N·E·W·S from Baptist Cardiac & Vascular Institute

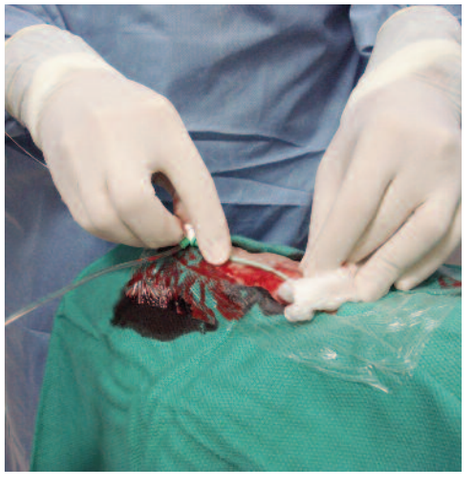
Fall 2010

Institute Excels at Transradial Coronary Interventions

Due to the growing weight of evidence in favor of radial over femoral access, even in cases of acute MI and chronic total occlusion, many interventional cardiologists will be migrating to this modality due to its comparable-to-femoral outcomes with significantly reduced hospital stay and bleeding risks.

As other centers embark on their new-modality learning curve, Baptist Cardiac & Vascular Institute is uniquely qualified to perform even the most complex coronary intervention transradially with a high degree of technical proficiency. That's because for much of the past 14 years, interventional cardiologists at the Institute have been using radial access as their default approach.

Based on that long record of experience, Ramon Quesada, M.D., the Institute's medical director of interventional cardiology, recently shared his operator tips and techniques for transradial access at the 2010 International Symposium on Endovascular Therapy (ISET) and in the May 2010 issue of Endovascular Today.



Ramon Quesada, M.D., accesses a patient's radial artery for a coronary intervention. This approach offers a lower complication rate and a higher degree of patient comfort.

"Radial artery interventions for ST-segment elevation and other acute MI have been proven not to extend door-to-balloon time. Furthermore, radial access offers unique advantages for this clinically complex population due to a markedly reduced incidence of bleeding, the number one predictor of mortality from any interventional procedure," Dr. Quesada said.

In one recent study, older and diabetic patients were safely discharged the same day as their transradial coronary intervention. In another study, acute, non-ST-elevation MI patients who were revascularized transradially were able to safely receive more intensive antiplatelet therapy for an improved prognosis.

At the 2010 ISET meeting, Dr. Quesada presented results of an Institute study of radial access in 700 consecutive complex coronary cases. In that single-center study, the procedural success rates ranged from as high as 98.5% in patients with complex B2-C lesions to 78.9% in patients with chronic total occlusions. Among acute MI patients, the success rate was 97%.

Although vessel tortuosity was encountered most frequently in patients over the age of 80, their vascular complication rates with radial access were just 2%, compared with 15% femorally.

Ramon Quesada, M.D.

Despite advantages like the 58% lower incidence of bleeding reported in one 2004-2007 study, transradial coronary interventions are rarely performed in the U.S. For example, only 1.32% of the 600,000 cases in that aforementioned study were performed transradially.

Even a recent study confirming that radial approaches are more likely to be abandoned than femoral access attempts did not find door-to-balloon or fluoroscopy times in these acute MI cases to be significantly lengthened.

"The biggest drawback to this approach is the learning curve," Dr. Quesada acknowledged.

The main technical requirements for radial access are: careful pre-procedure assessment of the integrity of the radial and ulnar arteries, proficient transradial cannulation, and successful navigation of radial, brachial and subclavian tortuosity. Newly classified anatomic vessel variants found to impact access can be identified and navigated angiographically by the experienced operator.

For more information, please contact: Ramon Quesada, M.D., 786-596-6654. ■

If you prefer to receive this in an e-mail format, please e-mail asmith@baptisthealth.net.

RESEARCH STUDIES

Left Atrial Appendage Closure versus Warfarin for Atrial Fibrillation

After participating in the WATCHMAN AF single-arm study of transcatheter left atrial appendage closure in patients with atrial fibrillation (AF), the Institute is embarking on a new dual-arm study of closure versus warfarin for stroke prevention.

The new prospective, randomized multicenter study, called PREVAIL, will enroll 475 patients at 50 sites in the U.S. Subjects will be randomized to closure or medical therapy in a 2:1 ratio.

To qualify, patients must have paroxysmal, persistent or permanent non-valvular AF and be eligible for long-term warfarin therapy. They must not have any comorbid condition that would contraindicate discontinuing warfarin after left atrial appendage closure.

Each candidate for the study will receive trans-thoracic and trans-esophageal echocardiograms to rule out thrombus and other exclusion criteria.

Pelvic Stenting for Erectile Dysfunction

The Institute is enrolling patients in the ZEN multicenter study of the Medtronic Zotarolimus-Eluting Peripheral Stent System for the treatment of erectile dysfunction (ED). This study is for men with suboptimal response to PDE5 inhibitors and atherosclerotic lesions of the hypogastric and/or internal pudendal arteries.

Revised study inclusion criteria now permit diabetic subjects with levels of HbA1c of 8% or less.

Based on positive results for angioplasty, ZEN will examine whether the deployment of Medtronic's drug-eluting stent can improve patient response to standard ED drug therapy. The study's primary clinical feasibility endpoint is improvement over pre-procedure ED at 30 days, as assessed by the ED domain score of the International Index of Erectile Function.

Patients in the single-arm study may be stented unilaterally or bilaterally, depending on the location and severity of their disease.

For more information about these studies, please call 786-596-6654 or e-mail *asmith@baptisthealth.net*. ■

Benenati Leads Society of Interventional Radiology

James F. Benenati, M.D

James F. Benenati, M.D., FSIR, a long-time member of the Institute's leadership team and medical director of its Noninvasive Vascular Laboratory, took office in March 2010 as president of the Society of Interventional Radiology (SIR). He has served on the Society's Executive Committee since 2004, when he chaired the SIR annual meeting.

Since taking SIR's helm, Dr. Benenati has embarked on an ambitious agenda for advancing the leadership of interventional radiology in minimally invasive, image-guided treatment modalities that improve patient care. "As a corollary," he said, "we, as a Society, will do everything we can to promote image-guided therapies as first-line treatments for a variety of diseases once treated only via open surgery. We have to get everyone—governments, insurers, hospital administrators—to understand just how integral to healthcare these modalities have become because they really are superior alternatives for patient care."

Dr. Benenati said he would focus his tenure on broad-based initiatives to advance the creative and innovative spirit of interventional radiology—supporting research, procedures and technology. Other areas of focus include: delivering a high level of member educational and professional services, communicating the value of the specialty to hospital administrators, increasing training and mentorship opportunities for young specialists, and ensuring adequate recognition of and reimbursement for interventional radiology services.

Dr. Benenati also recently became president of the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), which sets standards to ensure and improve the quality of noninvasive vascular labs nationally.

An international authority on uterine fibroid embolization and intravascular stents and thrombolysis for peripheral arterial disease, Dr. Benenati also directs the Institute's cardiovascular and interventional radiology fellowship program and is a clinical associate professor of radiology at the University of South Florida College of Medicine, Tampa. Before joining the Institute in 1990, he was an assistant professor of radiology and surgery at the Johns Hopkins Medical School. ■

Paravalvular Leak Repair

Institute structural heart interventionalists are percutaneously repairing prosthetic paravalvular leaks to prevent or treat congestive heart failure without the trauma of additional valve surgery.

Prosthetic mitral valve replacement is associated with paravalvular leak in up to 12.5% of patients. This typically occurs when sutures anchoring the prosthesis loosen or tear. Most of these leaks are small and not clinically significant. However, patients with larger leaks can be very symptomatic with NYH class III and IV heart failure.

At the Institute, interventional cardiologists experienced with atrial septal closure devices and vascular plugs, working together with cardiac anesthesiologists and Board-certified echocardiographers, can expertly repair multiple leaks of varying size and morphology.

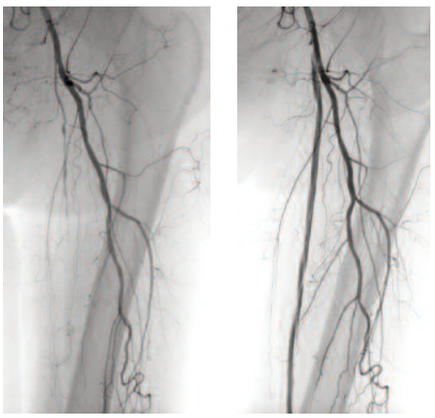
For more information, please contact: Ramon Quesada, M.D., Jonathan Roberts, M.D., Rafael Machado, M.D., 786-596-6654. ■

Circulation Article Supports Leg Stents

Barry T. Katzen, M.D., the Institute's founder and medical director, was second author of a June 2010 article in the journal Circulation: Cardiovascular Interventions, reporting positive results for leg stents from the groundbreaking RESILIENT clinical trial. The article concluded that stenting boosts freedom from target lesion revascularization almost 100% over angioplasty alone in the proximal popliteal and superficial femoral artery (SFA).

As RESILIENT's national co-PI, Dr. Katzen presented positive one-year results for the study's first 137 patients at the annual Transcatheter Cardiovascular Therapeutics (TCT) meeting. His Circulation article represents a final analysis of the RESILIENT data for all 206 patients from 24 centers across the U.S. and Europe, confirming very positive patency and functional results in the first randomized, prospective, controlled study of primary bare-metal stenting in the peripheral vasculature.

"Prior to the RESILIENT trial, there was great uncertainty about the value of stenting in the periphery," Dr. Katzen pointed out. "This trial has given clinicians clear direction regarding the value of stents in most patients with lesions in the SFA, based on the nitinol Edwards LifeStent experience."



Superficial femoral artery (SFA), pre- and post-stent.

Dr. Katzen added, "Anyone who wondered whether stenting adds long-term clinical value, as opposed to just an acute benefit over angioplasty, will be interested in our primary endpoint finding that stented vessels were more than twice as likely to be patent after one year."

RESILIENT enrolled patients with obstructive lesions and intermittent claudication and randomized them to implantation of the LifeStent or balloon angioplasty. The mean total lesion length was 71 mm for the stent group and 64 mm for the angioplasty group.

Acute lesion success (<30% residual stenosis) was superior for the stent group, compared with the angioplasty group (95.8% versus 83.9%; P<0.01). Twenty-nine patients (40.3%) in the angioplasty group underwent bailout stenting, which was treated as a target lesion revascularization and loss of primary patency, because of a suboptimal angiographic result or flow-limiting dissection.

At 12 months, freedom from target lesion revascularization was 87.3% for the stent group, compared with 45.1% for the angioplasty group (P<0.0001). Primary patency based on duplex ultrasound at 12 months was also better for the stent group (81.3% versus 36.7%; P<0.0001). (See Circ Cardiovasc Interv. 2010 Jun 1;3(3): 267-76. Epub 2010 May 18.)

For more information, please contact: Barry T. Katzen, M.D., James Benenati, M.D., Alex Powell, M.D., Shaun Samuels, M.D., Constantino Peña, M.D., Ripal Gandhi, M.D., 786-596-6654. ■

Live PFO Closure Webcast
Thursday, Feb. 24, 4 p.m.
View the webcast at *baptisthealth.net.*

HEART FAILURE ACCREDITATION

Baptist Hospital of Miami has become one of the first hospitals in the nation to receive full Cycle I Heart Failure Accreditation from the Society of Chest Pain Centers. "This confirms our success in adopting the Society's operational model for improving the process of patient care across the heart failure continuum, with special emphasis on the acutely decompensated heart failure patient," noted Ramon Lloret, M.D., an interventional radiologist and chair of Baptist's Heart Failure Collaborative.

To earn accreditation, Baptist had to demonstrate optimized coordination among emergency dispatch, EMS, emergency medicine and cardiology, as well as "best practice" medical care from emergency transport to discharge for optimum patient outcomes and continuous quality improvement. ■

Baptist Cardiac & Vascular Institute
BAPTIST HOSPITAL OF MIAMI

Editors: Barry T. Katzen, M.D., and Ramon Lloret, M.D.
Managing Editor: Anne Smith
Writer: Sandy Baksys
Editorial Contributor: Adrienne Sylver
Designer: Wendy Kornfield
Photography: Mabel Rodriguez

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Baptist Health South Florida
8900 North Kendall Drive
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Electrophysiology for ICD, Ablation Therapy

Serious cardiac arrhythmias are manifesting with greater regularity, as more heart attack patients survive longer with ischemic disease and the U.S. lifespan increases. Growing evidence supports the use of implantable cardioverter defibrillators (ICDs) to prevent ventricular tachycardia and sudden death, particularly in the initial months after acute MI.

While many centers today implant ICDs, few provide the proficient, dedicated follow-up necessary to fully optimize defibrillator therapy. For example, ICD programming glitches, undetected lead failure or incorrect lead placement all can result in a baffling array of symptoms. Instead of quickly resorting to device replacement for patients referred with ICD problems, Institute clinicians often achieve good results via skilled reprogramming of an existing device or laser extraction and replacement of errant or failed leads.

Led by a Board-certified subspecialist, the Institute's dedicated electrophysiology (EP) service includes pacemaker and other resynchronization therapy, catheter ablation for abnormal sinus rhythm, tilt table testing and insertable loop recorders for syncope, and intracardiac echocardiography. Moreover, the Institute's EP service is fully integrated with our cardiac surgery and interventional departments in a truly interdisciplinary model of care.

With regard to atrial fibrillation (AF), the Institute's participation in advanced EP research studies places us on the frontier of catheter ablation therapy for ventricular and supraventricular tachycardia, atrial flutter, and AF even in its moderate-to-persistent forms.

Patients with permanent AF are at significant risk for stroke and death compared to those with normal sinus rhythm. In addition, these patients often have life-impairing symptoms, such as palpitations, dizziness, fatigue and shortness of breath. Currently, the only approved surgical treatment is the open heart, on-pump Cox Maze III procedure.

In the Institute's experience, radiofrequency ablation can compensate for the paucity of treatment options for this group, providing both improved survival and quality of life.

For more information, please contact: Efrain Gonzalez, M.D., Fernando Mera, M.D., 786-596-6654. ■