HeartWATCH

SPRING 2004

A Newsletter Produced by the Texas Heart Institute

Texas Heart® Institute
at St. Luke's Episcopal Hospital

Percutaneous Heart Valve Replacement Emerges as Alternative to Traditional Approach

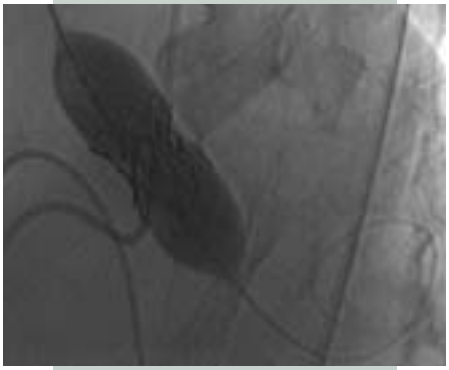
Abstract: Assisted by Latin American colleagues, cardiologists at the Texas Heart Institute have helped design a low-profile heart valve that can be implanted percutaneously using catheter techniques.

Traditionally, heart valve replacement has necessitated open heart surgery aided by cardiopulmonary bypass. According to the American Heart Association, more than 80,000 heart valve replacements are performed annually in the United States alone. Although valve replacement is often needed by elderly or otherwise high-risk patients with multiple comorbidities, in many cases it is contraindicated by a high risk of operative mortality. Thus, finding a nonsurgical alternative for valve replacement is a compelling field of research.

Since 1965, multiple investigators have tried to develop a valve that can be inserted percutaneously and that is suitable for clinical use. In 2002, Philipp Bonhoeffer, MD, performed the first human implantation of such a valve in the pulmonary position. The same year, Alain Cribier, MD, and associates, used the antegrade approach to percutaneously implant a valve in the aortic position. At about the same time, David Paniagua, MD, and coworkers performed the first retrograde implant of such a valve.

Dr. Paniagua, who trained at the Texas Heart Institute (THI) and has since joined its cardiology staff, has been working with R. David Fish, MD, director of Interventional Cardiology at THI, and with several Latin American cardiologists and surgeons, to design a percutaneously implantable heart valve. Drs. Paniagua and Fish each have an interest in Endoluminal Technology Research, LLC (Miami, FL), which holds the patent to the percutaneous heart valve they have designed.

"This valve has a unique geometric design and needs no supportive struts," he says. "It is made of specially treated porcine pericardium, has an extremely thin membrane (<40 µm), has a smooth blood-contacting surface, and is designed to resist tearing and calcification. The design incorporates a modified suture technique suggested to us by a tailor in the fashion industry. The valve is mounted in a stent that can be collapsed to a diameter of 4 mm for transcatheter delivery. It has been extensively tested in short- and long-term in vitro and in vivo studies in Costa Rica, in Miami, and here at THI. In every case, we were able to deliver the valve without subsequent embolization, and the device had excellent hemodynamic characteristics."



Balloon deployment of percutaneous valve in the aortic valve position.

"To place the valve, we advance an introducer through the femoral artery and into the abdominal aorta," explains Dr. Paniagua. "After crossing the aortic valve with a straight wire, we advance a pigtail catheter into the left ventricle to evaluate pressure gradients and anatomic characteristics. We then predilate the aortic valve with a valvuloplasty balloon. Valve implantation is achieved by superimposing the right coronary angiogram onto fluoroscopic landmarks in the same radiographic plane. We use a balloon-expandable frame to deliver the valve itself below the coronary arteries and above the mitral valve plane. This retrograde approach is more familiar than the antegrade approach, avoids creation of atrial punctures or atrial septal defects, and poses no threat of cardiac tamponade."

Until now, transcatheter treatment of diseased heart valves has mainly involved valvuloplasty, a procedure in which a specially designed balloon is used to dilate or split the commissures of a stenotic valve.

According to Dr. Paniagua, "Valvuloplasty yields excellent results in the pulmonary and mitral valve positions. With the aortic valve, however, valvuloplasty has been largely unsuccessful, relieving stenosis only partially and temporarily. Moreover, this technique cannot be used to treat aortic regurgitation. Therefore, a percutaneous aortic valve and delivery technique suitable for widespread use could benefit many patients."

Percutaneous valve replacement will be initially limited to patients who are not candidates for surgical valve replacement. With time, further device modifications should allow transcatheter valve replacement to be widely performed. ●

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Clinical Trials Update

A pair of multicenter clinical trials are underway to determine the safety and toxicity of 2 novel anti-inflammatory drugs in patients undergoing coronary artery bypass graft surgery. One of the drugs, a lipid A antagonist called E5564, is designed to lessen the systemic inflammatory response to bacterial endotoxin released from the bowel during cardiopulmonary bypass. The other drug, a blood complement inhibitor called CAB-2, is designed to thwart initiation of complement-mediated inflammation. The hope is that, by reducing systemic inflammation, the drugs will reduce the risk of postoperative organ dysfunction and death. The phase II lipid A antagonist study will enroll 150 patients; the phase I CAB-2 study, 80 patients. Charles D. Collard, MD, a THI cardiovascular anesthesiologist, is leading both trials.

Radiofrequency Catheter Ablation Advances Atrial Fibrillation Therapy

Abstract: For patients with atrial fibrillation, radiofrequency catheter ablation offers a nonsurgical and nonpharmacologic treatment option.

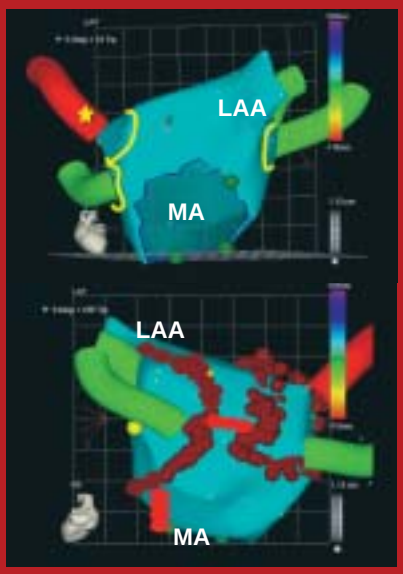
Atrial fibrillation (AF) is the most common sustained arrhythmia, during which the atria beat irregularly and rapidly. AF can cause shortness of breath, lethargy, palpitations, stagnation of blood in the atria, and other problems associated with a reduced cardiac output. The most serious threat is thromboembolism, which may result in a stroke.

At present, most patients with AF are treated pharmacologically by controlling either the heart rate or rhythm. However, antiarrhythmic drugs for rhythm maintenance are not consistently effective, and they frequently have side effects. Thus, there is increasing interest in curative strategies such as radiofrequency catheter ablation (RFCA).

Initially, RFCA involved guiding a radiofrequency catheter along designated courses within the atria, essentially reproducing the surgical Maze operation. The results were encouraging, but the procedure was long and the radiation exposure substantial. Today, RFCA procedures are directed at targeting AF triggers, isolating the AF triggers by interrupting the continuity of tissue between the triggers and the atrial myocardium, or modifying the atrial substrate. The procedure uses several recording catheters and an ablation catheter to accurately deliver the radiofrequency energy.

Early RFCA techniques entailed identifying and ablating AF triggers at precise locations, often within the pulmonary veins—hence the term "focal ablation." However, the technique has had limited success in patients with paroxysmal AF. Difficulty in eliciting the atrial ectopic beats responsible for initiating AF is the main limitation of focal ablation.

"In our experience with more than 400 patients who underwent RFCA for paroxysmal AF, less than 5% of the atrial ectopic beats emanating from within the pulmonary veins were amenable to focal ablation," says Jie Cheng, MD, PhD, a cardiologist and director of the Electrophysiology Research Laboratory at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH).



(Top) Map of anterior left atrium showing targets for focal ablation (star) and pulmonary vein isolation (yellow lines). (Bottom) Map of posterior left atrium showing targets for pulmonary vein isolation (brown dots) and for linear ablation to prevent atrial flutter (red dots). LAA, left atrial appendage; MA, mitral annulus.

The focal-ablation approach is also difficult in patients with chronic AF who have undergone cardioversion, because these patients have multiple ectopic sites dispersed throughout the atria. The alternative approach is isolation of the pulmonary veins from the left atrium, as most AF triggers are located within the pulmonary veins.

"We are now electrically isolating the pulmonary veins in the majority of patients undergoing RFCA and, in some cases, completely isolating the posterior left atrium that encompasses the pulmonary veins," says Dr. Cheng. "Before the procedure, we use MRI or CT scanning to define the anatomy of the left atrium and pulmonary veins, and we use transesophageal echocardiography to rule out intra-atrial thrombi or clots. This outpatient procedure has an 80% success rate in maintaining normal sinus rhythm and has led to an improved quality of life for many patients."

According to Dr. Cheng, serious complications are infrequent when RFCA is performed at experienced centers such as THI/SLEH. Atrial fibrillation can recur within 2 weeks after RFCA but may be a transient phenomenon, perhaps related to sterile pericarditis after the ablation. Therefore, a 2- to 3-month trial of antiarrhythmic drugs followed by an observation period is warranted before considering repeat ablation in these patients. Late-recurring AF after pulmonary vein isolation is rare and may be due to resumed conduction across the ablation scar, AF triggers outside the targeted pulmonary veins, or new reentrant circuits created by the RFCA lesions.

"RFCA is a significant breakthrough in the treatment of AF," says Dr. Cheng. "In our ongoing research, we are now focusing on modifying the autonomic innervations of the heart after AF ablation and developing new strategies that will further improve the efficacy of the ablation procedure." ●

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Implantable Hemodynamic Monitor Simplifies Treatment of Chronic Congestive Heart Failure

Abstract: The Chronicle® implantable hemodynamic monitor allows physicians to monitor congestive heart failure patients in real time, change medications promptly, and prevent acute episodes of heart failure.

For patients with moderate-to-severe congestive heart failure (CHF), which is the leading cause of death in the United States, the bad days typically outnumber the good. Many of these patients lack energy for even the simplest daily activities. For physicians, treating these CHF patients is also frustrating, since subtle changes in volume or in ventricular performance can quickly cause cardiac decompensation, often resulting in costly hospitalizations.

"Frequent follow-up examinations are currently a physician's best means of monitoring these patients' clinical status and adjusting their medications," says Frank W. Smart, MD, medical director of Advanced Heart Failure/Cardiac Transplantation at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH). "Yet, even when patients come in for follow-up examinations, we can seldom assess filling pressures without performing right-sided heart catheterization, which is costly and inconvenient for patients."

The Chronicle® implantable heart monitor is similar in size to a folded matchbook.

A new tool that can improve the quality of life for CHF patients is the Chronicle® implantable hemodynamic monitor (IHM) (Medtronic, Inc., Minneapolis, MN). This device, which can transmit data from the patient's home or any other remote location, can continuously monitor right ventricular diastolic and systolic pressures and right ventricular pulse pressure. It can also estimate pulmonary artery diastolic pressure and other clinical indicators (including heart rate and core temperature trends) to facilitate precise drug titration and to monitor the patient's response to therapy. About the size of a folded matchbook, the device is implanted below the skin in the infraclavicular region and is connected to a right ventricular lead. The implantation procedure takes about 45 minutes and can be done with local anesthesia on an outpatient basis.

By passing an electronic wand over the IHM, patients can download physiologic data to a home-based device that transmits those data to a secure Web site. Physicians can access the site at any time to review the most recent summary information, trend information, and detailed records from specified times or problem episodes. These data can indicate serious cardiac events days before their symptoms occur. Within minutes of receiving the data, a physician can adjust existing medications or prescribe additional ones as needed—before problems become life-threatening.

"The IHM allows us to address problems quickly and adjust therapy in real time. This enhances our ability to prevent acute episodes and improves our patients' quality of life," says Dr. Smart. "The IHM also helps us know that we're making the right decisions. For example, sometimes it can be hard to know whether a patient is retaining fluid. Physical findings may be sparse and lab tests misleading in the face of diminished cardiac output. Previously, catheterization was the only definitive diagnostic tool."

THI/SLEH was the first center in Texas to participate in clinical trials of the Chronicle IHM. Thus far, data from the Chronicle IHM have correlated well with data from Swan-Ganz catheters. A randomized, single-blind, phase III study is currently underway, and it is likely that the device will be approved by 2006 for use in patients with moderate-to-severe CHF.

More than 5 million Americans have some degree of CHF, and this number is rising as the population ages and more people survive heart attacks. Overall treatment costs exceed $40 billion annually, and CHF-related hospitalizations total more than 6.5 million days a year.

"Worsening heart failure is often disregarded by patients until it's too late to avoid hospitalization," says Dr. Smart. "Besides dramatically improving patients' lives, the Chronicle IHM should reduce unnecessary office visits and hospitalizations." ●

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Surgical and Endovascular Interventions for Carotid Artery Stenosis

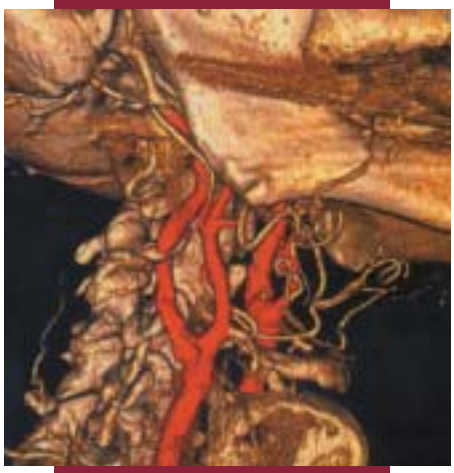
Abstract: Although carotid endarterectomy is the standard treatment for carotid artery stenosis, carotid angioplasty and stenting is under investigation as a possible alternative.

Stenosis of the common or internal carotid arteries, caused by the gradual buildup of atherosclerotic plaques, can cause serious neurologic problems, including strokes and transient ischemic attacks. When the arterial blockage is too severe to be managed medically, an interventional procedure is necessary to restore adequate blood flow to the brain.

Carotid endarterectomy (CEA) was the first interventional technique developed for treatment of carotid stenosis. First performed in 1956 by Denton A. Cooley, MD, now president and surgeon-in-chief of the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH), CEA involves clamping the affected carotid artery, opening it surgically, and removing the atherosclerotic blockage. The artery is then closed with a direct suture technique, a vein graft, or a synthetic or bioprosthetic patch. The CEA technique has a long history of safety and success.

"CEA has been the standard treatment for severe carotid stenosis for decades," says J. Michael Duncan, MD, a cardiovascular surgeon at THI/SLEH who has performed hundreds of CEAs. "The rate of perioperative stroke, which is the major risk in CEA, is 1% to 2%, and the rate of other morbidities is also low. That's why CEA has been, and should continue to be, the gold standard in evaluating any new form of treatment."

Since 1995, THI/SLEH physicians have been involved in trials of another procedure for treating carotid stenosis—carotid angioplasty and stenting (CAS). In CAS, a balloon catheter is inserted into the femoral artery and threaded up into the carotid artery, where the balloon is inflated to push plaque aside and restore normal blood flow. A stent is then inserted to keep the artery open. The procedure's safety depends on the use of an embolic protection device—a fine, wire-mesh screen that is inserted above the balloon to catch any plaque dislodged during angioplasty. This reduces the risk of stroke during the procedure.



Computed tomographic image of the carotid arteries.

The relative usefulness of CEA versus CAS has been the subject of intense debate. Because CAS is relatively new, developments in its technique—particularly the addition of embolic protection devices—have come quickly and have rapidly improved safety. Whereas older trials show a distinct advantage of CEA over CAS in terms of lower postoperative stroke and death rates, newer trials tend to show similar outcomes for the 2 techniques. Nonetheless, no CAS device has yet been approved by the U.S. Food and Drug Administration.

"THI has been involved in several large, multi-institutional trials of CAS," says cardiologist Zvonimir Krajcer, MD, codirector of the Peripheral Vascular Disease Service at THI/SLEH. "The results suggest that when an embolic protection device is used, CAS is as effective as CEA in lowering the risk of stroke and death. Furthermore, CAS doesn't involve a neck incision or general anesthesia, so recovery is generally quicker, and there is no risk of cranial nerve injury as there is with CEA."

Nevertheless, there is still debate over which patients are best suited for each procedure.

"In patients who have had a previous CEA, neck radiation, or radical neck surgery—especially those who have comorbid conditions—CAS appears to produce superior results," says Dr. Krajcer. "It may also be the better choice for patients with carotid blockage above the level of the neck, allergies to general anesthetics, or cranial nerve damage from a previous CEA that could be aggravated by a subsequent CEA. On the other hand, CEA would be preferred if a fresh thrombus in the carotid artery could become dislodged and embolize during CAS, or if the patient's vessels are too tortuous for catheterization."

More study and follow-up will be needed before physicians can firmly assert whether CEA or CAS is the best technique for any particular population of patients with carotid stenosis. Having a choice of treatments, however, is likely to improve the outcomes for all of these patients. ●

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12th AbioCor Implanted

On February 20, 2004, surgeons at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) performed the 12th implantation worldwide of an AbioCor Implantable Replacement Heart (ABIOMED, Inc., Danvers, MA). It was the fifth such implantation performed at THI/SLEH as part of an ongoing, FDA-sponsored multicenter clinical trial that will include a total of 15 patients.

Caregivers Seek New Approaches to Managing Postoperative Pain

Abstract: Direct delivery of anesthetic agents and use of minimally invasive surgical techniques can reduce pain after cardiac surgery.

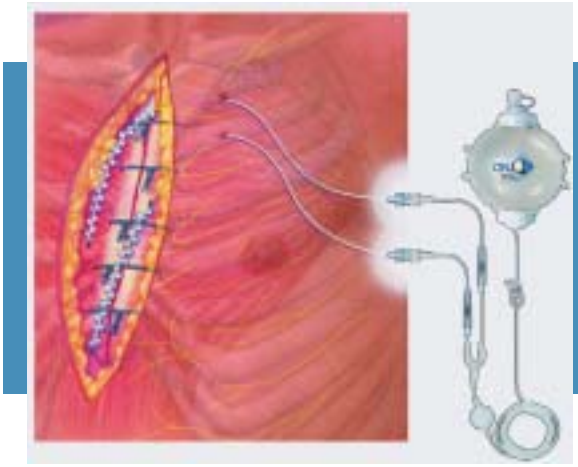
For the 6 million Americans who undergo cardiovascular operations each year, effective postoperative pain management is crucial. However, traditional methods of controlling postoperative pain have considerable drawbacks.

"Historically, postoperative pain has been treated with large doses of opioids (narcotics), which may cause excessive sleepiness and interfere with the recovery of bowel and bladder function," says Ross M. Reul, MD, director of Surgical Innovation at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) and a member of SLEH's Pain Management Committee. "Furthermore, not only can narcotics be abused, but they can also cause neurologic deficits. These complications are of special concern in our older patients, who make up a large subset of patients requiring cardiac surgery."

One alternative to using heavy doses of opioids is to deliver nonnarcotic relief directly and continuously to the incision site. A novel device designed for this purpose, the ON-Q® system (I-Flow Corp., Lake Forest, CA), is now being used at THI/SLEH.

"The system, which consists of a small balloon pump and catheter inserted during surgery, functions much like a soaker garden hose, directly and continuously irrigating the incision site with a long-acting local anesthetic, such as ropivacaine," explains Dr. Reul. "This approach decreases the incidence of breakthrough pain and provides relief without introducing the potential side effects of large doses of narcotics. The pump can be carried or attached to a patient's belt, and it may be removed during clinic visits or by the patient at home."

Two separate studies (*Anesthesiology* 2003; 99:918–23; *J Thorac Cardiovasc Surg* 2003; 126:1271–8) have shown that continuous catheter infusion of a local anesthetic (ropivacaine or bupivacaine) decreases pain and the need for opioids and improves patient satisfaction with pain management after a median sternotomy. Patients who received infusions of a local anesthetic were able to resume walking earlier, thus shortening their hospital stay.



Placement of the ON-Q® system in a sternotomy incision for delivery of nonnarcotic pain relief. (Reprinted with permission from I-Flow Corp.)

"Initially, we began using the ON-Q system in patients who could not tolerate narcotics or had previously shown a low pain threshold after surgery," says Dr. Reul. "Then, because of self-reported improvements in pain relief in this group, we began using the system routinely in selected patients undergoing a thoracotomy or sternotomy. Those who had previously undergone a sternotomy and received conventional pain treatment reported better pain control with the ON-Q system after their subsequent sternotomy."

The ON-Q system is not indicated in all cases, however. Immunosuppressed patients are not candidates because of the slight risk of infection during device insertion. Patients with hepatic failure are not candidates because local anesthetics such as ropivacaine are metabolized and eliminated by the liver.

In another approach to reducing postoperative pain, THI/SLEH surgeons are also exploring the potential of minimally invasive procedures such as endoscopic vein harvesting for coronary bypass procedures, ministernotomy for aortic valve replacement, and smaller incisions for mitral valve and right-sided heart procedures.

"Minimally invasive approaches," says Dr. Reul, "may lead to shorter intubation periods, earlier ambulation, less scarring, earlier hospital discharge, and, equally important, less postoperative pain."

In step with these efforts is the work of the Pain Management Committee, chaired by Brian Miles, MD, medical director of the Texas Cancer Institute, and Porter Storey, MD, medical director of the Palliative Care Center, both at SLEH. The committee was formed in 1999 to enhance pain management policies and practices and to increase knowledge about pain management among health care providers as well as patients and their families. The multidisciplinary group meets regularly to discuss pain resources, appropriate use of analgesics, documentation of pain as a fifth vital sign, and alternative therapies.

"The goal is to improve patient satisfaction without compromising surgical safety," says Dr. Reul. "Using small incisions, when safe, and providing nonnarcotic means of pain relief are reliable ways of improving postoperative pain control." ●

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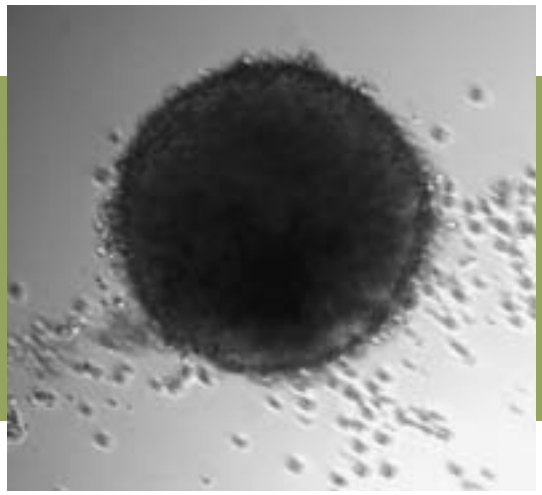
Nicotine May Trigger Stem Cells to Differentiate into Viable Cardiac Cells

Abstract: Recent laboratory research at the Texas Heart Institute suggests that nicotine given at low doses may be useful in treating heart failure.

Nicotine is a poisonous by-product of tobacco that increases heart rate, ventricular stroke volume, myocardial oxygen consumption, and breathing rate and causes arterial constriction. In cigarette smokers and smokeless tobacco users, increased concentrations of nicotine in the blood are associated with the pathogenesis of cardiovascular disease, particularly atherosclerosis. Yet, paradoxically, recent laboratory research at the Texas Heart Institute (THI) suggests that nicotine given at doses much lower than the harmful doses delivered by smoking or smokeless tobacco may become a new method for treating heart failure.

This novel therapy would involve the transplantation of nicotine-stimulated stem cells. Stem cells are precursor cells that are found in both embryonic and adult tissues and that can differentiate into many other types of cells. Because of ethical issues, U.S. law severely restricts research involving human embryonic stem cells to limited cell lines in the laboratory setting. Thus, information regarding stem cell biology has come largely from studies of animal embryonic stem cells.



Embryoid body containing mature, differentiated cardiac muscle cells derived from murine embryonic stem cells stimulated with nicotine.

Since spring 2003, researchers in THI's Heart Failure and Stem Cell Research Laboratory have been studying the effects of a purified form of nicotine on stem cell growth and differentiation. Led by Yong-Jian Geng, MD, PhD, the laboratory's director and director of the Center for Cardiovascular Biology and Atherosclerosis Research at The University of Texas Health Science Center at Houston, the THI researchers have found that nicotine can influence the differentiation of mouse embryonic cardiac stem cells in culture and can significantly increase the rate of stem cell division. Moreover, in studies at the molecular level, they have discovered that nicotine treatment can alter gene expression and increase the production of cellular proteins at different stages of cardiovascular cell development.

These findings complement other stem cell therapy research underway at THI. Dr. Geng and his team, along with James T. Willerson, MD, medical director and director of Cardiology Research, have found evidence that cardiac stem cells transplanted from one species of animal into another can develop into new cardiovascular tissue. In an ongoing collaboration with Brazilian cardiologists, THI researchers are continuing their follow-up of Brazilian heart failure patients who have undergone autologous adult stem cell transplantation.

Previous animal studies at other centers had already shown the potential usefulness of nicotine in treating heart failure. For example, one recent study in a rabbit model of hind-limb ischemia showed that nicotine could enhance the recruitment of circulating stem cells into damaged tissues, where the stem cells could promote the generation of new blood vessels (*J Am Coll Cardiol* 2003; 41:489–96). Another study, in rats, showed that nicotine could inhibit the lipopolysaccharide-induced apoptosis, or self-destruction, of cardiac myocytes (*J Am Coll Cardiol* 2003; 41:482–8). In both cases, however, the mechanisms underlying nicotine's apparent action remained unclear.

"Our recent laboratory findings confirm and extend earlier studies supporting the hypothesis that nicotine can boost the regenerative abilities of stem cells in patients with heart failure," says Dr. Geng. "Our findings also provide us with a better, though still incomplete, understanding of the genetic and cellular mechanisms by which nicotine regulates cardiovascular cell development."

"It's important to remember, however," cautions Dr. Geng, "that our observations made in animal cells may not translate directly into the clinical setting. The receptors of nicotine, whose pharmacology is very complex, perform many different functions throughout the body and activate neurohormonal systems whose effects can either cooperate with or antagonize each other. The body's responses to nicotine also depend on the dose and duration of exposure. Thus, whether nicotine will do more harm than good in treating heart failure will ultimately have to be determined in careful long-term studies in humans." ●

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Cover: Detail from artwork by Bettie Ward, donated by Jerry Goldstein, Post Gallery, for the Celebration of Hearts display in the Wallace D. Wilson Museum of the Texas Heart Institute at St. Luke's Episcopal Hospital—The Denton A. Cooley Building.

Calendar of Events

Texas Heart Institute Continuing Medical Education Symposium

Texas Heart Institute The Implantable Left Ventricular Assist Device: From Concept to Clinical Reality
May 21–22, 2004
Houston, Texas
Program Directors: Denton A. Cooley, MD; O.H. Frazier, MD; Frank W. Smart, MD; James T. Willerson, MD

Denton A. Cooley Cardiovascular Surgical Society 14th International Symposium A Homecoming
October 6–10, 2004
Houston, Texas
Program Directors: Francis Wellens, MD; James J. Livesay, MD; O.H. Frazier, MD; Michael J. Reardon, MD; Denton A. Cooley, MD
Abstract submission deadline: July 1, 2004

Texas Heart Institute Fourth Symposium on Congestive Heart Failure
October 21–22, 2004
Houston, Texas
Program Director: Sayed Feghali, MD

For information about the CME activities listed above, please contact cme@heart.thi.tmc.edu or call 832.355.2157.

Selected Upcoming National and International Meetings

International Society for Heart and Lung Transplantation 24th Annual Meeting and Scientific Sessions
April 21–24, 2004
San Francisco, California

American Heart Association Scientific Sessions 2004
November 7–10, 2004
New Orleans, Louisiana
Abstract submission deadline: May 28, 2004

Society of Thoracic Surgeons 41st Annual Meeting
January 23–26, 2005
Tampa, Florida
Abstract submission deadline: August 20, 2004

American College of Cardiology 54th Annual Scientific Session
March 6–9, 2005
Orlando, Florida
Abstract submission deadline: September 8, 2004

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