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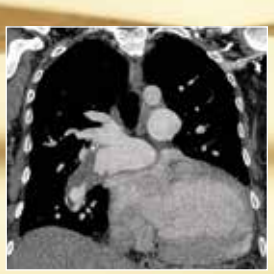
Cleveland Clinic

Cardiac Consult

Heart and Vascular News from Cleveland Clinic | Fall 2016

Keeping CTEPH in Check



Advancing Surgical and Interventional Strategies for Chronic Thromboembolic Pulmonary Hypertension

pp. 8-11

Dear Colleagues:

"Going into surgery with a plan A is never enough. We also need plans B, C and D." So writes our colleague Sudish Murthy, MD, PhD, in his piece on page 16 of this issue of *Cardiac Consult* recounting one remarkable case that stands out among the 7,000 or so patients he's treated as a thoracic surgeon.

Planning and resourcefulness served his patient very well in this case, and these traits may be more important than ever as we all navigate the technological, regulatory and reimbursement changes that are now shaping cardiovascular practice in unprecedented ways. In fact, the centrality of good planning and preparedness is evident in almost every story in this issue.

Some examples are obvious, like our "Image of the Issue" feature on page 7 profiling how our cardiac imaging specialists are using 3-D printing to develop novel functional models of severely stenotic aortic valves to individualize the planning of surgical repair.

Other examples are less overt, like the discussion on pages 14-15 of how heart transplant specialist Eileen Hsich, MD, is taking a lead role in sketching out how our nation can better align donor heart allocation policies to bridge the yawning gap between supply and demand on the heart transplant wait list. Carefully planned revisions based on diligent analysis are needed, and Dr. Hsich and colleagues are helping guide the way.

Or consider our cover story package on chronic thromboembolic pulmonary hypertension (CTEPH). While the first half focuses on the established but challenging surgical treatment of this underrecognized condition, the second half features a novel catheter-based procedure for inoperable cases called balloon pulmonary angioplasty. Cleveland Clinic physicians diligently planned and trained with Japanese specialists who pioneered this procedure before we successfully performed it in two cases earlier this year. As one of only three U.S. centers performing balloon pulmonary angioplasty in this population to date, Cleveland Clinic is able to offer a resourcefulness in managing CTEPH that few can match.

This tradition of careful and deliberate planning has been central to Cleveland Clinic's recognition by *U.S. News & World Report* as the nation's No. 1 hospital for cardiology and heart surgery for 22 straight years, including 2016-17. And it's a tradition that we are committed to continuing. We thank you, our colleagues and partners across the nation, for your enduring confidence in collaborating with us on some of your most complex cases. We look forward to together forging plans A, B, C and D for many more cases to come.

Respectfully,

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Heart & Vascular Vitals:
Focus on Cardiovascular Medicine

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

Four-Star Achievement

Cleveland Clinic achieved 4-star (highest) ratings in two voluntary public reporting metrics — (1) use of appropriate medications before and after PCI, and (2) use of appropriate medications after ICD implant — in the most recent reporting period.
(Source: American College of Cardiology [ACC] National Cardiovascular Data Registry [NCDR®] database)

Selected Procedural Volumes (2015)

8,153
Diagnostic cardiac catheterizations

1,559
EP ablations (863 for atrial fibrillation)

1,435
Device implants

1,038
Lead extractions

1,610
Interventional cardiac procedures

303
TAVR procedures

Outcomes Snapshots

0.9%
In-hospital mortality among patients undergoing PCI in 2015, vs. 1.8% average for comparable U.S. hospitals (Source: ACC NCDR CathPCI Registry®)

0.97%
Risk-adjusted ICD implant complication rate in 2015, vs. 1.41% national median and 1.09% national 90th-percentile threshold (Source: ACC NCDR ICD Registry™)

2.3% actual vs. 7.2% expected
In-hospital mortality among TAVR patients in 2015 (Source: Vizient Clinical Data Base/Resource Manager™, used by permission of Vizient. All rights reserved.)

Fast Facts

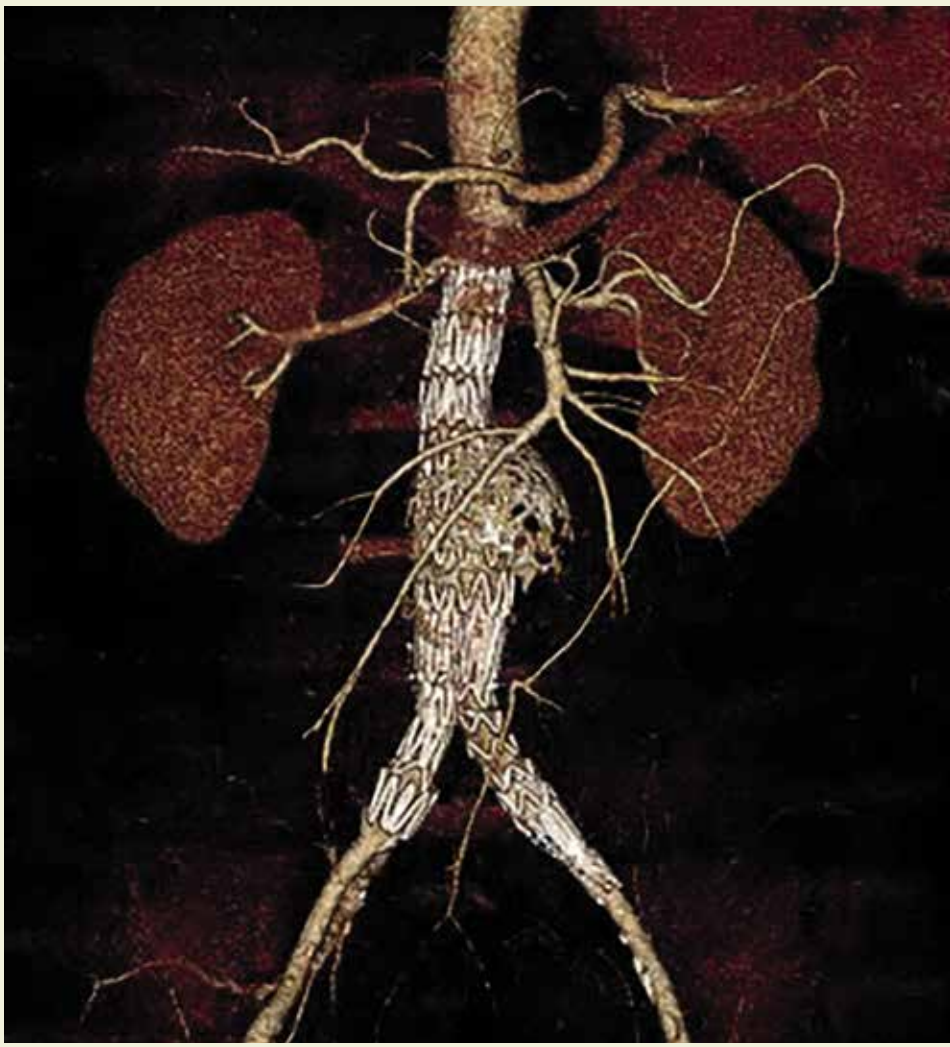
7 Number of consecutive quarters that 100% of STEMI patients have had a door-to-balloon time < 90 minutes (through Q2 2016)

2,027 Number of patient visits to Cleveland Clinic's Center for Pericardial Disease in 2015, a doubling of annual volume since 2011

The Changing AAA Repair Landscape: Insights on 5 Issues to Help Navigate It

Just two decades ago, the only treatment for an abdominal aortic aneurysm (AAA) was open surgery. Today, seven FDA-approved endograft devices provide many patients with a minimally invasive alternative.

Cleveland Clinic vascular surgeons participated in trials that led to the approval of nearly every new AAA repair device on the market, and they continue to contribute to refinements in AAA management. Two of those surgeons recently shared their insights on five leading issues and developments in AAA repair.



1. First Head-to-Head EVAR Device Comparison

In a recent study (*J Vasc Surg.* 2014;60:876-883), Endologix's AFX® Endovascular AAA System extended the proximal neck seal by about 5 mm in 70 percent of enrolled patients. Based on these promising data, the multicenter LEOPARD trial has been launched to compare the AFX device with other endograft devices in a real-world setting. In fact, LEOPARD will be the first industry-sponsored randomized trial to pit different FDA-approved devices for endovascular aneurysm repair (EVAR) against one another. Target enrollment is 800 patients across up to 80 centers. Follow-up will continue for five years.

Cleveland Clinic vascular surgeon Lee Kirksey, MD, believes LEOPARD has the potential to answer questions about which device best treats patients. "This is the first time we're getting a sense of head-to-head comparisons of innovative, minimally invasive devices to treat aneurysmal disease," he says.

2. Remaining Open to Open Surgery

While endografts have revolutionized AAA treatment, especially for community physicians, open surgery may still be the best option for patients with complex aortic anatomy. Cleveland Clinic performs many open surgeries for AAA patients with unfavorable anatomy or after endograft devices have failed.

"We have the world's largest experience in treating failures of endovascular technologies," says Sean Lyden, MD, Chairman of the Department of Vascular Surgery. "We see two modes of failure: early from use in unfavorable anatomy, and late from aortic disease progression and device failure (*J Vasc Surg.* 2014;59:886-893). We are uniquely able to perform minimally invasive fenestrated repair in some and open removal in others (*J Vasc Surg.* 2014;59:1479-1487)."

Younger and healthier AAA patients may also find open surgery to be a better option. For one, the lifelong surveillance

needed for endovascular repair poses a small but real cancer risk due to radiation from CT scans (*Acta Radiol.* 2016 Jun 8 [Epub ahead of print]; and *J Cardiovasc Surg (Torino)*. 2010;51:95-104). Additionally, endograft devices have been tested to last through a simulated 10-year life cycle, but many young and healthy AAA patients will live significantly longer than that. "We are now seeing some devices failing after 10 years and requiring removal," notes Dr. Lyden. "Yet removal of the device is associated with more complications and risk of death compared with open native AAA repair."

3. The End of Type II Endoleaks?

About 15 to 20 percent of AAA patients receiving an endograft will still have a flow into the aneurysm sac from the lumbar arteries or the inferior mesenteric artery (i.e., a type II endoleak) at one year. Type II endoleaks require treatment when growth of the aneurysm is found. "Even when the aneurysm is not growing, a type II endoleak can cause the patient to be anxious about the durability of the repair," explains Dr. Lyden. "We spend a lot of time reassuring the patient that treatment is not needed in many cases."

However, a promising new EVAR device under investigation at multiple sites, including Cleveland Clinic, has been shown to markedly reduce the presence of type II endoleaks (*J Vasc Surg.* 2016;63:23-31). The Nellix® EndoVascular Aneurysm Sealing System (Endologix) employs a unique mechanism using a polymer with the consistency of a pencil eraser to fill and seal the sac. The polymer also takes the pressure off the aortic wall, sealing the aneurysm sac.

"It's difficult not to be enthusiastic about the Nellix device," Dr. Kirksey says. "The idea that we may substantially mitigate the rate of type II endoleaks is exciting."

Dr. Lyden notes that early data suggest that "the elimination of concern over type II endoleaks" may be possible for many patients. "The approach of creating a sealing of the sac is unique," he says. "Secondary embolization procedures for type II endoleaks might become a thing of the past."

4. Operation vs. Observation

It's generally understood that patients with an AAA below a certain diameter may not need immediate treatment. Dr. Lyden says Cleveland Clinic surgeons generally treat aneurysms larger than 5.5 cm in diameter in men, based on findings of the UK Small Aneurysm Trial (*Br J Surg.* 2007;94:702-708) and the ADAM trial (*Arch Intern Med.* 2000;160:1425-1430). He treats aneurysms down to 5 cm in women, for whom better data on when best to treat are lacking.

Dr. Kirksey, citing the PIVOTAL trial (*J Vasc Surg.* 2010;51:1081-1087), says aneurysms in the 5- to 5.5-cm range can be considered for treatment, especially given the low mortality rates for minimally invasive surgery. But age matters too. "For patients in their 50s or 60s," he says, "you need to have a frank discussion of the long-term risks of endovascular stent graft failure, which loom larger for younger patients with longer life expectancy (*N Engl J Med.* 2015;373:328-338). Because you're talking about the potential for problems over a 20-year window, younger patients must fully understand all their options and be offered the option of open repair."

"We'll continue to be involved in the development and evaluation of new minimally invasive endovascular devices for treating aortic aneurysms," adds Dr. Lyden. "However, the ideal way to offer excellent care is by selecting the specific therapy best suited to each patient's individual needs, whether it's an endovascular approach, a larger open procedure or a combined approach. By drawing on Cleveland Clinic's decades of experience as a national leader in the treatment of aortic aneurysmal disease, we are equipped to offer patients whichever procedure they're most likely to fare well with."

5. To Go Off-Label or Not?

Patients who do receive a device are often treated outside FDA-approved instructions for use. Dr. Kirksey notes that increasing evidence suggests that off-label use yields inferior results (*Surg Today.* 2015;45:880-885). This was first observed by former Cleveland Clinic vascular surgeon Roy Greenberg, MD, who published findings (*Circulation.* 2011;123:2848-2855) that rates of compliance with EVAR device guidelines were low and rates of post-EVAR aneurysm sac enlargement were high, raising concern for long-term risk of aneurysm rupture.

Dr. Kirksey says the success of off-label use depends on the particular circumstances, with the proximal neck between the renal arteries and the start of the aneurysm proving to be an especially problematic region. "If that segment of the aorta is diseased or doesn't have adequate length or reasonable circumference to be treated with a standard endograft," he notes, "the patient is going to have more issues."

He adds that going off-label might be reasonable for sicker patients or those with limited life expectancy. But for healthy patients, alternatives like open surgery or a fenestrated or branched device should be considered.

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Finding Strength in Numbers to Tackle EP Management Challenges

Novel retreat for affiliated providers promotes best practices.

One of the most interesting aspects of leading a network of allied and affiliated provider organizations like the Cleveland Clinic Cardiovascular Specialty Network is the window it provides into which issues are repeatedly cited as challenges by hospitals and health systems around the country.

It was that type of insight that led to Cleveland Clinic's first Electrophysiology and Pacing Lab Management Retreat, held April 5, 2016, on Cleveland Clinic's main campus. The event drew representatives of hospitals from around the country with whom Cleveland Clinic's Miller Family Heart & Vascular Institute has forged affiliations or alliances or entered into arrangements to provide consulting services.

Born of Common Challenges

The idea stemmed from information gathered at more than 25 consulting site assessments performed by the Cleveland Clinic team that manages these collaborations (the "affiliate team"), made up of both clinical and operational experts. Although the assessments were done all over the country, team members noticed that a handful of themes and challenges related to electrophysiology (EP) surfaced again and again. They figured the best way to help these organizations identify opportunities to improve management of their EP departments might be to bring them together to share best practices and learn from one another at a retreat led by Cleveland Clinic EP content experts.

Interest Was Intense

Clinical leaders and administrators from over 20 hospitals across 13 states came to the one-day retreat. The event provided an opportunity for participants to network with EP leaders from like-sized hospitals as well as learn successful strategies implemented at organizations of various sizes.

The agenda covered common themes identified from the site assessments, as listed in the box below. Panel discussions provided a chance for participants to share their struggles and discuss potential solutions with EP experts and colleagues from both larger and smaller organizations.

Common EP Challenges Addressed at the Retreat

- Cardiac registries
- Staff onboarding
- Yearly competencies
- Role of the prep/recovery team in the care of EP patients
- Using block scheduling
- Process improvement and use of dashboards in the EP lab
- Hybrid OR utilization
- Running a device clinic
- Optimizing outpatient workflow

Dashboards Draw Special Attention

One topic that spurred significant discussion was process improvement and the use of homegrown dashboards in the EP lab. Participants noted that as more and more healthcare metrics are being publicly reported, it's more important than ever to routinely track key metrics. Attendees shared how using dashboards to assess a department's quality and efficiency can be an effective, transparent way to stimulate engagement and participation in improving key metrics. One organization discussed how its implementation of dashboards has improved room turnover times, reduced staff overtime, improved start times and more. Many participants expressed interest in learning more about how to use business analytics to improve productivity, efficiency and quality of care.

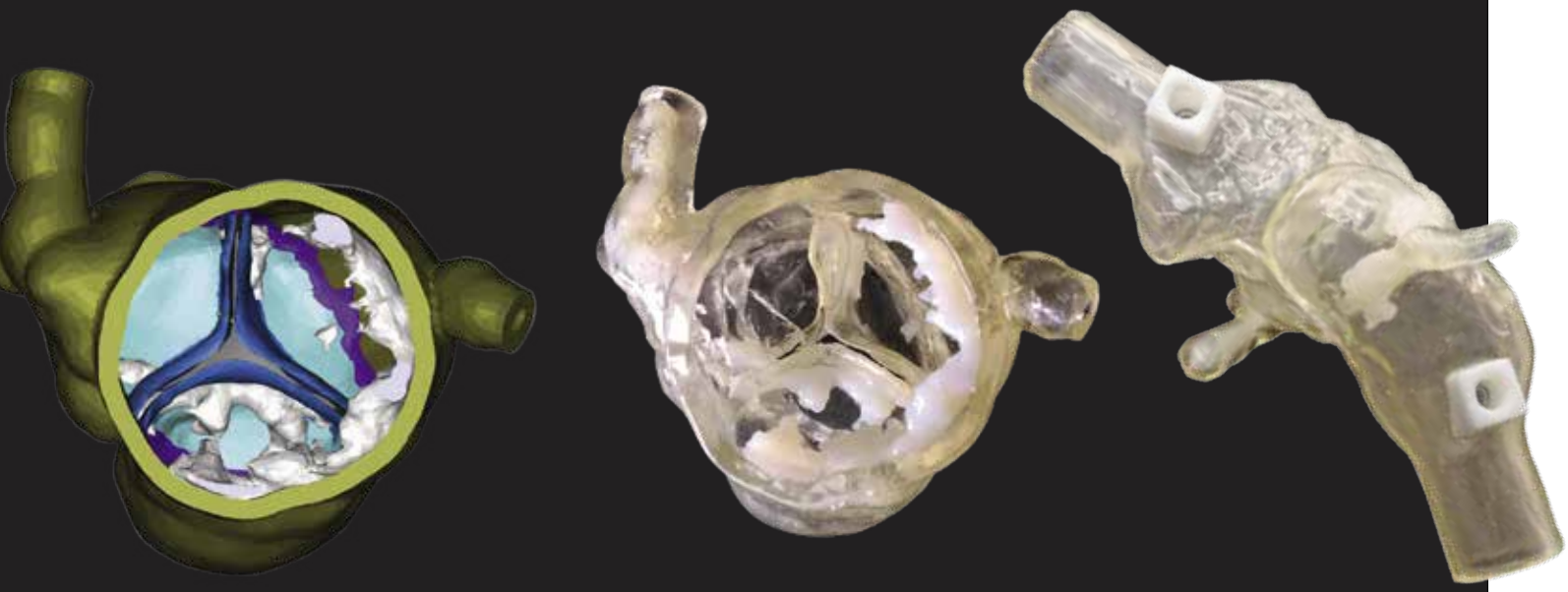
More Retreats to Come

Participant feedback consistently described the retreat as informative and valuable. The event's success has already prompted more retreats focused on recurring themes in other specialty areas noted from site visits: an Echo Quality Assurance Boot Camp was held in September, and a Cardiovascular Medicine Retreat is being considered for spring 2017. These and others will retain the focus on sharing best practices to promote efficiency, reduce healthcare costs and enhance care quality nationwide.

"The best get better by collaborating and learning from each other," says Joseph Cacchione, MD, Chair of Operations and Strategy for Cleveland Clinic's Miller Family Heart & Vascular Institute. ■

For more on advisory services and affiliation opportunities with Cleveland Clinic, see affiliatenetwork.clevelandclinic.org.

Image of the Issue



HOW 3-D PRINTING PROMISES TO ENHANCE AORTIC STENOSIS CARE

An innovative research project at Cleveland Clinic is revealing how three-dimensional (3-D) printing may enhance understanding of valvular pathophysiology in patients with atypical forms of aortic stenosis.

Using 3-D printing, advanced cardiac imaging fellow Serge Harb, MD, and several Cleveland Clinic colleagues developed a functional model of a severely stenotic aortic valve. They built a circuit around the valve and replicated the pressure gradients obtained through echocardiography. Manipulating the parameters allowed them to see how the valve would behave under various hemodynamic conditions.

Their successful proof-of-concept study, among the first to include a functional assessment of a 3-D-printed valve, was presented at the American Society of Echocardiography's annual scientific sessions earlier this year.

The images above show key steps in preparing the 3-D-printed model:

- **Left image:** Creation of an initial digital model based on a patient's CT scans
- **Center image:** Generation of a 3-D-printed sample part showing leaflet and calcium detail
- **Right image:** Generation of the full 3-D-printed model with tubing connectors and pressure ports

"Printing the particular valve of a patient with an atypical form of aortic stenosis may help us provide personalized management," says Dr. Harb, "and could be especially helpful in planning surgery or TAVR procedures."

"This is an exciting new field," says cardiac imaging specialist L. Leonardo Rodriguez, MD, staff adviser on the project. "We hope that by creating a 3-D-printed model that simulates various hemodynamic conditions, we'll be able to refine the diagnostic criteria for aortic stenosis."

For more on the proof-of-concept study, see **consultqd.clevelandclinic.org/3Dvalve**. ■

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Pulmonary Thromboendarterectomy for CTEPH:

A Challenging but Highly Curative Approach to a 'Vastly Underrecognized' Condition

Chronic thromboembolic pulmonary hypertension (CTEPH) is a potentially deadly and underdiagnosed condition that develops from unresorbed pulmonary emboli. A multidisciplinary team at Cleveland Clinic is one of just a handful across the U.S. that treats CTEPH, using a specialized surgical procedure called pulmonary thromboendarterectomy (PTE).

"We want to spread the word, because CTEPH is vastly underrecognized," says Gustavo Heresi-Davila, MD, Medical Director of the Pulmonary Thromboendarterectomy Program in Cleveland Clinic's Department of Pulmonary and Critical Care Medicine. "There are many people affected by CTEPH who are not being diagnosed, yet there's a highly effective surgical procedure that can cure most of them."

PTE: Grace Under Pressure Is a Must

Performing a PTE requires a dedicated team, a highly skilled surgeon and extreme efficiency under pressure. It involves quick yet painstaking removal of thin, scarred clot tissue lining the pulmonary arteries (Figure), with the patient rendered hypothermic to allow for periods of circulatory arrest on a heart-lung machine to enable a bloodless field.

Ideally, the procedure in each lung should be completed within 20 minutes, as that's the longest a patient can remain in circulatory arrest before reperfusion is necessary. "There's no tolerance for error," says Nicholas Smedira, MD, the cardiothoracic surgeon who first performed PTE at Cleveland Clinic, starting in the mid-1990s. "You have to do it fast. It's really, really hard surgery."

In 2010, Dr. Heresi-Davila established a team at Cleveland Clinic to standardize protocols for PTE patient selection, preoperative evaluation, medical optimization and postoperative follow-up. The team includes members from pulmonary medicine, cardiothoracic surgery, nuclear medicine, radiology, cardiology, anesthesiology and critical care medicine.

Cure Rates Above 90 Percent

Over the past 20 years, Dr. Smedira and the team have performed more than 160 PTE procedures, with current CTEPH cure rates of 90 to 95 percent. Since 2010, operative mortality has dropped from around 12 percent to less than 4 percent. And rates of significant complications — such as confusion and disorientation from neurologic injury, or respiratory dysfunction due to lung injury — are now below 10 percent.

The improvement over time is due mainly to the protocol and the team, both doctors say.

"Major changes have taken place in the management of patients on the heart-lung machine [perfusion therapy], anesthesiology and postoperative critical care management," notes Dr. Smedira. "Those have made a huge difference. But the way I do the operation today isn't much different from 20 years ago."

"It's what happens before and after the operation that we have improved," Dr. Heresi-Davila adds. "It's a whole package of medical optimization that improves outcomes."

As one of the nation's most experienced centers for PTE, Cleveland Clinic has achieved PTE outcomes comparable to those of the University of California, San Diego, which pioneered PTE for CTEPH in the U.S. in the 1980s.

CTEPH: What Referring Physicians Need to Know

For referring clinicians, the first step is recognizing CTEPH by considering it in the differential diagnosis of pulmonary hypertension of unclear etiology, and even in patients who merely have unexplained shortness of breath or exercise limitation.

"So much of treating CTEPH is recognizing its presence," Dr. Smedira says. He notes that some patients do not exhibit pulmonary hypertension at rest but have symptoms during exercise, as on a stress echo. For those in whom CTEPH is suspected, a lung ventilation/perfusion scan is the gold standard for screening.

The estimated incidence of CTEPH within two years of initial pulmonary embolism is about 4 percent, but that

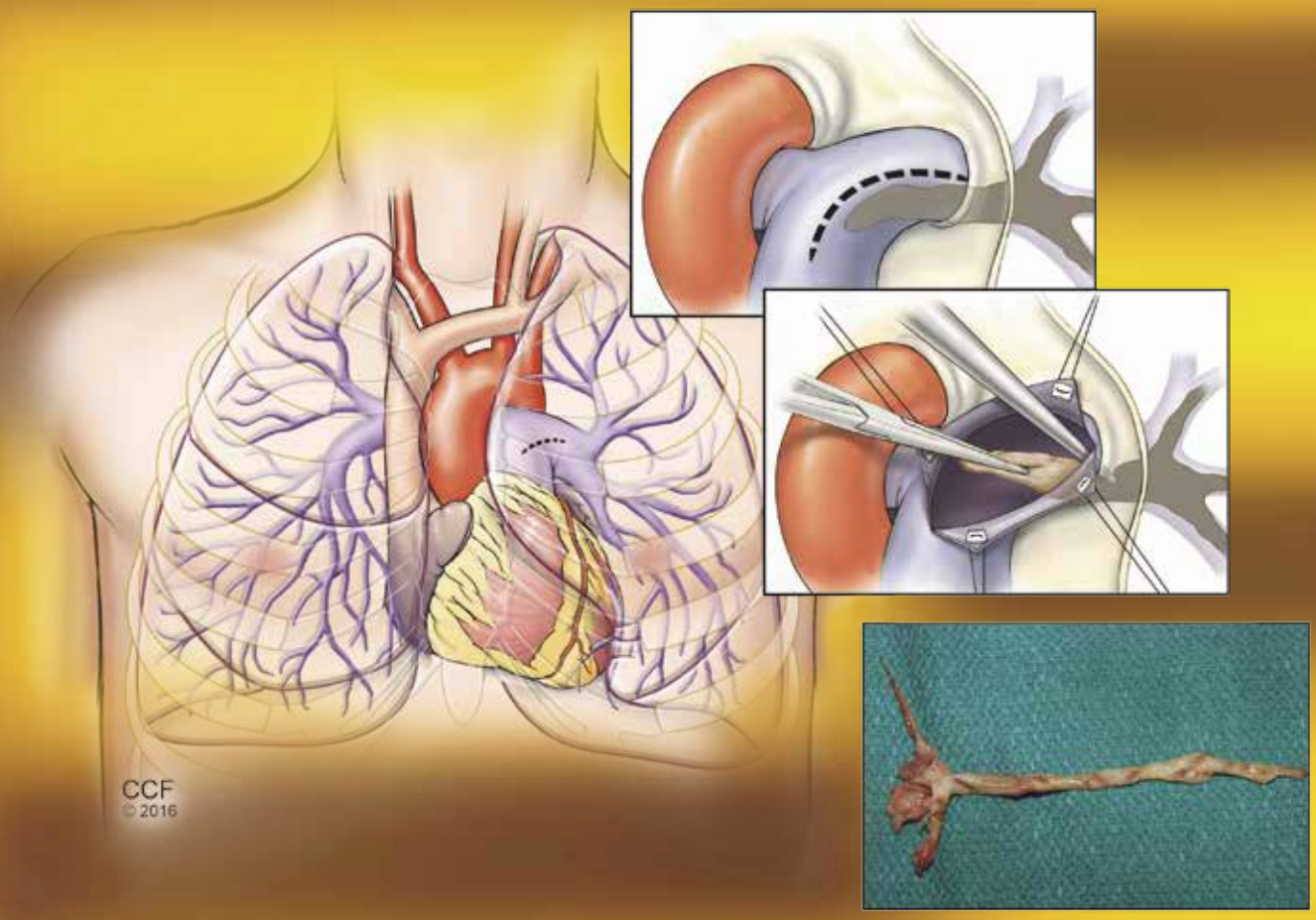


Figure. Pulmonary thromboendarterectomy for CTEPH involves quick but painstaking removal of thin, scarred clot tissue lining the pulmonary arteries. The residual scar is grasped and dissected from the lobar and segmental branches, as shown in the middle inset. The bottom inset shows an operative specimen. The procedure in each lung is ideally completed within 20 minutes to avoid the need for reperfusion.

doesn't account for the fact that many pulmonary emboli go unrecognized. In fact, some 30 percent of patients diagnosed with CTEPH have no history of pulmonary emboli even though all are likely to have experienced one.

Of the half-million U.S. cases of pulmonary emboli per year, conservative estimates place the number of CTEPH cases between 2,400 and 5,000 annually. With only roughly 500 PTE operations performed annually in the U.S., thousands of patients who might benefit from the procedure aren't receiving it, Dr. Heresi-Davila notes.

Debunking Misconceptions Around PTE

Part of the reason, he continues, is that even when CTEPH is diagnosed, several misconceptions prevent physicians from referring patients for PTE.

Although about one-third of patients will have contraindications to surgery — most notably very distal and surgically inaccessible clots or significant comorbidities — many other factors are not contraindications, such as older age or obesity. In fact, Dr. Smedira has performed successful PTEs in patients in their 70s and 80s and even in morbidly obese patients.

And severe pulmonary hypertension is no longer a deal-breaker. "There's no degree of pulmonary hypertension above which surgery is not feasible," Dr. Heresi-Davila explains.

Another misconception is that CTEPH can be managed medically. Although anticoagulants are indicated to prevent further embolic events, they do not improve established CTEPH or pulmonary hypertension. Although one medication, riociguat, was recently approved by the FDA to treat CTEPH, it is indicated only for patients who are not surgical candidates or who have residual or recurrent pulmonary hypertension after surgery.

In fact, Dr. Heresi-Davila notes, there are no hard end points that clearly identify nonoperable patients. "The decision about operability is complex, largely subjective and shaped by the team's experience and expertise, which is why it needs to be made at an expert center," he says. "The stakes are high. If the surgery is a possibility, it offers the best outcome." ■

Contact Dr. Smedira at smedirn@ccf.org and Dr. Heresi-Davila at heresig@ccf.org.

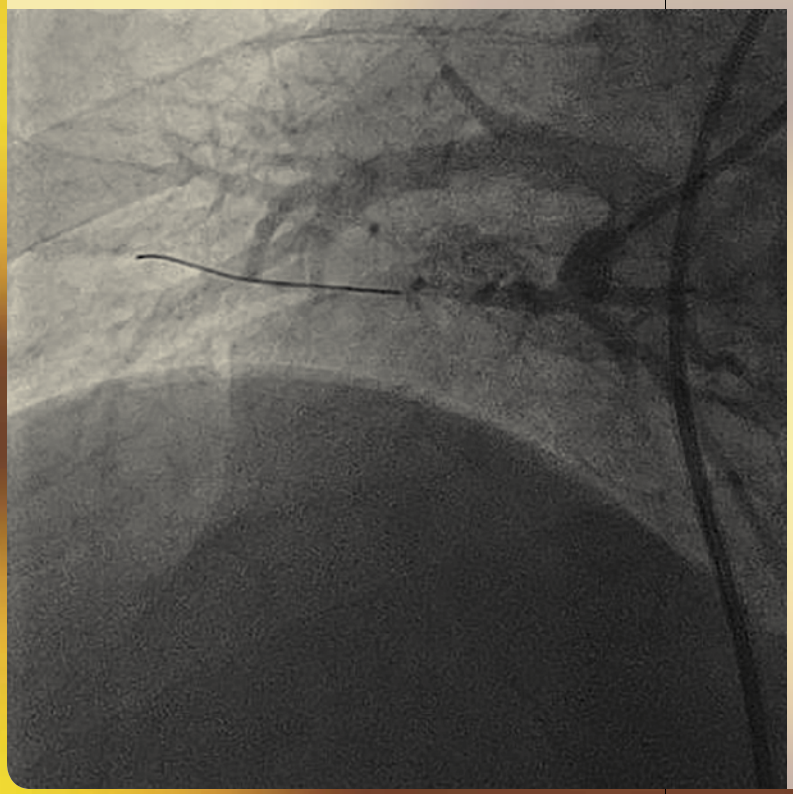
Reviving Balloon Pulmonary Angioplasty to Offer New Hope for Inoperable CTEPH

Left untreated, chronic thromboembolic pulmonary hypertension (CTEPH) can lead to right heart failure and death. Although pulmonary thromboendarterectomy is the gold-standard curative treatment (see preceding article), surgery's not an option for up to 40 percent of patients with CTEPH, either because their clots are too distal or because they have too many comorbidities.

Reviving Balloon Angioplasty for the Lungs

For those patients, Cleveland Clinic specialists are exploring a new option: balloon pulmonary angioplasty (BPA), a catheter-based procedure well established in its application for treating blocked vessels in the heart and brain. Although the use of balloon angioplasty in the lungs dates back 25 years, it was abandoned due to high rates of severe complications, including perforation and reperfusion edema.

Today, several medical centers in Japan have revived the procedure using modern equipment and techniques, with far better results.



From Japan to the U.S.

In the fall of 2015, Cleveland Clinic pulmonologist Gustavo Heresi-Davila, MD, and interventional cardiologist Mehdi Shishehbor, DO, MPH, PhD, traveled to Japan for two weeks to learn the technique. And in early 2016 — with the help of Japanese specialists who came to Cleveland to assist — Dr. Shishehbor performed Cleveland Clinic's first BPA procedures on two patients with CTEPH, both of whom were deemed inoperable due to distal disease.

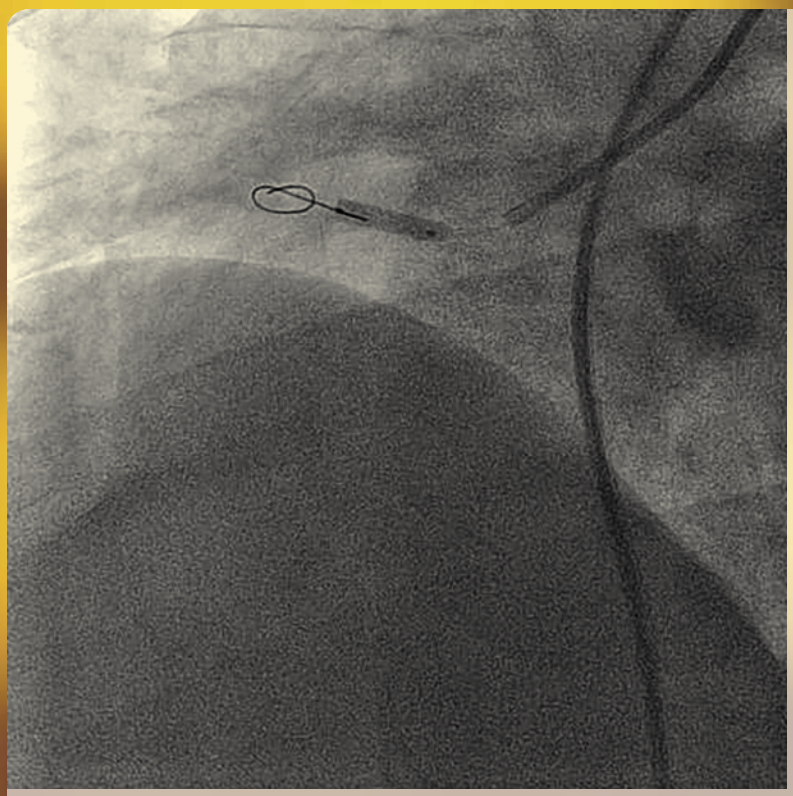
Dr. Shishehbor treated each patient "without any complications and with immediate radiographic improvement in pulmonary blood flow," says Dr. Heresi-Davila.

Thus far, Cleveland Clinic is one of only three centers in the U.S. that have performed the procedure. "As we emerge as one of the premier CTEPH centers in the country, BPA is a welcome addition to the treatment armamentarium for patients with inoperable disease," Dr. Heresi-Davila says.

A Complementary Procedure

Dr. Shishehbor, Director of Endovascular Services at Cleveland Clinic, foresees expansion of BPA here and at other specialized centers in the U.S. for treatment of inoperable CTEPH, but he doesn't see it replacing surgery for patients who can be treated surgically.

While BPA is far less invasive than thromboendarterectomy and patients are awake during the procedure, the arteries in the lung are very fragile and vulnerable to perforation. Moreover, to minimize the risk of reperfusion injury, BPA must be performed in two to five separate sessions — a process some patients might find difficult.



Figures. Imaging studies of the right lower lobe in one of the Cleveland Clinic CTEPH cases before (opposite page), during (left) and after (below) successful balloon pulmonary angioplasty.

"Even if we become very comfortable with angioplasty and can prove it's safe and efficacious, I still think it won't replace surgery," Dr. Shishehbor explains. "I believe it will always be complementary."

Nonetheless, the Japanese experience has been quite positive: Among approximately 700 BPA procedures conducted in about 170 patients over five years, there have been no deaths, a complication rate of less than 2 percent and only one case of restenosis. "They're doing a very good job and have improved significantly over time," Dr. Shishehbor observes.

Comprehensive Offerings Can Optimize CTEPH Outcomes

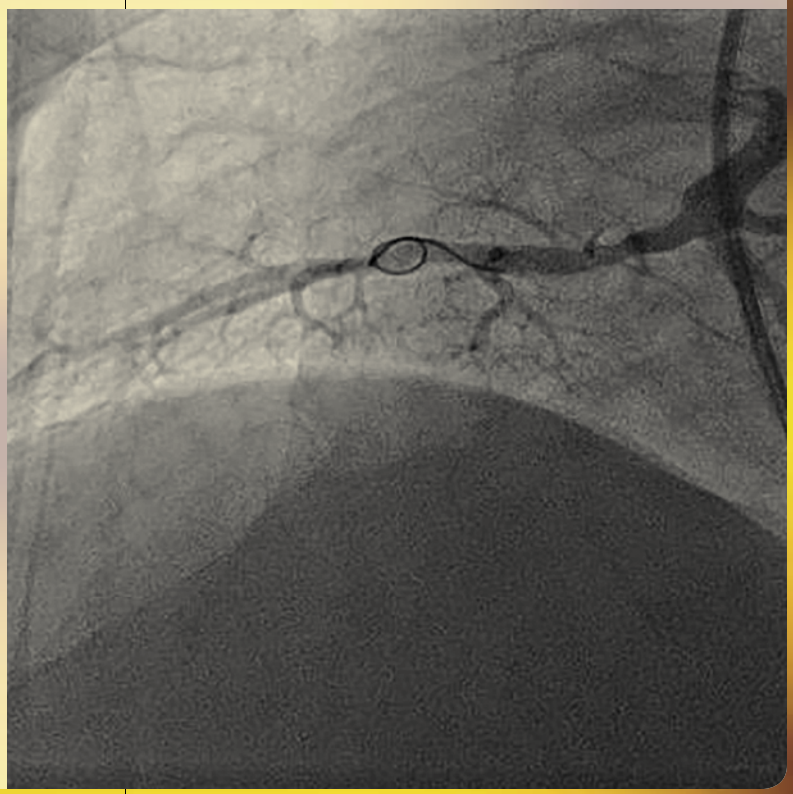
Deciding whether a patient with CTEPH is a surgical candidate isn't always straightforward, as it requires diverse expertise — cardiothoracic surgeon, pulmonologist, interventionalist, cardiologist and others — in concert with patient and family input to determine whether the correct path is medical therapy, surgery, angioplasty or a combination.

"At Cleveland Clinic we take a global and multidisciplinary approach," Dr. Shishehbor notes. "These patients are vetted very carefully."

Another key to success, he says, is limiting procedures to a small number of surgeons, interventionalists and institutions in order to build expertise. For now, Dr. Shishehbor is the only person performing BPA at Cleveland Clinic, while a single surgeon performs the thromboendarterectomies (see prior article).

"We are fortunate to have a high volume of patients, which allows us to do a lot of procedures and concentrate them so that surgeons become experts," Dr. Shishehbor says. "We hope that by mastering these techniques in specialized centers of excellence, we can provide an alternative that supplements surgical options for these patients." ■

Contact Dr. Shishehbor at shishem@ccf.org and Dr. Heresi-Davila at heresig@ccf.org.



Choosing Graft Types for CABG

Weighing the conduit options means balancing a host of factors.

Coronary artery bypass grafting (CABG) remains the gold-standard treatment for coronary artery disease. But which grafts are best for bypass surgery?

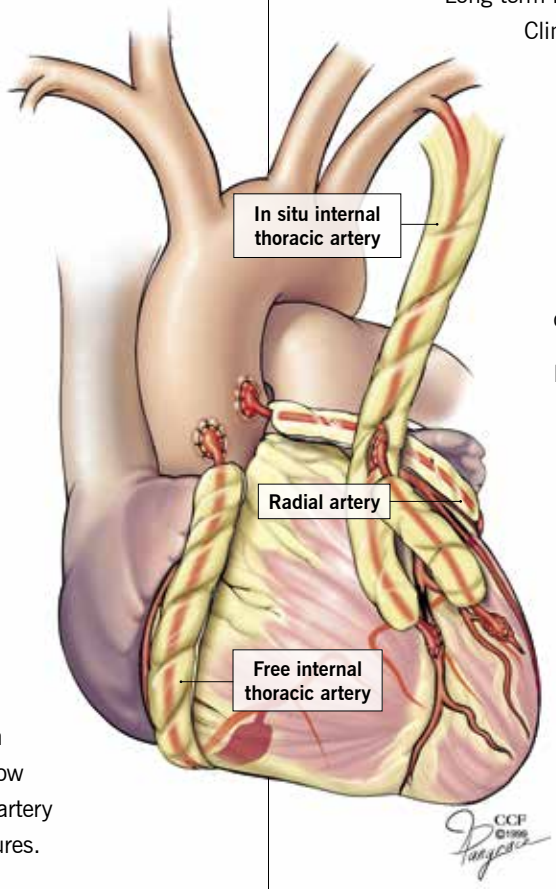
The choice of bypass graft depends on a number of factors:

- Location of the blockage
- Extent of the blockage
- Size of the coronary arteries
- Availability of arteries and veins
- Patient medical factors

The success of CABG over time depends on the long-term patency of the arterial or venous grafts used, notes Michael Zhen-Yu Tong, MD, MBA, a cardiac surgeon in Cleveland Clinic's Department of Thoracic and Cardiovascular Surgery.

"In general, arterial grafts are better and more durable than veins," he says, pointing out that arterial grafts are considered superior conduits over saphenous vein grafts based on experience using the left internal mammary artery to bypass the left anterior descending (LAD) coronary artery. The efficacy of the radial artery graft is less clear, he adds.

Cardiac Consult recently caught up with Dr. Tong for the following summary of how he weighs the pros and cons of various artery and vein graft options in CABG procedures.



Internal Thoracic Artery

As the most commonly used bypass grafts, internal thoracic (mammary) artery (ITA) grafts show the best long-term results. In most cases, the artery is left intact at its origin, with the opposite end sewn to the coronary artery below the site of the blockage. Use of ITA grafts is considered a quality indicator by the Society of Thoracic Surgeons (STS) and is factored into STS star-rating calculations for cardiac surgery programs. "We aim to use at least one ITA graft in 100 percent of patients undergoing isolated coronary bypass surgery," Dr. Tong notes.

ITA grafts are resistant to late failure. Studies of angiograms performed after CABG show that not only do left ITA-LAD grafts have a more than 90 percent chance of functioning well early, but these grafts continue to function well over the long term. Development of obstructions in these grafts has been shown to be extremely uncommon.

Long-term follow-up studies done at Cleveland Clinic from the 1980s showed that these grafts have an important long-term effect on clinical outcomes. Over time, patients with left ITA-LAD grafts were less likely to die or need reoperation compared with patients who received only vein grafts. This is now a standard for coronary bypass grafting.

In addition to the left ITA, the right ITA is also often used in patients age 65 or younger — as well as in older but otherwise relatively healthy patients when more than one graft is needed, says Dr. Tong. Long-term studies from Cleveland Clinic found that bilateral ITA grafts further decrease the long-term risks of death and reoperation compared with single ITA grafts. Use of both ITAs as bypass grafts is more complex and is not appropriate for some patients.

"When more than one graft is needed in younger patients, we will try to use the right and left mammary arteries," says Dr. Tong. "Exceptions are patients with coexisting obesity and diabetes, as this can make wound healing more difficult due to reduced blood flow to the sternum." Bilateral grafting can be considered in diabetics who are not obese and have good blood sugar control, he adds.

Radial Artery

Use of the radial artery (RA) in bypass surgery was revived in the past decade after having been abandoned following high rates of graft occlusion. The renewed interest stems from new methods of preparation and drug treatment with antispasmodic agents to improve long-term results.

Advantages of RA grafts include easy preparation and availability for use in most patients. Also, because RA grafts involve arteries rather than veins, they are more resistant to development of atherosclerosis, a problem that plagues vein grafts. While medium-term results with RA grafts are good, these grafts' long-term patency and outcomes are not yet fully known. RA grafts tend to work best when placed on an artery with a blockage of at least 70 percent (and preferably higher).

RA grafts are recommended for young patients when a third arterial graft is needed or if two arterial grafts are needed but the right ITA is unsuitable, Dr. Tong notes. They're also used in older patients more cautiously when other grafts are unavailable.

Because the RA has a relatively muscular wall, it has a tendency to go into spasm. If the RA is used as a graft, patients are placed on a calcium channel blocker for several months postoperatively to keep the artery open.

Before RA graft use, an Allen test is performed to determine whether blood flow to the hand is sufficient. The artery can be harvested minimally invasively through a small incision. Wrist or hand numbness may occur as a side effect.

Gastroepiploic Artery

The gastroepiploic artery (GEA) has been used as a bypass graft, usually to the right coronary artery. However, Dr. Tong notes that this rarely used graft type comes into play only if no other conduit is possible or when a fourth arterial graft is needed.

Bypass with a GEA graft is technically difficult and not a popular choice among surgeons. Because it requires entry via the abdomen, it is more invasive than other options but has a high likelihood of good long-term functioning when used in the right situation. In some patients a GEA graft represents an advantage over vein grafts.

Saphenous Vein

The saphenous vein is a commonly used conduit for bypass due to the ease of harvest, which is usually done through minimally invasive procedures, with less scarring and faster recovery. But the failure of vein grafts over the long term remains a significant problem. Reasons for high failure rates include variable vein quality and size, the presence of valves within veins and the potential for areas of dilatation (varicosities) within veins. These and other factors can cause flow-pattern disturbances within the veins that can lead to early failure. The 10-year patency of vein grafts is approximately 60 percent, Dr. Tong notes.

Bottom-Line Recommendations

"Many factors go into the choice of conduit used for bypass," says Dr. Tong. "For older patients, an ITA graft and a vein graft will likely be suitable. For medically unstable patients or older patients, use of two or more arterial grafts may not be ideal because it requires longer and more tedious surgery. But if the patient is young and healthy and can tolerate a longer surgery, using multiple arterial grafts gives the best long-term result." ■

Contact Dr. Tong at tongz@ccf.org.

First CABG Guidelines on Selecting Arterial Conduits

February 2016 saw the publication of the first set of guidelines specifically focused on the choice of arterial conduits for CABG.

The guidelines were developed by a Society of Thoracic Surgeons-convened expert writing group, including two Cleveland Clinic cardiothoracic surgeons, based on a systematic literature review. The document, published in *Annals of Thoracic Surgery* (2016;101:419-421), was described by an accompanying editorial as part of a long-overdue "shift from telling us when to operate to guiding us in how best to do so."

The guidelines distinguish themselves from previous CABG-related guideline documents in at least several notable ways:

- By recommending use of an internal thoracic artery (ITA), rather than specifically the left ITA, for bypassing the left anterior descending coronary artery
- By recommending consideration of a second arterial conduit — either the right ITA or a radial artery — as an adjunct to the left ITA in appropriate patients
- By recommending consideration of bilateral ITA grafting for patients without excessive risk of sternal wound infection
- By endorsing consideration of a radial artery graft (as an adjunct to left ITA grafting) for cases of "severe stenoses" rather than specifying a percentage threshold of coronary artery stenosis
- By avoiding use of an age threshold for arterial revascularization

Fresh Thinking on End-Stage Heart Failure

Revisiting Distinctions in LVAD Therapy; New Ways to Balance Transplant Supply and Demand

Don't mistake the multicenter MOMENTUM 3 trial as just another efficacy and safety study of a new left ventricular assist device (LVAD). The trial also holds potential to shift paradigms about how and when LVADs are used for patients with advanced heart failure.

Cleveland Clinic is among more than 60 centers participating in MOMENTUM 3, which is randomizing over 1,000 patients with advanced, refractory left ventricular heart failure to either the Thoratec HeartMate 3™ LVAD — available in Europe but still investigational in the U.S. — or Thoratec's currently marketed HeartMate II® LVAD. The new-generation device incorporates magnetic suspension technology designed to offer a more physiologic option for patients.

Moving Beyond the Bridge/Destination Distinction

Instead of categorizing LVAD use either as a bridge to heart transplant or as destination therapy, the trial is using the primary end points of complication-free survival at six months and two years, regardless of indication.

Indeed, the classification of "bridge" for patients awaiting transplant versus "destination" for others doesn't really make sense for a number of reasons, says Nader Moazami, MD, Director of Cleveland Clinic's Cardiac Transplantation and Ventricular Assist Device Therapy Program. These include the fact that patients with LVADs on the transplant list may become ineligible for transplant over time and end up keeping their device in place long-term.

The HeartMate 3™ device.
Reprinted with the permission of Thoratec Corporation.

"About a third of patients don't fit neatly into either category," Dr. Moazami explains. "In this trial, all patients who are eligible for an LVAD can get one. Some are transplant candidates in whom device use may be short-term; if not, it becomes long-term." He adds that although the traditional "bridge" and "destination" designations are highly arbitrary, for now the terminology is still needed for record-keeping and reimbursement.

Will Magnets Mean Better Outcomes?

Unfortunately, Dr. Moazami notes, even with advances in technology, many clinicians don't refer for LVAD evaluation until patients are severely impaired. "Referral patterns aren't changing much," he says. "Often patients are referred later in the course of heart failure than they should be," in part because of lingering concerns about complications despite significant improvements in LVAD outcomes over the past decade (see box on next page).

Depending on the results of MOMENTUM 3 and ultimate FDA approval, the HeartMate 3's advantages may help diminish those concerns, he adds.

All LVADs work by the same basic mechanism, using an impeller that rotates and augments blood flow. Differences relate to how the impeller is suspended. Earlier LVADs used solid bearings, while the newer ones — including the HeartMate 3 — use magnetic suspension, which allows for wider gaps between the impeller and the pump's housing.

"It's a tremendous engineering feat to develop a pump of this size that's fully magnetically suspended," Dr. Moazami says. "The idea is to cause less stress and trauma to blood elements." It also will likely reduce the risk of clot formation and resultant stroke risk.

The magnetic "levitation" also allows for the pump's action to be slowed or accelerated, thereby generating pulsation. "We think it's more physiologic than those that can't generate pulsation," Dr. Moazami adds. "It's a much more biocompatible pump."

MOMENTUM 3 enrolled patients rapidly and could be completed before its estimated completion date in 2018. Dr. Moazami believes FDA approval may be possible based on results at the six-month end point, before the trial is fully finalized.

Curbing LVAD Demand with Expanded Transplant Opportunities

Cleveland Clinic's experience with LVADs dates to the early 1990s, when it was among the first centers to implant them. Today Cleveland Clinic implants approximately 60 LVADs every year.

Unfortunately, some of that LVAD volume is attributable to static rates of heart transplantation — the most effective treatment for end-stage heart failure — due to recent scarcity of donor hearts across much of the U.S.

Cardiologist Eileen M. Hsich, MD, Associate Medical Director of Cleveland Clinic's Cardiac Transplantation Program, is helping shape national efforts to overcome the shortfall in donor hearts, as demonstrated by two recent papers on the subject.

The first is a review-style perspective article published by Dr. Hsich in *Circulation: Heart Failure* (2016;9:e002679) in the wake of two notable developments:

- Updated guidelines for transplant candidacy from the International Society for Heart and Lung Transplantation (*J Heart Lung Transplant.* 2016;35:1-23)
- A January 2016 proposal from the Organ Procurement and Transplantation Network (OPTN) to change adult heart allocation

LVAD Outcome Snapshots

› ~80%

Two-year survival rates among Cleveland Clinic LVAD recipients for the period 2012-2015

› 1.6%

In-hospital mortality among Cleveland Clinic LVAD recipients in 2015 (vs. 9.9% expected rate from University HealthSystem Consortium database)

While applauding these efforts, Dr. Hsich's paper notes that they address only parts of the problem. She argues that the only way to properly match supply with demand in heart transplantation is to *simultaneously* do the following:

- Increase the donor pool
- Reduce the wait list
- Improve the allocation system

Her paper explores each of these elements in detail, comparing strategies in the U.S. with those in other countries. She concludes that the U.S. heart transplant community should consider a three-pronged strategy:

- Using more organs from "high-risk" or marginal donors
- Thoughtfully tightening wait-list eligibility (with wider consideration of VADs as an alternative for appropriate patients) and standardizing eligibility criteria across centers
- Addressing disparities in the allocation system, in part by incorporating more tiers based on medical urgency and by creating an allocation score similar to those for liver and lung transplants

"Increasing the donor pool, reducing the wait list and improving the allocation system are necessary to better satisfy demand for heart transplants," says Dr. Hsich. "Although it's easier to focus on one strategy, pursuing all three simultaneously is key." (For more on this paper, see **consultqd.clevelandclinic.org/heartsupply**.)

A Call to Factor in Type of Underlying Heart Disease

Dr. Hsich's second paper is an analysis she led using data from the Scientific Registry of Transplant Recipients to examine outcomes of all adult U.S. heart failure patients awaiting transplantation between 2004 and 2014 (N = 30,747).

She and colleagues report in *JACC Heart Failure* (2016;4:689-697) that the following conditions were associated with the highest risk of death during the wait for transplant:

- Restrictive cardiomyopathy
- Congenital heart disease
- Prior heart transplantation

They conclude that donor heart allocation should be revised in light of these findings. "Our data support a change in the allocation system to prioritize restrictive cardiomyopathy, congenital heart disease and prior heart transplant," says Dr. Hsich. (For more on this analysis, see **consultqd.clevelandclinic.org/heartwaitlist**.) ■

Contact Dr. Moazami at moazamn@ccf.org and Dr. Hsich at hsiche@ccf.org.

We All Have a Case that Stands Out from the Rest. **Here's Mine.**

Never go to the operating room without a plan B (and C and D).

By Sudish Murthy, MD, PhD

Of the approximately 7,000 patients I've treated as a thoracic surgeon, Danielle Abraham is the one that stands out. In 2009, Danielle was an active 28-year-old — a happily married mother of an 8-month-old daughter. Life was good, she said, until she contracted the H1N1 flu virus.

Since she was postpartum, it may have been her suppressed immune system that allowed the influenza to trigger a devastating case of bacterial pneumonia. A relentless cough and severe pain sent her to the hospital near her home in Buffalo, New York. For four weeks, she lay in the ICU in an induced coma. When her right lung collapsed, and then her left lung, she was flown to Cleveland Clinic.

When I first saw Danielle, the bacterial infection had begun to dissolve her lung tissue. Pneumatoceles had developed and had begun to rupture. Air was filling her pleural space. Even multiple chest tubes couldn't keep up with the vigorous leak in her lungs. Air from the ventilator was coming straight out of the tubes.

We knew she could not be ventilated much longer.

A New Spin on an Old Idea

It was late in the evening when we brought Danielle into surgery. We didn't expect her to make it to the next morning on the ventilator.

At first, we tried reducing the pneumatoceles, but her lung tissue was so thin and diseased that our attempts to seal one hole just created more holes. The more we sewed or stapled, the worse the problem became. Within 15 minutes of opening her chest, we terminated our original plan and began brainstorming other ways to stabilize her.

In the 1930s, '40s and '50s, thoracic surgeons treated tuberculosis with collapse therapy, intentionally collapsing the lung. They believed that the tuberculosis bacteria would fail to thrive if denied oxygen, and lesions would heal if the lung were immobilized. Historically, surgeons would insert plombes, similar to plastic ping-pong balls, between the rib cage and the pleura, compressing the lung.

The concept worked — at least to resolve the tuberculosis. Unfortunately, it caused complications years later when the plombes began to erode or move. Putting biologically inert bodies into the thorax was not a lifelong solution.

While the technique was abandoned, the concept was still valid. And it's ultimately what we used to help Danielle.

We attempted to press the inner lining of her rib cage onto her lung to control the air leak. Instead of using inert objects, we balled up a biomaterial mesh that typically dissolves in about six weeks. We hoped that would give Danielle's pneumatoceles enough time to close before the lining would return to its normal position.

After closing up Danielle's chest, we saw that the amount of air escaping from her chest tubes had decreased by 95 percent. Our plan was working.

Danielle with her husband and daughter after a recent 5K walk.

We hoped that balling up a dissolvable biomaterial mesh to control the air leak in her lung would give the pneumatoceles enough time to close before the lining returned to its normal position.

A Shockingly Positive Outcome

Over the next several weeks, Danielle's lungs healed and her infection responded to antibiotics. After nearly three months of being hospitalized, she returned to Buffalo to complete months of rehabilitation.

Her recovery was heroic, one that many couldn't have endured. However, Danielle claims the hardest part was being unable to see her daughter, including missing her first Halloween, her first Thanksgiving and her first steps. I believe Danielle's family inspired her to fight as valiantly as she did.

When she returned for a follow-up months later, I was shocked. I had only known her as a patient on a ventilator. Now she was back to being the lively wife and mother she had been before her illness.

I had thrown a medical Hail Mary, but she had caught it and scored a touchdown. Her own drive and determination had cured her.

CTs showed no residual evidence of our procedure. The balls of mesh were completely gone. Although she did lose about 50 percent of her lung function due to the infection, she has been able to lead a normal life with moderate physical activity.

When I last saw Danielle, she had recently walked a 5K (photo).

The Only Constant Is the Unexpected

Since Danielle's surgery, we have used the same technique successfully on other critically ill patients with similar problems.

Having performed thousands of operations in my career, I wish I could say I've seen it all. But there will always be unexpected circumstances to keep me — and all of us — learning and innovating.

Going into surgery with a plan A isn't enough. We also need plans B, C and D. (For Danielle, plan C was to pack gauze into her left lung, hoping her right lung would carry her until cavities in the left lung scarred over. Plan D was to remove her left lung. I doubt either of those plans would have had outcomes as favorable.)

Everything we learn as physicians, no matter how seemingly trivial or historically insignificant, could become vitally important someday. When it comes to saving a life, sometimes we need every tool in the shed — including plain common sense. ■

Dr. Murthy (murthys1@ccf.org) is Section Head of Thoracic Surgery at Cleveland Clinic and Surgical Director of the Center of Major Airway Disease.

Research Roundup

Quick Takes on Recent Cardiovascular Studies of Note

Centralized Telemetry Monitoring Slashes Alarm Fatigue, Saves Lives

For noncritically ill inpatients, off-site central monitoring using standardized cardiac telemetry can result in monitored patient census reductions without increasing — and actually reducing — cardiopulmonary arrests. That's the takeaway from an analysis of the first 13 months of operation of Cleveland Clinic's technician-staffed off-site telemetry monitoring unit, developed to reduce the "alarm fatigue" endemic to typical telemetry monitoring.

As reported in *JAMA* (2016;316:519-524), compared with the 13 months before the unit's launch, telemetry standardization in the off-site unit enabled a 15.5 percent weekly monitored patient census reduction with no rise in cardiopulmonary arrests. Central monitoring detected rate and rhythm changes in 79 percent of patients within one hour of emergency response team activation, and discretionary direct notification was associated with successful resuscitation in 93 percent of patients who coded — a rate that compares very favorably to national benchmarks. "By eliminating low-risk patients from the monitor, we can better concentrate our efforts on the patients who really require our attention," says lead author Daniel Cantillon, MD. For more, see consultqd.clevelandclinic.org/telemetry.

Third Time's No Charm for CETP Inhibitors

Lingering hopes for the CETP inhibitor class of lipid-modifying drugs were dealt a major blow by data from the phase 3 ACCELERATE trial of evacetrapib, presented at the 2016 European Society of Cardiology meeting by Cleveland Clinic cardiologist A. Michael Lincoff, MD. The study of patients with high-risk vascular disease found that despite producing highly significant HDL cholesterol increases and LDL cholesterol reductions versus placebo, evacetrapib had no effect on major cardiovascular events relative to placebo out to three years of follow-up. The findings triggered early study termination.

"The outcome of this trial was counterintuitive," says Dr. Lincoff, adding that it also conflicted with phase 2 findings. "This raises serious questions about whether we'll ever see cardiovascular benefit from this mechanism of lipoprotein modification." Evacetrapib is the third CETP inhibitor to meet its demise in late-stage clinical trials. For more, see consultqd.clevelandclinic.org/accelerate.

Study: Abandoning CIED Leads Isn't Worth the Risk

As the popularity of cardiac implantable electronic devices (CIEDs) surges, the number of infections linked to abandoned leads is growing fast. These unwanted leads complicate management of CIED infections and result in worse outcomes, including death. So finds a large prospective registry study published online by *JACC: Clinical Electrophysiology* in September.

Among 1,386 consecutive patients undergoing transvenous lead extraction of infected CIEDs at Cleveland Clinic between 1996 and 2012, 23.3 percent had previously abandoned leads and 76.7 percent did not. Failure to achieve the study's primary end point — successful removal of the device and lead material from the vascular space without a major complication — was significantly more common in patients with abandoned leads (13.0 percent) than in those without abandoned leads (3.7 percent). Lead author Oussama Wazni, MD, says the study was done in response to frustration with the high rate of lead abandonment: "It's a common practice that postpones risk now but gambles on the patient's future." For more, see consultqd.clevelandclinic.org/abandonedleads.

RV Systolic Pressure Shapes Survival in Mitral Regurgitation

Elevated right ventricular systolic pressure (RVSP) is independently associated with worse long-term survival in patients with primary mitral regurgitation and preserved left ventricular ejection fraction. So concludes an observational cohort study of all 1,318 patients with primary myxomatous mitral regurgitation evaluated at Cleveland Clinic between 2005 and 2008. The study, published in *Journal of the American College of Cardiology* (2016;67:2952-2961), is the largest of its type by far and has the longest follow-up.

Corresponding author Milind Desai, MD, a Cleveland Clinic cardiologist, says the findings should prompt closer scrutiny of the optimal timing of mitral valve repair surgery in such patients. "It appears that even mild RVSP elevation — 35 mm Hg or above — might be a marker of early decompensation," he says, noting that waiting for RVSP to progress to 50 mm Hg or more before offering repair could worsen prognosis. For more, see consultqd.clevelandclinic.org/rvsp.

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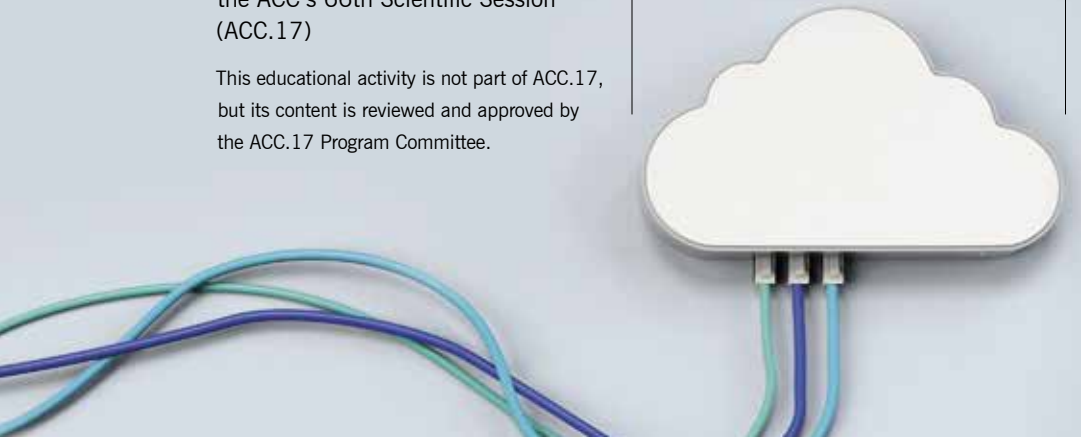

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