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A NEWSLETTER PRODUCED BY THE TEXAS HEART INSTITUTE





Hamster Study Shows the Potential Prognostic Value of Body Temperature in Human Cases of Congestive Heart Failure

Abstract: A study performed at the Texas Heart Institute at St. Luke's Episcopal Hospital showed that, in a hamster model of congestive heart failure, death is preceded by a decrease in core body temperature.

Hospitalization for congestive heart failure (CHF) is associated with high rates of postdischarge readmission and mortality. In the United States alone, hospitalizations for CHF rose from 400,000 in 1979 to 1.1 million in 2005 (a 171% increase), and the projected direct and indirect costs of CHF-related hospitalizations in 2008 total \$34.8 billion.

Although many clinical and investigational parameters are known to correlate with a poor prognosis in CHF patients, there is no unique, simple marker for identifying high-risk patients. However, researchers in the Advanced Physiologic Monitoring Laboratory at the Texas Heart Institute (THI) at St. Luke's Episcopal Hospital believe they have a promising lead.

"Of the variables that can be monitored in CHF patients, we are most interested in body temperature, for 2 reasons," says Amany Ahmed, MD, a research scientist in the Laboratory. "First, several THI studies led by Dr. Ward Casscells have shown that, in patients with decompensated CHF, hypothermia at hospital admission is a predictor of short-term mortality. However, these studies did not reveal whether hypothermia simply signals inevitable death or whether it could be a useful indicator for more intensive intervention. Second, temperature is easy to measure, in or out of the clinic."

To clarify the association of hypothermia with outcome in CHF patients, Dr. Ahmed and her colleagues studied body temperature and mortality in Bio-TO-2 Syrian dilated cardiomyopathic hamsters. These animals are genetically predisposed to cardiac enlargement and thinning of the cardiac walls, as seen in human CHF patients.

"These hamsters are not only a good model of CHF but are also large enough to allow implantation of the Data Sciences International [DSI; St. Paul, MN] transmitter that monitors body temperature and physical activity," says Alan Brewer, MBA, the Laboratory's assistant director.

Dr. Ahmed and colleagues randomly assigned 48 cardiomyopathic hamsters to 3 different temperature conditions. Sixteen hamsters were kept at 21 °C throughout the study; another 16 hamsters were kept at 21 °C until their average



The implantable temperature-andactivity monitor (top) can detect the gradual decline in core body temperature (bottom) that typically precedes death in a hamster model of congestive heart failure.

physical activity level dropped to 50% of baseline, after which they were kept at 26 °C; and 16 hamsters were kept at 26 °C throughout the study. The researchers expected that cardiomyopathic hamsters kept in a cooler environment would die of heart failure sooner than those kept in a warmer environment. The results, however, contradicted this expectation: the mean survival time was shortest (170 days) in the hamsters kept at 26 °C, somewhat longer (195 days) in the hamsters switched from 21 to 26 °C, and longest (210 days) in the hamsters kept at 21 °C. The researchers theorize that this occurred because of altered thermoregulation associated with heart failure. As a result, the temperature of 26 °C may have constituted a stressor for the hamsters.

The experimenters also observed that, before death, core temperature declined in 98% of the hamsters, regardless of the external temperature. Sreedevi Gondi, MD, a research fellow in the Laboratory, says, "On average, this decline began 8 days before death, suggesting that the core temperature may reflect a CHF patient's health status. It remains to be seen how this decline can be used to guide medical intervention and, thus, improve the prognosis in CHF patients."

Mr. Brewer adds, "In inpatient settings, many heart failure patients have devices, such as indwelling catheters, that can measure the core temperature continuously. Additionally, pacemakers and other implantable devices for CHF patients could include temperature sensors to monitor the core body temperature in outpatients. These temperature data could be used as prognostic indicators and perhaps as triggers for further intervention."

For more information:

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MICHAEL E. DEBAKEY, MD, HONORED AT DENTON A. COOLEY CARDIOVASCULAR SURGICAL SOCIETY MEETING

"Celebrating the Legacy" was an especially appropriate theme for the recent Denton A. Cooley Cardiovascular Surgical Society's 15th International Symposium. At that program, Dr. Cooley recognized Dr. Michael E. DeBakey for his lifetime achievements in surgery and presented him with honorary membership in the Cooley Society. Symposium guests joined members of the faculties of Baylor College of Medicine and the Texas Heart Institute in a standing ovation for the 99-year-old surgeonstatesman.



Dr. DeBakey and Dr. Cooley

New Standardized Treatment Practice Implemented for Patients With ST-Segment Elevation Myocardial Infarction

Abstract: Clinicians at the Texas Heart Institute at St. Luke's Episcopal Hospital have created a treatment protocol that surpasses national guidelines for managing ST-elevation myocardial infarction.

The American College

of Cardiology (ACC) and the American Heart Association (AHA) 2007 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (STEMI) provide practical recommendations for managing STEMI. The guidelines state that patients who present to the emergency department (ED) with symptoms of STEMI should be evaluated and treated according to a predetermined, institution-specific protocol. The goal is to provide antithrombotic therapy within 30 minutes of a patient's arrival at a minor emergency center or to initiate a percutaneous transcatheter intervention within 90 minutes of arrival at a hospital.

Clinicians at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI at SLEH) have created a STEMI treatment protocol that surpasses the ACC/AHA's guidelines. This initiative began in early 2007, when a few staff nurses from the Cardiac Catheterization Laboratory and the ED and a small focus committee decided that a more intensive effort was needed. Within 5 months, the group evolved into the STEMI Committee: a stand-alone interdepartmental, multidisciplinary team of physicians, nurses, and non-medical participants. The Committee reports to the hospital's Core Measures Committee and chief executive officer. Cardiologists and ED physicians provide peer review and medical direction.

"Getting a patient with STEMI to the catheterization laboratory is fairly straightforward if the ambulance team gives you a 30-minute warning, especially during the day, when all resources are readily available in-house," says Larry Brown, RN, a senior staff nurse in the Cardiac Catheterization Laboratory at THI at SLEH and an original member of the STEMI Committee. "It is much harder to achieve a 90-minute door-to-balloon time if patients drive themselves to the hospital in the middle of the night."

"Since the STEMI Committee was formed and the new protocol was implemented, all of our STEMI patients have had door-to-balloon times of less than 75 minutes," says James M. "We are working to ensure that, once patients with STEMI arrive at our hospital, each minute will be used effectively to maximize their chance of recovery."

Wilson, MD, director of Cardiology Education at THI at SLEH and a Committee member. "The new protocol standardizes all aspects of care, from treatment protocols to administrative processes. Even decisions about necessary supplies and equipment are predetermined and incorporated into the treatment plan, making patient care more efficient." Another new feature of the SLEH protocol is that it allows ED triage nurses to initiate the STEMI protocol without direction from an ED physician or cardiologist.

"Patients with chest pain immediately undergo 12-lead electrocardiography on admission to the ED," says Mr. Brown. "Because triage nurses receive basic training in ECG interpretation, it makes sense for them to initiate the STEMI protocol if the ED physician is not immediately available to interpret the electrocardiogram. This takes important minutes off the total treatment time."

Before patients are sent to the catheterization laboratory, an ED physician, a cardiology fellow, or a staff cardiologist examines them to confirm that their ST elevation is due to myocardial infarction.

The new protocol also streamlines caserelated communication. A single call to the page operator notifies the entire STEMI team, including the on-call interventional cardiologist. The ED unit secretary then contacts the patient's private cardiologist, if the patient has one. If the cardiologist responds to the page before catheterization is begun, he or she will provide primary medical direction. If, however, the private cardiologist cannot respond immediately, the interventional cardiologist assumes primary responsibility, ensuring that treatment is not delayed. If the private cardiologist responds at any time during treatment, the 2 cardiologists work together.

"Patients frequently ignore signs and symptoms of a heart attack instead of calling 9-1-1. Also, patients or family members often drive to a hospital instead of calling an ambulance," says Mr. Brown. "Although our new protocol does not address these issues, we are working to ensure that, once patients with STEMI arrive at our hospital, each minute will be used effectively to maximize their chance of recovery."

For more information:

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Researchers Compare Current and New Noninvasive Imaging Techniques for Characterizing Atherosclerotic Plaque

Abstract: Preclinical studies show that flat-panel computed tomography permits better in vivo detection and characterization of vulnerable plaques than does clinically used 64-slice multidetector computed tomography.

To identify atherosclerotic

lesions that are vulnerable to rupture, physicians must be able to distinguish plaques that are primarily lipid-rich from those that are mainly composition," says Ibrahim Aboshady, MD, a scientist in the department of Cardiovascular Pathology at the Texas Heart Institute (THI) at St. Luke's Episcopal Hospital (SLEH). "Howsoft plaque," says L. Maximilian Buja, MD, chief of Cardiovascular Pathology at THI at SLEH. "However, with FpCT scanning, we were able to identify more lipid pools, even those as small



calcified (fibrous). High-risk plaques usually comprise a large lipid core covered by a thin fibrous cap. The lipid core has considerable tissue heterogeneity and contains varying amounts of calcium deposits.

Currently, multidetector computed tomography (MDCT) is used to detect and evaluate vulnerable plaques. However, this method primarily measures calcification in the coronary arteries.

"Because MDCT scanners have a relatively low spatial and temporal resolution, they cannot provide detailed information about plaque



ever, technical advances in CT scanning and the use of plaque-specific contrast agents may allow more complete evaluation of the type and progression of atherosclerotic lesions."

One such advance is flat-panel computed tomography (FpCT), which is undergoing preclinical testing by Dr. Aboshady and his colleagues. They hypothesized that FpCT would permit better in vivo characterization of vulnerable atherosclerotic plaques than does 64-slice MDCT.

After sedating 8 Watanabe hyperlipidemic rabbits, Dr. Aboshady and his group performed 64-slice–MDCT scanning of the rabbits' aortas without a contrast agent. Suspended mechanical ventilation was used during imaging. Slices were reconstructed to a thickness of 0.625 mm. A contrast agent was then injected through an ear vein, and scanning was repeated 30, 60, and 90 seconds later. The rabbits were then transferred to an FpCT scanner, where imaging was repeated with the same contrast protocol. The images were reconstructed at voxel sizes down to 0.100 mm.

The rabbits were humanely killed, and their hearts and aortas were excised. The aortas were serially sectioned at 2- to 3-mm intervals, and the tissues were processed for light microscopy. When the histologic findings were compared with the 64-slice–MDCT and FpCT findings, all of the data correlated well. However, neither scanning technique could measure the thickness of the fibrous cap over larger lipid pools.

"The 2 imaging modalities were equally capable of distinguishing calcium deposits from

as 0.4 mm. Only with FpCT scanning could these pools be distinguished from fibrous wall thickening."

"FpCT imaging provides not only higher spatial resolution but also isotropic voxels," adds Dr. Aboshady. "Although the wide-angle cone geometries of FpCT scanners impose various system-level constraints and present new challenges, particularly in the areas of scatter correction and image reconstruction, the scanners can achieve the demanding resolution needed for imaging high-risk plaques."

"Compared to 64-slice MDCT, FpCT provides excellent resolution and contrast sensitivity for distinguishing components of atherosclerotic plaque," Dr. Buja continues. "On the basis of our results, we believe that FpCT would be useful in longitudinal studies of plaque development and progression. Our results may also have encouraged our investigators to study the use of FpCT for early prediction of atherosclerotic diseases of the brain, such as stroke or multi-infarct dementia, with a nanoparticulate contrast medium."

For more information:

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Molecular Studies Focus on the Genetics of Hypertrophic Cardiomyopathy

Abstract: The identification of genes responsible for hypertrophic cardiomyopathy has helped usher in the molecular era in the diagnosis and management of cardiovascular diseases.

Advances in molecular

genetics are paving the way for a new era of genomic medicine. Leading this effort, researchers at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI at SLEH) and the Brown Foundation Institute of Molecular Medicine are gearing up to provide genetic testing for patients with cardiovascular diseases. Ali J. Marian, MD, professor of Adult Cardiology at THI at SLEH and of Molecular Medicine and Internal Medicine (Cardiology) at The University of Texas Health Science Center (UTHSC) at Houston, and his colleagues are studying the genes and mutations that cause heart disease. This research, conducted in collaboration with James T. Willerson, MD, president-elect and medical director of THI at SLEH and president of UTHSC at Houston, is part of the TexGen research project, which has been designed as a clinical and genetic data resource for future research at the Texas Medical Center.

Initial studies in molecular cardiovascular medicine have focused on familial diseases such as hypertrophic cardiomyopathy (HCM), which are caused by a single mutation in a single gene and are inherited in an autosomal dominant pattern. Hypertrophic cardiomyopathy is a major cause of heart failure and sudden cardiac death. Over the last decade, more than 100 mutations in a dozen genes have been identified in patients with HCM. Although most of these mutations have been found in genes that code for contractile sarcomeric proteins, the causal genes are unknown in about a third of HCM patients.

Dr. Marian's group recently identified a novel causal gene for HCM (*Circ Res* 2007;100: 766-8). By studying a family in which 6 members have HCM, these researchers detected mutations in the *MYOZ2* gene, which encodes a Z-disk protein—myozenin 2 (calsarcin 1) —found only in striated muscles. Because myozenin interacts with calcineurin, a critical component of calcium-signaling pathways, mutations in the *MYOZ2* gene appear to cause HCM via a unique mechanism.

"The identification of mutations in the *MYOZ2* gene illustrates the diversity of the



The pedigree of an HCM family that underwent genetic study after an asymptomatic family member died young. The causal mutation was identified, allowing early diagnosis of HCM in a young member who then underwent placement of a defibrillator, which, 2 years later, corrected malignant ventricular arrhythmias that would have led to sudden cardiac death.

Black circles (females) and squares (males) indicate clinically affected individuals; slashed symbols represent family members who died early.

genetics and pathogenesis of HCM," states Dr. Marian. "In fact, we may have to define subsets of HCM according to genetic findings to implement gene-specific treatment for HCM patients."

The variability in the phenotypic expression of HCM, found even among affected family members with the same causal mutation, has led Dr. Marian's group to study modifier genes, genes other than the causal gene that contribute to the expression of hypertrophy in HCM patients. In a large-scale study of the genome of 100 members of an HCM family, Dr. Marian and associates recently mapped the locations of 4 modifier genes that affect the severity and expression of the disease (*Hum Mol Genetics* 2007;16:2463-71). These genes may affect cardiac fibrosis and apoptosis; however, the exact mechanisms are unknown.

Clinically, genetic testing is used in familial settings in which family members who carry the genetic defect, and thus are at risk of developing HCM, can be distinguished from those who do not have the mutated gene (*see Figure*). Furthermore, genetic testing provides information that, when combined with clinical data, can be used to individualize patient care and ascertain the risk of sudden death.

"Today's molecular technology allows us to identify the genetic defect in about 60% of patients with HCM. Within a few years, we should be able to identify the mutation in almost all cases," says Dr. Marian. "Genetic information will probably become part of the routine care of patients with cardiovascular disease."

Dr. Marian's and Dr. Willerson's research groups are applying the same genetic techniques used in patients with HCM to study the identification of genes that cause premature heart attacks. This research effort is in its early stages and is also part of the TexGen research project. ●

For more information:

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In Complicated Cases, Surgical Expertise and Experience Are Often Decisive Factors

Abstract: Surgeons at the Texas Heart Institute at St. Luke's Episcopal Hospital can often save patients who have complicated heart conditions considered inoperable by surgeons at other centers.

For most surgical procedures, including cardiac operations, the likelihood of a good outcome depends on the expertise of the involved hospital and surgical team. As a rule, centers with more experience have better outcomes, especially in treating rare or complicated conditions. No better proof of this principle may be found than in a patient recently treated by David A. Ott, MD, a cardiovascular surgeon at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI at SLEH) and a clinical professor of surgery at the University of Texas Medical School at Houston and at Baylor College of Medicine.

The patient was Vilmarie Talavera, a 32-year-old optometrist from Hatillo, Puerto Rico. In July 2007, she consulted her local cardiologist for shortness of breath, palpitations, dizziness, and fatigue. Radiography showed what appeared to be a large tumor in the left side of her chest, near her heart. She under-

TEXAS HEART INSTITUTE DEVELOPS A NEW RISK-SCORING PROTOCOL

To better treat high-risk cardiac patients, physicians and statisticians at the Texas Heart Institute (THI) at St. Luke's Episcopal Hospital have developed a simplified risk-assessment protocol based on preoperative and operative clinical criteria. Known as the THI Risk-Scoring Technique (THIRST), the protocol draws on THI's exceptionally large, accurate clinical database in order to predict in-hospital operative risk. Currently, the protocol includes 3 separate components for assessing the risk of coronary artery bypass grafting, valve replacement, and percutaneous coronary intervention. Other components will be added with time. According to MacArthur Elayda, MD, PhD, vice president and chief of Biostatistics & Epidemiology at THI, "By predicting the likelihood of postoperative in-hospital mortality, THIRST enhances the surgical decisionmaking process for physicians and patients alike. The availability of this protocol is one reason why heart surgery patients, especially those with complex conditions, tend to have excellent outcomes at our center."



Vilmarie Talavera and her husband, Josué Garayua, shortly before she was discharged from SLEH.

went a left thoracotomy in Puerto Rico, but the surgeons did not remove the tumor, saying that it was unresectable and malignant—probably a sarcoma.

In October 2007, believing that she was dying, Mrs. Talavera traveled to Houston to consult Jorge Garcia-Gregory, MD, a cardiologist at THI at SLEH. He recommended Dr. Ott for tackling this complex surgical problem. Preoperative magnetic resonance imaging could not clarify whether the mass was a cancerous tumor but did confirm that it was closely attached to the heart and perhaps not removable.

"We operated on Mrs. Talavera through a median sternotomy in order to have optimal surgical control in attempting to remove the mass from the back wall of her heart," states Dr. Ott. "We found that, instead of being a tumor, the mass was a walled-off, thrombusfilled coronary artery aneurysm that had turned into scar tissue. It was probably the largest coronary aneurysm we had ever seen. Fortunately, we were able to remove the lesion without damaging either the heart or its valves. We could do this without entering the heart muscle, because the mass was limited to the surface. However, we had to stop the heart in order to remove the mass safely."

For Mrs. Talavera, it was like a miracle to awaken from her operation and learn that she never had cancer at all. Her cardiac mass was indeed life-threatening, but now that it has been properly treated, she should have a normal life expectancy. When interviewed in her hospital room shortly before being discharged home (*see Figure*), she had the highest praise for her doctors and nurses at THI at SLEH. "My local physicians did their best," she said, "but they were unable to properly diagnose and treat my condition. If I had not sought treatment at THI, my life expectancy might have been quite short."

Mrs. Talavera's decision to seek treatment on the US mainland may have been influenced by the fact that she attended a university and an optometry college in the Midwest, so she had already spent considerable time here. She chose THI because of its extensive surgical experience, outstanding reputation, and excellent results in treating high-risk, complex cases.

"At THI at SLEH," concludes Dr. Ott, "we were fortunate to have resources that Mrs. Talavera's physicians in Puerto Rico did not have. Therefore, we were able to undertake a more extensive operation in an effort to help her. In view of the superb outcome, all of us who participated in her case are extremely happy for this young woman."

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Expanding the Options for Heart Failure Treatment: The AbioCor Total Artificial Heart

Abstract: The AbioCor Implantable Replacement Heart may now be available for a greater number of patients with end-stage heart failure who lack an alternative form of treatment.

Early this year, the United States Food and Drug Administration (FDA) granted Humanitarian Device Exemption (HDE) supplement approval to Abiomed, Inc. (Danvers, MA), on systems upgrades for the company's AbioCor® Implantable Replacement Heart. This device is intended for patients with end-stage heart failure who are mortally ill and who lack an alternative form of treatment. The supplement approval expands the options for using the AbioCor Heart. Under the new protocol, the Texas Heart Institute at St. Luke's candidates, such as those with cardiac tumors or amyloidosis of the heart.

The 2-pound AbioCor TAH consists of 2 artificial ventricles, their corresponding valves, and a motor-driven hydraulic pumping system. An implantable electronics package monitors and adjusts pump speed, based on the patient's activity level. The AbioCor's internal battery offers approximately 30 minutes of power without an external source, while the rechargeable external battery can power the device for more than 4 hours before it needs to be exchanged.



Episcopal Hospital (THI at SLEH) is 1 of 4 sites to implant the device.

In a previous FDA-approved trial, 14 patients received the AbioCor at 4 approved US implant centers, including THI. The trial showed that the device is safe and that it can extend survival by several months to more than a year in some cases. The longest-surviving recipient lived 512 days.

According to O. H. Frazier, MD, director of the Center for Cardiac Support at THI at SLEH, "Heart transplantation is an effective but limited method of treating terminal heart failure. It is limited not only by its dependence on an adequate supply of suitable donor hearts but also by its inapplicability to patients whose disease has progressed to such a degree that they may have a life expectancy of less than a month. In addition to benefiting these patients, a total artificial heart (TAH) could be lifesaving for heart failure patients who are otherwise not transplant Initial experience with the AbioCor showed a low risk of infection, probably because it is the only cardiac support device that offers transcutaneous energy transmission (TET). In TET, an external coil transmits electromagnetic waves across the skin to an internal coil, thereby powering the device without penetrating the skin. By avoiding skin penetration, this arrangement decreases contamination that can cause infection.

Because it is larger than the natural human heart, the current version of the AbioCor Heart is too big to fit 50% of the population (including most women and children). However, Abiomed is designing a smaller model, the AbioCor II, which should fit a wider range of patients.

"Our experience shows that the AbioCor TAH has potential for use in end-stage heart failure patients with no other treatment option," concludes Dr. Frazier. "The AbioCor not only can improve the survival but also can enhance the quality of life of these mortally ill patients. With further device improvements and wider clinical experience, this TAH should be applicable to a larger patient population."

For more information:

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Erratum

Correction to

"HeartMate II Left Ventricular Assist System Receives Approval for Commercial Use." *Heart Watch*, Winter 2008 Edition, page 2.

This story incorrectly states that the Heart-Mate II left ventricular assist system was approved by the United States Food and Drug Administration (FDA) for commercial use in the United States.

The editors inadvertently made this assumption on the basis of news stories regarding the FDA Advisory Panel, which reviewed the clinical trial results contained in the premarket approval (PMA) application and unanimously recommended to the FDA that the PMA be approved with conditions. This is not the same as granting FDA approval for commercial use. The conditions outlined in the Panel's recommendations pertained to clarifications on labeling for the device regarding small patients and those unable to be treated with anticoagulation therapy, and on elements of the post-approval study. The quotation attributed to Dr. O. H. Frazier resulted from a misunderstanding in a telephone interview held with him when he was out of the country and unable to read the final proofs of the article. Although Dr. Frazier has been involved in the development of mechanical circulatory support devices for well over 30 years, he has never been involved with the commercialization of any device. His interest has always been patient welfare. In no way were Dr. Frazier, the Texas Heart Institute, or St. Luke's Episcopal Hospital attempting to promote or market a device before FDA approval, and we apologize for the inadvertent error.





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Calendar of Events

TEXAS HEART INSTITUTE CONTINUING MEDICAL EDUCATION SYMPOSIA

Eighth Texas Update in Cardiovascular Advancements July 25–26, 2008 • Houston, Texas Program Director: James T. Willerson, MD

SELECTED UPCOMING LOCAL, NATIONAL, AND INTERNATIONAL MEETINGS

Joint Session of the 17th Congress of the Michael E. DeBakey International Surgical Society and the 6th Current Trends In Cardiothoracic Surgery Conference April 30–May 3, 2008 • Houston, Texas

International Society for Heart and Lung Transplantation 28th Annual Meeting and Scientific Sessions April 9–12, 2008 • Boston, Massachusetts

American Surgical Association 128th Annual Meeting April 24–26, 2008 • New York, New York

Society of Cardiovascular Anesthesiologists 30th Annual Meeting and Workshops June 18–22, 2008 • Vancouver, British Columbia, Canada

Western Thoracic Surgical Association 34th Annual Meeting June 25–28, 2008 • Kona, Hawaii

American Heart Association Scientific Sessions 2008 November 8–12, 2008 • New Orleans, Louisiana Abstract submission: April 15–May 6, 2008

For information about the Texas Heart Institute CME activities listed above, please e-mail cme@heart.thi.tmc.edu or call 832.355.2157. To view selected CME presentations and other physician resources online, visit cme.texasheart.org.



For 17 consecutive years, the Texas Heart Institute at St. Luke's Episcopal Hospital has been ranked among the top 10 heart centers in the United States by *U.S. News* & *World Report*'s annual guide to "America's Best Hospitals."

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