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Featured Article

Mitral Valve Repair:
Settling the Controversies
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Dear Colleagues,

Cardiovascular care moves fast. Look at the past 20 years. The technologies and techniques featured in this issue of *Cardiac Consult* were nonexistent or in their infancy in 1991.

Tirone E. David, MD, published the valve-sparing aortic root procedure that bears his name in 1992. The operation has matured under the hands of surgeons like the Cleveland Clinic Miller Family Heart & Vascular Institute's (HVI's) Lars Svensson, MD, PhD. As reported in this issue, Dr. Svensson's modification of the David procedure provides an elegant solution to one of the major challenges of this technically difficult operation.

Bare metal stenting was still *avant garde* in 1991. Contrast those early devices with the self-expanding, drug-eluting, nitinol stent for the superficial femoral artery that was recently studied at Cleveland Clinic and many sites nationwide in the Zilver PTX trial. You'll get some idea of how far the devices have come. Cleveland Clinic has been at the forefront of evaluating intravascular stents since the early 1990s. We're proud to see collaboration among our vascular surgeons, interventional radiologists and cardiologists carrying on this great tradition.

In 1991, mitral valve surgery still meant replacement with a bioprosthetic or mechanical valve. Mitral valve repair was less common. Both replacement and repair were being done through a median sternotomy. Over the next 20 years, mortality and incision size shrank dramatically. Now, virtually all mitral valve repair at Cleveland Clinic is performed minimally invasively, and in-hospital mortality is 0 percent. Despite (or because of) this success, there are still areas of controversy in mitral valve repair, one of which is addressed in a recent study by HVI surgeon A. Marc Gillinov, MD, reported in this issue.

Both Dr. Gillinov and HVI surgeon Tomislav Mihaljevic, MD, are experts in the most advanced and least invasive approach to mitral valve repair, robotically assisted surgery. Our double-feature on mitral valve repair includes a review of a new study by Dr. Mihaljevic on outcomes of robotic mitral valve repair vs. other approaches. You may be surprised by the results. They speak volumes on how far we've come, and what lays ahead for the always changing and perpetually engaging cardiovascular specialties.

Sincerely,

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Mitral Valve Repair:

Settling the Controversies



Mitral valve repair is one of the great success stories in modern surgery. It has taken the place of mitral valve replacement as the preferred treatment for mitral valve regurgitation and stenosis.

Mitral valve regurgitation is the second most common valvular heart diagnosis in the United States. Mitral valve repair can be done through a conventional sternotomy, or minimally invasively through a right mini-thoracotomy, or partial upper sternotomy. Significantly, mitral valve repair can also be performed through port-sized incisions, with robotic assistance. High-volume cardiac surgery centers like Cleveland Clinic's Miller Family Heart & Vascular Institute are able to repair 99 out of 100 cases of mitral valve regurgitation or prolapse, with 0 percent mortality.

Mitral valve repair still has its share of controversies and unknowns, however. At what stage of mitral valve disease is it appropriate to perform the repair? Some believe that patients should not be subjected to the rigors of surgery until the disease is significantly advanced. Others believe that the surgical risk is offset by the advantages of being able to repair healthier valve tissue at an earlier stage of the disease. In a study described in following pages, Cleveland Clinic thoracic and cardiovascular surgeon A. Marc Gillinov,

MD, reviews the world's largest database of mitral valve repair to see which side is supported by experience. His findings provide a strong case for early repair.

Another outstanding question of mitral valve repair is the comparative efficacy of robotic mitral valve repair versus conventional open or minimally invasive surgery. Cleveland Clinic thoracic and cardiovascular surgeon Tomislav Mihaljevic, MD, and Dr. Gillinov together have the world's largest experience in robotic mitral valve repair. Dr. Mihaljevic is the lead author of a study, which appeared in the *Journal of Thoracic and Cardiovascular Surgery*, comparing outcomes of robotic repair of posterior mitral valve prolapse, versus conventional approaches. Dr. Mihaljevic's study shows that robotic repair is as safe and effective as conventional approaches.

One of the advantages of being a high-volume center with a large registry of cardiovascular surgery cases is the ability to perform these types of comprehensive data reviews. Read on to learn more about these findings.

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Robotic Surgery as Good as Conventional Repair

A study led by Tomislav Mihaljevic, MD, (*Journal of Thoracic and Cardiovascular Surgery*, January 2011) comparing outcomes of robotic mitral valve repair to those of conventional approaches, shows that the robotic approach is as safe and effective as conventional approaches. It concludes lesser invasiveness and shorter hospital stays compensate for robotic surgery's technical complexity and longer operative times.

"The value of this study for cardiologists and patients who have heart disease is that it objectively validates the safety and quality of robotic surgery for mitral valve disease," says Dr. Mihaljevic.

Dr. Mihaljevic and his colleagues looked at the outcomes of 759 patients with degenerative mitral valve disease and posterior leaflet prolapse who underwent primary isolated mitral valve surgery between 2006 and 2009. These patients received a complete sternotomy, partial sternotomy, mini-right anterolateral thoracotomy, or robotic approach.

Repair was achieved in all patients but one. Quality of repair was similar among all groups. The complication rate among all groups was similar. Although the robotic surgeries took somewhat longer due to procedural complexity, this was compensated for by lesser invasiveness. The robotic patients had the lowest occurrences of atrial fibrillation and pleural effusion. Since robotic surgery is the least invasive approach,

the average hospital stay for the robot patients was also significantly shorter: median 4.2 days, roughly a day shorter than the other approaches.

Previous studies of robotic surgery have not compared the same operation performed by a minimally invasive method vs. a traditional, established approach. This study was the first of its kind and produced the highest ever reported repair rate in the world for MV robotic surgery: There were no in-hospital deaths. By contrast, the nationally reported mortality rate for mitral valve repair is 2.5 to 3 percent.

"Ours is zero," says Dr. Mihaljevic.

The average reported repair rate for MV repair in the U.S. is no greater than 60 percent. Centers of Excellence have MV repair rates that average 90 percent. Cleveland Clinic's repair rate is greater than 99 percent.

Dr. Mihaljevic believes the study goes a long way toward setting any remaining controversy about the robotic approach. "There has been a fair amount of press that questions the value, safety and cost of robotic surgery," says Dr. Mihaljevic. "A study that objectively validates the benefits of this technique has been long overdue. Robotic mitral valve repair should be considered for all patients with severe mitral valve prolapse."

Dr. Mihaljevic can be reached at 216.444.0648 or mihaljt@ccf.org.





Surgical Repair of MR: Delay Has its Price

Mitral valve repair is one of the great success stories in cardiac surgery. It has become the treatment of choice for severe degenerative mitral valve disease (MR). Nonetheless, there are differences of opinion about when surgical repair should be recommended for patients with this condition. Should repair be performed early or late in the course of the disease? There are good arguments on both sides of the question. Recently, cardiac surgeon A. Marc Gillinov, MD, of the Miller Family Heart & Vascular Institute, set out to resolve the controversy. He reviewed the records of 4,586 patients who'd had primary isolated surgery for degenerative MR at Cleveland Clinic since 1985. His findings, published in the *Annals of Thoracic Surgery*, have produced a detailed picture of mitral valve surgery and its effects on outcomes at all stages of disease etiology.

Dr. Gillinov's study used the classification system developed by the New York Heart Association (NYHA), which establishes four levels of increasing severity for MR. Level 1 produces no symptoms; level 2 is mildly symptomatic; and levels 3 and 4 are increasingly symptomatic up through end-stage heart failure.

Surgery – preferably repair – at a high-volume center (> 300 cases/year) for asymptomatic patients (levels 1 and 2) is recommended by the American College of Cardiology/American Heart Association. Studies of clinical practice,

however, show that only 30 to 60 percent of patients with asymptomatic severe degenerative MR are referred for surgery in the United States.

Some argue that patients in levels 1 and 2 should be medically managed and monitored by regular echocardiography. They maintain that asymptomatic patients should be spared the risks of surgery until it is absolutely necessary – especially since early repair does not affect long-term survival.

Others support early surgery based on abundant evidence that even asymptomatic disease has irreversible effects on cardiac structure and function, and that later surgical intervention is associated with poorer outcomes. While both early repair and “watchful waiting” are associated with similar long-term survival, many experts believe that early repair promises better quality of life.

Mitral valve repair was developed over the past 40 years as an alternative to mitral valve replacement. In the older procedure, a mechanical or tissue prosthetic is substituted for the native valve. Drawbacks to replacement include the need for lifelong anticoagulant therapy, and the likelihood that tissue valves will deteriorate after 10 to 15 years and require reoperation. Mitral valve repair, by contrast, is usually permanent and needs no blood thinning regimen. It implants a cloth ring that reinforces

continued on next page →

the native annulus and maintains the leaflets in proper alignment. Today, replacement is a last resort for valves rendered unsalvageable by long neglect or complications.

The 4,586 patients in Dr. Gillinov's study all had primary isolated surgery for severe degenerative MR. Most were from NYHA levels 1 and 2, with the rest distributed over the more severe levels 3 and 4. A comparison of level 1 and 2 patients showed that atrial fibrillation increased, left atria enlarged, left-ventricular function deteriorated, and right heart pressure rose from one stage to the next. (Left ventricular size, a diagnostic criterion for MR surgery, did not change.) These structural and functional changes intensified through levels 3 and 4. Hospital mortality was 0.37, clustered in level 4, and mostly associated with comorbidities.

"Waiting until patients develop symptoms has a price," Dr. Gillinov concludes. "Even mild symptoms are associated with adverse changes in cardiac structure and function. Early surgery improves the patients' chances of getting a repair, and that the repair will be successful. We find that repair is justified in asymptomatic patients with severe degenerative MR."

One important qualification to Dr. Gillinov's findings is the necessity for patients to have their mitral valve repair at a center with a great deal of expertise and experience in this procedure. Hospital mortality for mitral valve repair at such centers is very low – "similar to an appendectomy or tonsillectomy" marveled one surgeon, commenting on the study. Dr. Gillinov believes that repair of asymptomatic

severe degenerative MR is appropriate only at centers where hospital mortality is below 1 percent. "The asymptomatic patient is frequently going to be very young, so the operation must be very safe," he says. "In fact, for the asymptomatic patient undergoing mitral valve repair, operative mortality should be close to zero."

Dr. Tomislav Mihaljevic commented, "Most of the patients who present today with isolated mitral valve disease can be treated with minimally invasive techniques, often including the surgical robot. This reduces the hospital stay and speeds their recoveries."

As the nation's leading center for mitral valve surgery, the Miller Family Heart & Vascular Institute had 0 percent hospital mortality for mitral valve repair in 2009 – the lowest in the U.S. Fully 100 percent of surgeries for severe degenerative MR at Cleveland Clinic are repairs, and nearly 100 percent can be performed minimally invasively.

The results of Dr. Gillinov's study add to the growing body of evidence supporting ACC/AHA guidelines recommending early surgery be considered for asymptomatic patients with severe MR and preserved left ventricular size and function.

"Our inference is to continue to recommend and be aggressive about early surgery in asymptomatic patients with severe degenerative mitral-valve disease if we can provide a very high repair rate, greater than 90 percent, and a very low operative risk, well under 1 percent," says Dr. Gillinov.

Dr. Gillinov can be reached at 216.445.8841 or gillinom@ccf.org.



Case Study: Endovascular Treatment of Erectile Dysfunction

By Mehdi H. Shishebor, DO, MPH



Figure 1



Figure 2

Presentation

A 48-year-old happily married male with prior smoking history, hypertension, hyperlipidemia, coronary artery and peripheral arterial disease (PAD) presented with left leg claudication symptoms and erectile dysfunction for two years despite treatments with sildenafil (Viagra®) up to 100 mg. Prior to this, he was sexually active without any limitations.

Examination and Diagnosis

Physical examination revealed weak pulses in the popliteal, posterior tibial and dorsalis pedis arteries on the left side. An ankle-brachial index was abnormal for significant PAD in the left leg. Based on these findings and his claudication symptoms, he was brought in for angiography (Figure 1). This revealed totally occluded internal iliac arteries on both sides (Arrows).

Treatment

The patient underwent percutaneous endovascular treatment of the left internal iliac artery via the right groin using standard coronary wires. Four drug-coated stents were placed (Figure 2). A repeat CTA revealed patent internal iliac and pudendal artery on the left, two weeks post procedure.

Outcome

After two to three weeks, the patient was able to engage in sexual activity without the need for adjunctive medications, such as sildenafil. His quality of life was significantly improved and he inquired about treatment of the contralateral side (which is not necessary at this point).

Discussion

The importance of adequate arterial flow to the penis for initiation and maintenance of erection has been well described. Proximal arterial inflow deficiency was first described in 1923 by the French surgeon René Leriche, who observed that bi-aortoiliac occlusion caused impotence due to a failure of perfusion of the corporal bodies. This triad consists of impotence, buttock claudication and absent pulse in groins/legs due to occlusion at level of aortic bifurcation. Surgical revascularization of arterial inflow also can be performed successfully.

The internal pudendal artery courses as a straight line continuation of the internal iliac artery and can be accessed percutaneously from the contralateral femoral artery. There have been a few case reports of percutaneous revascularization of the internal pudendal artery in the pre-stent era. These initial success rates have been limited by recurrence of erectile dysfunction, presumably due to restenosis. As in the experience with coronary artery stenting and renal artery angioplasty, it stands to reason that treatment with stents may alter the restenosis rate and provide a more durable solution. While improvement in penile arterial inflow would be expected to improve erectile dysfunction in selected individuals, it will not serve as a panacea to treat all erectile dysfunction because of the many causes of this disorder.

Dr. Shishebor is an interventional cardiologist, specializing in peripheral interventions. He can be reached at 216.444.4420 or shishem@ccf.org.

Implanting an



Aortic stenosis patients who are deemed inoperable or at a very high risk for standard open heart surgery could be candidates for a less invasive option: transcatheter aortic valve implantation.

Alternative

While our population ages, more individuals with severe aortic stenosis are deemed not suitable or high-risk candidates for open heart surgery. The standard therapy for this group of people is limited. Now there is hope for this patient population.

Cleveland Clinic helped lead the research for a game-changer in heart care: transcatheter aortic valve implantation (TAVI), a now proven minimally invasive alternative to open heart surgery. TAVI involves transporting a synthetic valve to the heart through a small incision in the groin or chest. The procedure can be compared to placing a stent or performing balloon angioplasty.

“For many years, we have been exploring ways to solve this problem of life-limiting aortic stenosis in high-risk populations,” says Murat Tuzcu, MD, Vice-Chairman of the Cardiovascular Medicine Department/Interventional Cardiologist at the Sydell and Arnold Miller Family Heart & Vascular Institute at Cleveland Clinic. “TAVI is a very exciting, innovative way of helping these people.”

In the United States, TAVI is still an investigational device that was implanted only within the context of the Placement of Aortic Transcatheter Valves (PARTNER) trial. In September 2010, results from part of the trial focusing on patients who were deemed inoperable were released. “TAVI now is a proven solution for patients who cannot be operated on because of their co-morbidities,” Dr. Tuzcu says, noting that the results of TAVI on high-risk patients will be reported in spring.

“Cleveland Clinic has been one of the foremost leaders of this technology in the United States since the beginning,” notes Dr. Tuzcu, who collaborated on the PARTNER trial with co-investigators Lars Svensson, MD, (cardiac surgery) and Samir Kapadia (interventional cardiology).

Here, Dr. Tuzcu addresses questions concerning TAVI and what patients are candidates for this investigational device.

What was the PARTNER Trial?

The trial focused on the placement of prosthetic aortic valves using a catheter in two groups of patients: those who had symptomatic and severe aortic stenosis who were deemed inoperable for cardiac surgery; or those who could be operated on, but were high-risk candidates with an expected mortality rate of 15 percent or more and/or an STS score of 10 or

higher. Half of the trial population was treated with the TAVI technique, and the other half received standard therapy.

What were the results of the first part of the PARTNER Trial?

In the patient population with aortic stenosis who were deemed inoperable, those treated by TAVI compared to standard therapy had an absolute reduction in mortality of 20 percent. That translates to saving one life in every five patients who were treated with TAVI. Those who received traditional therapy had a mortality rate of 50 percent.

Who is a candidate for TAVI?

Patients who have severe, symptomatic aortic stenosis and are deemed too high-risk for open heart surgery can be considered for this technique. Candidates must meet requirements set by the PARTNER trial. Exclusion criteria includes dialysis treatment, an extremely weak heart (ejection fraction of less than 20 percent), and other forms of severe valvular heart disease. It is possible to include patients that are high-risk with an STS score of 10 or more provided they do not meet exclusion criteria.

What's next for TAVI in the United States?

The PARTNER trial results, which were released in September 2010, support TAVI as a solution for otherwise inoperable aortic stenosis patients. It's an exciting technology and, at this point, we are continuing to use the technology in patients under the FDA's Continued Access Clause, which allows inoperable aortic stenosis sufferers to be considered as candidates for this cutting-edge solution.

In spring, we will get the results of patients who were at very-high, but not prohibitively-high, risk for standard open heart surgery. In this study, TAVI was compared to standard aortic valve replacement with open heart surgery.

While TAVI is already widely used in high-risk cardiac patients in Europe and use of the device is starting to expand to lesser-risk patients, it still remains to be seen whether it will receive approval from the FDA. Stay tuned.

Contact Dr. Tuzcu at **216.444.8130** or tuzcum@ccf.org. For more information on the PARTNER trial, visit clinicaltrials.gov.

In Brief

\$3.8 Million Federal Grant Awarded to Study Heart Failure Cellular Processes

Cleveland Clinic has received a \$3.8 million federal grant to study the cellular processes that lead to heart failure. The goal of the project, called Cleveland Heart and Metabolic Prevention Study (CHAMPS), is to determine why some patients are at risk of developing heart failure while others are not – and identifying targets for future treatments.

“Say two people have heart attacks; in one, the heart function is relatively preserved, while in the other, the heart function deteriorates,” says the study’s primary investigator cardiologist W.H. Wilson Tang, MD. “With this study, we hope to discover why, so that we can personalize therapy and treat each patient accordingly.”

Study Finds Higher Heart Risk in Younger African Americans

African American’s higher risk for heart disease and stroke emerges at a fairly young age, according to a study led by Cleveland Clinic. The study emphasizes the need for prevention efforts targeting young African Americans.

The study found blacks ages 35 to 44 have nearly twice the prevalence of cardiovascular disease than their white counterparts. This racial gap persisted through the subjects’ 40s and 50s, declining until there was no significant disparity after age 60.

Researchers accounted for cardiovascular disease risk factors in the study group, including reported rates of high blood pressure, obesity, smoking; and

socioeconomic factors like education, income and access to healthcare. They concluded disparities in risk factors and socioeconomics largely explain the increased risk in younger African Americans.

Bisphosphonates Don’t Appear to Slow Aortic Stenosis Progression

According to findings presented by Cleveland Clinic researchers at the American Heart Association (AHA) Scientific Sessions 2010, bisphosphonates do not appear to postpone the progression of aortic stenosis.

Olcay Aksoy, MD, of Cleveland Clinic’s Tomsich Family Department of Cardiovascular Medicine, led a team that examined the impact of bisphosphonates on the progression of aortic stenosis in 842 women aged older than 60 years with aortic valve area (AVA) between 1.0 to 2.0 cm². Only those who had follow-up echocardiograms were included. Baseline demographics, echocardiography, laboratory and medication data were collected. Primary outcomes were the change in AVA and Valvular gradients (peak/mean) over time. Freedom from aortic valve replacement (AVR) was studied as a secondary outcome. Propensity matching method was applied for the probability of use of bisphosphonates.

The team concluded bisphosphonates do not seem to have a significant impact on the hemodynamic progression of AS; however a trend for lower likelihood of progressing to AVR is seen over a long time period. Long-term follow-up of patients may be required to determine treatment effect in AS progression studies given the pathophysiology of the disease.

\$11.65 Million NIH Grant to Study Role of HDL in Heart Disease

Researchers in Cleveland Clinic's Lerner Research Institute have been awarded an \$11.65 million grant from the National Institutes of Health to study the role of HDL in heart disease, why this "good" cholesterol sometimes goes bad, and how to possibly harness its plaque-fighting powers for new cholesterol-lowering therapies.

Stanley Hazen, MD, PhD, Department of Cell Biology of the Lerner Research Institute, and Section Head of Preventive Cardiology at Cleveland Clinic's Miller Heart & Vascular Institute, is the principal investigator, leading three projects that collectively focus on developing a comprehensive structural, functional, mechanistic

and clinical understanding of HDL biology and its relationship to atherosclerotic heart disease.

"Our goal is to discover the biologic mechanisms that render HDL dysfunctional, and to harness this information for both improved diagnostic tests, and new therapeutic interventions," Dr. Hazen says.



Project 1, led by Dr. Hazen, focuses on understanding how HDL — high-density lipoprotein — is rendered "dysfunctional" in atherosclerosis. The project will define how and where HDL becomes modified in the artery wall, inhibiting its function. It will also develop and validate clinical studies of a "dysfunctional HDL" test as a new and powerful diagnostic tool for heart disease risk.

Project 2, led by Jonathan Smith, PhD, a staff member in the Department of Cell Biology of the Cleveland Clinic Lerner Research Institute, focuses on understanding how HDL is made. The project will also test novel engineered "oxidant-resistant" forms of HDL as therapeutics for atherosclerosis.

Project 3, led by Ed Fisher, MD, PhD, Director of New York University Medical Center's Vascular

Biology and Disease Program, focuses on understanding the molecular mechanisms responsible for atherosclerotic plaque regression.

The inter-related projects of the research program may lead to new diagnostic and therapeutic approaches toward cardiovascular risk assessment and therapy.

Staff News

New HVI Hires



David Majdalany, MD, has joined the Section of Clinical Cardiology in the Tomsich Family Department of Cardiovascular Medicine at Cleveland Clinic. Dr. Majdalany received his medical degree from Marshall University School of Medicine,

Huntington, W.Va. He completed a combined residency in internal medicine and pediatrics at Mount Sinai Medical Center in New York, N.Y., followed by a fellowship in adult cardiology at the University of Louisville School of Medicine in Louisville, Ky. He subsequently completed a fellowship in advanced echocardiography at Columbia University Medical Center, New York, N.Y., before relocating to Rochester, Minn. for fellowships in adult congenital heart disease and critical care medicine at the Mayo Clinic. He joined Cleveland Clinic in 2010 upon completion of this subspecialty training. Dr. Majdalany is board-certified in internal medicine, general cardiology, nuclear cardiology, and echocardiography. He will be involved in our congenital clinic.



Perry Fleisher, MD, has joined Cleveland Clinic's Tomsich Family Department of Cardiovascular Medicine. Dr. Fleisher will practice at the Cleveland Clinic catheterization Lab at Ashtabula County Medical Center, Ashtabula, Ohio. Dr.

Fleisher received his medical degree from Albany Medical College of Union University, Albany, N.Y. and is board-certified in cardiology and internal medicine.

CME Calendar

Medical professionals are invited to attend the following upcoming symposia:

14th Diastology & New Echo Technologies Summit: Featuring Heart Valve and Contrast

Feb. 23-26
Echo Mini-Symposium
The Westin Beach Hotel
Ft. Lauderdale, Florida

Dimensions in Cardiac Care 2011

April 10-12
InterContinental Hotel & Bank of America
Conference Center
Cleveland, Ohio


Preceptorship in Carotid Ultrasound Interpretation

May 2-6 | June 20-24 | Oct. 3-7
Cleveland Clinic Heart & Vascular Institute
Noninvasive Vascular Laboratory
Cleveland, Ohio

2nd Annual Symposium on Interventional Pericardiology 2011 Heart Rhythm Society Satellite Meeting

May 3
San Francisco

For more information about the above events, call the Cleveland Clinic Department of Continuing Education at **216.444.5696** or **800.762.8173**, or visit ccfme.org.



To refer a patient to any staff at the Miller Family Heart & Vascular Institute, please call **800.553.5056**.

Cleveland Clinic's Kaufman Center For Heart Failure Intensive Care Unit Given Beacon Award Of Excellence

Cleveland Clinic's Kaufman Center for Heart Failure Intensive Care Unit (ICU), recently received The American Association of Critical Care Nurses (AACN) Beacon Award of Excellence for continuing improvements in providing the highest quality of care for patients.

With more than 6,000 ICUs in the U.S., Cleveland Clinic's Kaufman Center for Heart Failure ICU joins a distinguished group of just over 300 ICUs to receive the Beacon Award since the award's inception in 2003. The award recognizes individual critical care units that show the highest level of standards in patient safety and quality in acute and critical care.

Cleveland Clinic's Kaufman Center for Heart Failure ICU consists of 10 beds and is used primarily to evaluate and treat patients with advanced congestive heart failure, some of whom are in need of a heart transplant or left ventricular assist device. Patients with pulmonary hypertension needing intravenous medications and intensive monitoring, as well as general ICU patients with sepsis and respiratory failure also can be cared for in this unit.

"The nurses and each team member that has the pleasure to work in the Heart Failure ICU are well deserving of this recognition as we look for even more ways to improve on patient care," says Mazen Hanna, MD, Director of Cleveland Clinic's Kaufman Center for Heart Failure ICU.

Cleveland Clinic Non-invasive Vascular Laboratory Preceptorship in Carotid Ultrasound Interpretation

May 2 – 6, 2011 | June 20 – 24, 2011 | October 3 – 7, 2011 | Cleveland, Ohio

This intensive 4½-day program will train the participant to interpret carotid duplex ultrasound examinations through a series of activities, including didactic lectures, preceptored interpretation sessions with staff physicians of the Cleveland Clinic Noninvasive Vascular Laboratory, hands-on scanning sessions, and review of an extensive library of programmed learning cases with angiographic correlations. Training is geared toward cardiologists, vascular surgeons, vascular medicine physicians, radiologists and neurologists. By the end of the week, the participant will have interpreted approximately 125 carotid duplex ultrasound examinations. Enrollment will be limited to five participants per session to allow for ample opportunity for interaction and direct mentorship from course faculty.

At the end of the course, participants will receive documentation of their experience, including the number of examinations interpreted during the week. This documentation may be used toward application for vascular laboratory accreditation and/or physician certification in vascular testing (e.g. RPVI examination).

The Cleveland Clinic Foundation Center for Continuing Education designates this educational activity for a maximum of 32.75 AMA PRA Category 1 Credits™. To register, call 216-448-0777 or email cmregistration@ccf.org.

Peripheral Artery Disease

Even though Zilver PTX trial shows promising results for symptomatic femoropopliteal artery disease, uncertainties remain

Peripheral artery disease (PAD) affects more than 10 million Americans. Symptomatic femoropopliteal artery disease (SFA) accounts for approximately 50 percent of PAD cases.

Endovascular therapies such as percutaneous transluminal angioplasty (PTA) and bare-metal stenting (BMS) are regularly utilized to treat certain patients with moderate to severe SFA disease. Clinical experience, however, has shown these treatments fail to maintain long-term vessel patency. Restenosis rates can range from 30 percent to 70 percent six to 12 months following treatment.

This issue has led investigators to focus on evaluating whether drug-eluting stents can reduce these high rates of restenosis. Unfortunately, various past trials have not shown significant differences in outcome compared to patients treated with PTA and BMS. Recently, however, findings from the Zilver PTX (Cook Group) paclitaxel-eluting vascular stent research trial showed that after 12 months patency rates were 83.1 percent for stented segments treated with Zilver PTX compared to 65 percent patency rates for arteries treated with BMS.

Cleveland Clinic was among the 55 centers in the United States, as well as Germany and Japan, which participated in the Zilver PTX trial. The trial is the largest randomized trial of a peripheral endovascular therapy to-date.

Interventional radiologist Gregory Pierce, MD, served as an investigator for the trial, collaborating with co-investigators Sean Lyden, MD, vascular surgery, and Christopher Bajzer, MD, interventional cardiology.

Uncertainties remain

Whether or not the Zilver PTX will receive FDA approval remains to be seen. Currently, only two noncovered stents are approved for use in the SFA, explains Dr. Lyden, the Bard Lifesent and the eV3 Intrastent, which is no longer on the market.

“Most stents used commercially only have a biliary indication or an iliac artery indication,” he says. “This has been a big limitation for companies in the ability to investigate new devices in trials and bring the new technology to market.

Unlike the coronaries where drug eluting stents are common place and have excellent data, the SFA is an arterial bed with the longest segment and often very severe disease which no device or technology has found great results in treatment.”

Although the Zilver PTX trial has shown positive results, there are uncertainties as to whether its patency rates can be replicated in a clinical environment, Dr. Pierce adds.

“It has not been determined whether the Zilver PTX stents can be used as a practical treatment in clinic in patients with lesions of greater than 15 cm in length,” says Dr. Pierce. “Moreover, we do not know how these stents will perform among patients with co-morbidities.”

For example, in the prospective Zilver PTX trial, the average lesion length was 6.6 cm. The average vessel diameter was 4 mm to 9 mm. Investigators were limited by the U.S. Food and Drug Administration (FDA) to treat lesions that were no longer than 14 cm.

Specific findings

The Zilver PTX trial, which enrolled 479 patients, conducted two randomization protocols. In the first randomization, patients received PTA therapy or treatment with Zilver PTX. After 12 months, patients treated with Zilver PTX maintained vessel patency rates of 83.1 percent, compared to 32.8 percent vessel patency rates within the PTA-treated group.

In the second randomization, patients who did not respond to PTA were randomized to receive the bare-metal Zilver stent or the paclitaxel-eluting Zilver stent. Twelve-month patency rates were 89.9 percent in the Zilver PTX patients and 73 percent in patients treated with BMS.

“Even though there have been no drug-eluting stents approved for clinical use to treat SFA, the Zilver PTX has gotten further along based on the results of the trial, which are under review by the FDA,” says Dr. Pierce. “Initially, there is always a lot of optimism generated by these studies, but the true tests of this new treatment will be determined in the clinical environment.”

CLEVELAND CLINIC ACCESS GUIDE

Same-day Visits Now Available

The Miller Family Heart & Vascular Institute has begun offering same-day appointments for new patients and follow-up visits. Patients who want or need to be seen immediately will be scheduled with a HVI Cardiovascular Medicine staff member.

All same-day visits will be coordinated through our appointment office. To arrange a same-day visit, call 216.444.6697 or 800.659.7822.



Referrals

To refer patients to a Cleveland Clinic heart and vascular specialist please call:

Cardiovascular Medicine

216.444.6697

Thoracic and Cardiovascular Surgery

877.843.2781

Vascular Surgery

216.444.4508

New patients, in most cases, can be seen within one week of calling for an appointment.



Medical Concierge

Complimentary assistance for out-of-state patients and families **800.223.2273, ext. 55580**, or email medicalconcierge@ccf.org

Global Patient Services

Complimentary assistance for national and international patients and families **001.216.444.8184** or visit clevelandclinic.org/ic

Critical Care Transport Worldwide

Cleveland Clinic's critical care transport team, whose fleet includes mobile ICU vehicles, helicopters and fixed-wing aircraft, serves critically ill and highly complex patients across the globe. Call **216.444.3202** or **800.553.5056** or visit clevelandclinic.org/criticalcaretransport

DrConnect *Make Your Next Report Electronic*

DrConnect is an Internet-based service developed to provide our community physician colleagues real-time electronic medical record information about the treatment their patients receive at Cleveland Clinic.

After establishing a DrConnect account with a secure log-in name and password, referring physicians may identify office personnel to receive security rights, allowing DrConnect patient updates to be immediately integrated into a busy medical practice's daily activities and workflow.

A single daily email notification containing the DrConnect Web address (URL) gives you one-click access to all newly released patient-related information, which is presented in easy-to-navigate "What's New" screens for quick access and effective case and time management.

Establishing your own DrConnect account is easy. 1) Log onto drconnect.clevelandclinic.org. 2) Click on the OnLine Signup button. 3) Simply fill out your physician participant information, including choosing a secure password, and submit.



The Cleveland Clinic Foundation
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Cleveland, OH 44195

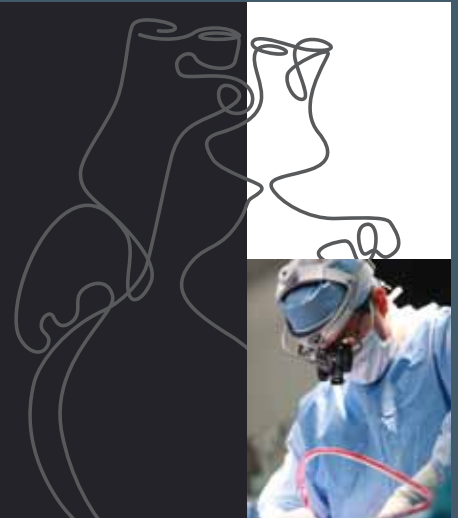
Cardiac Consult



2011 Medical Innovation Summit

State of the Heart

This year's annual event on **Oct. 3-5, 2011** will provide an unrivaled perspective on the newest cardiovascular technologies and their financial drivers. Confirmed Speakers include the CEOs Pfizer, GE, Medco, Novartis, Xerox, Boston Scientific, St. Jude Medical, Edwards Lifesciences and Maria Bartiromo. For more information, visit: clevelandclinic.org/summit.



CLEAR the date...

for **Shaping the Future of Cardiovascular Care: Science Driving Innovation**, Oct. 5-7, 2011, the major cardiovascular CME of the year. Hosted by the Cleveland Clinic Heart & Vascular Institute, this event connects you with the leading experts, the latest studies, and the science-and-technology breakthroughs that are transforming our specialties. Enhance your knowledge, strengthen your practice, meet colleagues and make friends at the crossroads of cardiovascular discovery. For more information, or to register, visit clevelandclinicmeded.com.