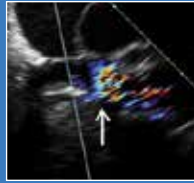
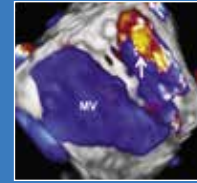




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Repair – p4



Second-Generation
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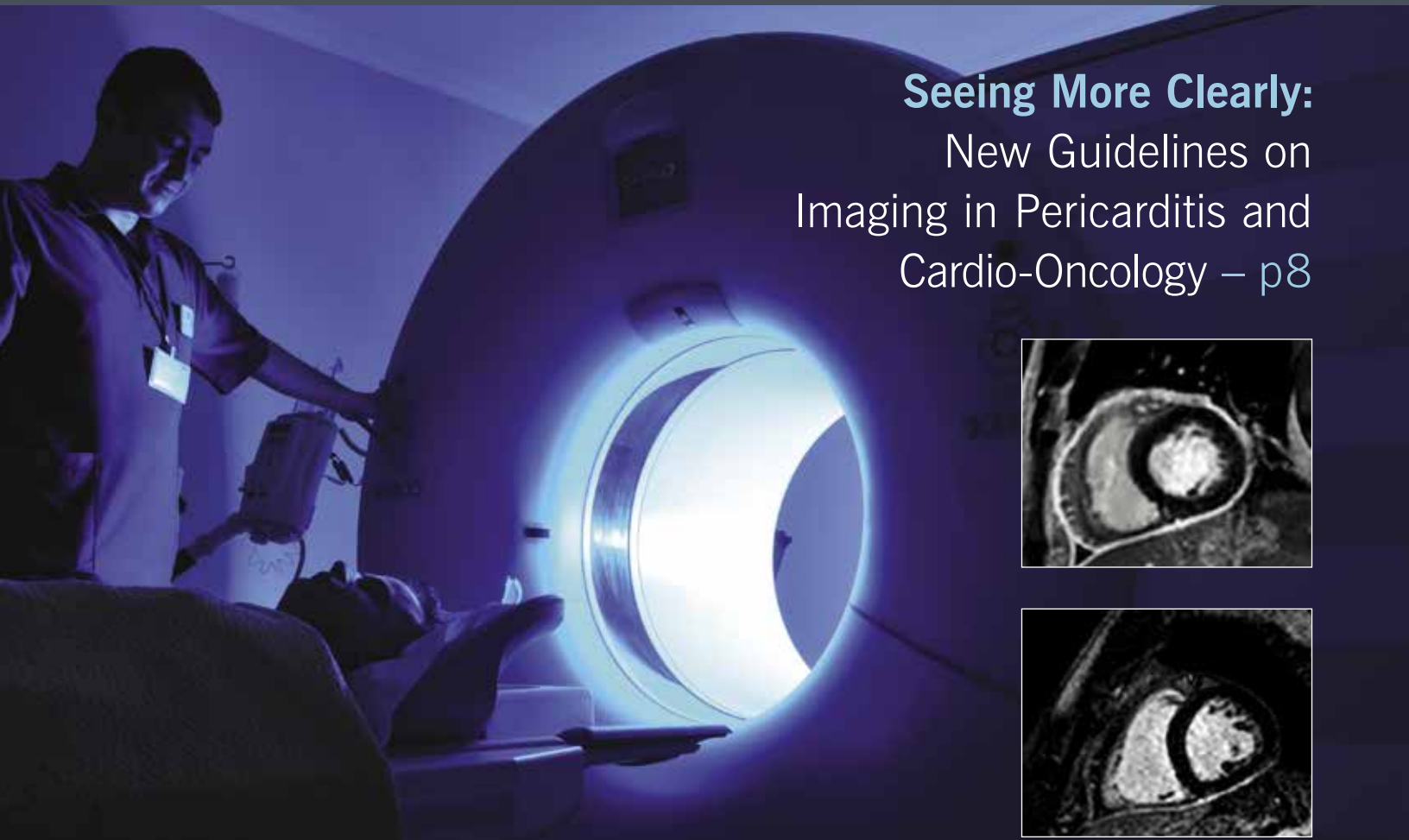


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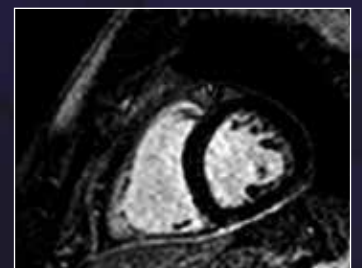
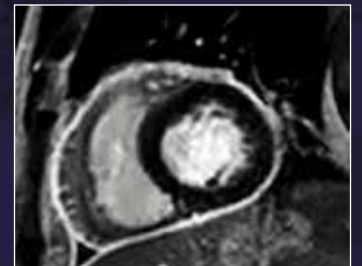


Cardiac Consult

Heart and Vascular News from Cleveland Clinic | Winter 2014 | Vol. XXIV No. 1



Seeing More Clearly:
New Guidelines on
Imaging in Pericarditis and
Cardio-Oncology – p8



Dear Colleagues:

We're all working to standardize treatments and reduce variability of outcomes.

Everyone wants to lower costs and improve quality. But we'll never totally eliminate the element of surprise. This issue of *Cardiac Consult* proves that. The thread of the unexpected runs through nearly every story.

Take multicenter clinical trials, for instance. The Cleveland Clinic Coordinating Center for Clinical Research (C5Research) designs and manages these massive undertakings for clients worldwide. On page 14 we report on two surprising C5Research trials: AQUARIUS and ASSURE. The first studied an antihypertensive drug with a suspected hidden talent for slowing atherosclerosis progression, but it found no significant effect on atherosclerosis despite a halving of cardiovascular events with the drug. The second tested an agent whose past success at raising HDL levels in the blood was expected to translate to plaque regression on intravascular ultrasound — but which did no such thing.

We all know some patients can't tolerate statins. But those patients may be far fewer than we think. On page 6 you can read the results of our 15-year study of statin intolerance. It shows that more than 72 percent of patients who complain of side effects like muscle pain can eventually benefit from some form of statin therapy. The key is to adjust the dosage or timing of administration.

It's an unpleasant surprise to learn that some important areas of cardiovascular care still lack evidence-backed guidelines. But we're proud to report on page 8 that experts from the Sydell and Arnold Miller Family Heart & Vascular Institute are leading the development of guidelines in neglected areas, such as multimodality imaging in the management of pericarditis and heart damage caused by cancer radiotherapy.

Finally, we want you to know that Cleveland Clinic is always here to help you deal with the unexpected. The back cover of this issue introduces our new Cardiovascular Consult Hotline (855.733.3712), which you can call whenever you have a case that may benefit from an outside point of view or a different experience set. This 24/7 hotline puts you directly in touch with a Cleveland Clinic heart specialist supported by the wisdom and knowledge of our nearly 200 staff cardiologists.

We're not surprised when *Cardiac Consult* readers turn to us for consultation. But we are always grateful for the trust and collegiality behind your requests, and we promise to do everything we can to help ensure the best patient outcome and experience.

Sincerely,

Christopher Bajzer, MD

Associate Director, Peripheral Interventional Cardiology

A. Marc Gillinov, MD

Staff Surgeon, Thoracic and Cardiovascular Surgery
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Image of the Issue

FROM KARL WEST, MS



A 3-D PERSPECTIVE ON AORTIC ANEURYSMS

Karl West, MS, Director of Cleveland Clinic Medical Device Solutions, holds a three-dimensional polymer model of an aortic aneurysm made by one of two rapid prototyping systems (3-D printers) in Cleveland Clinic's Lerner Research Institute. Cleveland Clinic heart and vascular surgeons are using 3-D-printed models like this to plan surgeries, test innovative devices, and enhance knowledge of the heart and vascular system. Technicians can upload data from high-resolution CT and MRI scans to make the models, which are printed in layers 6/10,000ths of an inch thick. In the cardiovascular field alone, Cleveland Clinic's 3-D printers have been used to help craft novel endovascular grafts, replacement valves and a new artificial heart.

FOR MORE INFORMATION, CONTACT KARL WEST, MS, AT 216.445.1944 OR WESTK2@CCF.ORG.



A Corkscrew Solution

for Secure Anchoring in Minimally Invasive Aortic Aneurysm Repair



Daniel Clair, MD

Nothing surpasses the reliability of regular sutures placed by an experienced surgeon in an open procedure. But a new device being investigated at Cleveland Clinic seeks to duplicate the security of surgical suturing in an endovascular procedure. The device, designed to attach endovascular stent grafts to the aortic wall, uses tiny, corkscrew-shaped anchors that can be screwed in and out for better placement.

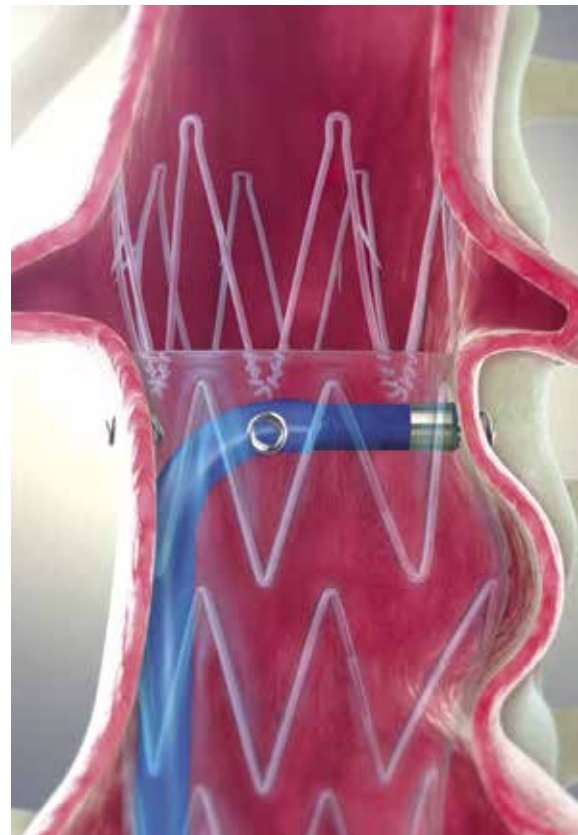
In Search of a Secure Seal

“Endovascular stent grafting is steadily gaining favor as a minimally invasive alternative to the open surgical repair of aortic aneurysms,” says Daniel Clair, MD, Chairman of Vascular Surgery at Cleveland Clinic. “For this procedure to have long-term success, however, the end of the stent graft proximal to the aneurysm must be firmly anchored with a perfect seal. A loosely anchored endograft can migrate from its original site, affecting the seal. An uneven or loose seal can allow blood to leak into the aneurysm sac. This could cause the sac to refill and potentially rupture.”

Dr. Clair is a local principal investigator in the study of the new device, the Aptus Heli-FX™ EndoAnchor System.

Why Reliability Matters

Cleveland Clinic’s Department of Vascular Surgery has been at the forefront of development and investigation of endovascular stent grafting for aortic aneurysms since the technique was introduced earlier this century. Cleveland Clinic surgeons have the world’s most extensive experience with branched and fenestrated endografts, which are used to address aneurysms involving the renal and other branching arteries in the abdominal and thoracic aorta



and the aortic arch. Endografts are delivered to the aneurysm site via catheter under fluoroscopic guidance, where they are expanded to fill the aneurysm sac and provide a new conduit for blood flow.

Endografts have hooks or barbs at their proximal opening, which cling to healthy tissue above the aneurysm, holding the device in place. In most cases, this provides adequate securement. But with more complex anatomy and aneurysms that are close to branches or tortuosity, the stent can migrate or shift, creating a leak around the proximal opening. Blood can pour into the aneurysm sac, refilling it and leading to complications including the possibility of fatal rupture.

The Aptus anchor system allows the surgeon to apply metal anchors evenly around the endograft radius from the inside. The anchors provide a seal that may be considered as reliable and leakproof as surgical sutures used in open repair of aortic aneurysms. The corkscrew-shaped anchors have a sharp point at one end and a lateral bend at the other. The sharp tip allows for traumatic entry. The lateral bend prevents the anchor from passing entirely through the aortic wall.

Partial Deployment to Ensure Proper Placement

The anchors are deployed by a steerable catheter using a special handheld control. The catheter tip can be bent up to 90 degrees, and beyond this if needed. The anchors are delivered to the tip through the angled catheter, which aims them directly into the aortic wall. “The system allows the anchor to be only partially deployed at first,” explains Dr. Clair. “If it’s not in the right place, it can be easily removed and reset in the correct spot.”

In addition to repairing leaking endografts, the system can be used to seal an endograft during its initial placement.

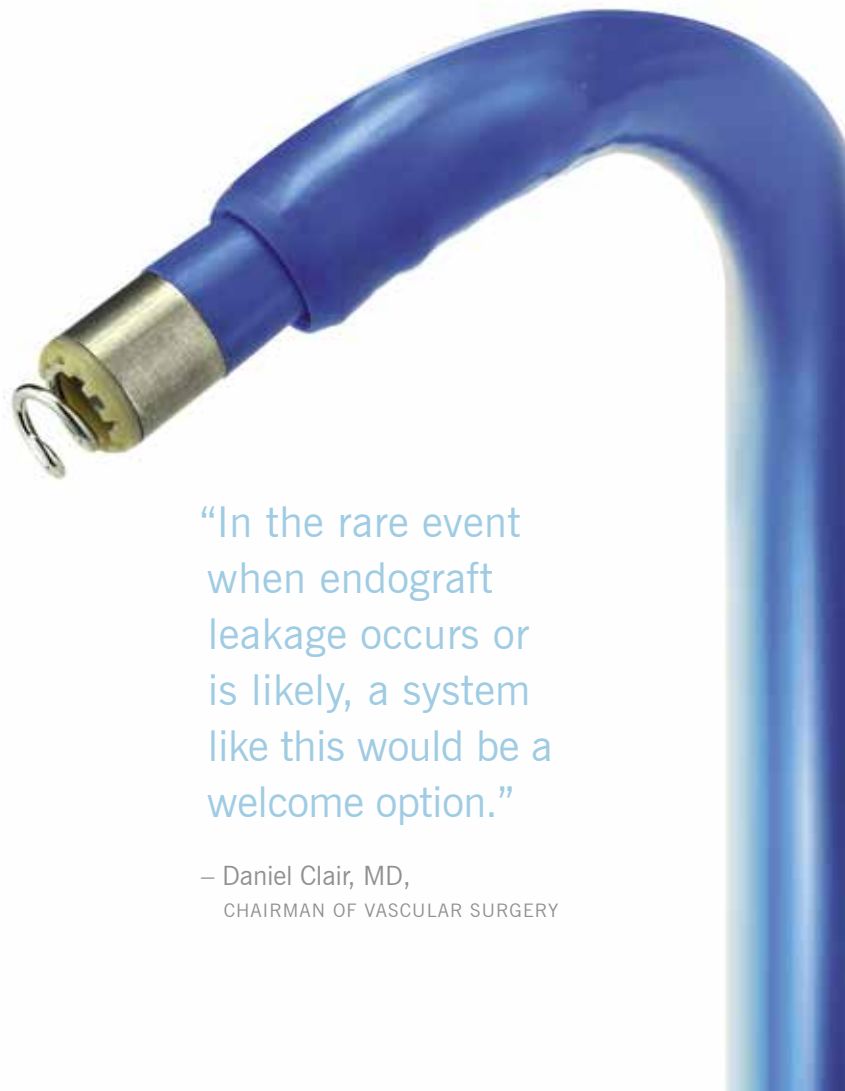
Studying Real-World Use and Effects on Cost, Quality of Life

The study involves creation of a registry, called ANCHOR, to compile knowledge on clinical use of the device in many different kinds of patients, by many practitioners and in diverse locales. A substudy will assess how cost-effective the system is and how it might affect patient quality of life.

“The vast majority of endografts attached by conventional means do perfectly well,” says Dr. Clair. “But in the rare event when leakage occurs or is likely, a system like this would be a welcome option.” ■

Contact Dr. Clair at 216.444.3857 or claird@ccf.org.

Images courtesy of Aptus Endosystems. All rights reserved.



“In the rare event when endograft leakage occurs or is likely, a system like this would be a welcome option.”

– Daniel Clair, MD,
CHAIRMAN OF VASCULAR SURGERY

Statin Intolerance Doesn't Rule Out Long-Term Treatment

Cleveland Clinic study shows subsequent trials, intermittent dosing can be effective.



Leslie Cho, MD



Michael Rocco, MD

Despite the controversy surrounding the new American Heart Association/American College of Cardiology guidelines for hyperlipidemia management, the guidelines may expand the number of patients using statins as first-line therapy. Yet some patients cannot tolerate statins due to muscle aches and weakness, gastrointestinal symptoms, liver enzyme abnormalities or other issues.

This poses a challenge for efforts to reduce patients' low-density lipoprotein cholesterol (LDL-C), considering statins' demonstrated benefits in primary and secondary prevention of cardiovascular morbidity and mortality.

A major observational study from Cleveland Clinic offers good news for these patients and their physicians: Nearly three-quarters of patients with previous intolerance can tolerate a subsequent statin trial. In addition, intermittent statin dosing can be effective in some patients and may result in reduction of LDL-C levels and even attainment of LDL-C goals.

Largest Statin Intolerance Study to Date

The study, published in the September *American Heart Journal* (2013;166[3]:597-603), is the largest to date to review different treatment regimens and their effect on LDL-C in patients with statin intolerance. The retrospective analysis included medical records of 1,605 patients referred for statin intolerance to Cleveland Clinic between 1995 and 2010 who had at least a six-month follow-up.

“We found that in patients who previously reported statin-related events, most were eventually able to tolerate long-term use of a statin and benefit from its cholesterol-lowering effects,” says lead author Leslie Cho, MD, Section Head of Preventive Cardiology and Rehabilitation in the Robert and Suzanne Tomsich Department of Cardiovascular Medicine.

“Even though statins work by similar mechanisms, intolerance to one does not predict a poor response to another,” adds co-author Michael Rocco, MD, Medical Director of Cardiac Rehabilitation and Stress Testing, Section of Preventive Cardiology.

Once Intolerant Doesn't Mean Always Intolerant

During a median follow-up of 31 months, 72.5 percent of patients previously identified as statin-intolerant remained on regular statin therapy, including 63.2 percent on a daily regimen and 9.3 percent on intermittent dosing (ranging from once weekly to six days a week). Statins were completely discontinued in only 27.5 percent of patients.

“Even if patients cannot tolerate a daily dose of a statin, it's possible to see a significant reduction in cholesterol levels from taking the drug less often, even as infrequently as once a week,” Dr. Cho says.

Indeed, compared with patients who discontinued statins, patients on intermittent statin dosing had significantly greater LDL-C reduction (21.3 ± 4 percent vs. 8.3 ± 2.2 percent; $P < .001$), and significantly more of them achieved Adult Treatment Panel III LDL-C goals (61 percent vs. 44 percent; $P < .05$). At the same time, patients on intermittent dosing had significantly less LDL-C reduction compared with those on daily dosing (21.3 ± 4 percent vs. 27.7 ± 1.4 percent; $P < .001$).

Higher Doses Not Always Needed

Some studies with atorvastatin, fluvastatin and rosuvastatin have suggested that every-other-day dosing regimens need to be nearly twice the daily dose to result in comparable LDL-C lowering. However, the Cleveland Clinic analysis found that reasonable reductions can be achieved with the same or even lower doses in both daily and intermittent dosing strategies.

Dr. Rocco notes: “Starting at a low dose of a potent statin with intermittent dosing and gradually increasing the dose and frequency over time can promote better tolerance.” ■

For more information, contact Dr. Cho at 216.445.6320 or chol@ccf.org or Dr. Rocco at 216.839.3300 or roccom@ccf.org.

How to Deal with Statin Intolerance

Many patients tolerate statins without side effects, but it's not uncommon for some patients to report symptoms they believe are caused by their lipid-lowering medication. The recommendations below can help you respond, but note that clinical trials have not compared the long-term outcomes of strategies for managing statin intolerance.

Get a complete patient history. Headaches, gastrointestinal complaints, muscle toxicity (weakness and/or pain) and elevated hepatic enzymes have been associated with statin use. Since these symptoms also may result from factors unrelated to statin intake — e.g., increased physical activity, hypothyroidism, heavy alcohol use, acute viral disease or drug interactions — it's important to first conduct a thorough patient history to rule out other causes.

Rechallenge. Discontinuing the statin to determine if muscle or hepatic events resolve, and then rechallenging with the previous dosage or a lower one to see if symptoms return, can help confirm whether intolerance is the root cause.

Try dosage or drug changes. If symptoms resume on rechallenge, consider reducing the dosage or administration frequency of the existing statin or prescribing a different one. Statins with alternate metabolic pathways may provide relief. Those with longer-acting formulations may enable intermittent — i.e., every-other-day or weekly — dosing while still reducing LDL-C. It remains unclear, however, if such intermittent dosing results in the same cardiac risk reduction as daily statin administration.

Consider alternatives. If statin-related symptoms persist, LDL-C-reducing options alone or in combination include nonstatin drugs such as ezetimibe, bile acid sequestrants and niacin. It is important to emphasize the role of exercise and dietary additions such as soy, viscous fiber (found in whole grains, beans and nuts), and plant sterols and stanols (from fruits, vegetables, nuts, seeds, cereals and legumes).

Seeing More Clearly: Consensus Statements Shine Light on Multimodality Imaging in Pericardial Disease and Cardio-Oncology

Cleveland Clinic cardiologists play lead roles in guideline development.



Allan Klein, MD



Juan Carlos Plana, MD

Clinicians looking for evidence-based guidance on cardiovascular imaging in two challenging subspecialty areas, pericardial disease and cardiovascular complications of radiotherapy for cancer, had long been out of luck — until a few months ago. That's when the American Society of Echocardiography, in conjunction with other major cardiovascular imaging societies, issued a pair of first-ever expert consensus statements on multimodality imaging in these areas (see box below).

Subspecialists from Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute played key roles in developing both guideline statements, which were published in the September 2013 *Journal of the American Society of Echocardiography*.

Guidance in Pericardial Disease Long Overdue

"Clinicians have been requesting protocols and recommendations for imaging in pericardial disease for several years," says Allan Klein, MD, who chaired the writing group of 15 U.S. authors for the guideline statement on pericardial disease. Dr. Klein, who is Director of the Heart & Vascular Institute's Center for the Diagnosis and Treatment of Pericardial Diseases and Vice President-Elect of the American Society of Echocardiography, was joined by four other Cleveland Clinic co-authors.

Expert Consensus Statements: The Essentials

Multimodality Cardiovascular Imaging of Patients with Pericardial Disease

American Society of Echocardiography, Society for Cardiovascular Magnetic Resonance, Society of Cardiovascular Computed Tomography (Klein AL, et al, *J Am Soc Echocardiogr*. 2013;26:965-1012)

Multimodality Imaging Evaluation of Cardiovascular Complications of Radiotherapy in Adults

European Association of Cardiovascular Imaging, American Society of Echocardiography (Lancellotti P, et al, *J Am Soc Echocardiogr*. 2013;26:1013-1032)

He explains that the guidelines — intended for use in primary care, emergency rooms, and rheumatology and cardiology subspecialty practice — aim to address poor awareness of the signs and symptoms of pericardial disease, inability to identify pericardial disease on imaging, and inappropriate treatment duration for an aggressive condition.

“Clinicians who encounter pericardial disease need to understand its spectrum of presentation and stages, as well as how to identify the presence of inflammation and calcification, in order to provide timely, appropriate treatment,” says Dr. Klein. He describes the condition as an “equal-opportunity disease” affecting a wide spectrum of patients of all ages, ranging from teenagers and college students to patients with systemic lupus erythematosus or recent open-heart surgery.

Making Sense of Potentially Puzzling Presentations

Recognition of pericardial disease is enhanced by understanding its etiology and pathophysiology. The guidelines present recommendations for each of seven clinical syndromes of pericardial disease with differing etiologies. Tables, images and other resources are provided to aid identification of acute, recurrent and constrictive pericarditis at presentation and on imaging.

For example, symptoms of constrictive pericarditis — e.g., dyspnea and leg/abdominal edema — are easily mistaken for those of other diseases. The guidelines offer a valuable pearl: Look at the neck veins.

“Have the patient stand or sit upright,” advises Dr. Klein, “and look for distended veins in the neck and an elevated jugular venous pulse. These are clear signs of constrictive pericarditis.” Treatment must begin immediately, he adds, and the following six months are critical because anti-inflammatory therapy can be initiated if there is a subacute presentation with ongoing inflammation. If the presentation is chronic, the patient will be referred directly for pericardiectomy.

Detailed Directives, Richly Illustrated

Once symptoms of acute, recurrent or constrictive pericarditis are recognized — including possible pericardial effusions (Figure 1) and tamponade — imaging confirms the diagnosis and helps in staging the disease. The guidelines note that echocardiography is generally the first-line method, with gadolinium-enhanced MRI (which shows the inflammation; see Figure 2) or CT added in more complex cases. All imaging modalities have their benefits and limitations, which are prominently outlined in an introductory table.

The guidelines are replete with images to aid recognition of the various forms, stages and etiologies of pericarditis as they

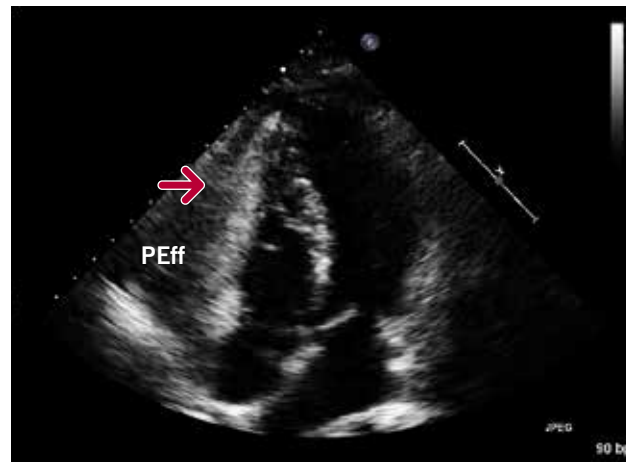


Figure 1. Two-dimensional echocardiogram showing localized pericardial effusion (PEff, arrow) in a 23-year-old woman with inflammatory constrictive pericarditis.

appear on various imaging modalities. Images are accompanied by detailed guidance on issues such as the following:

- Which modalities to use and in what order
- How often to repeat the studies
- How to distinguish inflammation from pericardial fat
- How to treat the various forms of the disease after diagnosis
- When to advise surgery
- How long to use approved medications

An appendix aimed at sonographers, cardiologists and radiologists provides instructions on performing a detailed evaluation.

Avoiding Recurrence with Imaging-Guided Treatment

According to Dr. Klein, undertreatment of acute or recurrent inflammatory pericarditis is the leading reason for incomplete disease resolution. “By the time I see patients, many have had up to five or 10 recurrences,” he says.

These patients must be treated intensively with double or triple anti-inflammatory therapy — an NSAID (ibuprofen, indomethacin or aspirin) plus colchicine, and sometimes prednisone as well (for those with constrictive physiology) — for several months with a very slow weaning process over three to six months.

Treating intractable recurrent pericarditis with anti-inflammatory medications as mentioned above, as well as with DMARDs (azathioprine) or biologic agents (anakinra), may help reduce recurrent episodes. Surgery should be performed as a last resort. Treatment should be individualized

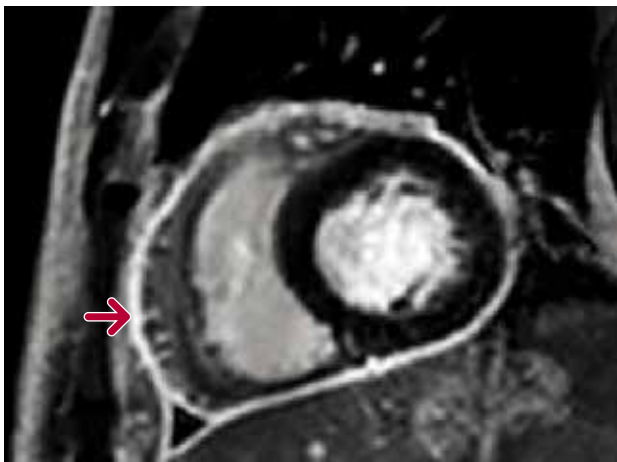


Figure 2. Cardiac MRIs of a 40-year-old man with recurrent pericarditis. The left image shows delayed gadolinium enhancement revealing pericardial inflammation seen as a white line surrounding the heart (arrow). The inflammation improved with triple anti-inflammatory therapy, as reflected in the right image.

through systematic serial imaging to provide insight on efficacy and when to start tapering medications (i.e., steroids). “This is a new concept,” says Dr. Klein. “It’s the opposite of the old shotgun approach, where we gave medications for a week or two with rapid tapering and hoped for the best. Too often this caused a ‘yo-yo effect,’ with rapid tapering of prednisone causing a recurrence.”

Most patients with chronic constrictive pericarditis require surgical intervention. When fibrotic or calcium deposits in the pericardium cause constrictive pericarditis, patients can obtain immediate symptom relief with pericardiectomy. However, functional response and long-term outcome often depend on the extent of the pericardial deposits and extension of the thickened pericardium into the heart muscle.

While many cases can be treated appropriately outside a dedicated center for pericardial disease, immediate referral to an expert center is advised when a patient presents with advanced symptoms or doesn’t respond to therapy, in view of the condition’s high morbidity with many recurrences and mortality from advanced heart failure. Within one or two days of an outpatient visit to Cleveland Clinic’s Center for the Diagnosis and Treatment of Pericardial Diseases, a patient will be seen by multiple subspecialists and undergo blood and advanced imaging tests with pericardial protocols, heart catheterization (if needed), appropriate medical treatment, and surgery, if necessary.

“The imaging, diagnosis and treatment of pericarditis are undergoing a renaissance,” Dr. Klein observes. “Our goal in developing these guidelines is that the disease become more widely recognized and appropriately treated so patients can feel better and get back on their feet.”

Visit clevelandclinic.org/pericarditisguidelinesvideo to watch writing group chairman Allan Klein, MD, answer frequently asked questions about the new pericardial disease imaging guidelines and pericarditis in general.

First Expert Consensus on Evaluating Radiation-Induced Heart Disease

The other new expert consensus statement — on multimodality imaging for the evaluation of cardiovascular complications of radiotherapy in adults — reflects a fundamental shift in mindset that has accompanied the advent of more successful cancer therapies. Today, many patients survive their cancer only to develop — and in some cases die from — cardiovascular complications from their treatments.

“Our goal is to revisit our approach to cancer treatment using a thoughtful strategy that balances the benefits of the cure against potential cardiovascular complications of the treatment used to achieve it,” says Juan Carlos Plana, MD, Co-Director of Cleveland Clinic’s Cardio-Oncology Center and a staff physician in the Section of Cardiovascular Imaging. He was a member of the international author team that developed the consensus statement.

The effects of radiation to the chest for malignancies such as breast cancer and Hodgkin’s lymphoma include thickening and calcification of the pericardium, resulting in constrictive pericarditis, and accelerated atherosclerosis and fibrosis in big and small vessels, leading to ventricular stiffness and valvular heart disease.

Mortality associated with surgery in radiation-treated patients appears to be much higher than in other populations. A retrospective study of cancer survivors with radiation-

induced heart disease who underwent cardiothoracic surgery at Cleveland Clinic found that 55 percent died over a mean follow-up of 7.6 years, as compared with 28 percent of a matched cohort undergoing similar procedures (*Circulation*. 2013;127:1476-1484).

Emerging Role for Strain Imaging

Strain imaging, an echocardiography technique pioneered at Cleveland Clinic and discussed in the guidelines, is poised to significantly enhance the ability to diagnose radiation-induced cardiac dysfunction. Using software that calculates the deformation of the heart, strain imaging provides clues about how well the heart is contracting (Figure 3). Strain imaging can identify a distressed heart much earlier than conventional assessment via ejection fraction.

“It allows us to recognize when the heart muscle has been damaged by the radiation,” Dr. Plana explains. “This is an important discussion to have with the patient, as it allows us to set realistic expectations for symptomatic improvement if cardiovascular surgery is performed.”

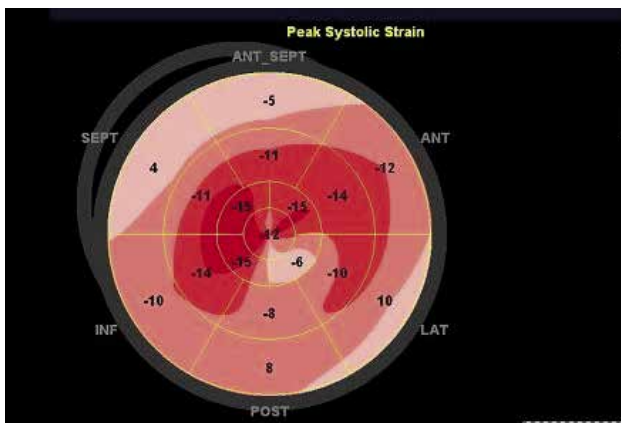
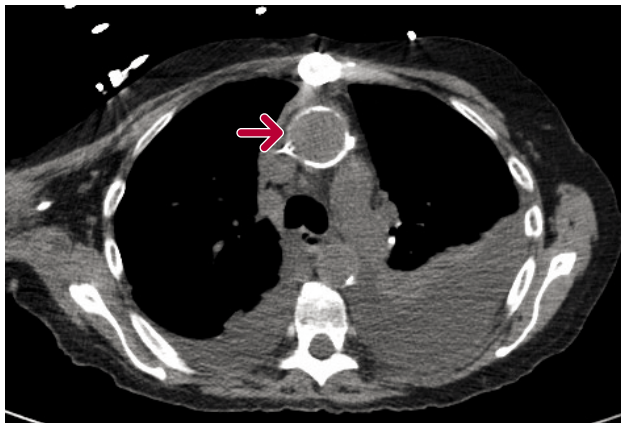


Figure 3. (Top) Noncontrast CT of the ascending aorta (porcelain aorta) in a 58-year-old woman with a history of radiation-induced heart disease. She was sent to Cleveland Clinic’s Cardio-Oncology Center for surgery before initiation of treatment for newly diagnosed breast cancer. (Bottom) The patient’s global longitudinal strain is abnormal (–11.4%), consistent with radiation-induced myocardial damage (restrictive heart disease).

Cardio-Oncology — A Work in Progress

As a new subspecialty area, cardio-oncology is evolving fast. Among the many issues of interest are the best ways to prevent radiation therapy from damaging the heart in patients with breast cancer. A variety of innovative techniques are used at Cleveland Clinic, including:

- The deep inspiration breath-hold technique to move the heart away from the radiation beam
- Whole-breast radiation in the prone position, allowing gravity to move the breast away from the heart
- Modulating the radiation dose to avoid the heart, including use of intensity-modulated radiation therapy

Dr. Plana emphasizes that treating heart disease in cancer survivors is best accomplished with a multidisciplinary team including cardiologists and thoracic and cardiovascular surgeons.

“The level of complexity is much higher than in other patients,” he notes. “Access to the chest may be challenging, because the tissues are thick and fibrotic. The risk of damaging structures with the scalpel is much higher. Calcifications may cause problems in clamping the aorta, requiring the replacement of the aorta prior to valve surgery.”

Despite these challenges, Dr. Plana is hopeful the new imaging guidelines — and forthcoming guidelines on cardiac evaluation after chemotherapy (see below) — will help clinicians understand the urgency of examining patients who have survived cancer treatment. ■

Contact Dr. Klein at 216.444.3932 or kleina@ccf.org and Dr. Plana at 216.444.5910 or planaj@ccf.org.

Coming soon: Expert consensus on the multimodality imaging evaluation of patients during and after cancer therapy

Chemotherapy agents, particularly anthracyclines and trastuzumab (Herceptin®), have been associated with heart failure development in up to 20 percent of young women with breast cancer and up to 42 percent of elderly patients.

To provide needed guidance on cardiac evaluation in chemotherapy recipients and build on its recent guidelines for cardiac imaging after radiation therapy, the American Society of Echocardiography — along with the European Association of Cardiovascular Imaging and the American Society of Clinical Oncology — is publishing a consensus statement in early 2014 on cardiac evaluation during and after chemotherapy. The writing committee is chaired by Juan Carlos Plana, MD, Co-Director of Cleveland Clinic’s Cardio-Oncology Center.

Case Study

Revision of Early Repair of Complex Congenital Heart Defects in an Adult Patient



Richard Krasuski, MD



Gosta Pettersson,
MD, PhD

Presentation

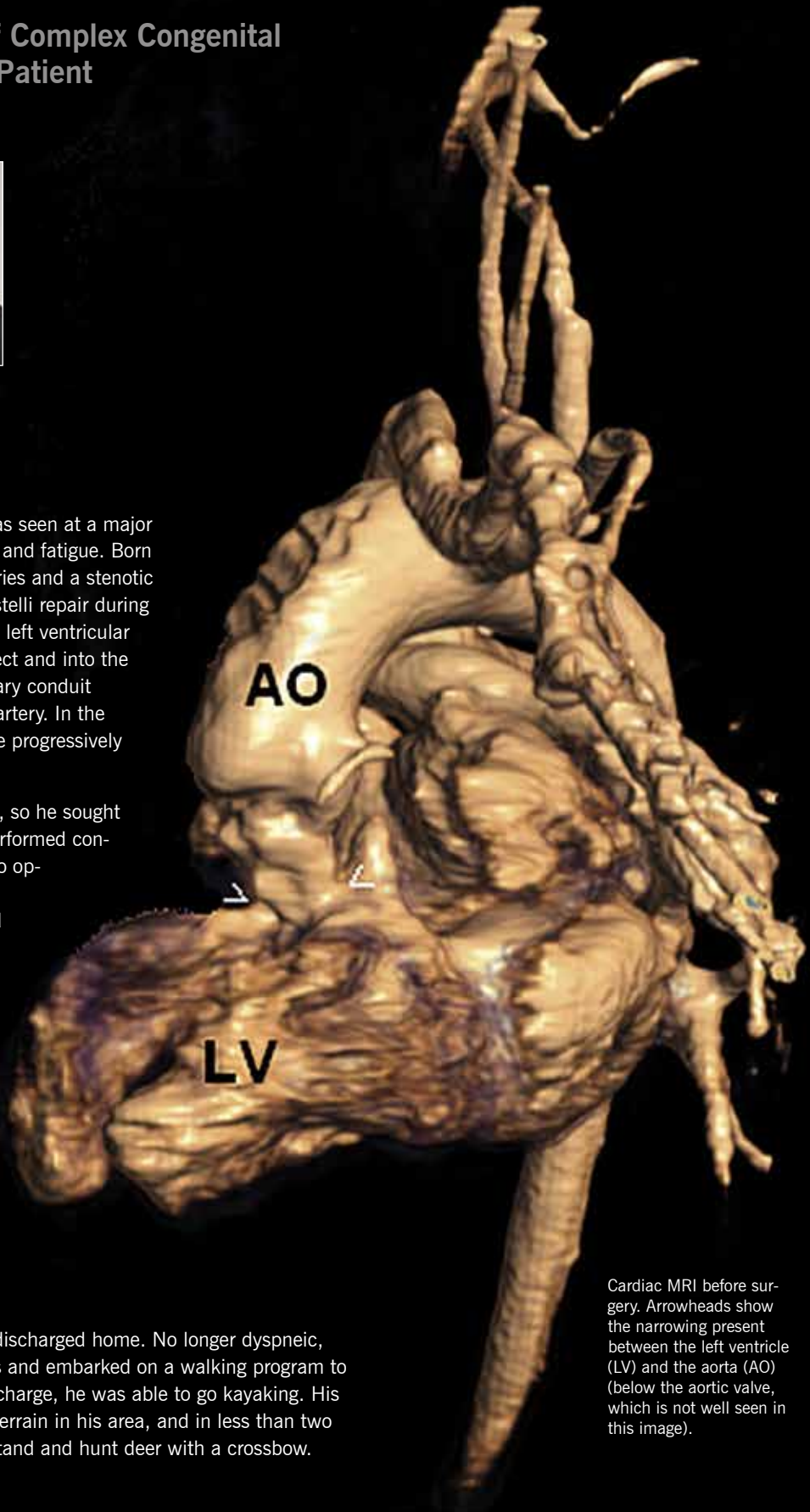
A 38-year-old man from southern Ohio was seen at a major medical center for incapacitating dyspnea and fatigue. Born with dextro-transposition of the great arteries and a stenotic pulmonary valve, he had undergone a Rastelli repair during childhood. This repair involves routing the left ventricular outflow through the ventricular septal defect and into the native aorta, with placement of a pulmonary conduit from the right ventricle to the pulmonary artery. In the years since, his aortic outflow had become progressively obstructed due to scar tissue.

The patient's original surgeons had retired, so he sought help at the nearest medical center that performed congenital heart surgery. The center refused to operate, however, likely due to the excessive risk he presented. His cardiologist referred him to Cleveland Clinic for evaluation.

Treatment

We reviewed the patient's medical history, discussed his anatomic anomalies and determined that enlarging the ventricular septal defect and directing left ventricular outflow through the defect into the aorta would be the best approach to revising his anatomy in the shortest operative time. Surgery was performed in this manner, and the old conduit from the right ventricle to the pulmonary artery was also replaced.

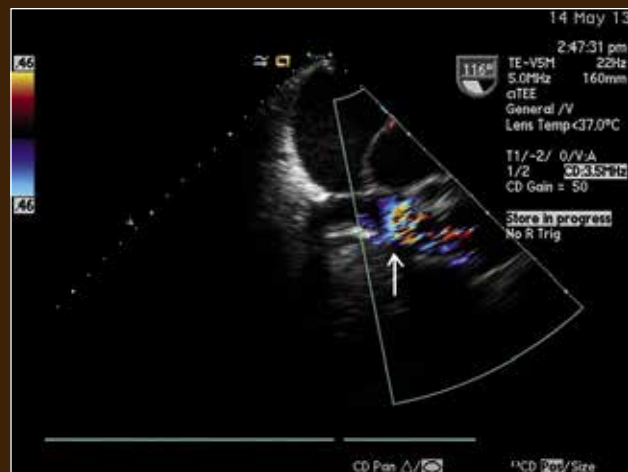
Two weeks after surgery, the patient was discharged home. No longer dyspneic, he was eager to return to normal activities and embarked on a walking program to improve his stamina. Five weeks after discharge, he was able to go kayaking. His walking progressed to hiking up the hilly terrain in his area, and in less than two months he was able to climb into a tree stand and hunt deer with a crossbow.



Cardiac MRI before surgery. Arrowheads show the narrowing present between the left ventricle (LV) and the aorta (AO) (below the aortic valve, which is not well seen in this image).



Transesophageal echocardiogram showing obstruction between the left ventricle (LV) and the aorta (AO). LA = left atrium; RA = right atrium.



Color Doppler transesophageal echocardiogram showing turbulence (color) at the level of the obstruction.

Discussion: New Challenges from a New Generation of Patients

The development of surgical procedures that enable children born with congenital heart defects to survive into adulthood has created a new generation of patients suffering from the secondary consequences of these early repairs. Cleveland Clinic's Adult Congenital Heart Disease Program was developed to treat these special patients.

Successful second-generation repairs require a specialized surgeon who understands the original defect and repair and can develop a unique approach to the next operation.

Dextro-transposition of the great arteries is one of the more common defects we see. In this case, the initial palliative repairs served the patient well for more than three decades. However, this case was unusual in that obstructed outflow had caused high pressure to develop in the left ventricle. If

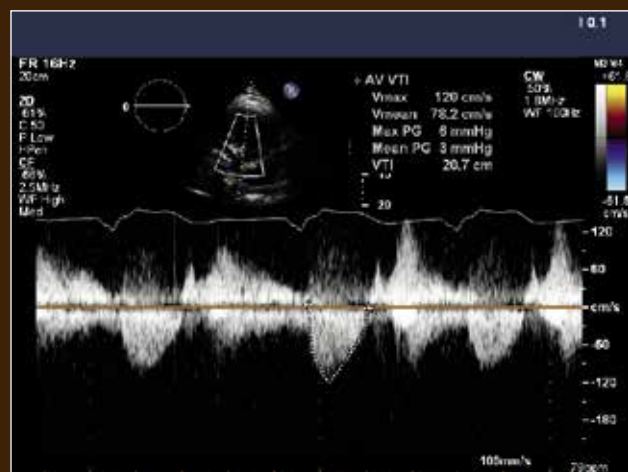
left uncorrected much longer, this would have resulted in progressive enlargement and eventual failure of the left ventricle.

If this patient had been born today, we most likely would have performed a different repair — an arterial switch and closure of the ventricular septal defect, in which normal anatomy is recreated by connecting the aorta directly to the left ventricle and the pulmonary artery directly to the right ventricle. Unfortunately, restoring normal anatomy was not an option. And although we hope the second round of repair will be a permanent solution, there is no guarantee that future surgery for acquired heart disease will not be required. ■

Contact Dr. Krasuski, Director of the Adult Congenital Heart Disease Center, at 216.445.7430 or krasusr@ccf.org. Contact Dr. Pettersson, Section Head of Pediatric and Adult Congenital Heart Surgery, at 216.444.2035 or petterg@ccf.org.



Continuous-wave Doppler (by transesophageal echo) showing high-velocity flow at the region of obstruction before surgery. The estimated pressure difference across the obstruction before surgery was 74 mm Hg, indicating that pressure was 74 mm Hg higher in the left ventricle than in the aorta as a result of the obstruction, leading to the patient's symptoms.



Continuous-wave Doppler (by transthoracic echo) showing resolution of the high velocity five months after surgery. The estimated pressure difference across the level of the prior obstruction was only 6 mm Hg, an impressive reduction from the presurgical difference.

Studies Find CAD Reversal Elusive While Fueling Further Questions

Cleveland Clinic Coordinating Center for Clinical Research spearheads multicenter trials of renin inhibition and apoA1 induction.



Steven Nissen, MD



Stephen J. Nicholls, MD, PhD

Incremental reductions in progression of coronary artery disease (CAD) are hard to come by. That's one conclusion that can be drawn from a pair of multicenter randomized trials presented by researchers from the Cleveland Clinic Coordinating Center for Clinical Research at the European Society of Cardiology (ESC) Congress 2013. Yet the studies, despite failing to demonstrate significant treatment effects in their primary endpoints, raise compelling follow-on questions:

- Does renin inhibition nevertheless have beneficial cardiovascular effects that manifest as reduced cardiovascular events?
- Does the “HDL hypothesis” — i.e., that raising high-density lipoprotein (HDL) cholesterol halts progression of atherosclerosis — remain plausible when a purported HDL-raising therapy fails to increase HDL levels in addition to failing to slow CAD progression?

AQUARIUS: Aliskiren Fails to Halt Atherosclerosis While Cutting Cardiac Events

The first follow-on question was raised by the AQUARIUS trial, whose full name and details are outlined in Table 1.

This international study set out to assess whether the renin inhibitor aliskiren could slow or reverse progression of CAD in patients with blood pressure in the prehypertension range. It aimed to build on evidence linking plasma renin activity to risk for future cardiovascular events and on animal models showing aliskiren to have favorable effects on atherosclerosis. Principal endpoints of AQUARIUS were changes in coronary atherosclerosis by intravascular ultrasound (IVUS) after 72 to 104 weeks of treatment with aliskiren or placebo.

“Aliskiren had a moderate effect on reducing blood pressure, substantially reduced renin activity and produced a compensatory increase in renin concentration in the blood plasma,” says principal investigator Stephen J. Nicholls, MD, PhD, senior consultant to the Cleveland Clinic Coordinating Center for Clinical Research and Deputy Director, South Australian Health & Medical Research Institute, Adelaide. “We also saw a bit of a trend toward regression in atherosclerosis. But the difference in our primary endpoint — a decrease in the volume of disease in the artery — did not meet statistical significance.”

Interestingly, a prespecified analysis showed a 50 percent reduction in adjudicated major cardiovascular events in the aliskiren group compared with the placebo group (see Table 1), but this was not a primary or secondary endpoint. Major cardiovascular events were defined as death, myocardial infarction, stroke, hospitalization for acute coronary syndrome or heart failure, or arterial revascularization.

“We have to be cautious interpreting our results on cardiovascular events because this trial was not formally designed to look at these outcomes,” says Steven Nissen, MD, chairman of the AQUARIUS trial executive committee and Chairman of the Robert and Suzanne Tomsich Department of Cardiovascular Medicine at Cleveland Clinic. “However, the data indicate that renin inhibition is safe in patients who have CAD and have their blood pressure under control, and it may have some beneficial cardiovascular effects.”

The AQUARIUS trial was published in *JAMA* (2013;310[11]:1135-1144).

ASSURE Yields No Assurance on Clinical Utility of ApoA1 Induction

Dr. Nicholls also presented results from the ASSURE trial evaluating the investigational agent RVX-208 for its effect on progression of CAD in patients with low HDL. Details of the placebo-controlled study are in Table 1.

Research interest centered on RVX-208 because it is the first oral agent to induce production of the HDL precursor protein apolipoprotein A1 (apoA1). Interest was bolstered by phase II studies finding the agent to have a direct effect on HDL at the molecular level.

Table 1. Profiles of the Studies

	AQUARIUS	ASSURE
Full name	Aliskiren Quantitative Atherosclerosis Regression Intravascular Ultrasound Study	ApoA1 Synthesis Stimulation and Intravascular Ultrasound for Coronary Atheroma Regression Evaluation
Design	Multicenter, double-blind, randomized, placebo-controlled	Multicenter, double-blind, randomized, placebo-controlled
Population/sample	613 patients with CAD, systolic BP 125-139 mm Hg (prehypertension) and two additional cardiovascular risk factors	324 patients with CAD, low HDL levels and a target blood vessel for imaging with < 50% stenosis
Interventions	<ul style="list-style-type: none"> • Baseline coronary IVUS imaging • 104 weeks of aliskiren (300 mg/day) or placebo orally • Repeat IVUS after ≥ 72 weeks of therapy 	<ul style="list-style-type: none"> • Baseline coronary IVUS imaging and measurements of apoA1 and HDL • 26 weeks of RVX-208 (200 mg/day) or placebo (plus atorvastatin or rosuvastatin in both groups) • Repeat IVUS and apoA1/HDL measurements after 26 weeks of therapy
Results	<ul style="list-style-type: none"> • Primary endpoint: Nonsignificant difference of 0.43% in PAV change from baseline • Secondary endpoints: No significant differences in TAV change or in proportion of patients showing PAV regression • Significant reduction in major cardiovascular events in aliskiren group (26 vs. 50; $P = .004$) 	<ul style="list-style-type: none"> • Primary endpoint: Nonsignificant difference of 0.1% in PAV change from baseline • No significant differences in other IVUS endpoints • No significant differences in change in levels of HDL and apoA1

BP = blood pressure; CAD = coronary artery disease; HDL = high-density lipoprotein cholesterol; IVUS = intravascular ultrasound; PAV = percent atheroma volume; TAV = total atheroma volume

The failure of RVX-208 to raise HDL levels means that ASSURE didn't actually test the HDL hypothesis.

Yet ASSURE did not find those effects to translate to the clinical level, as outlined in Table 1. “Our results show that RVX-208 treatment did not result in any measurable incremental benefit on plaque regression for patients with CAD and low HDL cholesterol,” says Dr. Nicholls. “The findings could reflect either a lack of efficacy of RVX-208 or the general inability to improve on the benefits produced by statins and other cardiovascular therapies,” as all ASSURE patients also received potent statin therapy. Notably, RVX-208 did not significantly raise HDL levels relative to placebo.

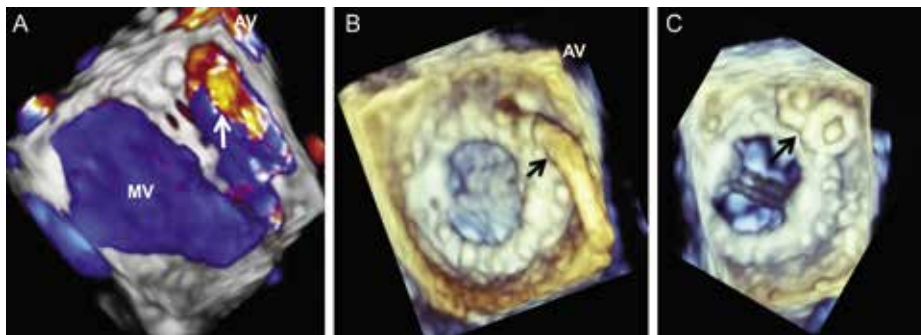
While Dr. Nicholls has called the results “disappointing and surprising,” he notes that the failure of RVX-208 to raise HDL levels means that ASSURE didn't actually test the HDL hypothesis.

Dr. Nissen, who served as ASSURE trial chairman, adds: “Ever since statins were approved more than 25 years ago, there has been an intensive, concerted effort in the scientific community to find an HDL-raising drug that will work in tandem with statins and improve cardiovascular outcomes. Unfortunately, that search must go on.”

Both AQUARIUS and ASSURE were academically directed trials. AQUARIUS was funded by Novartis Pharmaceuticals and governed by an independent executive committee. Funding and trial design input for ASSURE were provided by Resverlogix Corp. ■

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Contact Dr. Nissen at nissens@ccf.org.

Fixing Paravalvular Leaks Without Surgery



Percutaneous closure of a paravalvular leak (PVL). (A) 3-D transesophageal echocardiogram (TEE) with color Doppler demonstrates a large anteromedial PVL (arrow). (B) 3-D TEE with the delivery catheter in place (arrow). (C) 3-D TEE with two Amplatzer® Vascular Plugs II in place (arrow). AV = aortic valve; MV = mitral valve. Reproduced from Chenier M, Tuzcu EM, Kapadia SR, Krishnaswamy A. *Intervent Cardiol.* 2013;5(3):335-344.

Patients with prosthetic heart valves who present with symptoms of heart failure or hemolytic anemia may suffer from paravalvular regurgitation, also known as paravalvular leak (PVL). Traditionally, PVL has been repaired with repeat open-heart surgery, which can pose greater risk than a first-time operation and carries a risk of recurrent PVL. In recent years, experienced interventional cardiologists have achieved excellent results with percutaneous closure of PVL. Outcomes at Cleveland Clinic and other well-equipped centers suggest that this structural intervention has a promising future.

Essentials of PVL

PVL is the result of a space between the native cardiac tissue and the prosthetic valve. It occurs in about 2 to 12 percent of patients with bioprosthetic or mechanical valves, and more often in the mitral than the aortic position. PVL in the tricuspid position is rarer still, but it can occur. Risk factors for developing PVL include (among others) multiple valve replacements in the same position, severe calcification of the valve annulus and surgery for endocarditis.

Recognition of PVL usually starts with suspicion arising from the clinical history. The diagnosis is then made by echocardiography. Often, transthoracic echocardiography is limited by “shadowing” around a prosthetic valve, and transesophageal echocardiography (TEE) must be performed to confirm the diagnosis. Advanced imaging is critical to planning and performing the procedure. Operators may be guided by 2-D and 3-D TEE, intracardiac echocardiography, fluoroscopy/angiography and, recently, combined CT and fluoroscopy.

Procedure at a Glance

Leaks are repaired by placing one or more nitinol plugs in the defect, much like stuffing a cotton ball in the top of a medicine bottle. There are currently no devices specifically designed to treat PVL. Instead, operators use one or another vascular or septal occluder based on the leak’s size and shape. Choice of device is guided by preprocedural imaging and intraprocedural monitoring.

Percutaneous closure of a paravalvular mitral leak is performed one of three typical ways. Most often, catheters are placed via the femoral vein and introduced to the left atrium through a transseptal puncture, after which wires are advanced across the leak. Over these wires, delivery catheters are advanced to place the closure devices. In some cases, catheters are placed via the femoral artery. The third method is to place a catheter directly into the left ventricular apex percutaneously through the chest wall (with no incision). Aortic valve procedures are generally done via the femoral artery.

Aside from procedures for which apical access is necessary, percutaneous PVL closure at Cleveland Clinic is performed using local anesthesia and conscious sedation, not general anesthesia, and without endotracheal intubation.

Safe and Efficacious in Experienced Hands

Small reports and large series have been published over the past 20 years showing that percutaneous PVL closure is safe and efficacious. Most patients enjoy freedom from significant heart failure symptoms, blood transfusions due to hemolysis or need for repeat open-heart surgery.

The procedure requires a highly skilled and experienced team of interventional cardiologists, imaging cardiologists, and catheterization lab technicians and nurses with access to specialized equipment and advanced imaging modalities. Performed carefully, percutaneous PVL closure provides an effective but less-invasive alternative to repeat open-heart surgery for a number of patients suffering from this condition. ■

Percutaneous PVL closure is performed at Cleveland Clinic by the structural interventional team of E. Murat Tuzcu, MD (tuzcue@ccf.org), Samir R. Kapadia, MD (kapadis@ccf.org), and Amar Krishnaswamy, MD (krishna2@ccf.org). Feel free to contact them with questions.

NEWS IN BRIEF

from the Heart & Vascular Institute

Going 3 for 3 in Society of Thoracic Surgeons' Quality Ratings

Cleveland Clinic has received a coveted three-star rating in all three categories of the Society of Thoracic Surgeons' (STS) comprehensive risk-adjusted quality ratings for cardiac surgery among U.S. hospitals and surgical groups: (1) composite rating for coronary artery bypass graft surgery (CABG), (2) composite rating for aortic valve replacement (AVR) and (3) composite rating for combined CABG and AVR.

The ratings are reported under the STS Public Reporting Online initiative and based on data from July 1, 2012, through June 30, 2013.

Under the STS rating system, hospitals or surgical groups can be rated lower than average (one star), average (two stars) or higher than average (three stars). For the several years the STS has been issuing CABG quality ratings, about 10 to 15 percent of participants in its national database have achieved three-star ratings in the CABG category, according to the STS website. Ratings for the AVR and combined CABG-AVR categories are newer, and the STS website does not report rating breakdowns in these categories.

First Prize in Cardiology at BMA Medical Book Awards

The fourth edition of *Manual of Cardiovascular Medicine* (2012), edited by Cleveland Clinic's Brian P. Griffin, MD, won first prize in cardiology at the British Medical Association's Medical Book and Patient Information Awards. Dr. Griffin is a member of the Robert and Suzanne Tomsich Department of Cardiovascular Medicine, as are associate editors Thomas D. Callahan IV, MD, and Venugopal Menon, MD.

Gornik Named Editor of *Vascular Medicine*



Cleveland Clinic vascular medicine specialist Heather Gornik, MD, took on the editorship of *Vascular Medicine*, the peer-reviewed journal of the Society of Vascular Medicine, in January. Dr. Gornik was chosen by the society after an extensive national search for a replacement for founding editor Mark Creager, MD, who directed the journal since 1990.



In Memoriam: Roy Greenberg, MD

Cleveland Clinic mourns the passing of one of its most accomplished clinicians and innovators, Roy Greenberg, MD, in December 2013. Dr. Greenberg was a vascular surgeon in the Sydell and Arnold Miller Family Heart & Vascular Institute.

Dr. Greenberg had a passion for problem-solving that he routinely applied to the care of his patients. This made him a prolific researcher and clinical pioneer, developing a wide range of endovascular instruments and techniques to treat complex aortic disease. His innovations include unique endovascular grafts that enable less-invasive treatment of thoracoabdominal aortic aneurysms. He held more than 50 patents, and his efforts helped save the lives of many.

Dr. Greenberg was recognized in 2012 with Cleveland Clinic's Sones Innovation Award, a singular honor celebrating achievements that reflect the spirit of F. Mason Sones, MD, who pioneered cine-coronary angiography at Cleveland Clinic in 1958. And in 2013 the Society for Vascular Surgery established the annual Roy Greenberg Distinguished Lecture to recognize his lasting contributions to vascular surgery.

"Roy was a clinician and an engineer, and it was the melding of those two things that allowed him to really push forward the field of endografting for complex aortic disease," says Bruce Lytle, MD, Heart & Vascular Institute Chairman.

"Roy looked at and thought about things in ways the rest of us didn't," adds Daniel Clair, MD, Chairman of the Department of Vascular Surgery. "No other person I've known has had that thought process for getting things from his mind into patient use and so effectively enabling patients to benefit from innovation."

Save the Dates

For These Events and Conferences

Intensive Vascular Ultrasound Interpretation Review and Registry Preparation

April 12-13, 2014

Bunts Auditorium, Cleveland Clinic main campus, Cleveland, Ohio

Two days covering a wide spectrum of vascular lab diagnostics including both ultrasound and physiologic testing. Rapid-fire interpretation of vascular studies, mock registry-type exam questions, and vascular physics and technology drills are featured. New topics for 2014: use of ultrasound in planning and follow-up of venous ablation procedures, quality and accreditation in the vascular lab, and Cleveland Clinic's most unusual vascular ultrasound cases.

For more information, visit ccfcm.org/VasUltrasound14.

Pericardial Intervention in Cardiac Electrophysiology

May 6, 2014

7-9:30 p.m. (complimentary dinner program)
InterContinental Hotel, San Francisco, Calif.

Dinner symposium at the Heart Rhythm 2014 meeting on benefits, risks and practical considerations in the use of percutaneous procedures for accessing the pericardial space. Featured procedures include ventricular tachycardia ablation, atrial fibrillation ablation and left atrial appendage occlusion.

For more information, visit ccfcm.org/HRSintervention14.

Strategic Management of CIED Infections

May 7, 2014

7-10:30 p.m. (complimentary dinner program)
InterContinental Hotel, San Francisco, Calif.

Dinner symposium at the Heart Rhythm 2014 meeting exploring the prevention, recognition and management of cardiovascular implantable electronic device (CIED) infections. Features presentations, case studies and panel discussions led by national and international experts in the field.

For more information, visit ccfcm.org/HRSinfection14.

International Fibromuscular Dysplasia Research Network Symposium

May 15-16, 2014

InterContinental Hotel & Bank of America Conference Center, Cleveland, Ohio

Although it's a nonatherosclerotic disorder, fibromuscular dysplasia (FMD) is associated with major vascular morbidity. This two-day meeting combines a review of the latest knowledge and research activities surrounding FMD with sessions designed to establish a multidisciplinary FMD research network and set an agenda of research priorities. Featuring a faculty of global experts in FMD.

For more information, visit clevelandclinic.org/fmdsymposium.

15th Annual Intensive Review of Cardiology

Aug. 23-27, 2014

InterContinental Hotel & Bank of America Conference Center, Cleveland, Ohio

Intensive five-day course focused on the needs of practicing cardiologists and those preparing for cardiovascular board certification or recertification. Complex patient management decision-making is emphasized.

For more information, visit ccfcm.org/cardioreview.

Preceptorship in Carotid Ultrasound Interpretation

Aug. 25-29 | Oct. 13-17 | Dec. 1-5, 2014

Miller Family Heart & Vascular Institute,
Noninvasive Vascular Laboratory, Cleveland, Ohio

Intensive 4½-day training program in interpreting carotid duplex ultrasound examinations. Features lectures, preceptored interpretation sessions with physicians from Cleveland Clinic's Noninvasive Vascular Laboratory, hands-on screening sessions and extensive review of cases with angiographic correlations. Participants will interpret approximately 125 carotid duplex ultrasound exams. Class size limited to five participants to allow ample direct mentorship from faculty.

For more information, visit ccfcm.org/carotid14.

CLEVELAND CLINIC RESOURCES

About Cleveland Clinic

Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,000 physicians and researchers represent 120 medical specialties and subspecialties. We are a nonprofit academic medical center with a main campus, eight community hospitals, more than 75 northern Ohio outpatient locations (including 16 full-service family health centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada, Sheikh Khalifa Medical City and Cleveland Clinic Abu Dhabi.

In 2013, Cleveland Clinic was ranked one of America's top 4 hospitals in *U.S. News & World Report's* annual "America's Best Hospitals" survey. The survey ranks Cleveland Clinic among the nation's top 10 hospitals in 14 specialty areas, and the top in heart care for the 19th consecutive year.

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Physician Directory

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Cleveland Clinic offers same-day appointments to help your patients get the care they need, right away. Have your patients call our same-day appointment line, **216.444.CARE (2273)** or **800.223.CARE (2273)**.

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Establish a secure online DrConnect account for real-time information about your patients' treatment at Cleveland Clinic at clevelandclinic.org/drconnect.

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Outcomes Data

View Outcomes books at clevelandclinic.org/outcomes.

Clinical Trials

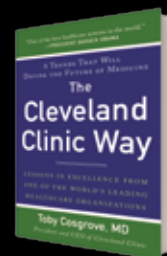
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The Cleveland Clinic Way

By Toby Cosgrove, MD
CEO and President, Cleveland Clinic

Great things happen when a medical center puts patients first. Visit clevelandclinic.org/ClevelandClinicWay for details or to order a copy.



The Cleveland Clinic Foundation
9500 Euclid Ave./AC311
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Cardiac Consult



INTRODUCING

Cleveland Clinic's Cardiovascular Consult Hotline [855.733.3712](tel:855.733.3712)

Your direct connection with subspecialist cardiology colleagues

Next time you need a sounding board when managing an especially complex case, call our new Cardiovascular Consult Hotline to connect directly for a consult with one of the expert cardiologists in Cleveland Clinic's Heart & Vascular Institute.

Chances are that one of our nearly 200 staff cardiologists, many of them highly subspecialized, may have encountered a case similar to yours and can share practical perspectives.

The hotline is covered 24/7 by a dedicated Heart & Vascular Institute specialist. If the covering expert cannot speak to the specifics of your call, the appropriate subspecialist will be identified and call you back promptly. The objective is streamlined connections from one cardiologist to another.

Text **cchotline** to **28748** to have the hotline number sent straight to your phone.

