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Robert Chait, M.D., F.A.C.C.

A Commitment to Quality

As the Palm Beach County population ages, more treatment is required for conditions such as congestive heart failure and atrial fibrillation, as well as preventive medicine. At The Heart and Vascular Institute at JFK Medical Center, our goal is to offer the latest procedures and treatments to ensure the community receives the best treatment provided by the best physicians.

In This Issue

Experienced in Cardiovascular Surgery

According to *U.S.News & World Report*'s recent rankings of the top hospitals in the country, one of the best methods of choosing a hospital and surgeon is by focusing on the volume of surgeries performed. The study found a strong link between volume and quality, citing a coronary bypass surgery study showing the mortality risk at hospitals that performed at least 600 bypasses a year (or at least 125 bypasses a year for each physician) was 29 percent lower than at hospitals with fewer procedures.

Physicians at The Heart and Vascular Institute put this theory into practice every day and perform a high volume of procedures, allowing them to develop an efficient team with precisely honed skills. In fact, JFK Medical Center's survival rate is the best in South Florida for this procedure—more than 99 percent, according to the Florida Agency for Health Care Administration.

Leading the Way

The Electrophysiology Lab at JFK Medical Center continues to lead the way in treating both atrial fibrillation and potentially fatal arrhythmias. These conditions are chief contributors to the heart disease epidemic, and physicians are improving the quality of life for these heart patients each day.

JFK Medical Center is home to a very busy, active catheterization lab, which aggressively treats coronary and peripheral artery blockages using the latest techniques. Furthermore, many national clinical trials are being conducted by the catheterization lab, the EP lab and the general cardiologists. By researching investigational drugs and procedures, the medical center can offer patients opportunities generally available only at university hospitals.

Our physicians not only learn these new techniques, they also teach them to others. Many of our cardiologists are on the faculty of the University of Miami School of Medicine at Florida Atlantic University. By teaching medical students, JFK physicians help give back to the community while at the same time providing high-quality, state-of-the-art care. Besides helping patients, this promotes the hospital's reputation as a leader in cardiovascular care across Palm Beach County and the region.

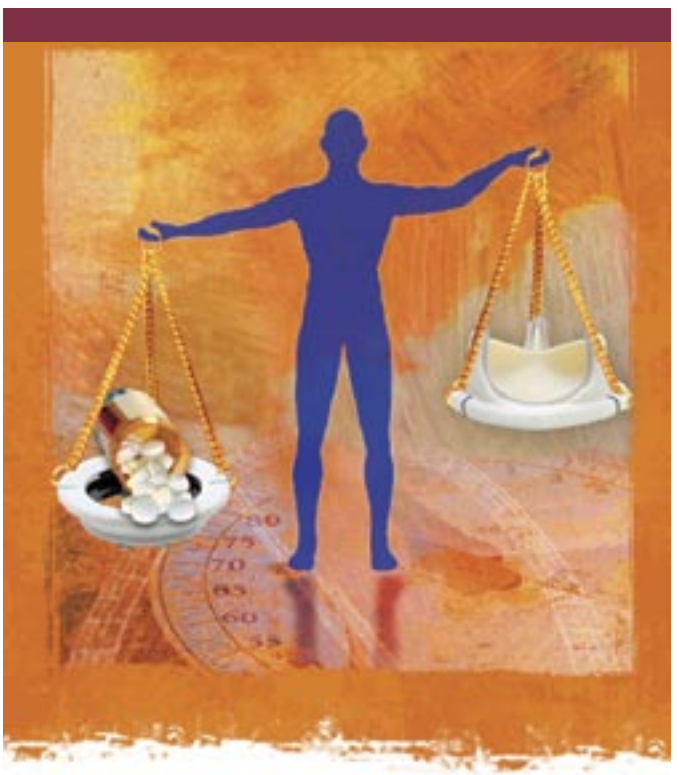
For more information about The Heart and Vascular Institute, call (800) 848-9809.

Robert Chait, M.D., F.A.C.C.

Robert Chait, M.D., F.A.C.C., Medical Director of Cardiovascular Services, is an attending cardiologist on staff at JFK Medical Center and is a clinical assistant professor of biomedical science at Schmidt School of Medicine at Florida Atlantic University in Boca Raton, Florida.

New Guidelines for Managing Patients with Heart Valve Disease

Valvular heart disease is one of several cardiac disorders that affect a large number of people who require diagnostic procedures, surgical intervention and long-term management. The American College of Cardiology (ACC) and the American Heart Association (AHA) have announced an updated version of their recommendations for the management of patients with valvular heart disease. The revisions were co-published in the August 1, 2006, issue of *The Journal of American College Cardiology* as well as in a recent issue of *Circulation*. The executive summary of the guidelines is also available online at www.acc.org and www.americanheart.org. This is the first comprehensive update to the practice guidelines since 1998.



Weighing the risks and benefits of tissue and mechanical heart valves

Tissue Valves Versus Mechanical Valves

Under the new guidelines, more emphasis is put on patient preference rather than strict age requirements for the choice of a tissue valve over a mechanical valve. The major advantage of a bioprosthesis over a mechanical prosthesis is the lack of need for antithrombotic therapy. The final decision regarding a mechanical valve versus a bioprosthesis is based on multiple factors, including patient age, overall longevity of the valve, relative contraindications to anticoagulation and lifestyle. Bovine pericardial valves appear to have a lower rate of structural valve deterioration than first generation porcine heterographs, with 15-year data indicating that 77 percent of valves in surviving patients of all ages are functioning without explantation. In addition, among patients undergoing primary aortic valve replacement (AVR) at an age greater than 65 years, fewer than 10 percent underwent valve explantation after 15 postoperative years.

Additionally, the recommended age for a tissue valve replacement in the mitral positon has been lowered from 70 to 65 years of age. Previous guidelines also recommended mechanical valves for patients in renal failure. The latest guidelines conclude that there is no significant difference in outcomes between mechanical and tissue valves in patients with end-stage renal disease. The guidelines also acknowledge difficulties in maintaining anticoagulation in these patients, a consideration that favors tissue valves.

These modifications reflect continuous improvements in tissue valve performance and cardiac surgery outcomes in general, as well as the consideration of patient lifestyle decisions. Fundamentally, the new guidelines open up the use of tissue valves to patients of all ages, assuming careful discussion of benefits with their doctors.

The new guidelines acknowledge the advancements in tissue valve design technology, especially the long-term hemodynamic benefits of stented pericardial tissue valves in the aortic position. Specifically, the new guidelines recognize the superior hemodynamic performance of stented pericardial valves compared to porcine valves for aortic valve replacement. JFK was one of the first hospitals to implant the CE Magna aortic valve, which is the latest generation of the Perimount pericardial bioprosthesis. It is now the most widely implanted tissue valve in the world because of its superior hemodynamics and durability.

New Recommendations for Aortic Stenosis

Each year, more than 300,000 people worldwide undergo open-heart surgery to treat their malfunctioning or diseased heart valves. These are primarily patients who exhibit clear symptoms of valve disease. However, the new ACC/AHA guidelines suggest more aggressive treatment of certain patients with asymptomatic aortic stenosis (AS). While AVR is indicated for symptomatic patients with severe AS, AVR is reasonable for patients with moderate AS undergoing coronary artery bypass graft (CABG) or surgery on the aorta or other heart valves. AVR may be considered for asymptomatic patients with severe or moderate AS and abnormal response to exercise or if there is a high likelihood of rapid progression because of age, calcification and coronary artery disease.

Early Intervention for Mitral Valve Regurgitation

For mitral valve regurgitation (MR), MV repair is recommended over MV replacement in the majority of patients with severe chronic MR. The guidelines recommend that patients should be referred to surgical centers experienced in MV repair. Controversy also surrounds the timing of surgery in the asymptomatic patient with severe MR and normal left ventricular (LV) function. The guidelines suggest that if MV repair can be performed with a high degree of success and the operative risk is low, it is reasonable to proceed with surgery to prevent irreversible LV dysfunction. However, the guidelines clearly state that this "early" operation should only be performed at centers with a high likelihood of successful MV repair because of demonstrated expertise in this area.

At JFK, I have successfully repaired a high percentage of mitral valves by utilizing an etiology-based mitral valve repair strategy. Our experience in valvular heart disease sets us apart from other community programs that focus primarily on coronary disease.

Aortic Magna Pericardial Bioprosthesis with ThermaFix anticalcification treatment

Malcolm Dorman, M.D.

Malcolm Dorman, M.D., is a world-renowned cardiovascular surgeon who was recruited to JFK Medical Center to become Medical Director of Cardiac Surgery. He was previously at Miami Heart Institute for 25 years where he served as Chair of Cardiothoracic Surgery and Co-Chair of the Department of Cardiovascular Medicine. In 1972 he was one of two residents selected to train with the renowned heart surgeon Michael Debakey, M.D., in Houston, Texas. In 1975 he was associated with Frank Spencer, M.D., and George Reed, M.D., as clinical research scientist at NYU Medical Center. Dr. Dorman is recognized for his research and clinical work in repairing mitral valves.

He is also recognized for using all arterial conduits in bypass surgery and has demonstrated their excellent long-term results. Dr. Dorman was honored by his medical school, receiving his distinguished alumnus award in 1997. In patients who are thought to be nonsurgical candidates, he is currently involved in the angiogenesis phase one clinical trial, which uses the human growth factor to generate new blood vessels. His last two years at JFK placed him under 1 percent mortality rate for coronary surgery and 0 percent for straight aortic and mitral valve surgery, whether repair or replacement.

Electroanatomic Substrate Mapping:
The Answer to Multiple ICD Shocks for Many Ischemic Cardiomyopathy Patients

The electrophysiologists at JFK Medical Center specialize in complex catheter ablations of both supraventricular and ventricular arrhythmias and are the Florida leaders in ablations for both ventricular tachycardia and atrial arrhythmias.

A Complex Condition

Ventricular tachycardia (VT) generally results from re-entry in the border zone (the area between the scar and the normal myocardium) of a region of scar in the ventricle. The scar itself is dead myocardium and thus is unable to generate arrhythmias, while the surrounding tissue is normal myocardium and also is not prone to generating arrhythmias.

However, the border zone consists of a complex architecture where strands of damaged but living myocardium intertwine with dead scar and healthy living tissue. This border zone region has the potential to support re-entry, which ultimately is the basis for the majority of both supraventricular and ventricular tachycardias. It is this border zone that is resected when a ventricular aneurysm is removed, explaining the high cure rate for arrhythmias following aneurysm resection.

In the recent past, EPS testing was often performed on patients with VT, but only relatively slow (usually under 160 BPM) induced VTs could be ablated. This limitation was the result of the past necessity to map the foci during tachycardia in order to ablate ventricular tachycardia foci. If the arrhythmia was too fast, the consequent hemodynamic collapse following its induction did not allow for safe mapping.

The Substrate Mapping Solution

These limitations have now been overcome with a technique termed electroanatomical substrate mapping. JFK has the most advanced cardiac mapping systems currently available.

In substrate mapping, a 3D mapping catheter is used to create a three-dimensional map of the patient's ventricle. Similar to the way GPS technology can locate a car, this catheter uses an external magnetic field to allow a computer to localize the catheter in a 3D space in the heart. The catheter is moved inside the left ventricle and touched to the walls of the heart. The mapping computer then re-creates an accurate 3D image of the patient's heart for the doctor to view.

The mapping computer also can measure endocardial voltages at all points on the map. Dead myocardium produces no voltage, while living myocardium produces voltages generally greater than 5mv. Scar border zone tissue produces voltage greater then zero but less then 5mv. A 3D voltage map of the ventricle can thus be created and the 3D location of the scar and its border zone delineated.

Following construction of this map, the electrophysiologist will selectively destroy tissue in this arrhythmogenic border

Robert Fishel, M.D., F.A.C.C.

Robert Fishel, M.D., F.A.C.C., is the Medical Director of the electrophysiology laboratory at JFK Medical Center and is a heart rhythm specialist. His group, Florida Electrophysiology Associates, is the largest group of heart rhythm specialists in the southeastern United States. He also is associate professor of medicine at The University of Miami and Florida Atlantic University Medical School.

Dr. Fishel and his group have performed some of the original clinical investigations on most of the currently approved devices used to treat heart rhythm problems, including research that led to the approval of implantable defibrillators, dual chamber defibrillators, biventricular pacemakers and biventricular defibrillators. They continue to be active clinical researchers and are at any given time participants in multiple studies on new implantable devices, drugs, catheter-based therapies and other treatments for the control of abnormal heart rhythms.

Dr. Fishel's major current interest is complex catheter ablations, including curative catheter ablations of atrial fibrillation.

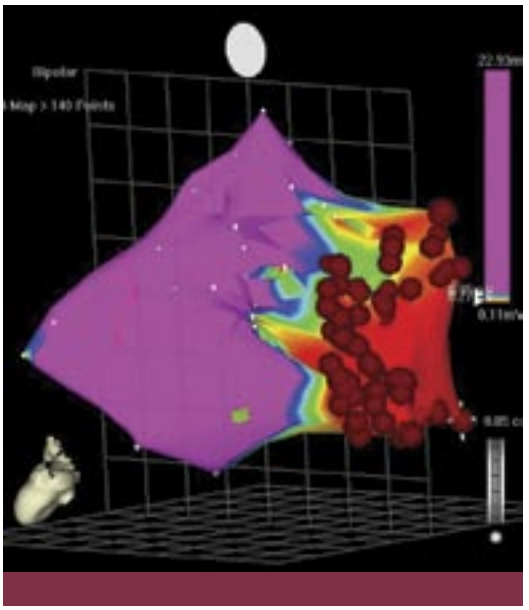


Figure 1: A 3D electroanatomical voltage map of the patient's left ventricle. The region in red represents dead myocardium with minimal or no voltages seen on mapping. The regions in purple represent healthy myocardium with normal voltages. The dark red dots are regions where ablations were delivered to the patient's endocardium. Note that ablations were delivered around the border zone of the old infarct, thus destroying regions of potential re-entry for ventricular tachycardia.

zone using radiofrequency energy delivered through the tip of an ablation catheter. With 3D mapping, the electrophysiologist can now track where he or she has ablated and what areas still need ablation.

JFK Medical Center currently utilizes a new generation of cardiac ablation catheters with microscopic holes drilled into the tip of the catheter. Cool saline is pumped through these holes during the procedure. This type of irrigated catheter technology prevents thrombus formation on the tip of the catheter during ablation delivery and, by cooling the surface of the catheter, delivers more current to the heart without the boiling of blood. This technology allows relatively deep ablation lesions to be created, penetrating up to a centimeter into the myocardium.

Hope for More Patients

Substrate mapping for ventricular tachycardia has multiple advantages over older techniques for ablation of VT. Since VT does not need to be induced to destroy the regions causing the arrhythmia, even previously "unablatable" forms of VT can now be treated. The potential risks of complications to the patient are also reduced.

Finally, because an entire zone of arrhythmogenic myocardium is targeted here, this technique has the potential to cure multiple VT circuits—both the current tachycardia and potential sites for future problems.

The clinical results of substrate mapping prove its theoretical potential with approximately 80 percent of patients treated with this technique either completely cured of their recurrent ICD shocks or substantially improved (e.g. to the level where one shock might occur yearly instead of weekly).

Case Study: Substrate-Mapped Ventricular Tachycardia Ablation

Problem: A 53-year-old patient from Orlando underwent implantation of a Medtronic defibrillator in 2003 following previous cardiac procedures. The patient had suffered a large anterior wall myocardial infarction two years before, and, subsequently, coronary bypass surgery was performed. Post-operatively, the patient was found to have a resting ejection fraction of 31 percent with multiple regions of akinesis on echocardiography. EPS testing revealed inducible monomorphic ventricular tachycardia, and an ICD was electively implanted in late 2001.

Then, in February 2006, during a family outing, he felt momentarily lightheaded, followed by a defibrillator shock. Interrogation of the ICD later that day revealed an appropriate shock for fast ventricular tachycardia at a rate of 280 beats per minute. A cardiac catheterization was performed but, as is most commonly the case in these situations, showed adequate revascularization with an anterior wall scar and an ejection fraction of 34 percent.

Attempted Solution: The patient was placed on amiodarone to help prevent further ICD shocks. Although chronic nausea and ataxia resulted from this medication, no further ICD shocks occurred for the first six weeks of use. Then in April, the patient was awakened from sleep with four defibrillator shocks in a row. He was admitted to a local hospital in Orlando and placed on lidocaine and IV amiodarone.

Over the next 12 days, he received 42 ICD shocks for fast ventricular tachycardia despite medications. Anti-tachycardia pacing in the ICD was turned on; however, this only accelerated each ventricular tachycardia episode to ventricular fibrillation. A resection of the anterior scar and its border zone was considered as an option, because the success rate for this type of surgery in curing VT is generally around 90 percent. However, the quoted potential mortality of 50 percent did not appeal to the patient.

How JFK Helped: The patient was transferred to JFK Medical Center's electrophysiology group. Once at JFK, his doses of IV amiodarone were stopped, and he underwent an electrophysiology study with 3D cardiac "substrate mapping" the next day.

Outcome: A substrate-mapped VT ablation was performed on him the day after admission. The following day, he was discharged from JFK with the amiodarone discontinued. He has remained arrhythmia-free since discharge.

James Jaffe, M.D.
Jack Zeltzer, M.D.

The Future of Vascular Surgery

For the past decade, the trend in most medical specialties has been toward more minimally invasive interventional procedures and away from the open, traditional procedures of today's vascular surgeons. So where does this leave the vascular surgeons at JFK Medical Center? They've chosen to evolve.

Many of the vascular procedures that used to be the norm—such as those that treat carotid artery disease and abdominal aortic aneurysms—have now become the mainstay of interventionalists. As a result, the field of vascular surgery has adapted, with current surgeons and fellowship programs expanding the training horizons to include more work with catheter-based interventions as well as more intense training in endovascular procedures.

"The field of vascular surgery won't become obsolete, because someone always has to be able to step in with surgery when complications arise," says Jack Zeltzer, M.D., vascular surgeon and Chair of the Department of Surgery at JFK. "There has definitely been a shift in responsibilities and, as a result, vascular surgeons are learning the techniques to become interventionalists as well."

Joining Forces

Interventional cardiologists and interventional radiologists have joined forces at JFK to develop The Heart and Vascular Institute to provide multi-specialty care to vascular patients.

"There's an old adage that says if all you have is a hammer, everything looks like a nail," Dr. Zeltzer says. "If you have an entire toolbox, you begin looking at different ways of using your tools. That's what we're doing at JFK, and the patients will benefit."

Patients in The Heart and Vascular Institute's clinic have access to consultations from both traditional surgeons and interventionalists, which means patients' treatments will be performed after consideration by a team of physicians.

"We're unique at JFK because we have a cooperative and collegial environment among the specialties," says James Jaffe, M.D., neurointerventional radiologist on staff at JFK. "Vascular surgeons and interventionalists work hand-in-hand every day while determining which type of procedure will provide the most benefit to the patient."

Evolving for the Future

As technology advances, vascular surgeons will use more catheters and intraluminal devices to repair occlusions, while continuing to provide procedures for difficult aneurysms, carotid arteries and femoroporliteal bypass surgery, either expanding their horizons to include more interventional work or referring those patients to interventionalists.

"We recognize that we're going to have to be skilled with technology, and fellowship programs are addressing those needs," Dr. Zeltzer says. "As vascular surgery evolves, the nature of our procedures will be more difficult."

For more information about vascular disease treatment at JFK Medical Center, contact Dr. Jaffe at (561) 548-3727 or Dr. Zeltzer at (561) 964-2211.

James Jaffe, M.D.

After graduating from Temple University magna cum laude, James Jaffe, M.D., neurointerventional radiologist on staff at JFK Medical Center, remained at the school to receive his medical degree before completing his residency in diagnostic radiology and a fellowship in angiography/interventional radiology at Temple University as well. In 2003, Dr. Jaffe completed an additional fellowship in neuroradiology at the University of Pennsylvania Health System.

Dr. Jaffe, who is certified by the American Board of Radiology in diagnostic radiology with added qualifications in vascular and interventional radiology, was a participant in both the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) and Maverick studies. He currently serves as a proctor for Acculink, the only FDA-approved carotid artery stent placement tool.

Jack Zeltzer, M.D.

Jack Zeltzer, M.D., a vascular surgeon on staff at JFK Medical Center, is currently the Chair of the Department of Surgery at JFK. Dr. Zeltzer is a member of the Florida Vascular Society as well as the President of the South Florida Society for Vascular Surgery.

Modern Approaches for Treatment of Peripheral Arterial Disease

Patients with peripheral arterial disease (PAD) have a relative five-year mortality rate higher than those diagnosed with breast or prostate cancer. Therefore it is important to initiate preventive measures, identify PAD in at-risk patients and treat existing problems.

"PAD is a common problem and exists in patients seen by all types of physicians and healthcare providers every day," says George K. Daniel, M.D., F.A.C.C., F.S.C.A.I., board-certified vascular specialist and interventional cardiologist, and Director of endovascular interventions at the cardiovascular laboratory at JFK Medical Center. "Patients with intermittent claudication are physically impaired and suffer from a poor quality of life similar to that of patients with congestive heart failure and emphysema."

Risk factors for PAD include smoking, diabetes, hypertension, hypercholesterolemia and older age. Twenty percent of men over 70 years of age have evidence of PAD regardless of other risk factors.

Lower extremity PAD is easily detected by an office-based evaluation that includes a medical history and physical examination as well as an ankle-brachial index evaluation. Other noninvasive imaging modalities may help better define the extent of the disease and treatment planning. These include ultrasound Duplex scanning, CT and MR angiography. Invasive angiography is usually performed prior to revascularization procedures.

Current Treatment Options

Effective treatment of PAD starts with prevention and risk factor modification. As in many vascular territories, endovascular therapy has seen many advances in technology and operator experience. Standard angioplasty balloons are more deliverable and require smaller sheath size for access.

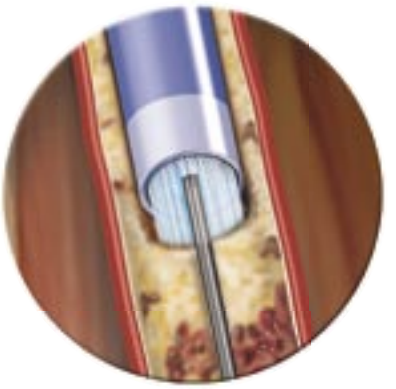


Figure 1: Spectranetics' laser ablation catheter for peripheral intervention shown vaporizing a blockage in a leg artery.

Stents used in peripheral arteries have also been revolutionized. They are currently made of nitinol, an alloy that has characteristics rendering the stent structure more flexible and resistant to compression and kinking. More importantly, a self-expanding nitinol stent has thermal memory, so the stent is always trying to reach its nominal diameter once exposed to body temperature, a feature that helps maintain vessel expansion and resists late lumen loss. All these features allow for more applications for stents with better results in the lower extremity.

A recent study published this year in *The New England Journal of Medicine* compared balloon angioplasty versus

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George K. Daniel, M.D., F.A.C.C., F.S.C.A.I.

George K. Daniel, M.D., F.A.C.C., F.S.C.A.I., is Director of Endovascular Interventions at the Cardiovascular Laboratory at JFK Medical Center. He completed his cardiology and interventional cardiology fellowship training at Indiana University, Krannert Institute of Cardiology, where he was elected chief cardiology fellow. He then became the first fellow in vascular medicine and interventions at the Washington Hospital Center in Washington, DC.

Dr. Daniel is board certified in vascular medicine, endovascular medicine, interventional cardiology, cardiology and internal medicine. As a leader in the field of vascular and endovascular medicine, Dr. Daniel has been a principal investigator in multiple national multi-center studies to evaluate new devices, stents, drugs and gene therapies.

Dr. Daniel's areas of interest and expertise include the treatment of claudication and limb salvage techniques, stroke prevention, aortic aneurysm repair and percutaneous cardiac/coronary angiography and other interventions.

primary implantation of nitinol stents in the superficial femoral artery. The study showed superior one-year patency result in the stent arm.

Recent Advances in Minimally Invasive Techniques

New technology focuses on restenosis, small vessel disease (tibial vessels), and thromboembolic disease. Also, treatment of long-term total occlusions is being addressed using new devices.

Cryoplasty is similar to a percutaneous transluminal angioplasty, except that the balloon is filled with liquid nitrous oxide, which expands into gas when it comes in contact with blood and the heat of the vessel walls, simultaneously freezing the vessel walls at a temperature of minus 10 degrees Celsius and expanding the balloon.

The freezing of the tissue kills about half of the smooth muscle cells of the vessel, which helps to prevent later myointimal hyperplasia. Cell death is by apoptosis, thus lowering inflammation. Interim results of the Below-the-Knee CHILL study evaluating cryoplasty in patients with critical limb ischemia showed a 94 percent amputation-free survival rate six months after the procedure.

An excimer laser, a "cool" ultraviolet light with a wavelength of 308 nanometers, is delivered in short, controlled energy pulses by fiber optic delivery catheters and dissolves arterial plaque without harming healthy tissue. Excimer laser ablation vaporizes the obstruction in a safe and simple fashion (see figure on page 7).

An excimer laser is capable of ablating or vaporizing plaque, thrombus and calcium into tiny particles that are easily absorbed into the bloodstream. This energy is transmitted along flexible glass fibers encased in catheters, which can be passed through arteries. The UV light energy is then focused on the diseased areas that need to be treated.

The Laser Angioplasty for Critical Limb Ischemia (LACI) trial was a prospective multi-center phase 2 trial using excimer laser-assisted angioplasty for treatment of patients with critical limb ischemia (rest pain, ischemic leg ulcers, gangrene) who are considered poor surgical candidates. The primary end-point was limb salvage at six months. Patients enrolled with critical limb ischemia had limb salvage of 93 percent at six months. This is considered a remarkable result. The excimer laser technology using ClearPath catheters was FDA approved based on the results of the LACI trial.

Atherectomy (plaque excision) is also a minimally invasive catheter-based procedure. The SilverHawk™ Plaque Excision System uses a rotating blade to shave plaque from inside the artery. As it is excised, the plaque collects in the tip of the device and then is removed from the patient. Various reports support the safety of the device, and operators with variable levels of experience are using it.

Many other new devices are now available to help treat long segments with total occlusion, traditionally a difficult and challenging problem. These devices include those with blunt dissection blades, re-entry catheters to assist return of guide wire into the true lumen in case of subintimal dissection, as well as the excimer laser.

Future Treatment Modalities

Many ongoing research trials are evaluating new and revolutionary treatment options for PAD.

Gene therapy for angiogenesis for treatment of PAD is being evaluated by multiple studies using different agents. JFK Medical Center is currently a site for two national multi-center trials for gene therapy for patients with claudication and patients with critical limb ischemia. The treatment is administered via intramuscular injections, and patients are followed for at least one year.

Drug-eluting stents for femoral artery interventions are also being evaluated using similar drugs to those used in the coronary stents.

Small stents for use in infrapopliteal vessels are currently being tested for safety and efficacy in prospective registry.

Conclusion

PAD is a common problem with serious and fatal consequences. Treatment options with minimally invasive techniques are currently available with reliable and effective results. The cardiovascular laboratory at JFK Medical Center remains on the cutting edge, providing state-of-the-art technology and therapy for patients with PAD.

JFK MEDICAL CENTER

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