Fall 2011

NEWS

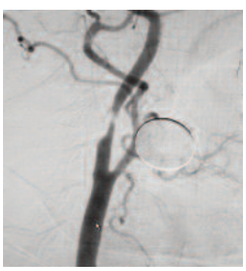
from Baptist Cardiac & Vascular Institute

FDA Approves First Carotid Stent for Standard Surgical Risk Patients

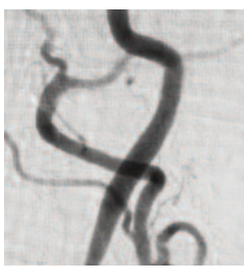
Carotid artery stenting (CAS) technology continued its rapid advance when the FDA recently approved an expanded, new CAS indication based on results from the groundbreaking 2010 NIH-sponsored CREST trial. The FDA confirmed its advisory panel's decision when it made Abbott's RX Acculink stent with embolic protection the first CAS system approved for stroke prevention in symptomatic and asymptomatic patients at standard surgical risk, not increased surgical risk. This vast new eligible population formerly had no indicated procedural options other than carotid endarterectomy (CEA).

The Level I science from the 10-year, 2,502-patient CREST trial that convinced FDA experts, was presented at the February 2010 American Stroke Association meeting, and reported in the New England Journal of Medicine.

In CREST, carotid artery stenting was associated with a 7.2% rate of adverse events vs. 6.8% for CEA during follow-up of up to four years, a non-significant difference. At 30 days, the rate of mild stroke was higher with stenting, at 4.1% vs. 2.3% for CEA. The rates of major stroke were equal: less than 1% in both groups. MI was more frequent in the CEA group: 2.3% vs. 1.1% for stenting. Rates of ipsilateral stroke on mean follow-up of 2.5 years were 2.0% for stenting and 2.4% for surgery.



Common carotid angiogram demonstrates a high grade stenosis in the internal carotid artery.



No significant residual stenosis after carotid stent placement.

Cranial nerve injury, which occurs in about 5% of CEAs, is not typically a clinical trial endpoint. However, it's another surgical risk that more patients with significant carotid stenosis and high stroke risk may now avoid with an expanded CAS indication.

Always on the forefront of carotid stent research, Institute interventional radiologists and vascular surgeons enrolled patients in CREST, and Institute medical director Barry T. Katzen, M.D., served on CREST's Interventional Management Committee.

Institute physicians have implanted more than 400 carotid stents since 1996, frequently under the exacting technical requirements of clinical trials. In fact, the Institute was the first in our region to participate in national, multi-center carotid stent research, namely the SAPPHIRE clinical trial, which provided the first scientific evidence for the non-inferiority of CAS vs. CEA.

Complication rates in both the Institute's CEA and CAS programs fall well below American Heart Association benchmarks. Combined with a long tradition of interdisciplinary decision-making, our dual CAS and CEA proficiency ensures that even the most subtle clinical and anatomic factors can be expertly navigated to optimize selection between the two modalities.

When CAS is indicated, the Institute's deep reservoir of experience and our access to a full portfolio of carotid stents, embolic filters and flow reversal devices allow us to refine device selection and customize technique to a degree unsurpassed in the region.

For more information, please contact: Barry T. Katzen, M.D., James F. Benenati, M.D., Athanassios Tsoukas, M.D., Alex Powell, M.D., Shaun Samuels, M.D., Constantino Peña, M.D., Ripal Gandhi, M.D., Italo Linfante, M.D., Guilherme Dabus, M.D., Abilio Coello, M.D., Howard Katzman, M.D., Ignacio Rua, M.D., 786-596-6654. ■

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

Open Heart Program Top Rated

Baptist Hospital's open heart surgery program ranks among the nation's best, according to The Society of Thoracic Surgeons (STS). The organization has awarded the hospital its highest quality rating of three stars for outstanding results in coronary artery bypass surgery. The STS database is the largest registry of its kind in the world with nearly 1,000 providers participating. Only 14 percent of those receive the maximum three-star rating. The STS rating system allows for comparisons on quality of cardiac surgery among hospitals based on survival rates, the absence of complications and hospital re-admissions and more. For the current reporting period, data was collected from July 1, 2010, through June 30, 2011. ■

CLINICAL TRIALS

The Institute is currently involved in nearly 30 clinical trials. A few are highlighted below. For more information on a specific study, please contact the Institute's Research and Outcomes Department at 786-596-2959.

Renal Denervation for Hypertension

SIMPLICITY HTN-3 is a multi-center, prospective, blinded, randomized and controlled study to learn whether renal denervation using the Simplicity Catheter System is a safe and effective treatment for uncontrolled hypertension. After a renal angiogram to confirm eligible anatomy, eligible patients will be randomized "on the table" to either renal denervation plus maintenance of baseline medications, or maintenance of baseline medications alone. Principal Investigators are Alex Powell, M.D., and David Hoffman, M.D.

Vagus Electrical Stimulation for Heart Failure

INOVATE-HF (INcrease Of VAgal TonE in chronic Heart Failure) is a multicenter, prospective, randomized trial to learn whether the implantable CardioFit electrical stimulator system can improve heart function in heart failure patients through controlled stimulation of the vagus nerve. A European pilot study suggested that vagus nerve stimulation acts to reduce left ventricular volumes, increase ejection fraction and improve NYHA functional classification. The Principal Investigator is Ramon Quesada, M.D.

Carotid Artery Disease

CHOICE (Carotid Stenting for High Surgical Risk Patients; Evaluating Outcomes Through the Collection of Clinical Evidence) is a multicenter open-label study that will collect data from Abbott Vascular's Carotid Stent Systems and Embolic Protection Systems when used by a broad group of physicians under commercial use conditions. The Principal Investigator is Barry T. Katzen, M.D.

Ischemic Stroke

TREVO 2 (Thrombectomy REvascularization of large Vessel Occlusions in acute ischemic stroke) is a multicenter open-label study to assess the revascularization rate, defined as at least TICI 2a in the treated vascular territory, at the end of a neuro-interventional procedure using the Trevo thrombectomy device. The Principal Investigator is Italo Linfante, M.D.

New CTA Techniques May Identify Ischemic Coronary Stenoses

The Institute is on the forefront of researching the comparative diagnostic capabilities of noninvasive coronary CT angiography (CTA) versus invasive coronary angiography. In fact, a recent registry study involving hundreds of Institute patients recently found that low-to-moderate risk acute chest pain patients who undergo CTA after presenting to the ER can be safely discharged home if their scan is negative or non-obstructive.

However, while conventional CTA can provide detailed anatomic information about coronary plaques, including obstructive severity, it cannot indicate which stenoses may be physiologically and clinically significant. Vessel-specific stenoses currently are identified as functionally ischemic only in the cath or nuclear lab.

To shed more light on the value of evolving coronary CTA technology as a potential noninvasive option for cardiac catheterization, the Institute participated in a multicenter study to determine if new computational techniques can improve the ability of CTA to detect hemodynamically significant stenoses.

When applied to CTA, such techniques may permit the noninvasive computation of fractional flow reserve (FFR), a measure of lesion-specific ischemia, which is currently taken at the time of invasive coronary angiography. Therefore, the design of the study, called DeFACTO, included the performance of computed FFR in connection with CTA (termed FFR_{CT}) for comparison with invasive FFR as a reference standard.

The 238 patients enrolled in DeFACTO, a prospective, international study, underwent CTA, invasive coronary angiography, and vessel-specific FFR. FFR_{CT} was computed with acquired CTA images without modification to CTA protocols or additional image acquisition or radiation dose. Blinded core laboratory interpretation was performed for CTA, invasive coronary angiography, FFR, and FFR_{CT}. FFR values ≤ 0.80 were considered hemodynamically significant.

The study enrolled patients over 18 who were scheduled to undergo non-emergent invasive coronary angiography, who had also undergone a >64 multidetector CTA within 60 days prior to catheterization.

DeFACTO's primary endpoints are the per-patient diagnostic accuracy of noninvasive FFR_{CT} for the detection and exclusion of ischemia-causing stenoses. Secondary endpoints include additional per-patient as well as per-vessel diagnostic performance characteristics, including sensitivity, specificity, positive predictive value, and negative predictive value. Study results should be available within six months.

The ability to acquire anatomical visualization of coronary artery stenosis — together with a physiological assessment of vessel-specific perfusion in a single study — could improve diagnostic accuracy while potentially reducing costs and the exposure to invasive cardiac catheterization.

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

Institute Studies Stents in Acute Ischemic Stroke

The Institute has published results of a single-center study on the use of self-expandable stents in the treatment of acute, large-vessel ischemic stroke refractory to other life-saving therapies. The study, published in Stroke, Journal of the American Heart Association (Stroke. 2011;42:00-00.), included a series of 19 Institute patients whose Median NIH Stroke Scale score on admission was 19.

Patients in the study underwent implantation of either a Boston Scientific Wingspan or Cordis Corporation Enterprise self-expanding stent after arterial thrombolysis or mechanical thrombectomy, or both, were tried and failed.

Despite failure of commonly used thrombectomy devices, stenting achieved recanalization in an astonishing 95% of the occlusions.

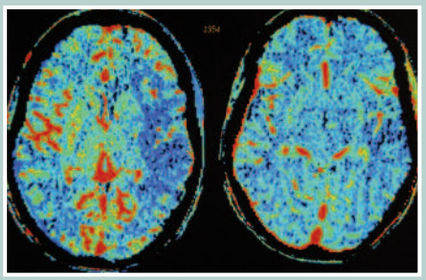
With regards to safety, symptomatic intracerebral hemorrhage occurred in three (16%) of the patients not related to stent deployment.

Lead investigator Italo Linfante, M.D., the Institute's director of interventional neuroradiology, concluded that the procedure itself was safe and produced good clinical outcomes in 42% of the patients. Good outcome was defined as a modified Rankin Scale score less than or equal to 2, one month after hospital discharge.

Without stenting, mortality or severe disability would have been in the range of 80-90%, according to previously published data.

The investigators concluded that interventional therapy with self-expanding stents "may be considered when currently available thrombectomy devices and/or intra-arterial thrombolysis fail."

For more information, please contact: Italo Linfante, M.D. or Guilherme Dabus, M.D., 786-596-6654. ■



58-year-old with acute stroke: CT perfusion. Left, CBF; Right, CBV.

Endovascular Repair for Ruptured Aortic Aneurysms

Since the first stent-graft for endovascular repair (EVAR) of abdominal aortic aneurysm (AAA) was approved in 1998, the technology has advanced so rapidly that EVAR now accounts for nearly half of the estimated 60,000 elective AAA repairs in the U.S. each year.

The success of elective EVAR to prevent aneurysm rupture has led to an extension of the same technology to ruptured AAA with durable results, minus the trauma of open surgery. In fact, an 18-year, retrospective, single-center study published recently in the Annals of Vascular Surgery (Ann Vasc Surg 2011; 25: 461-468) found EVAR and open surgery equivalent with regard to 30-day and long-term mortality in the treatment of ruptured AAA.

The investigators concluded that EVAR is now a viable primary repair modality for ruptured AAA, subject to the use of experienced clinical judgment and careful patient selection.

Despite improvements in technology, screening, and early intervention, ruptured AAA kills almost 15,000 patients each year in the U.S. First described in 1994, EVAR for ruptured AAA gained clinical confidence so quickly that it was performed in 17% of rupture patients nationally by 2005.

The Institute's 17-year record of elective EVAR proficiency, encompassing the most anatomically challenging AAAs, permits us to give preference to less-invasive EVAR for ruptured AAA when clinical conditions permit. Our equal proficiency in open surgical repair and EVAR and our tradition of interdisciplinary decision-making ensure that clinical and anatomic factors can be quickly navigated to optimize patient selection even in the most catastrophic ruptures.

EVAR technique has advanced so rapidly in recent years that even in free ruptures involving life-threatening systemic hypotension, an aortic occlusion balloon can be deployed percutaneously, obviating the need for open surgery to clamp the aorta.

The Institute's success in elective repair of even the most challenging AAAs with short proximal necks can be attributed to our wide access to pre-market and approved devices and our ability to customize those devices to the individual anatomy. In addition, it is our commitment to aggressively treat proximal fixation problems and Type IA endoleaks before the patient leaves the table.

In recent years, we have leveraged our research-site experience with microchip aneurysm sac pressure sensors to offer this additional monitoring and follow-up modality to many of our elective EVAR patients.

The Institute also recently participated in the PYTHAGORUS multi-center study of Lombard Medical's Aorfix stent-graft for AAAs with extremely angulated necks (between 60-90 degrees). In addition, our interventionalists have participated in a multi-center, randomized study of an endograft with a unique "stapling" system for permanent fixation.

In the arena of descending thoracic aortic aneurysm repair, the Institute has a track record of success using a variety of endografts and hybrid surgical / interventional aortic debranching techniques.

For more information, please contact: Barry T. Katzen, M.D., James F. Benenati, M.D., Alex Powell, M.D., Shaun Samuels, M.D., Constantino Peña, M.D., Ripal Gandhi, M.D., Abilio Coello, M.D., Howard Katzman, M.D., Ignacio Rua, M.D., Athanassios Tsoukas, M.D., Alvaro Montoya, M.D., Niberto Moreno, M.D., Lynn Harrison, M.D., or Lisardo Garcia-Covarrubias, M.D., at 786-596-6654. ■

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Resecting Carotid Body Tumors

One mark of an advanced vascular surgery program is its ability to deliver outstanding results, not just in high-volume practice areas, but also in rare and complex cases when patients may have few options.

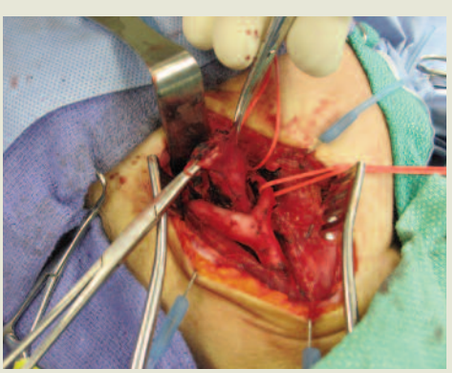
Institute vascular surgeons recently resected several carotid body tumors and a 6 cm symptomatic vagal paraganglioma that engulfed parts of the 10th and 12th cranial nerves.

Cranial nerve injuries are one of the most frequent and dangerous complications of carotid body tumor removal, with risk proportional to tumor size. However, in the case of the 31-year-old Miami woman with the 6 cm vagal paraganglioma tumor, the dissection was performed freeing the involved nerves without injury.

The anatomic position of vagal gangliomae higher in the neck and closer to the skull base often requires subluxating the jaw.

However, in this particular case, the mandible was left intact. No concomitant repair or resection of the carotid artery was required.

In about 20% of similar cases, Institute vascular surgeons work together with interventional neuroradiologists to reduce the size of carotid body tumors with transcatheter embolization prior to surgery. The Institute's multidisciplinary team also typically involves the expert contributions of neurosugeons.



Carotid body tumor at the bifurcation of the carotid artery.

In 60% to 70% of patients, tumor resection can be accomplished without concomitant repair or resection of the carotid artery. More complicated carotid artery repair may be necessary in up to 25% of cases, including patching a hole created by tumor resection, or replacing a segment of the carotid artery with a bypass graft. During the most complex repairs, a temporary shunt is placed in the carotid artery to provide uninterrupted circulation to the brain.

The carotid body paraganglioma (chemodectoma) is a relatively rare neoplasm of obscure origin found at the branching of the carotid artery. It is usually benign and commonly presents as an asymptomatic cervical mass. Vagal paragangliomae are even rarer.

When symptomatic, such masses most commonly produce difficulty swallowing and other space-occupying dysfunctions.

For more information, please contact: Ignacio Rua, M.D., Howard Katzman, M.D., Abilio Coello, M.D., and Athanassios Tsoukas, M.D., at 786-596-6654, or *asmith@baptisthealth.net.*

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