St. Francis Hospital a Part of Nationwide Study on Transcatheter Aortic Valve Replacement

St. Francis Hospital, The Heart Center® has been selected as one of 40 centers nationwide to test a device that may offer new hope for patients with symptomatic, severe aortic stenosis. The Medtronic CoreValve® system for transcatheter aortic valve implantation (TAVI) has recently received conditional approval from the FDA for clinical trials. St. Francis is one of the first hospitals in the U.S. to be activated as an investigational site in the study, called the Medtronic CoreValve U.S. Pivotal Clinical Trial. St. Francis cardiologists are asking for help in identifying appropriate candidates for the trial, and have begun the process of implanting it in patients who are at high risk, or are ineligible, for open-heart surgery.

Approximately 300,000 people worldwide have been diagnosed with the condition, which prevents the valve from opening completely, thereby preventing healthy blood flow from the aorta to the rest of the body. But about one third of these patients are deemed at too high a risk for open-heart surgery. Although the CoreValve system has been implanted in 12,000 patients outside the U.S., it has not been available to patients in this country until now.

“This is the most revolutionary device I’ve seen in my more than 20 years of being a cardiologist. Nothing that I have witnessed in the past can change the way we practice interventional cardiology in such a dramatic way,” says George Petrossian, M.D., Director of Interventional Cardiovascular Procedures. He is part of a four member clinical team that includes: Newell Robinson, M.D., Chairman of the Department of Cardiothoracic and Vascular Surgery; Andrew Berke, M.D., interventional cardiologist; and Roberto Colangelo, M.D., cardiothoracic surgeon.

“CoreValve has been used extensively in Europe. The expectation is that after the study is completed, and safety and effectiveness have been proven in the U.S., we will be able to treat patients that otherwise we could not have treated, and be able to improve their lifestyles so they can stay out of heart failure for a longer period of time even though they aren’t a candidate for surgery,” says Dr. Robinson.

The Hospital’s Chairman of Cardiology, Richard Shlosfritz, M.D., was instrumental in bringing the study to St. Francis. He sees a time in the future when the benefits of these types of innovative devices will be available to a broader segment of patients. “This new approach is likely to have the same impact on the treatment of valvular disease as stenting did on coronary artery disease.”

For more information on the study, including criteria for inclusion and exclusion, log on to www.clinicaltrials.gov, search on “corevalve” and see “Safety and Efficacy” study. For information about referring patients for the study, call (516) 562-6790.
Clinical Trials at St. Francis

At St. Francis Hospital, the following studies are enrolling patients:

ANTIPLATELET MEDICATION TRIALS
Richard Shlofmitz, M.D., Chairman of Cardiology, is the principal investigator of the following trials focusing on antiplatelet therapy after drug eluting stent implantation:
- The 2009 STOP (Safe Termination of Plavix) Trial focused on the level of platelet response to the antiplatelet medication, clopidogrel, in patients who receive a drug eluting coronary stent. This study demonstrated the value of testing blood platelet reactivity in patients receiving drug eluting stents.
- The PPD (Plavix, Prasugrel & Drug eluting Stents Pilot) Trial evaluates the safety and efficacy of switching patients from one antiplatelet agent to another, if the platelet response testing shows that platelet reactivity is too high on either clopidogrel or prasugrel.
Contact lyn.santiago@chsli.org or call (516) 562-6763.

HEART VALVE STUDY
Andrew Berkek, M.D., is the principal investigator of the EVEREST (Endovascular Valve Edge-to-Edge Repair) II-REPAIR Trial, which studies the safety and effectiveness of the EVALVE MitraClip® in repairing mitral regurgitation. The MitraClip®, inserted via a catheter delivery system in the cardiac catheterization lab, connects the leaflets of the mitral valve to reduce regurgitation.
Contact jeannette.mclaughlin@chsli.org or call (516) 562-6790.

CAROTID STENT TRIALS
George Petrossian, M.D., is the principal investigator of the following trials designed to study the usefulness of carotid artery stenting as a means of stroke prevention:
- The CHOICE Trial, examines the “real world” experiences of carotid artery stenting for patients at high risk for carotid endarterectomy surgery.
- The ACT I Trial, is designed to study the use of stents versus carotid endarterectomy in treating carotid stenosis in asymptomatic patients.
Contact carol.obrien@chsli.org or call (516) 562-6790.

CONVERT AF TRIAL
St. Francis cardiovascular surgeons are participating in a study of the safety and efficacy of the Epicor LP Cardiac Ablation System used to treat permanent atrial fibrillation during concomitant open chest and/or open-heart surgery.
Contact joanwendy.stovold@chsli.org or call (516) 562-6904.

IMAGING & INTERVENTION STUDIES
Nathaniel Reichek, M.D. (above), is conducting a study that explores the basis of remote ischemic conditioning (RIPC). By using a blood pressure cuff to repeatedly compress a blood vessel in the arm, RIPC may protect the heart in such procedures as stenting. The cuff is inflated during three 5-minute intervals and researchers use cardiac MRI to evaluate the effects.
- Dr. Reichek & Richard Shlofmitz, M.D., are collaborating in the SAFIR Trial (St. Francis Remote Ischemic Preconditioning Trial) designed to determine whether there is long-term benefit if RIPC is performed prior to stent implantation in patients with coronary disease.
Contact elizabeth.haag@chsli.org or call (516) 562-6790.

Miniature Cardiac Assist Devices Offer Patients More Options

Two years after undergoing coronary artery bypass surgery (CABG) and valve repair, Alice Wallace, a 79-year-old woman, underwent complex valve surgery to replace her mitral and aortic valves. The 12-hour procedure left her with a seriously weakened heart and an uncertain prognosis.

At 82, Stanley Hirsch also had a complicated history of heart disease. His issues involved extensive CABG and an implanted cardiac defibrillator (ICD) to control ventricular tachycardia. When he experienced a potentially lethal arrhythmia, despite the ICD, an angiogram revealed 95 percent blockage in a coronary artery, but he was at high risk for additional open surgery. While angioplasty with cardiac stenting was recommended, it was clear that his heart would be severely strained during the procedure.

Not too long ago, such critically ill patients would have had few, if any, options. But with the today’s highly advanced, miniature cardiac assist devices, their prospects have improved dramatically. The technology — heart pumps that provide temporary support for patients’ weakened hearts — allows the organs to rest, recover and ultimately pump more effectively on its own. Used with patients undergoing cardiac procedures that would seriously tax the heart, the devices also provide bridge therapy for patients undergoing other treatments or awaiting heart transplants.

TandemHeart®
After Alice Wallace’s valve surgery, Newell Robinson, M.D., Chairman of Cardiothoracic Surgery at St. Francis Hospital and his colleague, Harold Fernandez, M.D., inserted a TandemHeart® Pump to supplement her heart’s pumping action. The TandemHeart® is a small continuous-flow external pump connected percutaneously to the patient’s circulatory system via cannulas inserted through the femoral vein and advanced into the left atrium. The system withdraws oxygenated blood from the left atrium and returns it to one or both femoral arteries via arterial cannulas.

“The device served as a much-needed life preserver,” said Dr. Robinson. “It relieved the burden of her heart so that it could recover enough to pump on its own.” According to Dr. Fernandez, the TandemHeart® allows surgeons to support the heart and perform more complex procedures on high-risk patients. “It can provide sustained support for patients in cardiogenic shock and take over circulation even when the heart stops functioning.”

Impella 2.5
In the case of Stanley Hirsch — to reduce the heart’s work burden during angioplasty and cardiac stenting — Richard Shlofmitz, M.D., the Hospital’s Chairman of Cardiology, used an Impella 2.5 heart pump.
Insertion of the Impella pump involves the percutaneous navigation of a catheter across the aortic valve and into the left ventricle. Once in place, the device temporarily assumes left ventricular function, removing blood from the chamber and sending it through the body at the rate of up to 2.5 L per minute.

“Indications for use of the Impella pump include weak heart muscles, high risk for angioplasty, significant valvular and/or multivessel disease with decreased left ventricular function and <25 percent ejection fraction,” explained Dr. Shlomitz. “It is especially effective with patients who can’t be managed medically and are not candidates for surgery.”

Both Alice Wallice and Stanley Hirsch benefited enormously from the cardiac assist devices. After the TandemHeart®, she recovered sufficiently to continue “enjoying the pleasures of life.” And he improved so much due to stenting with support of the Impella pump that he recently fulfilled his dream to travel to Israel.

“At St. Francis, we use leading-edge high-tech tools to enable us to care for any heart patient, with any heart condition,” said Dr. Fernandez.

Recent Developments in CT Surgery
The cardiac surgical team at St. Francis Hospital, under the leadership of Newell Robinson, M.D., Chairman of Cardiothoracic and Vascular Surgery, has demonstrated extensive expertise in thoracic aortic surgery and minimally invasive heart surgery, which use smaller incisions, endoscopic techniques, and in some cases, robotic surgery. Since 1995, St. Francis Hospital has done pioneering work in these areas. “In addition to these advanced surgical techniques, the tradition of experienced operators in a high volume cardiac surgery environment has led to the outstanding outcomes that have come to be expected of the St. Francis Hospital experience,” says Dr. Robinson.

Minimally Invasive Surgery
Recently, a 38-year-old woman with severe mitral insufficiency and was symptomatic came to Dr. Robinson. She hoped to have a less invasive procedure, without having to undergo the standard operation that would result in the opening of her sternum and a long scar on her chest, Dr. Robinson was able to perform a minimally invasive surgery that allowed for a small incision through the side under her right breast. “A mitral valve repair was performed successfully and she was completely recovered within three weeks and returned to normal as a result of this minimally invasive approach,” says Dr. Robinson.

Thoracic Aortic Surgery
Led by James Taylor, M.D., Vice Chair of CT Surgery and Director of Thoracic Aortic Surgery, the thoracic aortic surgery program focuses on the treatment of large vessel disease of the chest including the ascending transfers and descending aorta both by surgical techniques as well as endovascular stenting and hybridized approaches to the care of aortic disease. The program has been committed to providing quality care to patients, while exploring new techniques that increase comfort and reduce recovery times.

Coming Next: Hybrid Operating Room Suite
This spring, St. Francis will open a new hybrid operating room suite that will allow CT surgeons and interventional cardiologists to combine minimally invasive cardiac surgical techniques and advanced interventional procedures for simultaneous treatment.

Carotid Stenting: Effective as Surgery for Stroke Prevention
Until recently, surgical carotid endarterectomy (CEA) was considered the gold-standard for treating carotid stenosis. However, the recently published National Institutes of Health CREST study (Carotid Revascularization Endarterectomy Versus Stenting Trial) has concluded that endovascular carotid artery stenting (CAS) — to improve carotid blood circulation — is as safe and effective as the surgery.

Under the direction of George Petrossian, M.D., a leading interventional cardiologist, St. Francis Hospital was the only Long Island hospital to participate in the eight-year CREST investigation – a multicenter, randomized, controlled trial that compared CEA to CAS with primary endpoints of stroke, myocardial infarction or death.

“Our analysis involved 2,500 low surgical risk patients with obstructed carotid arteries,” said Dr. Petrossian. “While every patient is different, we determined that the primary endpoint between the two modalities is equal in this low risk population. It is a huge step forward.”

Candidates for carotid revascularization include those with:
• Greater than 80 percent carotid stenosis in asymptomatic patients
• Indications for carotid stenting, based upon the landmark 2004 SAPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) study – another multicenter, randomized clinical trial designed to compare the efficacy of carotid endarterectomy with carotid artery angioplasty and stent placement in high-risk surgical patients — include:
  • Age greater than 80
  • Presence of severe cardiac disease (e.g., cardiomyopathy, unstable angina)
  • Presence of severe pulmonary disease
  • Previous radical neck surgery
  • Previous endarterectomy with restenosis
• Previous radiation of the neck with resulting scar tissue
• Contralateral carotid occlusion
• Surgically inaccessible lesions
  “The SAPHIRE trial conclusions revealed that at 30 days post procedure, the incidence of myocardial infarctions and stroke was 50 percent lower with stenting,” said Dr. Petrossian.

Using local anesthesia and X-ray guidance, Dr. Petrossian threads a catheter through the aorta into the carotid artery. He then performs a balloon angioplasty with Distal Embolic Protection at the site of the stenosis in order to widen the lumen and enable him to position the stent that will maintain vessel patency and improve cerebral blood flow.

“At St. Francis, we have implanted more than 800 carotid stents to prevent stroke, and we’ve found that stenting is as good or better an option than surgery, with restenosis rates of three-to-five percent,” reported Dr. Petrossian. “It is less invasive and offers patients a quicker recovery. Carotid stenting can, and should be, the predominant method of revascularization in 90 percent of patients.”
Integrated PET/CT — Powerful Diagnostic Modality — Debuts on L.I. at St. Francis

Building on advances in molecular imaging and image fusion, integrated PET/CT (positron emission tomography/computed tomography) scanners have joined the best of the two imaging technologies, transforming cardiologists’ ability to detect cardiac disease earlier and more accurately than ever.

At St. Francis Hospital — which has the only hospital-based PET/CT program on Long Island — the latest 64-slice, multi-detector PET/CT scanner produces PET images of coronary blood flow corrected with low-dose CT images to eliminate artifacts. The PET images can also be fused, or perfectly aligned, with detailed CT views of the heart’s internal anatomy. “This new technology gives us a much more powerful approach to assessing stress myocardial perfusion,” said cardiologist Nathaniel Reichek, M.D., the Hospital’s Director of Research.

The PET’s rubidium-82 radioactive tracer, injected into the patient’s arm, emits positrons carried by the blood stream to the heart muscle. The special PET camera detects the emitted positrons and constructs an image of the heart, revealing the distribution of blood flow in the myocardium. “With the new type of LYSO crystal, we can take more rapid count rates,” explained Dr. Reichek. “And, the high-speed, multi-detector CT, used for attenuation correction at a low radiation dose, can provide exquisite anatomic detail of coronary artery disease. As a result, it’s possible to obtain better coronary images and improved quantitative analyses of perfusion.”

Since the technologies’ integration provides unparalleled comprehensive data about cardiac function and structure, physicians can identify the full extent of a patient’s heart disease. “Because some patients’ hearts are weak, we are not sure if they’re candidates for coronary artery bypass surgery (CABG),” said Dr. Reichek. “PET/CT testing can show how much of the myocardium can potentially benefit from CABG and help determine whether it’s worth taking the risk of open-heart surgery.” Cardiac PET/CT scans, which are non-invasive and painless, can detect more than 95 percent of individuals who have significant coronary artery blockages and rarely produce false positives.

At St. Francis, the PET/CT program is provided by a nationally recognized team of nuclear medicine experts with advanced training in the new modality. “This new technology is rapidly becoming the gold standard for determining myocardial viability,” said Dr. Reichek. “It can be of enormous benefit to patients not well-served by conventional cardiac imaging.”

Wireless Pacemakers Becoming a Mainstay of Care

In 2009, Steven Greenberg, M.D. (above), Coordinator of St. Francis Hospital’s renowned Arrhythmia and Pacemaker Center, implanted the nation’s first Internet-linked, wireless pacemaker. Today, the new devices are rapidly becoming mainstays in cardiac arrhythmia care.

The technology, which provides daily, convenient home monitoring, enables physicians to provide round-the-clock care through a secure notification system that can be programmed to meet each patient’s needs. As a server and remote monitor communicate once a day, automatic reports notify physicians — and patients — when rapid atrial rates, atrial tachycardia or atrial fibrillation exceed the programmed value of the pacemaker or occur over an extended period of time. They also call immediate attention to device malfunction.

“Rather than checking a device a few times a year, the daily reports enable me to really keep tabs on patients and act more quickly,” said Dr. Greenberg. “We can pick up atrial fibrillation early on and possibly prevent stroke. The new system reduces patients’ concerns about health and device malfunction, and provides them with peace of mind.”

Peace of mind had been eluding 61-year-old Carol Kasyianski. While she had a conventional pacemaker for 20 years, she had experienced chronic technical and health difficulties. These were resolved once Dr. Greenberg implanted the new device. “I rest easier now, knowing that if there are any sudden changes in my condition or problems with the pacemaker, the wireless monitor will let me and my doctor know immediately,” she said.

Connect with St. Francis
For physician referral, please call 1-888-HEARTNY (437-2869). For information about cardiovascular services at St. Francis Hospital, call (516) 562-6725.

St. Francis Hospital
CARDIOVASCULAR Report
is published by St. Francis Hospital, The Heart Center. Questions or comments can be directed to St. Francis Hospital, Office of Development and Public Affairs, 100 Port Washington Blvd., Roslyn, New York 11576. (516) 705-6655. Copyright © 2011. All Rights Reserved. St. Francis Hospital is a member of Catholic Health Services of Long Island, the healthcare ministry of the Diocese of Rockville Centre.

Writers: Phyllis Abrams, Rosemary Gomez, LaSheka Hunter
Contributing photographer: William Baker
Designer: Roger Gorman, Reiner Design

www.stfrancisheartcenter.com