Rapid and correct diagnosis is critical until a donor heart becomes available.
Dear Colleagues,

In 2005, the Cleveland Clinic Heart and Vascular Institute recorded nearly a quarter million total patient visits, and 60 percent of our heart patients traveled from outside the state of Ohio to see us.

Accommodating this large volume of patients is our first priority. Last year, our center saw more than 6,000 new patients, leading us to enhance access and streamline the appointment process. Today, in most cases, new patients can be seen by a cardiologist within one week of calling for an appointment. Most patients requiring surgery also can be accommodated within one week or sooner.

Many people simply are searching for information or answers to questions. Our Resource and Information Center is staffed with cardiovascular RNs who answer hundreds of telephone calls and Web mails each month. In 2005, our Web site logged 1.5 million visitors.

Treating and preventing heart disease in women is the latest initiative industry-wide. Cleveland Clinic has a long history of promoting heart health to women, but we have formalized our program by creating a Women’s Cardiovascular Center, directed by Leslie Cho, M.D. Leading a staff of cardiologists, Dr. Cho is fully focused on improving awareness of heart disease in women and expanding current knowledge to impact heart disease treatment for women.

Finally, thank you for making the Cleveland Clinic #1 in the nation for heart care 12 years in a row. This milestone would not have been possible without your confidence and support.

Sincerely,

Christopher Bajzer, M.D.
Associate Director, Peripheral Intervention
Interventional Cardiology

A. Marc Gillinov, M.D.
Surgical Director, Center for Atrial Fibrillation
Thoracic and Cardiovascular Surgery

New Technique Offers Encouraging Results for Severe Valvular Disease

Percutaneous aortic valve replacement is being evaluated clinically at the Cleveland Clinic Heart and Vascular Institute as a treatment for elderly patients with severe aortic valve stenosis who are highly symptomatic but not surgical candidates due to multiple co-morbidities.

Cleveland Clinic is one of three centers nationwide designated by the U.S. FDA as study sites for the percutaneous technique. The Cleveland Clinic team, which includes cardiologists, cardiac surgeons, anesthesiologists, nurses and technicians, has performed nine of these procedures with no deaths or strokes.

“Percutaneous aortic valve replacement is not an alternative to surgery but is considered only for those patients without other treatment options for their valvular disease,” interventional cardiologist Dr. Tuzcu, the principal investigator explains. Patients are selected based on strict criteria that delineate their surgical risk and disease stage, including co-morbidities, age, ejection fraction and blood pressure. “The percutaneous technique may offer these patients their only chance for improved cardiac function and quality of life,” he adds.

The first percutaneous aortic valve replacement in a human in the U.S. was performed in May 2005, so long-term data on outcomes and safety are not yet available. However, short-term results have been “encouraging,” says cardiac surgeon Lars Svensson, M.D., Ph.D., and the Cleveland Clinic team believes that this technique is worth further exploration.

“The first iteration of the device and technique had significant problems, but these are increasingly being overcome. The initial valve was too small, in some patients resulting in significant leakage around it. With the newer valve, this rate of leakage has been reduced. At the same time, the opening of the valve is larger, which is also beneficial,” says Dr. Svensson. “Furthermore, we have developed a different technique of inserting the valves that is easier and safer. We expect results will continue to improve.”

The procedure, performed off-pump without any incision in the chest and in the catheterization lab with the patient under general anesthesia, requires close collaboration among the cardiac surgeon, interventional cardiologist, echocardiologist, and other teams.

The stent valve is snaked around the aortic arch over a guide wire for positioning across the native aortic valve.
“During deployment of the prosthesis, the heart is paced to 220 beats per minute to temporarily reduce cardiac output and left ventricular pressure, which minimizes the movement of the balloon, allowing for more stable and precise positioning of the valve,” explains interventional cardiologist Samir Kapadia, M.D. Total elapsed time from inflation of the balloon to restoration of normal heart rhythm is less than 20 seconds, he adds.

Following implantation, a hemodynamic assessment, angiogram and echocardiogram to assess valve function and to check for perivalvular leakage are performed. The femoral artery is repaired surgically after sheath removal.

The FDA has been reviewing data from the study carefully and recently approved extension of the protocol among the three participating institutions.

For more information, contact Dr. Murat Tuzcu at 216.444.8130 or at tuzcue@ccf.org; Dr. Lars Svensson at 216.445.4813 or at svenssl@ccf.org; Dr. Samir Kapadia at 216.444.6735 or kapadia@ccf.org; or Gale Grano, R.N., at 216.445.7837 or at granog@ccf.org.
Case Study –
Giant Cell Myocarditis

Giant cell myocarditis is an idiopathic condition that can be difficult to diagnose. It occurs mainly in young, otherwise healthy people. A recent case seen at Heart and Vascular Institute is in many ways typical, with a few notable anomalies.

The 26-year-old patient was a pediatric cardiology fellow at a hospital in southern Ohio. She’d had a two-week history of worsening fatigue, shortness of breath and mild chest pain. While on duty one evening, she experienced particularly severe shortness of breath climbing the stairs. Having recently learned how to do an echocardiogram, she performed an ultrasound on herself and saw unmistakable evidence of pericardial effusion.

She presented to a local emergency department with low blood pressure. A right heart catheterization suggested the pericardial fluid was inhibiting heart function. A small amount of bloody fluid was aspirated with a needle and analyzed. Edematous at this time, she was also experiencing fluid buildup at the base of one lung. Steroids were administered. A further echo showed impaired left-ventricular function with an ejection fraction of 35 percent to 40 percent.

Dopamine was administered and withdrawn after the patient developed ventricular tachycardia, and she was started on neosynephrine for blood pressure support. Her blood work showed elevated cardiac enzymes and troponin levels, indicating myocardial injury. Searches for infectious, autoimmune or malignant causes were not productive. Over the course of the next day, her condition deteriorated swiftly, and she developed complete heart block.

On the evening of Sept. 1, 2004, she was transferred to Cleveland Clinic by air transport.

Shortly after arrival at Cleveland Clinic, ventricular tachycardia led to a cardiac arrest and another episode of complete heart block. Based on the patient’s rapidly progressive heart failure, the cardiologist on call, Robert E. Hobbs, M.D., suspected giant cell myocarditis. He came to the Heart Failure ICU in the middle of the night and assessed the patient. Realizing that she was deteriorating rapidly and on the verge of death, he emergently phoned the surgical team to implant ventricular assist devices to take over function of the failing heart. An operating room was readied and the surgical team quickly assembled. At the door of the operating room, the patient had another episode of ventricular fibrillation and her heart stopped completely.

With the patient having gone into arrest at the threshold of surgery, there would have been little hope for survival under most circumstances. Transplant workup and listing takes several days at best. However, Cleveland Clinic surgeons were able to implant two Thoratec ventricular assist devices (VADs), which provided total biventricular support for the patient’s non-functional heart while she was activated for transplant. Because of her unstable state, she was listed as a status 1A candidate.

Soon after she was listed, the pathology report came back confirming the diagnosis of giant cell myocarditis.

A donor heart became available 11 days later. She was taken to the operating room to have the pumps explanted and a heart transplant. She was placed on oral immunosuppressive agents and treated with steroids for early rejection. Soon, her echo showed good transplanted heart function, and she was discharged after 18 days.

Because Cleveland Clinic sees such a high volume of cardiac cases, giant cell myocarditis – a disease rarely seen at most centers – was quickly recognized. Cleveland Clinic also has among the nation’s largest experience with the implantation of VADs as well as access to nearly all available models.

Rapid and correct diagnosis was critical in this case, as was the ability to quickly and successfully implant the appropriate VAD devices and successfully manage the patient until a donor heart became available. Today, the patient is in good health. Because she will be on lifelong immunosuppressive therapy, she probably will need to change her medical specialty from pediatric cardiology to one with less potential for infectious exposure.

Dr. Robert Hobbs can be contacted at 216.444.6936 or at hobbsr@ccf.org.
Cleveland Clinic is among the first U.S. medical centers to use fetal transcatheter intervention to correct certain structural heart defects prior to birth. Improved interventional expertise and minimally invasive approaches, a better understanding of the natural history of these lesions, and superior ultrasound resolution have made fetal intervention possible.

Intervention is considered only in select cases, for instance when there is evidence of aortic valve stenosis, which can lead to left ventricular failure and hypoplastic left heart syndrome.

The potential advantages of in utero valvuloplasty are clear. “These defects have a very poor prognosis without treatment, and the risk of fetal demise or decompensation after birth is very high,” says Larry Latson, M.D., Director of the Pediatric Cardiac Catheterization Lab, Department of Cardiovascular Medicine. “We hope that an intervention to improve blood flow in the fetus can fundamentally alter the heart’s development.” Options for the neonate born with hypoplastic left heart syndrome are surgical palliation, comfort care or transplant.

Dr. Latson, along with Elliot Philipson, M.D., an expert in maternal and fetal medicine, and Rich Lorber, M.D., pediatric cardiac imaging specialists, performs the procedures at Cleveland Clinic’s main campus. Before attempting the operation in humans, the team perfected its techniques using a fetal lamb model. Dr. Latson, who tests various devices used to repair congenital heart defects in children, worked with a manufacturer to modify needles, catheters and balloons for fetal use.

Fetal cardiac interventions are most often performed between 20 and 30 weeks’ gestation, after the team counsels the patient extensively regarding maternal and fetal risks as well as expectations.

The team is assisted by an obstetrical anesthesiologist, obstetrical nurses and surgical assistants. Staff from both neonatal and pediatric intensive care units stand by during procedures in the event complications arise.

After epidural anesthesia is administered to the mother, the obstetrician attempts to manipulate the fetus into position for percutaneous transabdominal uterine puncture. This is extremely well-tolerated and allows the mother to remain a candidate for vaginal delivery. If successful, an intramuscular anesthetic is administered to the fetus and an extra-abdominal ultrasound is performed.

If manipulation proves impossible, general anesthesia is administered and a midline vertical incision is made to the level of the uterus. The pediatric imaging specialist then places draped ultrasound probes directly onto the uterus, which provide exquisite views with dramatic resolution.

Guided by ultrasound, the obstetrician massages the fetus into position to pass a 19-gauge needle through the uterine wall. The needle is advanced into the amniotic sac, through the fetal chest wall and into the left ventricle.

At this point, Dr. Latson inserts a guidewire through the needle to the aortic valve, which measures about 3 mm. He advances a balloon over the wire and inflates it several times to dilate the valve. All instruments are then withdrawn, and blood velocity and flow are compared to baseline values.

The uterus offers a perfect environment for recovery in terms of temperature, fluid volume, electrolytes and glucose. The patient is discharged on the same day of percutaneous in utero balloon valvuloplasty, or after a few days following an open procedure.

“Growing experience indicates that for very high-risk fetuses, the procedure may offer hope for a better outcome,” says Dr. Latson.

In the event of a suspected cardiac abnormality or when a four-chamber maternal ultrasound suggests a cardiac abnormality, immediate referral to a maternal-fetal medicine specialist, fetal cardiologist or fetal ultrasonographer is advised.

For more information or to refer a patient, contact Dr. Larry Latson at 216.445.6532 or latsonl@ccf.org; Dr. Elliot Philipson at 440.312.7774 or philipe@ccf.org; or Dr. Richard Lorber at 216.444.5182 or lorberr@ccf.org.

“In Utero Balloon Valvuloplasty Can Relieve Fetal Aortic Stenosis

“We hope that an intervention to improve blood flow in the fetus can fundamentally alter the heart’s development.”
PAD is caused by plaque blockages of the arteries that deliver blood flow to the arms and legs. It is estimated that up to 12 million Americans have PAD, but less than half know it. What’s more, published research shows that one in five people older than 70 have PAD.

**Higher Heart Attack/Stroke Risk**

“Patients with PAD are three to six times more likely to have a heart attack or stroke than patients without PAD,” says Heather Gornik, M.D., Cleveland Clinic cardiovascular medicine specialist with expertise in diagnosing and managing vascular disorders. “More than 60 percent of PAD patients will have significant blockages in coronary arteries.”

Because of this, the American Heart Association, the American College of Cardiology and the American Diabetes Association have recommended new screening guidelines for patients at high risk for PAD, which includes everyone above the age of 70, and patients above the age of 50 who are diabetic or who have ever smoked. Other risk factors are hypertension and high cholesterol.

**Diagnosis**

Only 11 percent of PAD patients have classic symptoms of leg pain or intermittent claudication, such as the sensation of aching, burning, heaviness or tightness in the muscles of the legs that usually begins after walking a certain distance, walking up a hill or stairs. The pain, which is commonly felt in the buttocks, thighs or calves, usually abates after a few minutes of rest. Although physicians may suspect a patient has PAD after a thorough physical exam and medical history review, an ankle/brachial index (ABI) is a highly accurate method for PAD detection. Blood pressure cuffs are placed around the arm and leg and inflated. A hand-held device (called a Doppler) is used to listen to the blood flow in the leg and arm. This helps evaluate the blood flow to the legs and feet.

**From Modifying Risk Factors to Revascularization**

Because PAD patients are at very high risk for heart attack or stroke, Dr. Gornik recommends that primary care physicians aggressively modify the cardiac risk factors, including smoking cessation, prescribing antiplatelet therapy and cholesterol-lowering medications, and controlling the patient’s blood sugar and blood pressure. PAD patients also should consider enrolling in a supervised exercise program designed specifically for PAD patients, such as the program that is offered by Cleveland Clinic.

When these treatments do not relieve the symptoms, or if the symptoms become worse, physicians have the option of referring patients to a vascular specialist for revascularization, which improves the blood flow in the limb where the artery is blocked with plaque. Imaging tests are conducted to determine the exact location of the blockage and to help physicians decide the best approach for revascularization.

**First Line of Treatment**

Balloon angioplasty and stenting have generally replaced invasive surgery as the first line of treatment for PAD because of lower risks and quicker patient recovery, says Chris Bajzer, M.D., a cardiologist who specializes in coronary intervention and peripheral vascular intervention. In fact, angioplasty and stenting were used to treat PAD before they were used for coronary disease.

For blockages that cannot be opened via angioplasty, the vascular specialist may recommend open surgery. During the surgery, blocked arteries are bypassed with segments of a surface vein from the leg, or from synthetic grafts.

For more information or to refer a patient, call Dr. Heather Gornik at 216.445.3689 or gornikh@ccf.org, or Dr. Chris Bajzer at 216.445.3210 or bajzerc@ccf.org.
Erectile Dysfunction May Signify Vascular Disease

When was the last time you asked your patients about sex?

Are you sexually active? If so, do you have any problems in this area? These may seem all too personal — even awkward — questions to ask your male patients. But Drogo Montague, M.D., section head of Prosthetic Surgery and Genitourthral Reconstruction at Cleveland Clinic’s Urological Institute, says it has been his experience that primary care physicians don’t ask their male patients these questions, and they should.

Erectile dysfunction (ED) is a common problem among middle-aged men. It’s estimated that 10 million to 20 million men have ED. According to the Massachusetts Male Aging study, 52 percent of men between the ages of 40 and 70 have mild, moderate or severe ED. Even more important, however, is that ED is usually caused by an underlying health issue such as vascular disease, diabetes or drug use.

“Physicians don’t have to ask a detailed sexual history of their patients, but they ought to open the door so that patients can feel free to discuss it,” says Dr. Montague. “After all, it’s a body function like any other.”

ED may be a gradual occurrence in a man’s life after well-established, normal sexual function. Generally, if a man has a problem getting and maintaining an erection 25 percent of the time, then it is considered a problem.

Underlying Causes

Physicians need to determine if a patient’s ED is being triggered by an underlying disease. They should check the patient’s lipids, blood pressure and perhaps do a stress test. A patient’s blood sugar also needs to be tested. The probability of diabetics getting ED at an earlier age is at least 50 percent higher than patients without diabetes.

A patient also should be asked about history of drug and alcohol use. In fact, drug use — including prescription medication and recreational drugs — accounts for 25 percent of ED cases, says Chris Bajzer, M.D., a cardiologist who specializes in coronary and peripheral vascular disease intervention. In addition to vascular disease, physicians also should check for hormonal or neurological problems.

“I think the biggest take-home message is that ED is a prevalent problem and shares a lot of risk factors that we as cardiologists see in terms of contributing to coronary disease or vascular disease,” Dr. Bajzer says.

When Heart Disease is Suspected

While it’s appropriate to prescribe medications such sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) for mild to moderate erection problems, physicians should not prescribe those medications if they suspect the patient has coronary disease.

Even though these medications are effective and popular, they are not panaceas and they do have side effects. The ED drugs also must not be taken by men who are on nitroglycerin for a heart condition as these combined drugs can significantly lower blood pressure and can cause death.

Dr. Bajzer recommends that doctors should first address and manage the cardiac risk factors, and then treat the ED issues through medications, or refer the patient to a urologist.

If the medications don’t work, there are other options available. For example, testosterone may be prescribed by either injection or skin patch, particularly if the ED problem is age-related. Also, alprostadil, which is injected at the penis or inserted as pellets, improves blood flow to the penis. For some patients, a vacuum pump or penile prosthesis (implant) also may be recommended.

Contact Dr. Drogo Montague at 216.444.5590 or montagd@ccf.org, or Dr. Chris Bajzer at 216.445.3210 or bajzer@ccf.org.

Cleveland Clinic Surgeon to Lead National Society

Bruce W. Lytle, M.D., Chairman of the Department of Thoracic and Cardiovascular Surgery, was named the new President of the American Association for Thoracic Surgery, the nation’s prestigious academic society for thoracic surgeons. Founded in 1917 by the earliest pioneers in the field of thoracic surgery, the AATS is now an international organization of almost 1,200 members representing 35 countries. Dr. Lytle will serve as president until May 2007.

New Director of Cardiovascular Coordinating Center Named

Michael Lincoff, M.D., has been appointed Director of the Cleveland Clinic Cardiovascular Coordinating Center (C5), the mission of which is to conduct pivotal research that changes the practice of medicine. He has been involved as a principal investigator for many of the trials run by C5 over the last 10 years. Working with Dr. Lincoff are Associate Directors Deepak Bhatt, M.D., Patrick Whitlow, M.D., and Wilson Tang, M.D., all of whom are respected clinical trialists. Dr. Bhatt will focus on studies involving pharmacological therapies, Dr. Whitlow on cardiovascular device trials, and Dr. Tang on studies related to heart failure and transplantation.

Cleveland Clinic Physician Wins ACC Research Award

Heather Gornik, M.D., Cardiovascular Medicine, has been awarded the 2006 American College of Cardiology Foundation/William F. Keating, Esq., Endowment Fund Award for Hypertension and Peripheral Vascular Disease. The research award was announced at the convocation ceremony during the 55th Annual Scientific Session of the ACC. Dr. Gornik was honored for Effects of Catheter-Based Revascularization on Functional Capacity, Quality of Life, and the Cardiovascular Risk Factor Profile of Patients with Intermittent Claudication. The award is designed to foster the early research career development of junior cardiovascular faculty in the research area of hypertension and peripheral vascular disease.
Although congenital heart disease (CHD) in the adult is fairly common (estimates show ~1 million patients by 2010), recognizing and treating it remains challenging.

Two groups require special consideration, says Richard Krasuski, M.D., director of Cleveland Clinic’s Adult Congenital Heart Disease Service. In the first, CHD was diagnosed in pediatric patients who underwent surgical repair but now have problems as adults. The second group consists of adult patients just now getting the diagnosis.

“Increasingly, people born with heart defects are surviving into adulthood because of advanced treatment they received as children,” he says. But later issues that may arise, including rhythm disturbances, heart failure and fatigue, affect quality of life and can be life-threatening.

“Patients write it off as getting older, but it’s not necessarily true,” stresses Dr. Krasuski. “Adults who thought they were cured in childhood don’t visit their doctor regularly, and that’s when problems start.”

Only a handful of physicians are trained specifically in this field, he says, and many times the adult cardiologist is not well-versed in congenital heart issues.

Cleveland Clinic’s Congenital Clinic consists of interventional cardiologists working closely with electrophysiologists to diagnose and treat all types of CHD. Expert resources include congenital heart imaging and a solid surgical program that can handle both pediatric and adult patients. Pulmonary hypertension specialists are available as well.

Physicians work with Cleveland Clinic’s active heart and heart/lung transplant program for particularly complex cases.

For more information or to refer a patient, call Dr. Richard Krasuski at 216.445.7430.

Cleveland Clinic Ranked #3 in Nation

Heart ranked #1

Cleveland Clinic has been ranked among the top three hospitals in the country, according to the latest U.S. News & World Report’s annual survey of “America’s Best Hospitals.” For the 12th consecutive year, Cleveland Clinic’s heart program has been ranked No. 1 in the nation. The report, which rates hospitals in 16 specialties, ranks Cleveland Clinic among the nation’s best in all, and 11 Cleveland Clinic specialties are ranked among the nation’s Top 10. For details, visit clevelandclinic.org.