

## TAVR Shows Promise for Patients With Inoperable Aortic Stenosis

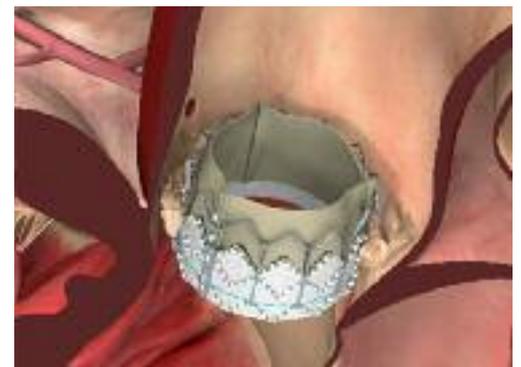
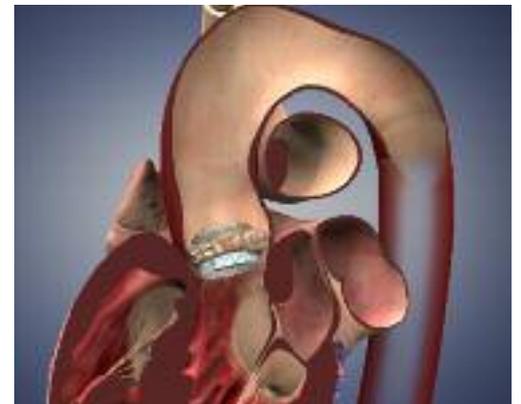
As minimally invasive heart valve procedures gain momentum, secondary to promising results of a clinical trial, heart centers and patients are paying attention. The Transcatheter Aortic Valve Replacement (TAVR) procedure, previously known as Transcatheter Aortic Valve Implantation (TAVI), may be an alternative for patients with severe or critical aortic stenosis, who are not candidates for traditional open-heart surgery, due to advanced age or other health-related reasons. The nonsurgical method uses a valve mounted on a balloon catheter, inserted through a tiny incision, to replace a diseased heart valve with an artificial valve. The heart continues beating throughout the procedure. Currently, the FDA has only approved access to replace the valve through the femoral artery; however, access via the apex of the heart (left lower ventricle) is still under investigation.

There are concerns in regards to the increased risk of stroke and vascular injury in patients who undergo TAVR

versus traditional surgical valve replacement; however, these selected patients are deemed inoperable and have a very poor prognosis. Now, TAVR offers them an opportunity to improve the quality and duration of their life.

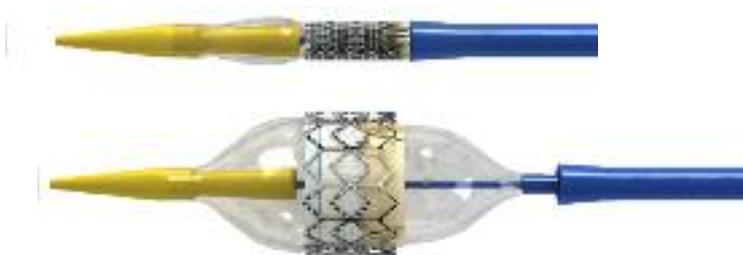
The Institute assembled a multi-disciplinary team of interventional cardiologists, interventional radiologists, cardiothoracic surgeons and cardiology specialists to perform TAVR in the Institute's cardiac cath lab hybrid medical room. Institute physicians have worked in the hybrid environment for several years, prior to performing TAVR. A team of Institute physicians, to include clinical cardiologists, will evaluate potential patients to ensure that they meet a rigorous selection criteria.

For more information about the TAVR procedure at the Institute, please contact Ramon Quesada, M.D., Niberto Moreno, M.D., Jonathan Roberts, M.D., or Lisardo Garcia, M.D., at 855-596-6000. ■



Top: The catheter is threaded through the aorta to the precise spot of deployment at the aortic valve.

Bottom: The replacement valve in the open position.



Top: The transcatheter with the heart valve crimped for deployment.

Bottom: When in position, the balloon is inflated and the transcatheter heart valve is placed. The balloon is then deflated and the catheter is retracted.



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

### New Clinical Trial Under Way to Treat Patients With Resistant Hypertension

Baptist Cardiac & Vascular Institute, among the first facilities in the United States to offer an experimental treatment for unmanageable hypertension, has been selected to participate in the pivotal SYMPLICITY HTN-3, a single-blind randomized controlled trial. Sponsored by Medtronic Ardian, the study will evaluate the safety and effectiveness of renal sympathetic nerve disruption technology using the company's Symplicity catheter

system. Trial participants are being selected based on a systolic blood pressure greater than 160mm of mercury and their taking three or more anti-hypertensive medications.

The study consists of a treatment group and a control group. Treatment group patients receive therapeutic renal denervation; control group patients will not be treated with the device, but at six months can elect to receive treatment if still eligible. The study has two main endpoints: 1) A change in blood pressure from baseline to six months after randomization; and 2) Incidence of major adverse events at one month after randomization.

Renal denervation is a minimally invasive, catheter-based procedure that uses a low-energy radio frequency to disable selected nerves located around the kidney

arteries. This deliberate disruption of nerves that connect the kidneys with the central nervous system reduces sympathetic control of renal function (renin release, sodium excretion and renal blood flow) and removes the renal afferent sympathetic contribution to central blood pressure elevation.

In initial European studies, 84 percent of patients showed a reduction in systolic blood pressure of 10mm Hg or greater after six months. In 39 percent of patients, blood pressure dropped to normal levels.

For more information, contact Barry T. Katzen, M.D., Alex Powell, M.D., David Hoffman, M.D., James F. Benenati, M.D., Shaun Samuels, M.D., Constantino Peña, M.D., or Ripal Gandhi, M.D., at 786-596-7860. ■

## ACC Endorses Aquapheresis Therapy for Hypervolemia

Whether caused by congestive heart failure, hypertension, liver cirrhosis or kidney disease, fluid overload (hypervolemia) poses a risk of severe swelling and associated problems. Baptist Cardiac & Vascular Institute is utilizing aquapheresis therapy in patients who have not responded to diuretics and are more than 10 pounds over their dry weight. An inpatient procedure resembling IV therapy, aquapheresis removes excess water and salt from the body and restores euvolemia. It may be used in conjunction with diuretics or inotropic and vasoactive medications. The therapy is approved in the American College of Cardiology guidelines.

For acutely ill patients, aquapheresis takes four to six hours and requires a three-to-four-day hospital stay. Equipment includes a console with two pumps, a blood filter circuit and venous catheter. Aquapheresis is considered a less invasive, more portable option than a dialysis machine, which has been the standard treatment for hypervolemia for two decades.

Once the patient is connected to the aquapheresis machine, the excess salt and water are removed by a central or peripheral venous catheter. They are then separated from the blood via a hemofilter, which applies varying amounts of pressure to push different elements in the blood through the fiber walls. The filtered blood is then returned to the patient's body and the excess fluid is collected for disposal. Up to 500ml of fluid can be removed per hour. The aquapheresis machine is adjusted to specify a precise amount and rate of fluid removal to maintain stable blood pressure, heart rate and electrolyte balance. The process extracts approximately six liters of water per day from a patient's body, in contrast with diuretic medication, which generally expels about one liter per day.

The UNLOAD clinical trial, a national, multicenter study of 200 patients, demonstrated that patients who underwent aquapheresis lost 28 percent more fluid and 38 percent more weight than patients who received diuretics. Ninety days after treatment, these patients also had less occurrence of worsening heart failure or cardiac arrest than patients who received diuretics. However, the patients who underwent ultrafiltration did experience hypotension and arrhythmia in greater numbers than did patients who received standard treatment.

Aquapheresis has other drawbacks as well. In order for blood to flow through the filters, patients must be given an anticoagulant, increasing the risk of bleeding. However, since the Institute first implemented aquapheresis therapy in 2007, its physicians have found aquapheresis to be safe and effective, with patients experiencing immediate relief and remaining normalized for longer periods. Though the machine's filters are costlier than those used with dialysis machines, the reduced length of stay and decreased need for readmission in patients treated with aquapheresis help compensate for the expense of the filter.

A study published in the Journal of the American College of Cardiology assessed the safety and effectiveness of ultrafiltration versus standard care in patients with decompensated congestive heart failure (CHF) and acute fluid overload. It concluded that early intervention with ultrafiltration for CHF patients was viable and well-tolerated, and resulted in substantial fluid removal and weight loss.

For more information about aquapheresis therapy, please contact Ramon Lloret, M.D., at 786-596-7860. ■

# Institute Performs 1,000th AAA Repair

In March 2012, Baptist Cardiac & Vascular Institute made history as its physicians performed the 1,000th endovascular aortic repair (EVAR) for an abdominal aortic aneurysm (AAA). The patient, a 63-year-old male, was discharged the following day. The procedure was pioneered by a team of physicians at the Institute nearly 20 years ago. The Institute, established in 1987, was one of the first in the nation to integrate all disciplines related to the heart and blood vessels, enabling its physicians to be ready for medical innovations. Institute physicians, who continue to perform the most AAA repair procedures in South Florida, are invited to teach their knowledge around the state, the nation and the world.

## Pre-close Technique Avoids Surgical Incisions and Allows for Totally Percutaneous Endovascular Repair of Aortic Aneurysms

A large number of endovascular aortic repair procedures to repair abdominal aortic aneurysm (AAA) and thoracic aortic aneurysm (TAA) can now be performed without surgical incisions, using a “pre-close” technique. The procedure time associated with this technique is shorter and general anesthesia is not required. Other benefits to patients undergoing percutaneous endovascular aneurysm repair (PEVAR) with the pre-close method are earlier ambulation, less pain, decreased blood loss and fewer complications.

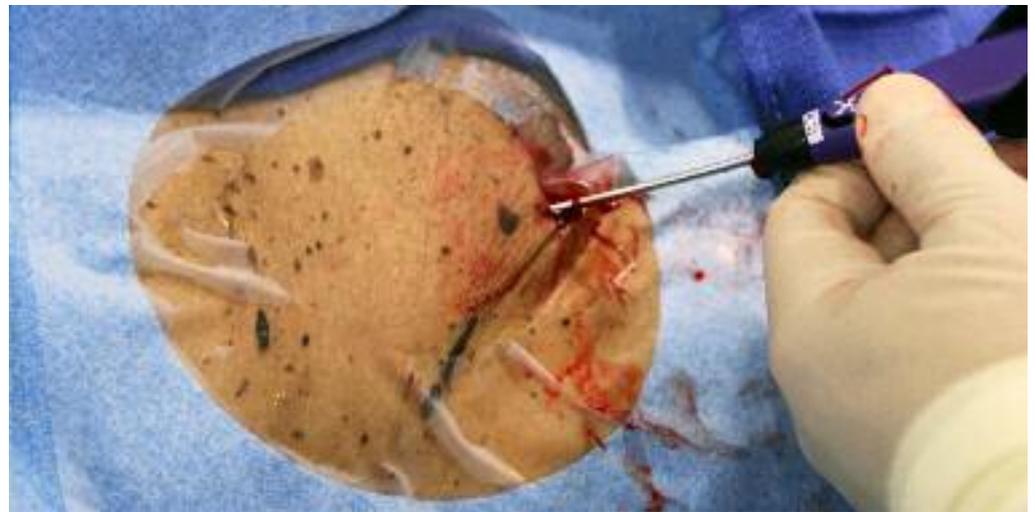
Baptist Cardiac & Vascular Institute has employed PEVAR with the pre-close technique to treat patients with AAA or TAA for several years. The Institute was one of 19 centers around the U.S. that participated in the randomized, multi-center PEVAR trial. The Institute published its own data in the February 2011 issue of the *Journal of Vascular and Interventional Radiology*.

As opposed to traditional endo-

vascular aneurysm repair, which requires two surgical incisions, PEVAR generally requires only two puncture wounds in the common femoral artery (CFA) for the insertion of a sheath and endograft device. The pre-close technique was developed to help physicians percutaneously close large arteriotomy holes that traditionally required an open surgical incision. The pre-close technique employs suture-mediated wound-closure devices during the PEVAR procedure. At the start of the procedure, the suture needles are deployed into the CFA and are used to close the artery when the

procedure is complete. This allows the physician to close larger punctures than would be possible if the suture needles were not deployed until the end of the procedure.

For more information, please contact Barry T. Katzen, M.D., Ripal Gandhi, M.D., James F. Benenati, M.D., Alex Powell, M.D., Shaun Samuels, M.D., Constantino Peña, M.D., Abilio Coello, M.D., Howard Katzman, M.D., Ignacio Rua, M.D., Athanassios Tsoukas, M.D., or Libby Watch, M.D., at 786-596-7860. ■



Deployment of proglide sutures. Two devices are needed when using a pre-close technique.

Two small incisions in the common femoral artery are all that's required for PEVAR. There are no surgical wounds.

## Cath Labs Receive ACE Accreditation

Heart catheterization labs at Baptist Cardiac & Vascular Institute and South Miami Heart Center, both part of Baptist Health South Florida, have become the first in Florida to be accredited for diagnostic heart catheterization and angioplasty or percutaneous coronary intervention.

The designation awarded by the Accreditation for Cardiovascular Excellence (ACE) means that the highest-quality standards for cardiovascular and endovascular care were met by doctors and staff caring for patients undergoing diagnostic and interventional catheterization procedures in both facili-

ties. An independent credentialing agency, ACE examines safety and patient outcomes when accrediting facilities and compares these factors, among others, to nationally accepted best practices. Applying for ACE accreditation is voluntary on the part of healthcare organizations.

Combined, Baptist Cardiac & Vascular Institute and South Miami Heart Center perform nearly 4,000 catheterizations a year. ■



**ACE**<sup>™</sup>  
Accreditation for  
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## Institute Physician First in Southeast U.S. to Perform LARIAT Procedure

A new surgical procedure offers hope for approximately 2.66 million Americans affected by atrial fibrillation (AF), and may be especially helpful to those at risk for thromboembolism, a cause of stroke. Less invasive than an open-heart procedure, the LARIAT Suture Delivery Device targets the left atrial appendage (LAA), a common source for thromboemboli. A catheter-based method for soft tissue closure, it does not leave behind a metal implant or clip in the patient's body. LARIAT was developed by physicians and tissue closure engineers at the SentreHEART Company for the purpose of creating an endothelium-to-endothelium closure solution. Baptist Cardiac & Vascular Institute was the first facility in the Southeastern United States to perform this procedure.

The LARIAT's two magnet-tipped guide wires are guided to the heart by a balloon catheter. One wire enters through the femoral vein; the other through a small incision below the

rib cage. Once the LARIAT reaches the left atrial appendage, the magnets inside the device click together, connecting the guide wires. A pretied suture loop is then "lassoed" around the wires, the balloon and left atrial appendage. Once the loop is tightened, the balloon is deflated and the guide wires are removed. The tightened loop is left around the LAA, starving it of blood flow.

The FDA-approved procedure may be useful to patients who are not able to take anticoagulant medications.

For more information on how to refer patients to the Institute for the LARIAT procedure, contact Ramon Quesada, M.D., at 786-596-7860. ■

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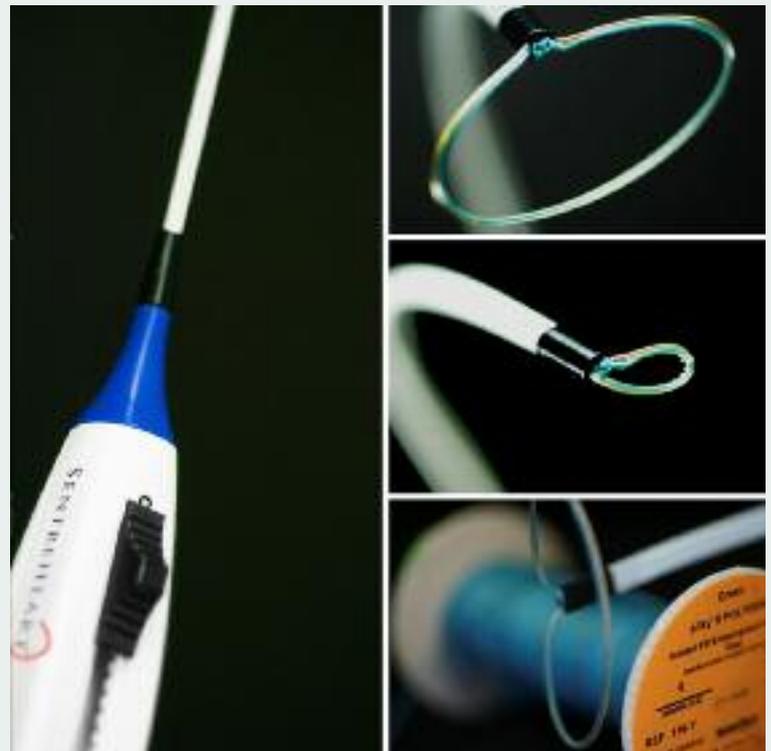
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The LARIAT Suture Delivery Device uses a Teflon-coated, braided polyester suture. When the loop is tightened, complete closure leaves behind no metal, clips or fabrics.