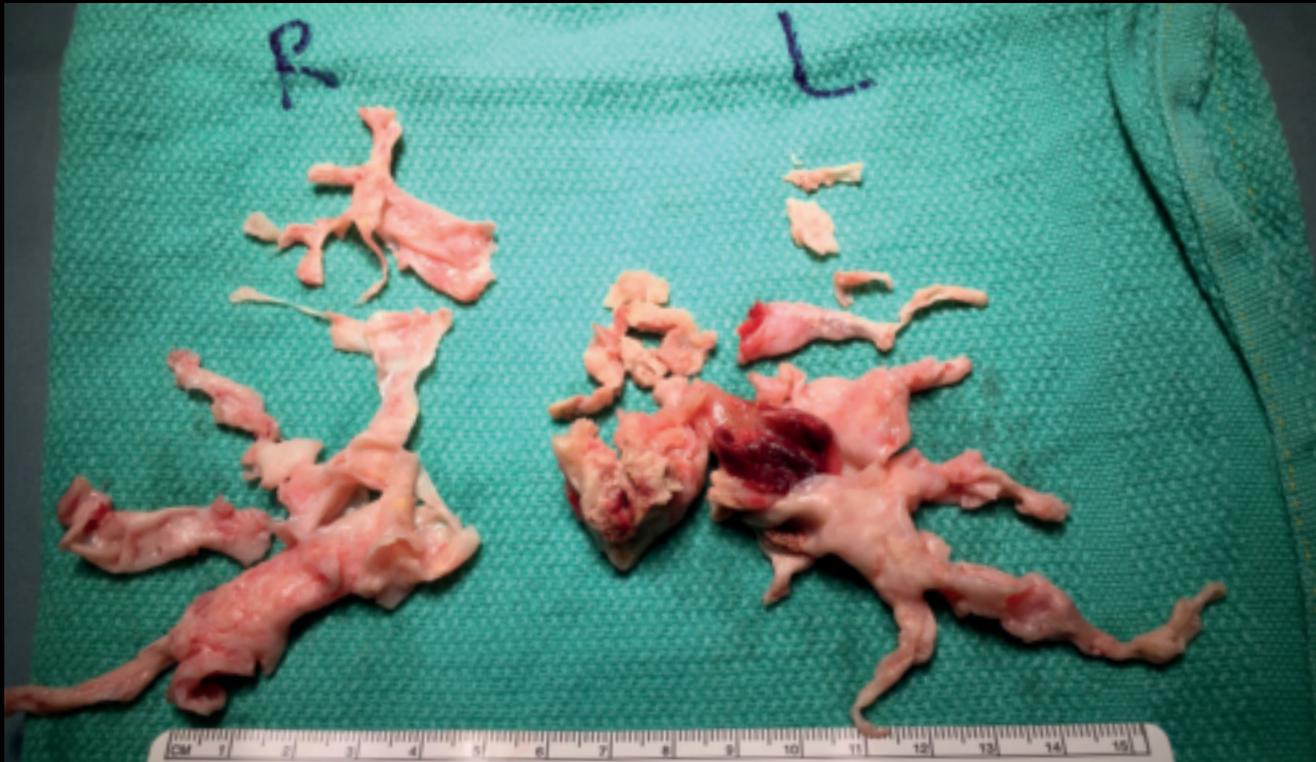
- **The Role of Lipoprotein(a) in CVD: Present and Future Therapeutic Options.** Elevated lipoprotein(a) has been virtually untreatable to date, but Cleveland Clinic is leading an international phase 3 trial of an antisense oligonucleotide that promises to potentially change that. Section Head of Preventive Cardiology Leslie Cho, MD, will update attendees on Lp(a)’s role in atherosclerotic disease and details of the new trial.
- **Glucose-Lowering Therapies for Cardiovascular Risk Reduction in Type 2 Diabetes Mellitus.** Few areas of CVD management have seen as much recent research activity as glucose-lowering therapies, yet the results demand careful interpretation. Section Head of Clinical Cardiology Venu Menon, MD, will help translate the evidence for real-world application.
- **Who Is a Candidate for Afib Ablation? And Does It Tackle Death, Stroke and Bleeding Risk?** Section Head of Electrophysiology Oussama Wazni, MD, will recap and interpret the latest findings in catheter ablation for atrial fibrillation, from patient selection and timing of ablation to effects on clinical event rates in the wake of the CABANA trial.
- **Optimizing Care for Patients with Valvular Disease: Recognition, Referral and Timing.** Dr. Kapadia will share takeaways from the 2019 multisociety expert consensus document on this topic and provide insights on the latest in transcatheter therapies for aortic and mitral valve disease from his perspective as a key investigator in trials such as PARTNER 3, COAPT and more.
- **A Surgeon’s Perspective on Management of Valvular Disease: What Transcatheter Tools and Outcomes Are Necessary to Achieve Surgical Results?** Cardiothoracic surgeon Douglas Johnston, MD, adds a multidisciplinary take with an outcomes-based comparison of transcatheter and surgical strategies and which patients are best served by each.

“This survey of new developments across a range of cardiovascular disease areas is an ideal way to prep yourself for the ACC meeting that begins in earnest the next day,” says Dr. Kapadia. “We hope you can join us.” ■

Register at ccfcme.org/cvprevention.

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

Image of the Issue



PULMONARY THROMBOENDARTERECTOMY FOR CTEPH

Chronic thromboembolic pulmonary hypertension (CTEPH) is a potentially lethal condition that develops from unresorbed pulmonary emboli. It's estimated to develop in about 3% of patients who survive a pulmonary embolism (PE), but as many as half of patients present without that history.

Clinicians should be on the lookout for CTEPH in patients with a prior PE who exhibit shortness of breath — and in any patient with unexplained shortness of breath or pulmonary hypertension, even in the absence of prior PE.

Vigilance is in order since CTEPH remains underrecognized and carries a high mortality if left untreated. Fortunately, pulmonary thromboendarterectomy is curative in many cases of CTEPH. The operation involves removal of clot and scar tissue lining the pulmonary arteries while the patient is under deep hypothermic arrest on a heart-lung machine. A specimen extracted from a recent case is shown above.

Cleveland Clinic is one of a handful of high-volume centers with the multidisciplinary expertise to conduct this delicate and difficult procedure, performing about 40 of the 350 to 400 cases done in the U.S. each year. While the operation has historically carried a 30-day mortality of about 5% to 10%, Cleveland Clinic's mortality is approximately 2%.

“Contrary to lingering misperceptions, there are few CTEPH patients who aren't likely to benefit from pulmonary thromboendarterectomy,” says Michael Tong, MD, MBA, one of the Cleveland Clinic cardiothoracic surgeons who performs the operation. Potential candidates include the elderly and those with high body mass index or with extremely high pulmonary pressures and severe right heart failure.

“We'll offer this operation even to patients in their 80s,” Dr. Tong says. “Treating CTEPH patients makes a profound difference. They can essentially go back to a normal life.” ■

Contact Dr. Tong at 216.445.0807.

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19-HRT-3916

Live CME Events from Cleveland Clinic

Valve Disease, Structural Interventions and Diastology Summit

Fri.-Sun., Feb. 28-March 1, 2020

Diplomat Beach Resort
Hollywood, Florida

Information/registration:
ccfcme.org/echo

Prevention and Management of CV Risk and Disease: Old Problems, Novel Approaches and New Evidence

Fri., March 27, 2020, 7-9:15 p.m.
(complimentary dinner symposium)

InterContinental Hotel
Chicago, Illinois

An independent certified session at the American College of Cardiology Scientific Session (ACC.20)

Information/registration:
ccfcme.org/cvprevention

(see page 14 for more detail)

Emerging Concepts in Cardiac Electrophysiology: The Present and the Future

Tues., May 5, 2020, 6:30-9:15 p.m.

(complimentary dinner program)
San Diego, Calif.

An official educational satellite session at Heart Rhythm 2020

Information/registration:
ccfcme.org/epconcepts2020

Lead Management 2020: Predicting Risks, Strengths and Limitations

Wed., May 6, 2020, 6:30-9:15 p.m.

(complimentary dinner program)
San Diego, Calif.

An official educational satellite session at Heart Rhythm 2020

Information/registration:
ccfcme.org/leadmgmt20

2nd Multidisciplinary Master Class in Endocarditis and Other Cardiovascular Infections

Thu.-Fri., May 14-15, 2020

InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration:
ccfcme.org/endocarditis20

Heart Failure 2020

Fri., May 29, 2020

InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration:
ccfcme.org/heartfailure2020

21st Annual Intensive Review of Cardiology

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

InterContinental Hotel & Conference Center | Cleveland, Ohio

Information/registration:
ccfcme.org/cardioreview20

State of the Art Echocardiography 2020

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

Hilton Cleveland | Cleveland, Ohio

Information/registration:
ccfcme.org/echocardio20

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



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