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

Spring 2011

Institute to Publish Positive Data on Visceral Aneurysm Repair

Always in the forefront of endovascular aneurysm therapy, the Institute will soon publish a series of visceral aneurysm repairs with strongly positive outcomes. The Institute's series will be one of the largest ever reported in this therapeutic arena.

The top-line finding from the Institute's data set of 41 consecutive cases from 2000-2010 is that percutaneous repair (embolization) of visceral aneurysms is safe and effective with significant long-term survival.

Considering the invasive nature of the surgical option and its associated morbidities, Institute physicians hope these outcomes lend further support to embolization as a first-line therapy.

With growing access to high-quality diagnostic screenings and an aging population, there has been a dramatic increase in aneurysm findings throughout the body — particularly in the abdominal cavity — with a corresponding need for less invasive treatment options.

Visceral artery aneurysms occur in the abdominal branch vessels of the aorta, including the renal and mesenteric arteries.

In the renal arteries, in particular, growing evidence suggests that endovascular therapy may help patients avoid the complications of aneurysm surgery. About 20% of aneurysm-related resections, reconstructions and/or bypasses traditionally result in nephrectomy.

Fortunately, recent advances in microcatheters and embolization techniques, in the hands of experienced operators, are providing new endovascular treatment options. Access to percutaneous therapy is particularly important for patients concomitantly at unacceptably high risk for surgery and lethal aneurysm rupture.

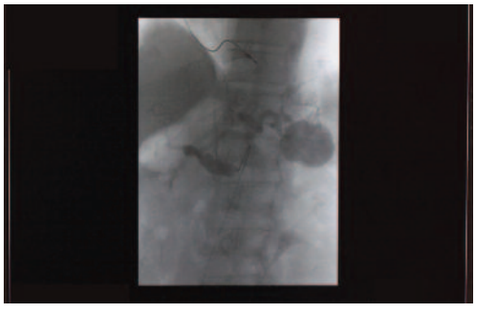
One of the new technologies making more visceral aneurysm repairs possible is the detachable, bioactive coil. With push-button detachment, Institute operators can retract and reposition each embolization coil until they achieve optimal placement within the aneurysm. This minimizes the risk of coil migration.

Many of the new coils also have superior volume-filling characteristics for improved mechanical stability, packing density and occlusion efficacy.

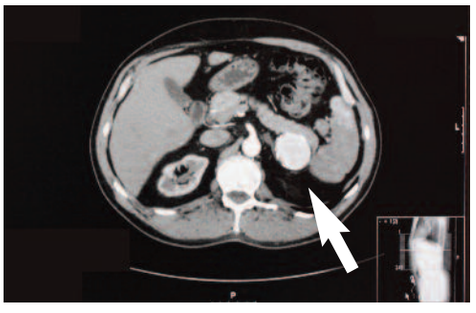
Among the 40 patients in the Institute study who underwent aneurysm repair, physicians achieved a 97.6% rate of technical success, defined as cessation of hemorrhage or blood flow into the aneurysm sac. There was no mortality within the 30-day periprocedural period, and side effects such as distal embolization and end organ infarcts were not found to be clinically significant.

The mean length of hospital admission was one and two days, respectively, for asymptomatic versus symptomatic patients. The mean length of clinical follow-up was 44.5 months and the estimated nine-year survival rate was 92%.

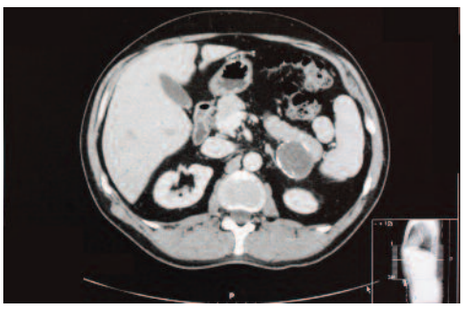
For more information, please contact: Barry T. Katzen, M.D., James Benenati, M.D., Alex Powell, M.D., Shaun Samuels, M.D., Constantino Peña, M.D., and Ripal Gandhi, M.D., 786-596-6654, or *asmith@baptisthealth.net.* ■



Angiogram demonstrating visceral aneurysm prior to embolization.



CT image of visceral aneurysm.



CT image of visceral aneurysm after embolization.

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

Percutaneous Heart Repair for Patients at High Stroke Risk

The Institute's structural heart disease program is breaking new ground regionally and nationally in the pursuit of percutaneous protection from embolic stroke — without warfarin therapy — for patients with nonvalvular atrial fibrillation (AF).

Since 2005, our interventional cardiologists have been successfully implanting transcatheter left atrial appendage (LAA) occluders in selected atrial fibrillation patients for stroke prophylaxis. Percutaneous LAA closures at the Institute were initially part of the PROTECT AF multicenter, randomized study. Now, the Institute is preparing to build on its LAA occlusion experience in a follow-up study called PREVAIL.

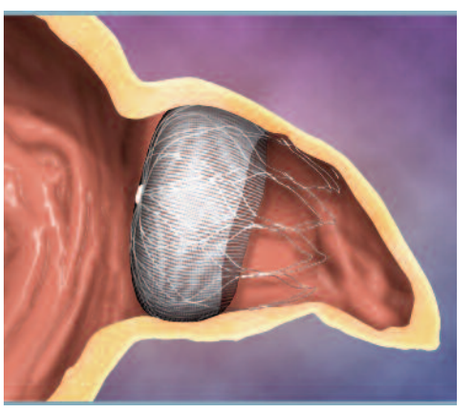
PROTECT AF evaluated Atritech's WATCHMAN occluder versus the warfarin standard of care in 800 patients from February 2005 to June 2008. Published results (The Lancet, Volume 374, Issue 9689, Pages 534-542, 15 August 2009) demonstrated a 30% reduction in the combined risk of cardiovascular death and stroke for WATCHMAN over anticoagulation therapy.

PROTECT AF also found an almost 100% reduction in bleeding complications for occlusion versus warfarin therapy. This result is especially significant for patients with atrial fibrillation and a concomitant high risk of cerebral bleeding on prolonged anticoagulation. Moreover, with multiple occlusion devices in the pipeline, there is also growing hope for stroke prophylaxis that doesn't involve lifelong warfarin for the youngest and most active atrial fibrillation patients.

PROTECT AF's findings led to FDA panel approval for the WATCHMAN occluder on condition that a smaller confirmatory study be launched. In the meantime, updated data on the safety and efficacy of the occluder were presented at the 2010 TCT meeting in Washington, D.C.

These data continue to demonstrate a relative risk reduction of 30% for all stroke, cardiovascular death and systemic embolism, compared with long-term warfarin therapy, through an average follow-up of 27 months.

The top-line finding from the updated data is a significant improvement in the safety profile of the LAA closure procedure with increasing operator experience, particularly with regard to pericardial effusion complications. The Institute's participation in PROTECT AF has allowed its operators to gain significant experience with the anatomy of the left atrial appendage and to develop advanced catheter skills that can be applied to these specialized cases.



WATCHMAN device seals the left atrial appendage.

About 2.5 million, mostly elderly, Americans suffer chronic atrial fibrillation, which is linked to thousands of the most serious embolic strokes each year.

Published results of PROTECT AF in The Lancet found the primary efficacy event rate (combining stroke, CV death and systemic embolism) per 100 patient-years was 3.0 in the occluder group, compared with 4.9 in the control group. For the primary safety end point (combining major bleeding, pericardial effusion and device embolization), event rates (especially pericardial effusion) were higher in the occluder group than the medical therapy arm: 7.4 per 100 patient years versus 4.4, respectively.

However, the PROTECT AF authors reported that despite a higher initial safety event rate for device implantation, adverse events were without long-term sequelae for most patients.

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Institute Acquires Powerful New Cardiac MR Technology

As part of our continuing commitment to provide the most powerful and advanced coronary MR angiography in South Florida, the Institute has become one of the first centers in the nation to acquire a Philips Cardiac/Torso RF coil with an array of 32 elements. This new multi-element coil delivers high resolution and high acceleration factors, giving our physicians the ability to acquire extremely high-resolution images of a full cardiac cycle with full left ventricle coverage in a single breath-hold.

The new array also features a volumetric design that enables the Institute to perform multi-planar cardiac sensitivity encoding (SENSE) MR imaging in all directions, and to optimize acceleration factors for the anatomy, decreasing exam time while optimizing image quality.

The same new array also will enable the Institute to provide advanced 4D MR imaging, as well as higher-resolution 2D and 3D imaging with a single breath-hold.

What this means for patients is high-resolution images for improved diagnostic power in the emergency room — with no exposure to ionizing radiation.

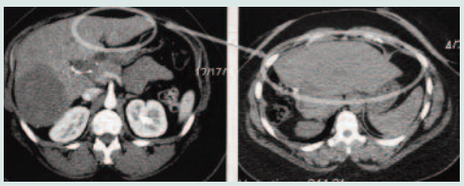
What this means for physicians is the most optimized MR available for patients with ischemic heart disease and nonischemic cardiomyopathies.

In our experience, high-resolution images of the myocardium can provide the referring physician the critical input on myocardial function, perfusion and viability necessary to assess options for revascularization. In cardiomyopathic patients, myocardial scar tissue can be distinguished from

Embolization Enables Extensive Right Hepatectomy

A 35-year-old Miami mother of three with a primary salivary gland malignancy is cancer-free today, two years after undergoing portal vein embolization followed by extensive right hepatectomy to treat a 12 cm liver metastasis.

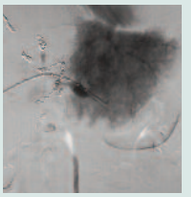
The Institute's vascular surgeons and interventional radiologists collaborated in this carefully staged, complex case to enable a hepatic tumor resection so extensive that it would otherwise have been impossible.



Pre- and post-embolization of the right portal vein demonstrating significant hypertrophy of the left hepatic lobe. This enabled an extensive right hepatectomy.

After advanced CT volumetric imaging of the involved liver segments and tumor, the patient's portal vein branches feeding the involved right lobe were carefully embolized (occluded). This caused the cancer-free left lobe to hypertrophy, permitting an extensive right hepatectomy.

Eight to 12 weeks after embolization, up to 80% — or six segments — of the patient's liver was surgically removed, leaving behind only healthy hepatic tissue that was viable and free of any tumor burden.



Successful embolization of right portal vein.

The Institute also offers interventional oncology treatments for hepatocellular carcinoma that rely on tumor hypervasculature and selective tumor uptake of radioactive tumoricidal agents.

For more information, please contact: Ignacio Rua, M.D., Constantino Peña, M.D., James Benenati, M.D., Abilio Coello, M.D., Ripal Gandhi, M.D., Barry T. Katzen, M.D., Howard Katzman, M.D, Alex Powell, M.D., Shaun Samuels, M.D., and Athanassios Tsoukas, M.D., 786-596-6654, or *asmith@baptisthealth.net*. ■

Iliac Stenting's Benefits Both Broad and Durable

A recent article in the Journal of Vascular and Interventional Radiology provides the most compelling evidence to date in support of iliac stenting for symptomatic peripheral artery disease (PAD).

Barry T. Katzen, M.D., the Institute's founder and medical director, was co-author of the article, "Two-year Clinical Evaluation of the Zilver Vascular Stent for Symptomatic Iliac Artery Disease" (JVIR, Volume 21, Issue 10, Pages 1489-1494, October 2010).

"The Zilver PTX study was groundbreaking because the study documented the benefits of this vascular stent in significant detail," Dr. Katzen said. "For example, clinical benefits are documented at regular intervals up to two years post-procedure along three clinical parameters, and the same benefits are experienced regardless of gender and location or length of the blockage."

Dr. Katzen added: "We, as physicians, can now say that we have a percutaneous procedure that can improve walking for patients with pain and claudication for at least up to two years."

The single-arm study's before-and-after measurements are given in terms of Kaplan-Meier overall patency estimates, ankle-brachial index (ABI), and scores from the Walking Impairment Questionnaires, a validated measure of perceived walking performance for PAD patients.

Zilver PTX drug-eluting vascular stents manufactured by Cook, Inc., were placed in 151 consecutive patients whose iliac arteries remained stenotic after angioplasty. Stents were placed in a total of 177 lesions: 90 in the common iliac, 64 in the external iliac and 23 in lesions involving both common and external iliac branches. The most common diameter of the Zilver stents placed was 10 mm, and the most common length was 40 mm.

Postprocedure, vessel patency was measured with duplex ultrasound at three days, one month, nine months and two years. Overall patency at two years was 90% (n=117). Significant improvement in ABI and WIQ scores was seen at two years, compared with preprocedural values ($P < .01$). The two-year overall success rate was 91%. The degree of initial stenosis, stent location and patient gender did not affect the success of the Zilver stent (P=.65, P=.58, and P=.77).

In addition, the Kaplan-Meier estimate of the probability of experiencing a major adverse event (MAE) related to the device or stent placement procedure two years postprocedure was only 2.7%.

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viable tissue with enough accuracy for the physician to precisely locate and grade areas of fibrosis and differentiate the various types of nonischemic cardiomyopathies (myocarditis, hypertrophic cardiomyopathy, sarcoidosis and amyloidosis, among others), shedding new light on treatment options.

Arrhythmogenic right ventricular dysplasia may also be diagnosed and staged in patients subject to syncope, ventricular tachycardia and sudden cardiac death.

So-called "bright blood" and "phase contrast" imaging also provide unparalleled diagnostic views of valvular disease.

For more information or to discuss a case, please contact: Ricardo C. Cury, M.D., at 786-596-5917. ■

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Coronary CTA Accurately Screens Low-Risk Chest Pain Patients

Low-to-moderate-risk acute chest pain patients who undergo coronary CT angiography (CTA) after presenting to the ER can be safely discharged home if their scan is negative or nonobstructive, according to results from the first 500 patients enrolled in a new Baptist Health South Florida registry.

"This is compelling new evidence for the negative predictive value of CTA in emergent chest pain triage," said Ricardo C. Cury, M.D., the Institute's medical director of cardiac imaging. "Determining which chest pain patients can safely and quickly be discharged to physician follow-up without costly and time-consuming hospital admission is one of the holy grails of emergency medicine."

Among the other conclusions of the study Dr. Cury presented at the 2010 Annual Scientific Sessions of the American Heart Association in Chicago:

A positive CTA finding in the study correlated well with subsequent cath lab results and rates of revascularization.

The Institute experienced a decrease in time to diagnosis and hospital length-of-stay as it incorporated a dedicated chest pain protocol using CTA.

Inclusion criteria for the registry were TIMI Risk score of two or less and two negative cardiac enzyme tests (two hours apart), plus negative or non-diagnostic EKG. Patients with TIMI scores of two or greater had assessment with SPECT myocardial perfusion imaging instead, as did those with bypass grafts, heart rates too high despite a beta blocker, atrial fibrillation and/or GFR less than 45.

Of 529 consecutive chest pain patients who met inclusion criteria, 468 (88.5%) were discharged from the ER without further testing once their CTA classified them as low-to-mild risk with stenoses of 0-49%. Of the remaining 14.5% with CTA findings of stenoses of 50% or greater, those in the 50-70% (moderate risk) range were sent to stress nuclear perfusion testing.

Those with stenoses of >70+% (high-risk) were admitted to the cath lab. Five patients in the moderate-risk group and 15 in the high-risk group underwent percutaneous coronary interventions.

Over the registry period — January 2009 to June 2010 — the average CTA radiation dose administered to patients in the study dropped more than 50%. The time elapsed from patient presentation at the ER through performance of a CTA to the reading of results dropped from 20 to 14 hours. Median length-of-stay dropped by almost half in the mild- and moderate-risk groups.

For more information, please contact: Ricardo C. Cury, M.D., at 786-596-5917. ■

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